

1 **SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SE-**
2 **CURITY ACT; REFERENCES TO BIPA AND**
3 **SECRETARY; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the “Medi-
5 care Prescription Drug, Improvement, and Modernization Act
6 of 2003”.

7 (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as
8 otherwise specifically provided, whenever in division A of this
9 Act an amendment is expressed in terms of an amendment to
10 or repeal of a section or other provision, the reference shall be
11 considered to be made to that section or other provision of the
12 Social Security Act.

13 (c) BIPA; SECRETARY.—In this Act:

14 (1) BIPA.—The term “BIPA” means the Medicare,
15 Medicaid, and SCHIP Benefits Improvement and Protec-
16 tion Act of 2000, as enacted into law by section 1(a)(6) of
17 Public Law 106–554.

18 (2) SECRETARY.—The term “Secretary” means the
19 Secretary of Health and Human Services.

20 (d) TABLE OF CONTENTS.—The table of contents of this
21 Act is as follows:

Sec. 1. Short title; amendments to Social Security Act; references to BIPA
and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Medicare prescription drug benefit.

“PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

“Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

“Sec. 1860D–1. Eligibility, enrollment, and information.

“Sec. 1860D–2. Prescription drug benefits.

**“Sec. 1860D–3. Access to a choice of qualified prescription drug cov-
erage.**

**“Sec. 1860D–4. Beneficiary protections for qualified prescription drug
coverage.**

“Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

“Sec. 1860D–11. PDP regions; submission of bids; plan approval.

**“Sec. 1860D–12. Requirements for and contracts with prescription
drug plan (PDP) sponsors.**

“Sec. 1860D–13. Premiums; late enrollment penalty.

**“Sec. 1860D–14. Premium and cost-sharing subsidies for low-income
individuals.**

**“Sec. 1860D–15. Subsidies for part D eligible individuals for qualified
prescription drug coverage.**

**“Sec. 1860D–16. Medicare Prescription Drug Account in the Federal
Supplementary Medical Insurance Trust Fund.**

“Subpart 3—Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans

“Sec. 1860D-21. Application to Medicare Advantage program and related managed care programs.

“Sec. 1860D-22. Special rules for employer-sponsored programs.

“Sec. 1860D-23. State pharmaceutical assistance programs.

“Sec. 1860D-24. Coordination requirements for plans providing prescription drug coverage.

“Subpart 4—Medicare Prescription Drug Discount Card and Transitional Assistance Program

“Sec. 1860D-31. Medicare prescription drug discount card and transitional assistance program.

“Subpart 5—Definitions and Miscellaneous Provisions

“Sec. 1860D-41. Definitions; treatment of references to provisions in part C.

“Sec. 1860D-42. Miscellaneous provisions.

Sec. 102. Medicare Advantage conforming amendments.

Sec. 103. Medicaid amendments.

Sec. 104. Medigap amendments.

Sec. 105. Additional provisions relating to medicare prescription drug discount card and transitional assistance program.

Sec. 106. State Pharmaceutical Assistance Transition Commission.

Sec. 107. Studies and reports.

Sec. 108. Grants to physicians to implement electronic prescription drug programs.

Sec. 109. Expanding the work of medicare Quality Improvement Organizations to include parts C and D.

Sec. 110. Conflict of interest study.

Sec. 111. Study on employment-based retiree health coverage.

TITLE II—MEDICARE ADVANTAGE

Subtitle A—Implementation of Medicare Advantage Program

Sec. 201. Implementation of Medicare Advantage program.

Subtitle B—Immediate Improvements

Sec. 211. Immediate improvements.

Subtitle C—Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition

Sec. 221. Establishment of MA regional plans.

Sec. 222. Competition program beginning in 2006.

Sec. 223. Effective date.

Subtitle D—Additional Reforms

Sec. 231. Specialized MA plans for special needs individuals.

Sec. 232. Avoiding duplicative State regulation.

Sec. 233. Medicare MSAs.

Sec. 234. Extension of reasonable cost contracts.

Sec. 235. 2-year extension of municipal health service demonstration projects.

Sec. 236. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.

Sec. 237. Reimbursement for Federally qualified health centers providing services under MA plans.

Sec. 238. Institute of Medicine evaluation and report on health care performance measures.

Subtitle E—Comparative Cost Adjustment (CCA) Program

Sec. 241. Comparative Cost Adjustment (CCA) program.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Sec. 301. Medicare secondary payor (MSP) provisions.

Sec. 302. Payment for durable medical equipment; competitive acquisition of certain items and services.

Sec. 303. Payment reform for covered outpatient drugs and biologicals.

Sec. 304. Extension of application of payment reform for covered outpatient drugs and biologicals to other physician specialties.

Sec. 305. Payment for inhalation drugs.

Sec. 306. Demonstration project for use of recovery audit contractors.

Sec. 307. Pilot program for national and State background checks on direct patient access employees of long-term care facilities or providers.

TITLE IV—RURAL PROVISIONS

Subtitle A—Provisions Relating to Part A Only

Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.

Sec. 402. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.

Sec. 403. Adjustment to the medicare inpatient hospital prospective payment system wage index to revise the labor-related share of such index.

Sec. 404. More frequent update in weights used in hospital market basket.

Sec. 405. Improvements to critical access hospital program.

Sec. 406. Medicare inpatient hospital payment adjustment for low-volume hospitals.

Sec. 407. Treatment of missing cost reporting periods for sole community hospitals.

Sec. 408. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.

Sec. 409. Rural hospice demonstration project.

Sec. 410. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.

Sec. 410A. Rural community hospital demonstration program.

Subtitle B—Provisions Relating to Part B Only

Sec. 411. 2-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under the prospective payment system for hospital outpatient department services.

Sec. 412. Establishment of floor on work geographic adjustment.

Sec. 413. Medicare incentive payment program improvements for physician scarcity.

Sec. 414. Payment for rural and urban ambulance services.

Sec. 415. Providing appropriate coverage of rural air ambulance services.

Sec. 416. Treatment of certain clinical diagnostic laboratory tests furnished to hospital outpatients in certain rural areas.

Sec. 417. Extension of telemedicine demonstration project.

Sec. 418. Report on demonstration project permitting skilled nursing facilities to be originating telehealth sites; authority to implement.

4

Subtitle C—Provisions Relating to Parts A and B

- Sec. 421. 1-year increase for home health services furnished in a rural area.
- Sec. 422. Redistribution of unused resident positions.

Subtitle D—Other Provisions

- Sec. 431. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
- Sec. 432. Office of Rural Health Policy improvements.
- Sec. 433. MedPAC study on rural hospital payment adjustments.
- Sec. 434. Frontier extended stay clinic demonstration project.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

- Sec. 501. Revision of acute care hospital payment updates.
- Sec. 502. Revision of the indirect medical education (IME) adjustment percentage.
- Sec. 503. Recognition of new medical technologies under inpatient hospital prospective payment system.
- Sec. 504. Increase in Federal rate for hospitals in Puerto Rico.
- Sec. 505. Wage index adjustment reclassification reform.
- Sec. 506. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.
- Sec. 507. Clarifications to certain exceptions to medicare limits on physician referrals.
- Sec. 508. 1-Time appeals process for hospital wage index classification.

Subtitle B—Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services.
- Sec. 512. Coverage of hospice consultation services.
- Sec. 513. Study on portable diagnostic ultrasound services for beneficiaries in skilled nursing facilities.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Provisions Relating to Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
- Sec. 602. Treatment of physicians' services furnished in Alaska.
- Sec. 603. Inclusion of podiatrists, dentists, and optometrists under private contracting authority.
- Sec. 604. GAO study on access to physicians' services.
- Sec. 605. Collaborative demonstration-based review of physician practice expense geographic adjustment data.
- Sec. 606. MedPAC report on payment for physicians' services.

Subtitle B—Preventive Services

- Sec. 611. Coverage of an initial preventive physical examination.
- Sec. 612. Coverage of cardiovascular screening blood tests.
- Sec. 613. Coverage of diabetes screening tests.
- Sec. 614. Improved payment for certain mammography services.

Subtitle C—Other Provisions

- Sec. 621. Hospital outpatient department (HOPD) payment reform.
- Sec. 622. Limitation of application of functional equivalence standard.
- Sec. 623. Payment for renal dialysis services.
- Sec. 624. 2-year moratorium on therapy caps; provisions relating to reports.

- Sec. 625. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
- Sec. 626. Payment for services furnished in ambulatory surgical centers.
- Sec. 627. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
- Sec. 628. Payment for clinical diagnostic laboratory tests.
- Sec. 629. Indexing part B deductible to inflation.
- Sec. 630. 5-year authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.

Subtitle D—Additional Demonstrations, Studies, and Other Provisions

- Sec. 641. Demonstration project for coverage of certain prescription drugs and biologicals.
- Sec. 642. Extension of coverage of Intravenous Immune Globulin (IVIG) for the treatment of primary immune deficiency diseases in the home.
- Sec. 643. MedPAC study of coverage of surgical first assisting services of certified registered nurse first assistants.
- Sec. 644. MedPAC study of payment for cardio-thoracic surgeons.
- Sec. 645. Studies relating to vision impairments.
- Sec. 646. Medicare health care quality demonstration programs.
- Sec. 647. MedPAC study on direct access to physical therapy services.
- Sec. 648. Demonstration project for consumer-directed chronic outpatient services.
- Sec. 649. Medicare care management performance demonstration.
- Sec. 650. GAO study and report on the propagation of concierge care.
- Sec. 651. Demonstration of coverage of chiropractic services under medicare.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

- Sec. 701. Update in home health services.
- Sec. 702. Demonstration project to clarify the definition of homebound.
- Sec. 703. Demonstration project for medical adult day care services.
- Sec. 704. Temporary suspension of OASIS requirement for collection of data on non-medicare and non-medicaid patients.
- Sec. 705. MedPAC study on medicare margins of home health agencies.
- Sec. 706. Coverage of religious nonmedical health care institution services furnished in the home.

Subtitle B—Graduate Medical Education

- Sec. 711. Extension of update limitation on high cost programs.
- Sec. 712. Exception to initial residency period for geriatric residency or fellowship programs.
- Sec. 713. Treatment of volunteer supervision.

Subtitle C—Chronic Care Improvement

- Sec. 721. Voluntary chronic care improvement under traditional fee-for-service.
- Sec. 722. Medicare Advantage quality improvement programs.
- Sec. 723. Chronically ill medicare beneficiary research, data, demonstration strategy.

Subtitle D—Other Provisions

- Sec. 731. Improvements in national and local coverage determination process to respond to changes in technology.

6

- Sec. 732. Extension of treatment of certain physician pathology services under medicare.
- Sec. 733. Payment for pancreatic islet cell investigational transplants for medicare beneficiaries in clinical trials.
- Sec. 734. Restoration of medicare trust funds.
- Sec. 735. Modifications to Medicare Payment Advisory Commission (MedPAC).
- Sec. 736. Technical amendments.

TITLE VIII—COST CONTAINMENT

Subtitle A—Cost Containment

- Sec. 801. Inclusion in annual report of medicare trustees of information on status of medicare trust funds.
- Sec. 802. Presidential submission of legislation.
- Sec. 803. Procedures in the House of Representatives.
- Sec. 804. Procedures in the Senate.

Subtitle B—Income-Related Reduction in Part B Premium Subsidy

- Sec. 811. Income-related reduction in part B premium subsidy.

TITLE IX—ADMINISTRATIVE IMPROVEMENTS, REGULATORY REDUCTION, AND CONTRACTING REFORM

- Sec. 900. Administrative improvements within the Centers for Medicare & Medicaid Services (CMS).

Subtitle A—Regulatory Reform

- Sec. 901. Construction; definition of supplier.
- Sec. 902. Issuance of regulations.
- Sec. 903. Compliance with changes in regulations and policies.
- Sec. 904. Reports and studies relating to regulatory reform.

Subtitle B—Contracting Reform

- Sec. 911. Increased flexibility in medicare administration.
- Sec. 912. Requirements for information security for medicare administrative contractors.

Subtitle C—Education and Outreach

- Sec. 921. Provider education and technical assistance.
- Sec. 922. Small provider technical assistance demonstration program.
- Sec. 923. Medicare Beneficiary Ombudsman.
- Sec. 924. Beneficiary outreach demonstration program.
- Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.
- Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Subtitle D—Appeals and Recovery

- Sec. 931. Transfer of responsibility for medicare appeals.
- Sec. 932. Process for expedited access to review.
- Sec. 933. Revisions to medicare appeals process.
- Sec. 934. Prepayment review.
- Sec. 935. Recovery of overpayments.
- Sec. 936. Provider enrollment process; right of appeal.
- Sec. 937. Process for correction of minor errors and omissions without pursuing appeals process.
- Sec. 938. Prior determination process for certain items and services; advance beneficiary notices.
- Sec. 939. Appeals by providers when there is no other party available.

- Sec. 940. Revisions to appeals timeframes and amounts.
- Sec. 940A. Mediation process for local coverage determinations.

Subtitle E—Miscellaneous Provisions

- Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.
- Sec. 942. Improvement in oversight of technology and coverage.
- Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.
- Sec. 944. EMTALA improvements.
- Sec. 945. Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group.
- Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.
- Sec. 947. Application of OSHA bloodborne pathogens standard to certain hospitals.
- Sec. 948. BIPA-related technical amendments and corrections.
- Sec. 949. Conforming authority to waive a program exclusion.
- Sec. 950. Treatment of certain dental claims.
- Sec. 951. Furnishing hospitals with information to compute DSH formula.
- Sec. 952. Revisions to reassignment provisions.
- Sec. 953. Other provisions.

TITLE X—MEDICAID AND MISCELLANEOUS PROVISIONS

Subtitle A—Medicaid Provisions

- Sec. 1001. Medicaid disproportionate share hospital (DSH) payments.
- Sec. 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.
- Sec. 1003. Extension of moratorium.

Subtitle B—Miscellaneous Provisions

- Sec. 1011. Federal reimbursement of emergency health services furnished to undocumented aliens.
- Sec. 1012. Commission on Systemic Interoperability.
- Sec. 1013. Research on outcomes of health care items and services.
- Sec. 1014. Health care that works for all Americans: Citizens Health Care Working Group.
- Sec. 1015. Funding start-up administrative costs for medicare reform.
- Sec. 1016. Health care infrastructure improvement program.

TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

Subtitle A—Access to Affordable Pharmaceuticals

- Sec. 1101. 30-month stay-of-effectiveness period.
- Sec. 1102. Forfeiture of 180-day exclusivity period.
- Sec. 1103. Bioavailability and bioequivalence.
- Sec. 1104. Conforming amendments.

Subtitle B—Federal Trade Commission Review

- Sec. 1111. Definitions.
- Sec. 1112. Notification of agreements.
- Sec. 1113. Filing deadlines.
- Sec. 1114. Disclosure exemption.
- Sec. 1115. Enforcement.
- Sec. 1116. Rulemaking.
- Sec. 1117. Savings clause.
- Sec. 1118. Effective date.

1 individual who is enrolled in an MA–PD plan ob-
 2 tains such coverage through such plan.

3 “(ii) LIMITATION ON ENROLLMENT OF MA
 4 PLAN ENROLLEES IN PRESCRIPTION DRUG
 5 PLANS.—Except as provided in clauses (iii) and
 6 (iv), a part D eligible individual who is enrolled in
 7 an MA plan may not enroll in a prescription drug
 8 plan under this part.

9 “(iii) PRIVATE FEE-FOR-SERVICE ENROLLEES
 10 IN MA PLANS NOT PROVIDING QUALIFIED PRE-
 11 SCRIPTIION DRUG COVERAGE PERMITTED TO EN-
 12 ROLL IN A PRESCRIPTION DRUG PLAN.—A part D
 13 eligible individual who is enrolled in an MA private
 14 fee-for-service plan (as defined in section
 15 1859(b)(2)) that does not provide qualified pre-
 16 scription drug coverage may obtain qualified pre-
 17 scription drug coverage through enrollment in a
 18 prescription drug plan.

19 “(iv) ENROLLEES IN MSA PLANS PERMITTED
 20 TO ENROLL IN A PRESCRIPTION DRUG PLAN.—A
 21 part D eligible individual who is enrolled in an
 22 MSA plan (as defined in section 1859(b)(3)) may
 23 obtain qualified prescription drug coverage through
 24 enrollment in a prescription drug plan.

25 “(2) COVERAGE FIRST EFFECTIVE JANUARY 1, 2006.—
 26 Coverage under prescription drug plans and MA–PD plans
 27 shall first be effective on January 1, 2006.

28 “(3) DEFINITIONS.—For purposes of this part:

29 “(A) PART D ELIGIBLE INDIVIDUAL.—The term
 30 ‘part D eligible individual’ means an individual who is
 31 entitled to benefits under part A or enrolled under part
 32 B.

33 “(B) MA PLAN.—The term ‘MA plan’ has the
 34 meaning given such term in section 1859(b)(1).

35 “(C) MA–PD PLAN.—The term ‘MA–PD plan’
 36 means an MA plan that provides qualified prescription
 37 drug coverage.

1 “(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG
2 PLANS.—

3 “(1) ESTABLISHMENT OF PROCESS.—

4 “(A) IN GENERAL.—The Secretary shall establish
5 a process for the enrollment, disenrollment, termi-
6 nation, and change of enrollment of part D eligible in-
7 dividuals in prescription drug plans consistent with this
8 subsection.

9 “(B) APPLICATION OF MA RULES.—In establishing
10 such process, the Secretary shall use rules similar to
11 (and coordinated with) the rules for enrollment,
12 disenrollment, termination, and change of enrollment
13 with an MA–PD plan under the following provisions of
14 section 1851:

15 “(i) RESIDENCE REQUIREMENTS.—Section
16 1851(b)(1)(A), relating to residence requirements.

17 “(ii) EXERCISE OF CHOICE.—Section 1851(c)
18 (other than paragraph (3)(A) of such section), re-
19 lating to exercise of choice.

20 “(iii) COVERAGE ELECTION PERIODS.—Subject
21 to paragraphs (2) and (3) of this subsection, sec-
22 tion 1851(e) (other than subparagraphs (B) and
23 (C) of paragraph (2) and the second sentence of
24 paragraph (4) of such section), relating to coverage
25 election periods, including initial periods, annual
26 coordinated election periods, special election peri-
27 ods, and election periods for exceptional cir-
28 cumstances.

29 “(iv) COVERAGE PERIODS.—Section 1851(f),
30 relating to effectiveness of elections and changes of
31 elections.

32 “(v) GUARANTEED ISSUE AND RENEWAL.—
33 Section 1851(g) (other than paragraph (2) of such
34 section and clause (i) and the second sentence of
35 clause (ii) of paragraph (3)(C) of such section), re-
36 lating to guaranteed issue and renewal.

1 “(vi) MARKETING MATERIAL AND APPLICA-
 2 TION FORMS.—Section 1851(h), relating to ap-
 3 proval of marketing material and application forms.
 4 In applying clauses (ii), (iv), and (v) of this subpara-
 5 graph, any reference to section 1851(e) shall be treated
 6 as a reference to such section as applied pursuant to
 7 clause (iii) of this subparagraph.

8 “(C) SPECIAL RULE.—The process established
 9 under subparagraph (A) shall include, in the case of a
 10 part D eligible individual who is a full-benefit dual eli-
 11 gible individual (as defined in section 1935(c)(6)) who
 12 has failed to enroll in a prescription drug plan or an
 13 MA–PD plan, for the enrollment in a prescription drug
 14 plan that has a monthly beneficiary premium that does
 15 not exceed the premium assistance available under sec-
 16 tion 1860D–14(a)(1)(A)). If there is more than one
 17 such plan available, the Secretary shall enroll such an
 18 individual on a random basis among all such plans in
 19 the PDP region. Nothing in the previous sentence shall
 20 prevent such an individual from declining or changing
 21 such enrollment.

22 “(2) INITIAL ENROLLMENT PERIOD.—

23 “(A) PROGRAM INITIATION.—In the case of an in-
 24 dividual who is a part D eligible individual as of No-
 25 vember 15, 2005, there shall be an initial enrollment
 26 period that shall be the same as the annual, coordi-
 27 nated open election period described in section
 28 1851(e)(3)(B)(iii), as applied under paragraph
 29 (1)(B)(iii).

30 “(B) CONTINUING PERIODS.—In the case of an in-
 31 dividual who becomes a part D eligible individual after
 32 November 15, 2005, there shall be an initial enrollment
 33 period which is the period under section 1851(e)(1), as
 34 applied under paragraph (1)(B)(iii) of this section, as
 35 if ‘entitled to benefits under part A or enrolled under
 36 part B’ were substituted for ‘entitled to benefits under
 37 part A and enrolled under part B’, but in no case shall

1 such period end before the period described in subpara-
2 graph (A).

3 “(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—

4 The Secretary shall establish special enrollment periods, in-
5 cluding the following:

6 “(A) INVOLUNTARY LOSS OF CREDITABLE PRE-
7 SCRIPTION DRUG COVERAGE.—

8 “(i) IN GENERAL.—In the case of a part D eli-
9 gible individual who involuntarily loses creditable
10 prescription drug coverage (as defined in section
11 1860D–13(b)(4)).

12 “(ii) NOTICE.—In establishing special enroll-
13 ment periods under clause (i), the Secretary shall
14 take into account when the part D eligible individ-
15 uals are provided notice of the loss of creditable
16 prescription drug coverage.

17 “(iii) FAILURE TO PAY PREMIUM.—For pur-
18 poses of clause (i), a loss of coverage shall be treat-
19 ed as voluntary if the coverage is terminated be-
20 cause of failure to pay a required beneficiary pre-
21 mium.

22 “(iv) REDUCTION IN COVERAGE.—For pur-
23 poses of clause (i), a reduction in coverage so that
24 the coverage no longer meets the requirements
25 under section 1860D–13(b)(5) (relating to actu-
26 arial equivalence) shall be treated as an involuntary
27 loss of coverage.

28 “(B) ERRORS IN ENROLLMENT.—In the case de-
29 scribed in section 1837(h) (relating to errors in enroll-
30 ment), in the same manner as such section applies to
31 part B.

32 “(C) EXCEPTIONAL CIRCUMSTANCES.—In the case
33 of part D eligible individuals who meet such exceptional
34 conditions (in addition to those conditions applied
35 under paragraph (1)(B)(iii)) as the Secretary may pro-
36 vide.

1 “(D) MEDICAID COVERAGE.—In the case of an in-
2 dividual (as determined by the Secretary) who is a full-
3 benefit dual eligible individual (as defined in section
4 1935(c)(6)).

5 “(E) DISCONTINUANCE OF MA–PD ELECTION DUR-
6 ING FIRST YEAR OF ELIGIBILITY.—In the case of a
7 part D eligible individual who discontinues enrollment
8 in an MA–PD plan under the second sentence of sec-
9 tion 1851(e)(4) at the time of the election of coverage
10 under such sentence under the original medicare fee-
11 for-service program.

12 “(4) INFORMATION TO FACILITATE ENROLLMENT.—

13 “(A) IN GENERAL.—Notwithstanding any other
14 provision of law but subject to subparagraph (B), the
15 Secretary may provide to each PDP sponsor and MA
16 organization such identifying information about part D
17 eligible individuals as the Secretary determines to be
18 necessary to facilitate efficient marketing of prescrip-
19 tion drug plans and MA–PD plans to such individuals
20 and enrollment of such individuals in such plans.

21 “(B) LIMITATION.—

22 “(i) PROVISION OF INFORMATION.—The Sec-
23 retary may provide the information under subpara-
24 graph (A) only to the extent necessary to carry out
25 such subparagraph.

26 “(ii) USE OF INFORMATION.—Such informa-
27 tion provided by the Secretary to a PDP sponsor
28 or an MA organization may be used by such spon-
29 sor or organization only to facilitate marketing of,
30 and enrollment of part D eligible individuals in,
31 prescription drug plans and MA–PD plans.

32 “(5) REFERENCE TO ENROLLMENT PROCEDURES FOR
33 MA–PD PLANS.—For rules applicable to enrollment,
34 disenrollment, termination, and change of enrollment of
35 part D eligible individuals in MA–PD plans, see section
36 1851.

1 “(6) REFERENCE TO PENALTIES FOR LATE ENROLL-
2 MENT.—Section 1860D–13(b) imposes a late enrollment
3 penalty for part D eligible individuals who—

4 “(A) enroll in a prescription drug plan or an MA–
5 PD plan after the initial enrollment period described in
6 paragraph (2); and

7 “(B) fail to maintain continuous creditable pre-
8 scription drug coverage during the period of non-enroll-
9 ment.

10 “(c) PROVIDING INFORMATION TO BENEFICIARIES.—

11 “(1) ACTIVITIES.—The Secretary shall conduct activi-
12 ties that are designed to broadly disseminate information to
13 part D eligible individuals (and prospective part D eligible
14 individuals) regarding the coverage provided under this
15 part. Such activities shall ensure that such information is
16 first made available at least 30 days prior to the initial en-
17 rollment period described in subsection (b)(2)(A).

18 “(2) REQUIREMENTS.—The activities described in
19 paragraph (1) shall—

20 “(A) be similar to the activities performed by the
21 Secretary under section 1851(d), including dissemina-
22 tion (including through the toll-free telephone number
23 1–800–MEDICARE) of comparative information for
24 prescription drug plans and MA–PD plans; and

25 “(B) be coordinated with the activities performed
26 by the Secretary under such section and under section
27 1804.

28 “(3) COMPARATIVE INFORMATION.—

29 “(A) IN GENERAL.—Subject to subparagraph (B),
30 the comparative information referred to in paragraph
31 (2)(A) shall include a comparison of the following with
32 respect to qualified prescription drug coverage:

33 “(i) BENEFITS.—The benefits provided under
34 the plan.

35 “(ii) MONTHLY BENEFICIARY PREMIUM.—The
36 monthly beneficiary premium under the plan.

1 “(iii) QUALITY AND PERFORMANCE.—The
2 quality and performance under the plan.

3 “(iv) BENEFICIARY COST-SHARING.—The cost-
4 sharing required of part D eligible individuals
5 under the plan.

6 “(v) CONSUMER SATISFACTION SURVEYS.—
7 The results of consumer satisfaction surveys re-
8 garding the plan conducted pursuant to section
9 1860D–4(d).

10 “(B) EXCEPTION FOR UNAVAILABILITY OF INFOR-
11 MATION.—The Secretary is not required to provide
12 comparative information under clauses (iii) and (v) of
13 subparagraph (A) with respect to a plan—

14 “(i) for the first plan year in which it is of-
15 fered; and

16 “(ii) for the next plan year if it is impracti-
17 cable or the information is otherwise unavailable.

18 “(4) INFORMATION ON LATE ENROLLMENT PEN-
19 ALTY.—The information disseminated under paragraph (1)
20 shall include information concerning the methodology for
21 determining the late enrollment penalty under section
22 1860D–13(b).

23 “PRESCRIPTION DRUG BENEFITS

24 “SEC. 1860D–2. (a) REQUIREMENTS.—

25 “(1) IN GENERAL.—For purposes of this part and
26 part C, the term ‘qualified prescription drug coverage’
27 means either of the following:

28 “(A) STANDARD PRESCRIPTION DRUG COVERAGE
29 WITH ACCESS TO NEGOTIATED PRICES.—Standard pre-
30 scription drug coverage (as defined in subsection (b))
31 and access to negotiated prices under subsection (d).

32 “(B) ALTERNATIVE PRESCRIPTION DRUG COV-
33 ERAGE WITH AT LEAST ACTUARIALLY EQUIVALENT
34 BENEFITS AND ACCESS TO NEGOTIATED PRICES.—Cov-
35 erage of covered part D drugs which meets the alter-
36 native prescription drug coverage requirements of sub-
37 section (c) and access to negotiated prices under sub-

1 section (d), but only if the benefit design of such cov-
 2 erage is approved by the Secretary, as provided under
 3 subsection (c).

4 “(2) PERMITTING SUPPLEMENTAL PRESCRIPTION
 5 DRUG COVERAGE.—

6 “(A) IN GENERAL.—Subject to subparagraph (B),
 7 qualified prescription drug coverage may include sup-
 8 plemental prescription drug coverage consisting of ei-
 9 ther or both of the following:

10 “(i) CERTAIN REDUCTIONS IN COST-SHAR-
 11 ING.—

12 “(I) IN GENERAL.—A reduction in the an-
 13 nual deductible, a reduction in the coinsurance
 14 percentage, or an increase in the initial cov-
 15 erage limit with respect to covered part D
 16 drugs, or any combination thereof, insofar as
 17 such a reduction or increase increases the actu-
 18 arial value of benefits above the actuarial value
 19 of basic prescription drug coverage.

20 “(II) CONSTRUCTION.—Nothing in this
 21 paragraph shall be construed as affecting the
 22 application of subsection (c)(3).

23 “(ii) OPTIONAL DRUGS.—Coverage of any
 24 product that would be a covered part D drug but
 25 for the application of subsection (e)(2)(A).

26 “(B) REQUIREMENT.—A PDP sponsor may not
 27 offer a prescription drug plan that provides supple-
 28 mental prescription drug coverage pursuant to subpara-
 29 graph (A) in an area unless the sponsor also offers a
 30 prescription drug plan in the area that only provides
 31 basic prescription drug coverage.

32 “(3) BASIC PRESCRIPTION DRUG COVERAGE.—For
 33 purposes of this part and part C, the term ‘basic prescrip-
 34 tion drug coverage’ means either of the following:

35 “(A) Coverage that meets the requirements of
 36 paragraph (1)(A).

1 “(B) Coverage that meets the requirements of
2 paragraph (1)(B) but does not have any supplemental
3 prescription drug coverage described in paragraph
4 (2)(A).

5 “(4) APPLICATION OF SECONDARY PAYOR PROVI-
6 SIONS.—The provisions of section 1852(a)(4) shall apply
7 under this part in the same manner as they apply under
8 part C.

9 “(5) CONSTRUCTION.—Nothing in this subsection
10 shall be construed as changing the computation of incurred
11 costs under subsection (b)(4).

12 “(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For
13 purposes of this part and part C, the term ‘standard prescrip-
14 tion drug coverage’ means coverage of covered part D drugs
15 that meets the following requirements:

16 “(1) DEDUCTIBLE.—

17 “(A) IN GENERAL.—The coverage has an annual
18 deductible—

19 “(i) for 2006, that is equal to \$250; or

20 “(ii) for a subsequent year, that is equal to
21 the amount specified under this paragraph for the
22 previous year increased by the percentage specified
23 in paragraph (6) for the year involved.

24 “(B) ROUNDING.—Any amount determined under
25 subparagraph (A)(ii) that is not a multiple of \$5 shall
26 be rounded to the nearest multiple of \$5.

27 “(2) BENEFIT STRUCTURE.—

28 “(A) 25 PERCENT COINSURANCE.—The coverage
29 has coinsurance (for costs above the annual deductible
30 specified in paragraph (1) and up to the initial cov-
31 erage limit under paragraph (3)) that is—

32 “(i) equal to 25 percent; or

33 “(ii) actuarially equivalent (using processes
34 and methods established under section 1860D-
35 11(c)) to an average expected payment of 25 per-
36 cent of such costs.

1 “(B) USE OF TIERS.—Nothing in this part shall
2 be construed as preventing a PDP sponsor or an MA
3 organization from applying tiered copayments under a
4 plan, so long as such tiered copayments are consistent
5 with subparagraph (A)(ii).

6 “(3) INITIAL COVERAGE LIMIT.—

7 “(A) IN GENERAL.—Except as provided in para-
8 graph (4), the coverage has an initial coverage limit on
9 the maximum costs that may be recognized for pay-
10 ment purposes (including the annual deductible)—

11 “(i) for 2006, that is equal to \$2,250; or

12 “(ii) for a subsequent year, that is equal to
13 the amount specified in this paragraph for the pre-
14 vious year, increased by the annual percentage in-
15 crease described in paragraph (6) for the year in-
16 volved.

17 “(B) ROUNDING.—Any amount determined under
18 subparagraph (A)(ii) that is not a multiple of \$10 shall
19 be rounded to the nearest multiple of \$10.

20 “(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EX-
21 PENDITURES.—

22 “(A) IN GENERAL.—

23 “(i) IN GENERAL.—The coverage provides ben-
24 efits, after the part D eligible individual has in-
25 curred costs (as described in subparagraph (C)) for
26 covered part D drugs in a year equal to the annual
27 out-of-pocket threshold specified in subparagraph
28 (B), with cost-sharing that is equal to the greater
29 of—

30 “(I) a copayment of \$2 for a generic drug
31 or a preferred drug that is a multiple source
32 drug (as defined in section 1927(k)(7)(A)(i))
33 and \$5 for any other drug; or

34 “(II) coinsurance that is equal to 5 per-
35 cent.

36 “(ii) ADJUSTMENT OF AMOUNT.—For a year
37 after 2006, the dollar amounts specified in clause

1 (i)(I) shall be equal to the dollar amounts specified
 2 in this subparagraph for the previous year, in-
 3 creased by the annual percentage increase de-
 4 scribed in paragraph (6) for the year involved. Any
 5 amount established under this clause that is not a
 6 multiple of a 5 cents shall be rounded to the near-
 7 est multiple of 5 cents.

8 “(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

9 “(i) IN GENERAL.—For purposes of this part,
 10 the ‘annual out-of-pocket threshold’ specified in
 11 this subparagraph—

12 “(I) for 2006, is equal to \$3,600; or

13 “(II) for a subsequent year, is equal to the
 14 amount specified in this subparagraph for the
 15 previous year, increased by the annual percent-
 16 age increase described in paragraph (6) for the
 17 year involved.

18 “(ii) ROUNDING.—Any amount determined
 19 under clause (i)(II) that is not a multiple of \$50
 20 shall be rounded to the nearest multiple of \$50.

21 “(C) APPLICATION.—In applying subparagraph
 22 (A)—

23 “(i) incurred costs shall only include costs in-
 24 curred with respect to covered part D drugs for the
 25 annual deductible described in paragraph (1), for
 26 cost-sharing described in paragraph (2), and for
 27 amounts for which benefits are not provided be-
 28 cause of the application of the initial coverage limit
 29 described in paragraph (3), but does not include
 30 any costs incurred for covered part D drugs which
 31 are not included (or treated as being included) in
 32 the plan’s formulary; and

33 “(ii) such costs shall be treated as incurred
 34 only if they are paid by the part D eligible indi-
 35 vidual (or by another person, such as a family
 36 member, on behalf of the individual), under section
 37 1860D–14, or under a State Pharmaceutical As-

1 assistance Program and the part D eligible individual
2 (or other person) is not reimbursed through insur-
3 ance or otherwise, a group health plan, or other
4 third-party payment arrangement (other than
5 under such section or such a Program) for such
6 costs.

7 “(D) INFORMATION REGARDING THIRD-PARTY RE-
8 IMBURSEMENT.—

9 “(i) PROCEDURES FOR EXCHANGING INFOR-
10 MATION.—In order to accurately apply the require-
11 ments of subparagraph (C)(ii), the Secretary is au-
12 thorized to establish procedures, in coordination
13 with the Secretary of the Treasury and the Sec-
14 retary of Labor—

15 “(I) for determining whether costs for
16 part D eligible individuals are being reimbursed
17 through insurance or otherwise, a group health
18 plan, or other third-party payment arrange-
19 ment; and

20 “(II) for alerting the PDP sponsors and
21 MA organizations that offer the prescription
22 drug plans and MA–PD plans in which such in-
23 dividuals are enrolled about such reimburse-
24 ment arrangements.

25 “(ii) AUTHORITY TO REQUEST INFORMATION
26 FROM ENROLLEES.—A PDP sponsor or an MA or-
27 ganization may periodically ask part D eligible indi-
28 viduals enrolled in a prescription drug plan or an
29 MA–PD plan offered by the sponsor or organiza-
30 tion whether such individuals have or expect to re-
31 ceive such third-party reimbursement. A material
32 misrepresentation of the information described in
33 the preceding sentence by an individual (as defined
34 in standards set by the Secretary and determined
35 through a process established by the Secretary)
36 shall constitute grounds for termination of enroll-
37 ment in any plan under section 1851(g)(3)(B) (and

1 as applied under this part under section 1860D–
 2 1(b)(1)(B)(v)) for a period specified by the Sec-
 3 retary.

4 “(5) CONSTRUCTION.—Nothing in this part shall be
 5 construed as preventing a PDP sponsor or an MA organi-
 6 zation offering an MA–PD plan from reducing to 0 the
 7 cost-sharing otherwise applicable to preferred or generic
 8 drugs.

9 “(6) ANNUAL PERCENTAGE INCREASE.—The annual
 10 percentage increase specified in this paragraph for a year
 11 is equal to the annual percentage increase in average per
 12 capita aggregate expenditures for covered part D drugs in
 13 the United States for part D eligible individuals, as deter-
 14 mined by the Secretary for the 12-month period ending in
 15 July of the previous year using such methods as the Sec-
 16 retary shall specify.

17 “(c) ALTERNATIVE PRESCRIPTION DRUG COVERAGE RE-
 18 QUIREMENTS.—A prescription drug plan or an MA–PD plan
 19 may provide a different prescription drug benefit design from
 20 standard prescription drug coverage so long as the Secretary
 21 determines (consistent with section 1860D–11(c)) that the fol-
 22 lowing requirements are met and the plan applies for, and re-
 23 ceives, the approval of the Secretary for such benefit design:

24 “(1) ASSURING AT LEAST ACTUARIALLY EQUIVALENT
 25 COVERAGE.—

26 “(A) ASSURING EQUIVALENT VALUE OF TOTAL
 27 COVERAGE.—The actuarial value of the total coverage
 28 is at least equal to the actuarial value of standard pre-
 29 scription drug coverage.

30 “(B) ASSURING EQUIVALENT UNSUBSIDIZED
 31 VALUE OF COVERAGE.—The unsubsidized value of the
 32 coverage is at least equal to the unsubsidized value of
 33 standard prescription drug coverage. For purposes of
 34 this subparagraph, the unsubsidized value of coverage
 35 is the amount by which the actuarial value of the cov-
 36 erage exceeds the actuarial value of the subsidy pay-

1 ments under section 1860D–15 with respect to such
2 coverage.

3 “(C) ASSURING STANDARD PAYMENT FOR COSTS
4 AT INITIAL COVERAGE LIMIT.—The coverage is de-
5 signed, based upon an actuarially representative pat-
6 tern of utilization, to provide for the payment, with re-
7 spect to costs incurred that are equal to the initial cov-
8 erage limit under subsection (b)(3) for the year, of an
9 amount equal to at least the product of—

10 “(i) the amount by which the initial coverage
11 limit described in subsection (b)(3) for the year ex-
12 ceeds the deductible described in subsection (b)(1)
13 for the year; and

14 “(ii) 100 percent minus the coinsurance per-
15 centage specified in subsection (b)(2)(A)(i).

16 “(2) MAXIMUM REQUIRED DEDUCTIBLE.—The deduct-
17 ible under the coverage shall not exceed the deductible
18 amount specified under subsection (b)(1) for the year.

19 “(3) SAME PROTECTION AGAINST HIGH OUT-OF-POCK-
20 ET EXPENDITURES.—The coverage provides the coverage
21 required under subsection (b)(4).

22 “(d) ACCESS TO NEGOTIATED PRICES.—

23 “(1) ACCESS.—

24 “(A) IN GENERAL.—Under qualified prescription
25 drug coverage offered by a PDP sponsor offering a pre-
26 scription drug plan or an MA organization offering an
27 MA–PD plan, the sponsor or organization shall provide
28 enrollees with access to negotiated prices used for pay-
29 ment for covered part D drugs, regardless of the fact
30 that no benefits may be payable under the coverage
31 with respect to such drugs because of the application
32 of a deductible or other cost-sharing or an initial cov-
33 erage limit (described in subsection (b)(3)).

34 “(B) NEGOTIATED PRICES.—For purposes of this
35 part, negotiated prices shall take into account nego-
36 tiated price concessions, such as discounts, direct or in-
37 direct subsidies, rebates, and direct or indirect remu-

1 nerations, for covered part D drugs, and include any
2 dispensing fees for such drugs.

3 “(C) MEDICAID-RELATED PROVISIONS.—The
4 prices negotiated by a prescription drug plan, by an
5 MA–PD plan with respect to covered part D drugs, or
6 by a qualified retiree prescription drug plan (as defined
7 in section 1860D–22(a)(2)) with respect to such drugs
8 on behalf of part D eligible individuals, shall (notwith-
9 standing any other provision of law) not be taken into
10 account for the purposes of establishing the best price
11 under section 1927(c)(1)(C).

12 “(2) DISCLOSURE.—A PDP sponsor offering a pre-
13 scription drug plan or an MA organization offering an MA-
14 PD plan shall disclose to the Secretary (in a manner speci-
15 fied by the Secretary) the aggregate negotiated price con-
16 cessions described in paragraph (1)(B) made available to
17 the sponsor or organization by a manufacturer which are
18 passed through in the form of lower subsidies, lower
19 monthly beneficiary prescription drug premiums, and lower
20 prices through pharmacies and other dispensers. The provi-
21 sions of section 1927(b)(3)(D) apply to information dis-
22 closed to the Secretary under this paragraph.

23 “(3) AUDITS.—To protect against fraud and abuse
24 and to ensure proper disclosures and accounting under this
25 part and in accordance with section 1857(d)(2)(B) (as ap-
26 plied under section 1860D–12(b)(3)(C)), the Secretary may
27 conduct periodic audits, directly or through contracts, of
28 the financial statements and records of PDP sponsors with
29 respect to prescription drug plans and MA organizations
30 with respect to MA–PD plans.

31 “(e) COVERED PART D DRUG DEFINED.—

32 “(1) IN GENERAL.—Except as provided in this sub-
33 section, for purposes of this part, the term ‘covered part D
34 drug’ means—

35 “(A) a drug that may be dispensed only upon a
36 prescription and that is described in subparagraph
37 (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or

1 “(B) a biological product described in clauses (i)
 2 through (iii) of subparagraph (B) of such section or in-
 3 sulin described in subparagraph (C) of such section and
 4 medical supplies associated with the injection of insulin
 5 (as defined in regulations of the Secretary),
 6 and such term includes a vaccine licensed under section
 7 351 of the Public Health Service Act and any use of a cov-
 8 ered part D drug for a medically accepted indication (as
 9 defined in section 1927(k)(6)).

10 “(2) EXCLUSIONS.—

11 “(A) IN GENERAL.—Such term does not include
 12 drugs or classes of drugs, or their medical uses, which
 13 may be excluded from coverage or otherwise restricted
 14 under section 1927(d)(2), other than subparagraph (E)
 15 of such section (relating to smoking cessation agents),
 16 or under section 1927(d)(3).

17 “(B) MEDICARE COVERED DRUGS.—A drug pre-
 18 scribed for a part D eligible individual that would oth-
 19 erwise be a covered part D drug under this part shall
 20 not be so considered if payment for such drug as so
 21 prescribed and dispensed or administered with respect
 22 to that individual is available (or would be available but
 23 for the application of a deductible) under part A or B
 24 for that individual.

25 “(3) APPLICATION OF GENERAL EXCLUSION PROVI-
 26 SIONS.—A prescription drug plan or an MA–PD plan may
 27 exclude from qualified prescription drug coverage any cov-
 28 ered part D drug—

29 “(A) for which payment would not be made if sec-
 30 tion 1862(a) applied to this part; or

31 “(B) which is not prescribed in accordance with
 32 the plan or this part.

33 Such exclusions are determinations subject to reconsider-
 34 ation and appeal pursuant to subsections (g) and (h), re-
 35 spectively, of section 1860D–4.

1 “ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG
2 COVERAGE

3 “SEC. 1860D–3. (a) ASSURING ACCESS TO A CHOICE OF
4 COVERAGE.—

5 “(1) CHOICE OF AT LEAST TWO PLANS IN EACH
6 AREA.—The Secretary shall ensure that each part D eligi-
7 ble individual has available, consistent with paragraph (2),
8 a choice of enrollment in at least 2 qualifying plans (as de-
9 fined in paragraph (3)) in the area in which the individual
10 resides, at least one of which is a prescription drug plan.
11 In any such case in which such plans are not available, the
12 part D eligible individual shall be given the opportunity to
13 enroll in a fallback prescription drug plan.

14 “(2) REQUIREMENT FOR DIFFERENT PLAN SPON-
15 SORS.—The requirement in paragraph (1) is not satisfied
16 with respect to an area if only one entity offers all the
17 qualifying plans in the area.

18 “(3) QUALIFYING PLAN DEFINED.—For purposes of
19 this section, the term ‘qualifying plan’ means—

20 “(A) a prescription drug plan; or

21 “(B) an MA–PD plan described in section
22 1851(a)(2)(A)(i) that provides—

23 “(i) basic prescription drug coverage; or

24 “(ii) qualified prescription drug coverage that
25 provides supplemental prescription drug coverage
26 so long as there is no MA monthly supplemental
27 beneficiary premium applied under the plan, due to
28 the application of a credit against such premium of
29 a rebate under section 1854(b)(1)(C).

30 “(b) FLEXIBILITY IN RISK ASSUMED AND APPLICATION
31 OF FALLBACK PLAN.—In order to ensure access pursuant to
32 subsection (a) in an area—

33 “(1) the Secretary may approve limited risk plans
34 under section 1860D–11(f) for the area; and

35 “(2) only if such access is still not provided in the
36 area after applying paragraph (1), the Secretary shall pro-

1 offering such plan shall provide information similar (as deter-
 2 mined by the Secretary) to the information described in
 3 subparagraphs (A), (B), and (C) of section 1852(c)(2) to
 4 such individual.

5 “(3) PROVISION OF SPECIFIC INFORMATION.—

6 “(A) RESPONSE TO BENEFICIARY QUESTIONS.—

7 Each PDP sponsor offering a prescription drug plan
 8 shall have a mechanism for providing specific informa-
 9 tion on a timely basis to enrollees upon request. Such
 10 mechanism shall include access to information through
 11 the use of a toll-free telephone number and, upon re-
 12 quest, the provision of such information in writing.

13 “(B) AVAILABILITY OF INFORMATION ON
 14 CHANGES IN FORMULARY THROUGH THE INTERNET.—

15 A PDP sponsor offering a prescription drug plan shall
 16 make available on a timely basis through an Internet
 17 website information on specific changes in the for-
 18 mulary under the plan (including changes to tiered or
 19 preferred status of covered part D drugs).

20 “(4) CLAIMS INFORMATION.—A PDP sponsor offering
 21 a prescription drug plan must furnish to each enrollee in
 22 a form easily understandable to such enrollees—

23 “(A) an explanation of benefits (in accordance
 24 with section 1806(a) or in a comparable manner); and

25 “(B) when prescription drug benefits are provided
 26 under this part, a notice of the benefits in relation to—

27 “(i) the initial coverage limit for the current
 28 year; and

29 “(ii) the annual out-of-pocket threshold for the
 30 current year.

31 Notices under subparagraph (B) need not be provided
 32 more often than as specified by the Secretary and no-
 33 tices under subparagraph (B)(ii) shall take into ac-
 34 count the application of section 1860D–2(b)(4)(C) to
 35 the extent practicable, as specified by the Secretary.

36 “(b) ACCESS TO COVERED PART D DRUGS.—

37 “(1) ASSURING PHARMACY ACCESS.—

1 “(A) PARTICIPATION OF ANY WILLING PHAR-
2 MACY.—A prescription drug plan shall permit the par-
3 ticipation of any pharmacy that meets the terms and
4 conditions under the plan.

5 “(B) DISCOUNTS ALLOWED FOR NETWORK PHAR-
6 MACIES.—For covered part D drugs dispensed through
7 in-network pharmacies, a prescription drug plan may,
8 notwithstanding subparagraph (A), reduce coinsurance
9 or copayments for part D eligible individuals enrolled
10 in the plan below the level otherwise required. In no
11 case shall such a reduction result in an increase in pay-
12 ments made by the Secretary under section 1860D–15
13 to a plan.

14 “(C) CONVENIENT ACCESS FOR NETWORK PHAR-
15 MACIES.—

16 “(i) IN GENERAL.—The PDP sponsor of the
17 prescription drug plan shall secure the participation
18 in its network of a sufficient number of pharmacies
19 that dispense (other than by mail order) drugs di-
20 rectly to patients to ensure convenient access (con-
21 sistent with rules established by the Secretary).

22 “(ii) APPLICATION OF TRICARE STANDARDS.—
23 The Secretary shall establish rules for convenient
24 access to in-network pharmacies under this sub-
25 paragraph that are no less favorable to enrollees
26 than the rules for convenient access to pharmacies
27 included in the statement of work of solicitation
28 (#MDA906–03–R–0002) of the Department of De-
29 fense under the TRICARE Retail Pharmacy
30 (TRRx) as of March 13, 2003.

31 “(iii) ADEQUATE EMERGENCY ACCESS.—Such
32 rules shall include adequate emergency access for
33 enrollees.

34 “(iv) CONVENIENT ACCESS IN LONG-TERM
35 CARE FACILITIES.—Such rules may include stand-
36 ards with respect to access for enrollees who are re-
37 siding in long-term care facilities and for phar-

1 macies operated by the Indian Health Service, In-
 2 dian tribes and tribal organizations, and urban In-
 3 dian organizations (as defined in section 4 of the
 4 Indian Health Care Improvement Act).

5 “(D) LEVEL PLAYING FIELD.—Such a sponsor
 6 shall permit enrollees to receive benefits (which may in-
 7 clude a 90-day supply of drugs or biologicals) through
 8 a pharmacy (other than a mail order pharmacy), with
 9 any differential in charge paid by such enrollees.

10 “(E) NOT REQUIRED TO ACCEPT INSURANCE
 11 RISK.—The terms and conditions under subparagraph
 12 (A) may not require participating pharmacies to accept
 13 insurance risk as a condition of participation.

14 “(2) USE OF STANDARDIZED TECHNOLOGY.—

15 “(A) IN GENERAL.—The PDP sponsor of a pre-
 16 scription drug plan shall issue (and reissue, as appro-
 17 priate) such a card (or other technology) that may be
 18 used by an enrollee to assure access to negotiated
 19 prices under section 1860D–2(d).

20 “(B) STANDARDS.—

21 “(i) IN GENERAL.—The Secretary shall pro-
 22 vide for the development, adoption, or recognition
 23 of standards relating to a standardized format for
 24 the card or other technology required under sub-
 25 paragraph (A). Such standards shall be compatible
 26 with part C of title XI and may be based on stand-
 27 ards developed by an appropriate standard setting
 28 organization.

29 “(ii) CONSULTATION.—In developing the
 30 standards under clause (i), the Secretary shall con-
 31 sult with the National Council for Prescription
 32 Drug Programs and other standard setting organi-
 33 zations determined appropriate by the Secretary.

34 “(iii) IMPLEMENTATION.—The Secretary shall
 35 develop, adopt, or recognize the standards under
 36 clause (i) by such date as the Secretary determines

1 shall be sufficient to ensure that PDP sponsors uti-
2 lize such standards beginning January 1, 2006.

3 “(3) REQUIREMENTS ON DEVELOPMENT AND APPLICA-
4 TION OF FORMULARIES.—If a PDP sponsor of a prescrip-
5 tion drug plan uses a formulary (including the use of tiered
6 cost-sharing), the following requirements must be met:

7 “(A) DEVELOPMENT AND REVISION BY A PHAR-
8 MACY AND THERAPEUTIC (P&T) COMMITTEE.—

9 “(i) IN GENERAL.—The formulary must be de-
10 veloped and reviewed by a pharmacy and thera-
11 peutic committee. A majority of the members of
12 such committee shall consist of individuals who are
13 practicing physicians or practicing pharmacists (or
14 both).

15 “(ii) INCLUSION OF INDEPENDENT EX-
16 PERTS.—Such committee shall include at least one
17 practicing physician and at least one practicing
18 pharmacist, each of whom—

19 “(I) is independent and free of conflict
20 with respect to the sponsor and plan; and

21 “(II) has expertise in the care of elderly or
22 disabled persons.

23 “(B) FORMULARY DEVELOPMENT.—In developing
24 and reviewing the formulary, the committee shall—

25 “(i) base clinical decisions on the strength of
26 scientific evidence and standards of practice, in-
27 cluding assessing peer-reviewed medical literature,
28 such as randomized clinical trials,
29 pharmacoeconomic studies, outcomes research data,
30 and on such other information as the committee
31 determines to be appropriate; and

32 “(ii) take into account whether including in
33 the formulary (or in a tier in such formulary) par-
34 ticular covered part D drugs has therapeutic ad-
35 vantages in terms of safety and efficacy.

36 “(C) INCLUSION OF DRUGS IN ALL THERAPEUTIC
37 CATEGORIES AND CLASSES.—

1 “(i) IN GENERAL.—The formulary must in-
2 clude drugs within each therapeutic category and
3 class of covered part D drugs, although not nec-
4 essarily all drugs within such categories and class-
5 es.

6 “(ii) MODEL GUIDELINES.—The Secretary
7 shall request the United States Pharmacopeia to
8 develop, in consultation with pharmaceutical benefit
9 managers and other interested parties, a list of cat-
10 egories and classes that may be used by prescrip-
11 tion drug plans under this paragraph and to revise
12 such classification from time to time to reflect
13 changes in therapeutic uses of covered part D
14 drugs and the additions of new covered part D
15 drugs.

16 “(iii) LIMITATION ON CHANGES IN THERA-
17 PEUTIC CLASSIFICATION.—The PDP sponsor of a
18 prescription drug plan may not change the thera-
19 peutic categories and classes in a formulary other
20 than at the beginning of each plan year except as
21 the Secretary may permit to take into account new
22 therapeutic uses and newly approved covered part
23 D drugs.

24 “(D) PROVIDER AND PATIENT EDUCATION.—The
25 PDP sponsor shall establish policies and procedures to
26 educate and inform health care providers and enrollees
27 concerning the formulary.

28 “(E) NOTICE BEFORE REMOVING DRUG FROM
29 FORMULARY OR CHANGING PREFERRED OR TIER STA-
30 TUS OF DRUG.—Any removal of a covered part D drug
31 from a formulary and any change in the preferred or
32 tiered cost-sharing status of such a drug shall take ef-
33 fect only after appropriate notice is made available
34 (such as under subsection (a)(3)) to the Secretary, af-
35 fected enrollees, physicians, pharmacies, and phar-
36 macists.

1 “(F) PERIODIC EVALUATION OF PROTOCOLS.—In
2 connection with the formulary, the sponsor of a pre-
3 scription drug plan shall provide for the periodic eval-
4 uation and analysis of treatment protocols and proce-
5 dures.

6 The requirements of this paragraph may be met by a PDP
7 sponsor directly or through arrangements with another en-
8 tity.

9 “(c) COST AND UTILIZATION MANAGEMENT; QUALITY AS-
10 SURANCE; MEDICATION THERAPY MANAGEMENT PROGRAM.—

11 “(1) IN GENERAL.—The PDP sponsor shall have in
12 place, directly or through appropriate arrangements, with
13 respect to covered part D drugs, the following:

14 “(A) A cost-effective drug utilization management
15 program, including incentives to reduce costs when
16 medically appropriate, such as through the use of mul-
17 tiple source drugs (as defined in section
18 1927(k)(7)(A)(i)).

19 “(B) Quality assurance measures and systems to
20 reduce medication errors and adverse drug interactions
21 and improve medication use.

22 “(C) A medication therapy management program
23 described in paragraph (2).

24 “(D) A program to control fraud, abuse, and
25 waste.

26 Nothing in this section shall be construed as impairing a
27 PDP sponsor from utilizing cost management tools (includ-
28 ing differential payments) under all methods of operation.

29 “(2) MEDICATION THERAPY MANAGEMENT PRO-
30 GRAM.—

31 “(A) DESCRIPTION.—

32 “(i) IN GENERAL.—A medication therapy
33 management program described in this paragraph
34 is a program of drug therapy management that
35 may be furnished by a pharmacist and that is de-
36 signed to assure, with respect to targeted bene-
37 ficiaries described in clause (ii), that covered part

1 D drugs under the prescription drug plan are ap-
 2 propriately used to optimize therapeutic outcomes
 3 through improved medication use, and to reduce
 4 the risk of adverse events, including adverse drug
 5 interactions. Such a program may distinguish be-
 6 tween services in ambulatory and institutional set-
 7 tings.

8 “(ii) TARGETED BENEFICIARIES DE-
 9 SCRIBED.—Targeted beneficiaries described in this
 10 clause are part D eligible individuals who—

11 “(I) have multiple chronic diseases (such
 12 as diabetes, asthma, hypertension,
 13 hyperlipidemia, and congestive heart failure);

14 “(II) are taking multiple covered part D
 15 drugs; and

16 “(III) are identified as likely to incur an-
 17 nual costs for covered part D drugs that exceed
 18 a level specified by the Secretary.

19 “(B) ELEMENTS.—Such program may include ele-
 20 ments that promote—

21 “(i) enhanced enrollee understanding to pro-
 22 mote the appropriate use of medications by enroll-
 23 ees and to reduce the risk of potential adverse
 24 events associated with medications, through bene-
 25 ficiary education, counseling, and other appropriate
 26 means;

27 “(ii) increased enrollee adherence with pre-
 28 scription medication regimens through medication
 29 refill reminders, special packaging, and other com-
 30 pliance programs and other appropriate means; and

31 “(iii) detection of adverse drug events and pat-
 32 terns of overuse and underuse of prescription
 33 drugs.

34 “(C) DEVELOPMENT OF PROGRAM IN COOPERA-
 35 TION WITH LICENSED PHARMACISTS.—Such program
 36 shall be developed in cooperation with licensed and
 37 practicing pharmacists and physicians.

1 “(D) COORDINATION WITH CARE MANAGEMENT
2 PLANS.—The Secretary shall establish guidelines for
3 the coordination of any medication therapy manage-
4 ment program under this paragraph with respect to a
5 targeted beneficiary with any care management plan
6 established with respect to such beneficiary under a
7 chronic care improvement program under section 1807.

8 “(E) CONSIDERATIONS IN PHARMACY FEES.—The
9 PDP sponsor of a prescription drug plan shall take
10 into account, in establishing fees for pharmacists and
11 others providing services under such plan, the resources
12 used, and time required to, implement the medication
13 therapy management program under this paragraph.
14 Each such sponsor shall disclose to the Secretary upon
15 request the amount of any such management or dis-
16 pensing fees. The provisions of section 1927(b)(3)(D)
17 apply to information disclosed under this subpara-
18 graph.

19 “(d) CONSUMER SATISFACTION SURVEYS.—In order to
20 provide for comparative information under section 1860D-
21 1(c)(3)(A)(v), the Secretary shall conduct consumer satisfaction
22 surveys with respect to PDP sponsors and prescription drug
23 plans in a manner similar to the manner such surveys are con-
24 ducted for MA organizations and MA plans under part C.

25 “(e) ELECTRONIC PRESCRIPTION PROGRAM.—

26 “(1) APPLICATION OF STANDARDS.—As of such date
27 as the Secretary may specify, but not later than 1 year
28 after the date of promulgation of final standards under
29 paragraph (4)(D), prescriptions and other information de-
30 scribed in paragraph (2)(A) for covered part D drugs pre-
31 scribed for part D eligible individuals that are transmitted
32 electronically shall be transmitted only in accordance with
33 such standards under an electronic prescription drug pro-
34 gram that meets the requirements of paragraph (2).

35 “(2) PROGRAM REQUIREMENTS.—Consistent with uni-
36 form standards established under paragraph (3)—

1 “(A) PROVISION OF INFORMATION TO PRE-
2 SCRIBING HEALTH CARE PROFESSIONAL AND DIS-
3 PENSING PHARMACIES AND PHARMACISTS.—An elec-
4 tronic prescription drug program shall provide for the
5 electronic transmittal to the prescribing health care
6 professional and to the dispensing pharmacy and phar-
7 macist of the prescription and information on eligibility
8 and benefits (including the drugs included in the appli-
9 cable formulary, any tiered formulary structure, and
10 any requirements for prior authorization) and of the
11 following information with respect to the prescribing
12 and dispensing of a covered part D drug:

13 “(i) Information on the drug being prescribed
14 or dispensed and other drugs listed on the medica-
15 tion history, including information on drug-drug
16 interactions, warnings or cautions, and, when indi-
17 cated, dosage adjustments.

18 “(ii) Information on the availability of lower
19 cost, therapeutically appropriate alternatives (if
20 any) for the drug prescribed.

21 “(B) APPLICATION TO MEDICAL HISTORY INFOR-
22 MATION.—Effective on and after such date as the Sec-
23 retary specifies and after the establishment of appro-
24 priate standards to carry out this subparagraph, the
25 program shall provide for the electronic transmittal in
26 a manner similar to the manner under subparagraph
27 (A) of information that relates to the medical history
28 concerning the individual and related to a covered part
29 D drug being prescribed or dispensed, upon request of
30 the professional or pharmacist involved.

31 “(C) LIMITATIONS.—Information shall only be dis-
32 closed under subparagraph (A) or (B) if the disclosure
33 of such information is permitted under the Federal reg-
34 ulations (concerning the privacy of individually identifi-
35 able health information) promulgated under section
36 264(c) of the Health Insurance Portability and Ac-
37 countability Act of 1996.

1 “(D) TIMING.—To the extent feasible, the infor-
2 mation exchanged under this paragraph shall be on an
3 interactive, real-time basis.

4 “(3) STANDARDS.—

5 “(A) IN GENERAL.—The Secretary shall provide
6 consistent with this subsection for the promulgation of
7 uniform standards relating to the requirements for
8 electronic prescription drug programs under paragraph
9 (2).

10 “(B) OBJECTIVES.—Such standards shall be con-
11 sistent with the objectives of improving—

12 “(i) patient safety;

13 “(ii) the quality of care provided to patients;

14 and

15 “(iii) efficiencies, including cost savings, in the
16 delivery of care.

17 “(C) DESIGN CRITERIA.—Such standards shall—

18 “(i) be designed so that, to the extent prac-
19 ticable, the standards do not impose an undue ad-
20 ministrative burden on prescribing health care pro-
21 fessionals and dispensing pharmacies and phar-
22 macists;

23 “(ii) be compatible with standards established
24 under part C of title XI, standards established
25 under subsection (b)(2)(B)(i), and with general
26 health information technology standards; and

27 “(iii) be designed so that they permit elec-
28 tronic exchange of drug labeling and drug listing
29 information maintained by the Food and Drug Ad-
30 ministration and the National Library of Medicine.

31 “(D) PERMITTING USE OF APPROPRIATE MES-
32 SAGING.—Such standards shall allow for the messaging
33 of information only if it relates to the appropriate pre-
34 scribing of drugs, including quality assurance measures
35 and systems referred to in subsection (c)(1)(B).

36 “(E) PERMITTING PATIENT DESIGNATION OF DIS-
37 PENSING PHARMACY.—

1 “(i) IN GENERAL.—Consistent with clause (ii),
 2 such standards shall permit a part D eligible indi-
 3 vidual to designate a particular pharmacy to dis-
 4 pense a prescribed drug.

5 “(ii) NO CHANGE IN BENEFITS.—Clause (i)
 6 shall not be construed as affecting—

7 “(I) the access required to be provided to
 8 pharmacies by a prescription drug plan; or

9 “(II) the application of any differences in
 10 benefits or payments under such a plan based
 11 on the pharmacy dispensing a covered part D
 12 drug.

13 “(4) DEVELOPMENT, PROMULGATION, AND MODIFICA-
 14 TION OF STANDARDS.—

15 “(A) INITIAL STANDARDS.—Not later than Sep-
 16 tember 1, 2005, the Secretary shall develop, adopt, rec-
 17 ognize, or modify initial uniform standards relating to
 18 the requirements for electronic prescription drug pro-
 19 grams described in paragraph (2) taking into consider-
 20 ation the recommendations (if any) from the National
 21 Committee on Vital and Health Statistics (as estab-
 22 lished under section 306(k) of the Public Health Serv-
 23 ice Act (42 U.S.C. 242k(k))) under subparagraph (B).

24 “(B) ROLE OF NCVHS.—The National Committee
 25 on Vital and Health Statistics shall develop rec-
 26 ommendations for uniform standards relating to such
 27 requirements in consultation with the following:

28 “(i) Standard setting organizations (as defined
 29 in section 1171(8))

30 “(ii) Practicing physicians.

31 “(iii) Hospitals.

32 “(iv) Pharmacies.

33 “(v) Practicing pharmacists.

34 “(vi) Pharmacy benefit managers.

35 “(vii) State boards of pharmacy.

36 “(viii) State boards of medicine.

37 “(ix) Experts on electronic prescribing.

1 “(x) Other appropriate Federal agencies.

2 “(C) PILOT PROJECT TO TEST INITIAL STAND-
3 ARDS.—

4 “(i) IN GENERAL.—During the 1-year period
5 that begins on January 1, 2006, the Secretary shall
6 conduct a pilot project to test the initial standards
7 developed under subparagraph (A) prior to the pro-
8 mulgation of the final uniform standards under
9 subparagraph (D) in order to provide for the effi-
10 cient implementation of the requirements described
11 in paragraph (2).

12 “(ii) EXCEPTION.—Pilot testing of standards
13 is not required under clause (i) where there already
14 is adequate industry experience with such stand-
15 ards, as determined by the Secretary after con-
16 sultation with effected standard setting organiza-
17 tions and industry users.

18 “(iii) VOLUNTARY PARTICIPATION OF PHYSI-
19 CIANS AND PHARMACIES.—In order to conduct the
20 pilot project under clause (i), the Secretary shall
21 enter into agreements with physicians, physician
22 groups, pharmacies, hospitals, PDP sponsors, MA
23 organizations, and other appropriate entities under
24 which health care professionals electronically trans-
25 mit prescriptions to dispensing pharmacies and
26 pharmacists in accordance with such standards.

27 “(iv) EVALUATION AND REPORT.—

28 “(I) EVALUATION.—The Secretary shall
29 conduct an evaluation of the pilot project con-
30 ducted under clause (i).

31 “(II) REPORT TO CONGRESS.—Not later
32 than April 1, 2007, the Secretary shall submit
33 to Congress a report on the evaluation con-
34 ducted under subclause (I).

35 “(D) FINAL STANDARDS.—Based upon the evalua-
36 tion of the pilot project under subparagraph (C)(iv)(I)
37 and not later than April 1, 2008, the Secretary shall

1 promulgate uniform standards relating to the require-
2 ments described in paragraph (2).

3 “(5) RELATION TO STATE LAWS.—The standards pro-
4 mulgated under this subsection shall supersede any State
5 law or regulation that—

6 “(A) is contrary to the standards or restricts the
7 ability to carry out this part; and

8 “(B) pertains to the electronic transmission of
9 medication history and of information on eligibility,
10 benefits, and prescriptions with respect to covered part
11 D drugs under this part.

12 “(6) ESTABLISHMENT OF SAFE HARBOR.—The Sec-
13 retary, in consultation with the Attorney General, shall pro-
14 mulgate regulations that provide for a safe harbor from
15 sanctions under paragraphs (1) and (2) of section
16 1128B(b) and an exception to the prohibition under sub-
17 section (a)(1) of section 1877 with respect to the provision
18 of nonmonetary remuneration (in the form of hardware,
19 software, or information technology and training services)
20 necessary and used solely to receive and transmit electronic
21 prescription information in accordance with the standards
22 promulgated under this subsection—

23 “(A) in the case of a hospital, by the hospital to
24 members of its medical staff;

25 “(B) in the case of a group practice (as defined
26 in section 1877(h)(4)), by the practice to prescribing
27 health care professionals who are members of such
28 practice; and

29 “(C) in the case of a PDP sponsor or MA organi-
30 zation, by the sponsor or organization to pharmacists
31 and pharmacies participating in the network of such
32 sponsor or organization, and to prescribing health care
33 professionals.

34 “(f) GRIEVANCE MECHANISM.—Each PDP sponsor shall
35 provide meaningful procedures for hearing and resolving griev-
36 ances between the sponsor (including any entity or individual
37 through which the sponsor provides covered benefits) and en-

1 rollees with prescription drug plans of the sponsor under this
2 part in accordance with section 1852(f).

3 “(g) COVERAGE DETERMINATIONS AND RECONSIDER-
4 ATIONS.—

5 “(1) APPLICATION OF COVERAGE DETERMINATION
6 AND RECONSIDERATION PROVISIONS.—A PDP sponsor
7 shall meet the requirements of paragraphs (1) through (3)
8 of section 1852(g) with respect to covered benefits under
9 the prescription drug plan it offers under this part in the
10 same manner as such requirements apply to an MA organi-
11 zation with respect to benefits it offers under an MA plan
12 under part C.

13 “(2) REQUEST FOR A DETERMINATION FOR THE
14 TREATMENT OF TIERED FORMULARY DRUG.—In the case of
15 a prescription drug plan offered by a PDP sponsor that
16 provides for tiered cost-sharing for drugs included within a
17 formulary and provides lower cost-sharing for preferred
18 drugs included within the formulary, a part D eligible indi-
19 vidual who is enrolled in the plan may request an exception
20 to the tiered cost-sharing structure. Under such an excep-
21 tion, a nonpreferred drug could be covered under the terms
22 applicable for preferred drugs if the prescribing physician
23 determines that the preferred drug for treatment of the
24 same condition either would not be as effective for the indi-
25 vidual or would have adverse effects for the individual or
26 both. A PDP sponsor shall have an exceptions process
27 under this paragraph consistent with guidelines established
28 by the Secretary for making a determination with respect
29 to such a request. Denial of such an exception shall be
30 treated as a coverage denial for purposes of applying sub-
31 section (h).

32 “(h) APPEALS.—

33 “(1) IN GENERAL.—Subject to paragraph (2), a PDP
34 sponsor shall meet the requirements of paragraphs (4) and
35 (5) of section 1852(g) with respect to benefits (including a
36 determination related to the application of tiered cost-shar-
37 ing described in subsection (g)(2)) in a manner similar (as

1 determined by the Secretary) to the manner such require-
2 ments apply to an MA organization with respect to benefits
3 under the original medicare fee-for-service program option
4 it offers under an MA plan under part C. In applying this
5 paragraph only the part D eligible individual shall be enti-
6 tled to bring such an appeal.

7 “(2) LIMITATION IN CASES ON NONFORMULARY DE-
8 TERMINATIONS.—A part D eligible individual who is en-
9 rolled in a prescription drug plan offered by a PDP sponsor
10 may appeal under paragraph (1) a determination not to
11 provide for coverage of a covered part D drug that is not
12 on the formulary under the plan only if the prescribing
13 physician determines that all covered part D drugs on any
14 tier of the formulary for treatment of the same condition
15 would not be as effective for the individual as the nonfor-
16 mulary drug, would have adverse effects for the individual,
17 or both.

18 “(3) TREATMENT OF NONFORMULARY DETERMINA-
19 TIONS.—If a PDP sponsor determines that a plan provides
20 coverage for a covered part D drug that is not on the for-
21 mulary of the plan, the drug shall be treated as being in-
22 cluded on the formulary for purposes of section 1860D-
23 2(b)(4)(C)(i).

24 “(i) PRIVACY, CONFIDENTIALITY, AND ACCURACY OF EN-
25 ROLLEE RECORDS.—The provisions of section 1852(h) shall
26 apply to a PDP sponsor and prescription drug plan in the same
27 manner as it applies to an MA organization and an MA plan.

28 “(j) TREATMENT OF ACCREDITATION.—Subparagraph (A)
29 of section 1852(e)(4) (relating to treatment of accreditation)
30 shall apply to a PDP sponsor under this part with respect to
31 the following requirements, in the same manner as it applies
32 to an MA organization with respect to the requirements in sub-
33 paragraph (B) (other than clause (vii) thereof) of such section:

34 “(1) Subsection (b) of this section (relating to access
35 to covered part D drugs).

36 “(2) Subsection (c) of this section (including quality
37 assurance and medication therapy management).

1 establish PDP regions which are not the same as MA re-
 2 gions if the Secretary determines that the establish-
 3 ment of different regions under this part would improve
 4 access to benefits under this part.

5 “(C) AUTHORITY FOR TERRITORIES.—The Sec-
 6 retary shall establish, and may revise, PDP regions for
 7 areas in States that are not within the 50 States or the
 8 District of Columbia.

9 “(3) NATIONAL PLAN.—Nothing in this subsection
 10 shall be construed as preventing a prescription drug plan
 11 from being offered in more than one PDP region (including
 12 all PDP regions).

13 “(b) SUBMISSION OF BIDS, PREMIUMS, AND RELATED IN-
 14 FORMATION.—

15 “(1) IN GENERAL.—A PDP sponsor shall submit to
 16 the Secretary information described in paragraph (2) with
 17 respect to each prescription drug plan it offers. Such infor-
 18 mation shall be submitted at the same time and in a simi-
 19 lar manner to the manner in which information described
 20 in paragraph (6) of section 1854(a) is submitted by an MA
 21 organization under paragraph (1) of such section.

22 “(2) INFORMATION DESCRIBED.—The information de-
 23 scribed in this paragraph is information on the following:

24 “(A) COVERAGE PROVIDED.—The prescription
 25 drug coverage provided under the plan, including the
 26 deductible and other cost-sharing.

27 “(B) ACTUARIAL VALUE.—The actuarial value of
 28 the qualified prescription drug coverage in the region
 29 for a part D eligible individual with a national average
 30 risk profile for the factors described in section 1860D-
 31 15(c)(1)(A) (as specified by the Secretary).

32 “(C) BID.—Information on the bid, including an
 33 actuarial certification of—

34 “(i) the basis for the actuarial value described
 35 in subparagraph (B) assumed in such bid;

36 “(ii) the portion of such bid attributable to
 37 basic prescription drug coverage and, if applicable,

1 the portion of such bid attributable to supplemental
2 benefits;

3 “(iii) assumptions regarding the reinsurance
4 subsidy payments provided under section 1860D–
5 15(b) subtracted from the actuarial value to
6 produce such bid; and

7 “(iv) administrative expenses assumed in the
8 bid.

9 “(D) SERVICE AREA.—The service area for the
10 plan.

11 “(E) LEVEL OF RISK ASSUMED.—

12 “(i) IN GENERAL.—Whether the PDP sponsor
13 requires a modification of risk level under clause
14 (ii) and, if so, the extent of such modification. Any
15 such modification shall apply with respect to all
16 prescription drug plans offered by a PDP sponsor
17 in a PDP region. This subparagraph shall not
18 apply to an MA–PD plan.

19 “(ii) RISK LEVELS DESCRIBED.—A modifica-
20 tion of risk level under this clause may consist of
21 one or more of the following:

22 “(I) INCREASE IN FEDERAL PERCENTAGE
23 ASSUMED IN INITIAL RISK CORRIDOR.—An
24 equal percentage point increase in the percents
25 applied under subparagraphs (B)(i), (B)(ii)(I),
26 (C)(i), and (C)(ii)(I) of section 1860D–
27 15(e)(2). In no case shall the application of
28 previous sentence prevent the application of a
29 higher percentage under section 1869D–
30 15(e)(2)(B)(iii).

31 “(II) INCREASE IN FEDERAL PERCENTAGE
32 ASSUMED IN SECOND RISK CORRIDOR.—An
33 equal percentage point increase in the percents
34 applied under subparagraphs (B)(ii)(II) and
35 (C)(ii)(II) of section 1860D–15(e)(2).

36 “(III) DECREASE IN SIZE OF RISK COR-
37 RIDORS.—A decrease in the threshold risk per-

1 centages specified in section 1860D–
2 15(e)(3)(C).

3 “(F) ADDITIONAL INFORMATION.—Such other in-
4 formation as the Secretary may require to carry out
5 this part.

6 “(3) PAPERWORK REDUCTION FOR OFFERING OF PRE-
7 SCRIPTION DRUG PLANS NATIONALLY OR IN MULTI-REGION
8 AREAS.—The Secretary shall establish requirements for in-
9 formation submission under this subsection in a manner
10 that promotes the offering of such plans in more than one
11 PDP region (including all regions) through the filing of
12 consolidated information.

13 “(c) ACTUARIAL VALUATION.—

14 “(1) PROCESSES.—For purposes of this part, the Sec-
15 retary shall establish processes and methods for deter-
16 mining the actuarial valuation of prescription drug cov-
17 erage, including—

18 “(A) an actuarial valuation of standard prescrip-
19 tion drug coverage under section 1860D–2(b);

20 “(B) actuarial valuations relating to alternative
21 prescription drug coverage under section 1860D–
22 2(c)(1);

23 “(C) an actuarial valuation of the reinsurance sub-
24 sidy payments under section 1860D–15(b);

25 “(D) the use of generally accepted actuarial prin-
26 ciples and methodologies; and

27 “(E) applying the same methodology for deter-
28 minations of actuarial valuations under subparagraphs
29 (A) and (B).

30 “(2) ACCOUNTING FOR DRUG UTILIZATION.—Such
31 processes and methods for determining actuarial valuation
32 shall take into account the effect that providing alternative
33 prescription drug coverage (rather than standard prescrip-
34 tion drug coverage) has on drug utilization.

35 “(3) RESPONSIBILITIES.—

36 “(A) PLAN RESPONSIBILITIES.—PDP sponsors
37 and MA organizations are responsible for the prepara-

1 tion and submission of actuarial valuations required
2 under this part for prescription drug plans and MA-
3 PD plans they offer.

4 “(B) USE OF OUTSIDE ACTUARIES.—Under the
5 processes and methods established under paragraph
6 (1), PDP sponsors offering prescription drug plans and
7 MA organizations offering MA–PD plans may use actu-
8 arial opinions certified by independent, qualified actu-
9 aries to establish actuarial values.

10 “(d) REVIEW OF INFORMATION AND NEGOTIATION.—

11 “(1) REVIEW OF INFORMATION.—The Secretary shall
12 review the information filed under subsection (b) for the
13 purpose of conducting negotiations under paragraph (2).

14 “(2) NEGOTIATION REGARDING TERMS AND CONDI-
15 TIONS.—Subject to subsection (i), in exercising the author-
16 ity under paragraph (1), the Secretary—

17 “(A) has the authority to negotiate the terms and
18 conditions of the proposed bid submitted and other
19 terms and conditions of a proposed plan; and

20 “(B) has authority similar to the authority of the
21 Director of the Office of Personnel Management with
22 respect to health benefits plans under chapter 89 of
23 title 5, United States Code.

24 “(e) APPROVAL OF PROPOSED PLANS.—

25 “(1) IN GENERAL.—After review and negotiation
26 under subsection (d), the Secretary shall approve or dis-
27 approve the prescription drug plan.

28 “(2) REQUIREMENTS FOR APPROVAL.—The Secretary
29 may approve a prescription drug plan only if the following
30 requirements are met:

31 “(A) COMPLIANCE WITH REQUIREMENTS.—The
32 plan and the PDP sponsor offering the plan comply
33 with the requirements under this part, including the
34 provision of qualified prescription drug coverage.

35 “(B) ACTUARIAL DETERMINATIONS.—The Sec-
36 retary determines that the plan and PDP sponsor meet
37 the requirements under this part relating to actuarial

1 determinations, including such requirements under sec-
2 tion 1860D–2(c).

3 “(C) APPLICATION OF FEHBP STANDARD.—

4 “(i) IN GENERAL.—The Secretary determines
5 that the portion of the bid submitted under sub-
6 section (b) that is attributable to basic prescription
7 drug coverage is supported by the actuarial bases
8 provided under such subsection and reasonably and
9 equitably reflects the revenue requirements (as
10 used for purposes of section 1302(8)(C) of the
11 Public Health Service Act) for benefits provided
12 under that plan, less the sum (determined on a
13 monthly per capita basis) of the actuarial value of
14 the reinsurance payments under section 1860D–
15 15(b).

16 “(ii) SUPPLEMENTAL COVERAGE.—The Sec-
17 retary determines that the portion of the bid sub-
18 mitted under subsection (b) that is attributable to
19 supplemental prescription drug coverage pursuant
20 to section 1860D–2(a)(2) is supported by the actu-
21 arial bases provided under such subsection and rea-
22 sonably and equitably reflects the revenue require-
23 ments (as used for purposes of section 1302(8)(C)
24 of the Public Health Service Act) for such coverage
25 under the plan.

26 “(D) PLAN DESIGN.—

27 “(i) IN GENERAL.—The Secretary does not
28 find that the design of the plan and its benefits (in-
29 cluding any formulary and tiered formulary struc-
30 ture) are likely to substantially discourage enroll-
31 ment by certain part D eligible individuals under
32 the plan.

33 “(ii) USE OF CATEGORIES AND CLASSES IN
34 FORMULARIES.—The Secretary may not find that
35 the design of categories and classes within a for-
36 mulary violates clause (i) if such categories and
37 classes are consistent with guidelines (if any) for

1 such categories and classes established by the
2 United States Pharmacopeia.

3 “(f) APPLICATION OF LIMITED RISK PLANS.—

4 “(1) CONDITIONS FOR APPROVAL OF LIMITED RISK
5 PLANS.—The Secretary may only approve a limited risk
6 plan (as defined in paragraph (4)(A)) for a PDP region if
7 the access requirements under section 1860D–3(a) would
8 not be met for the region but for the approval of such a
9 plan (or a fallback prescription drug plan under subsection
10 (g)).

11 “(2) RULES.—The following rules shall apply with re-
12 spect to the approval of a limited risk plan in a PDP re-
13 gion:

14 “(A) LIMITED EXERCISE OF AUTHORITY.—Only
15 the minimum number of such plans may be approved
16 in order to meet the access requirements under section
17 1860D–3(a).

18 “(B) MAXIMIZING ASSUMPTION OF RISK.—The
19 Secretary shall provide priority in approval for those
20 plans bearing the highest level of risk (as computed by
21 the Secretary), but the Secretary may take into ac-
22 count the level of the bids submitted by such plans.

23 “(C) NO FULL UNDERWRITING FOR LIMITED RISK
24 PLANS.—In no case may the Secretary approve a lim-
25 ited risk plan under which the modification of risk level
26 provides for no (or a de minimis) level of financial risk.

27 “(3) ACCEPTANCE OF ALL FULL RISK CONTRACTS.—
28 There shall be no limit on the number of full risk plans
29 that are approved under subsection (e).

30 “(4) RISK-PLANS DEFINED.—For purposes of this
31 subsection:

32 “(A) LIMITED RISK PLAN.—The term ‘limited risk
33 plan’ means a prescription drug plan that provides
34 basic prescription drug coverage and for which the
35 PDP sponsor includes a modification of risk level de-
36 scribed in subparagraph (E) of subsection (b)(2) in its

1 bid submitted for the plan under such subsection. Such
2 term does not include a fallback prescription drug plan.

3 “(B) FULL RISK PLAN.—The term ‘full risk plan’
4 means a prescription drug plan that is not a limited
5 risk plan or a fallback prescription drug plan.

6 “(g) GUARANTEEING ACCESS TO COVERAGE.—

7 “(1) SOLICITATION OF BIDS.—

8 “(A) IN GENERAL.—Separate from the bidding
9 process under subsection (b), the Secretary shall pro-
10 vide for a process for the solicitation of bids from eligi-
11 ble fallback entities (as defined in paragraph (2)) for
12 the offering in all fallback service areas (as defined in
13 paragraph (3)) in one or more PDP regions of a fall-
14 back prescription drug plan (as defined in paragraph
15 (4)) during the contract period specified in paragraph
16 (5)).

17 “(B) ACCEPTANCE OF BIDS.—

18 “(i) IN GENERAL.—Except as provided in this
19 subparagraph, the provisions of subsection (e) shall
20 apply with respect to the approval or disapproval of
21 fallback prescription drug plans. The Secretary
22 shall enter into contracts under this subsection
23 with eligible fallback entities for the offering of fall-
24 back prescription drug plans so approved in fall-
25 back service areas.

26 “(ii) LIMITATION OF 1 PLAN FOR ALL FALL-
27 BACK SERVICE AREAS IN A PDP REGION.—With re-
28 spect to all fallback service areas in any PDP re-
29 gion for a contract period, the Secretary shall ap-
30 prove the offering of only 1 fallback prescription
31 drug plan.

32 “(iii) COMPETITIVE PROCEDURES.—Competi-
33 tive procedures (as defined in section 4(5) of the
34 Office of Federal Procurement Policy Act (41
35 U.S.C. 403(5))) shall be used to enter into a con-
36 tract under this subsection. The provisions of sub-
37 section (d) of section 1874A shall apply to a con-

1 tract under this section in the same manner as
2 they apply to a contract under such section.

3 “(iv) TIMING.—The Secretary shall approve a
4 fallback prescription drug plan for a PDP region in
5 a manner so that, if there are any fallback service
6 areas in the region for a year, the fallback prescrip-
7 tion drug plan is offered at the same time as pre-
8 scription drug plans would otherwise be offered.

9 “(V) NO NATIONAL FALLBACK PLAN.—The
10 Secretary shall not enter into a contract with a sin-
11 gle fallback entity for the offering of fallback plans
12 throughout the United States.

13 “(2) ELIGIBLE FALLBACK ENTITY.—For purposes of
14 this section, the term ‘eligible fallback entity’ means, with
15 respect to all fallback service areas in a PDP region for a
16 contract period, an entity that—

17 “(A) meets the requirements to be a PDP sponsor
18 (or would meet such requirements but for the fact that
19 the entity is not a risk-bearing entity); and

20 “(B) does not submit a bid under section 1860D-
21 11(b) for any prescription drug plan for any PDP re-
22 gion for the first year of such contract period.

23 For purposes of subparagraph (B), an entity shall be treat-
24 ed as submitting a bid with respect to a prescription drug
25 plan if the entity is acting as a subcontractor of a PDP
26 sponsor that is offering such a plan. The previous sentence
27 shall not apply to entities that are subcontractors of an MA
28 organization except insofar as such organization is acting
29 as a PDP sponsor with respect to a prescription drug plan.

30 “(3) FALLBACK SERVICE AREA.—For purposes of this
31 subsection, the term ‘fallback service area’ means, for a
32 PDP region with respect to a year, any area within such
33 region for which the Secretary determines before the begin-
34 ning of the year that the access requirements of the first
35 sentence of section 1860D-3(a) will not be met for part D
36 eligible individuals residing in the area for the year.

1 “(4) FALLBACK PRESCRIPTION DRUG PLAN.—For pur-
2 poses of this part, the term ‘fallback prescription drug
3 plan’ means a prescription drug plan that—

4 “(A) only offers the standard prescription drug
5 coverage and access to negotiated prices described in
6 section 1860D–2(a)(1)(A) and does not include any
7 supplemental prescription drug coverage; and

8 “(B) meets such other requirements as the Sec-
9 retary may specify.

10 “(5) PAYMENTS UNDER THE CONTRACT.—

11 “(A) IN GENERAL.—A contract entered into under
12 this subsection shall provide for—

13 “(i) payment for the actual costs (taking into
14 account negotiated price concessions described in
15 section 1860D–2(d)(1)(B)) of covered part D drugs
16 provided to part D eligible individuals enrolled in a
17 fallback prescription drug plan offered by the enti-
18 ty; and

19 “(ii) payment of management fees that are
20 tied to performance measures established by the
21 Secretary for the management, administration, and
22 delivery of the benefits under the contract.

23 “(B) PERFORMANCE MEASURES.—The perform-
24 ance measures established by the Secretary pursuant to
25 subparagraph (A)(ii) shall include at least measures for
26 each of the following:

27 “(i) COSTS.—The entity contains costs to the
28 Medicare Prescription Drug Account and to part D
29 eligible individuals enrolled in a fallback prescrip-
30 tion drug plan offered by the entity through mecha-
31 nisms such as generic substitution and price dis-
32 counts.

33 “(ii) QUALITY PROGRAMS.—The entity pro-
34 vides such enrollees with quality programs that
35 avoid adverse drug reactions and overutilization
36 and reduce medical errors.

1 “(iii) CUSTOMER SERVICE.—The entity pro-
2 vides timely and accurate delivery of services and
3 pharmacy and beneficiary support services.

4 “(iv) BENEFIT ADMINISTRATION AND CLAIMS
5 ADJUDICATION.—The entity provides efficient and
6 effective benefit administration and claims adju-
7 dication.

8 “(6) MONTHLY BENEFICIARY PREMIUM.—Except as
9 provided in section 1860D–13(b) (relating to late enroll-
10 ment penalty) and subject to section 1860D–14 (relating to
11 low-income assistance), the monthly beneficiary premium to
12 be charged under a fallback prescription drug plan offered
13 in all fallback service areas in a PDP region shall be uni-
14 form and shall be equal to 25.5 percent of an amount equal
15 to the Secretary’s estimate of the average monthly per cap-
16 ita actuarial cost, including administrative expenses, under
17 the fallback prescription drug plan of providing coverage in
18 the region, as calculated by the Chief Actuary of the Cen-
19 ters for Medicare & Medicaid Services. In calculating such
20 administrative expenses, the Chief Actuary shall use a fac-
21 tor that is based on similar expenses of prescription drug
22 plans that are not fallback prescription drug plans.

23 “(7) GENERAL CONTRACT TERMS AND CONDITIONS.—

24 “(A) IN GENERAL.—Except as may be appropriate
25 to carry out this section, the terms and conditions of
26 contracts with eligible fallback entities offering fallback
27 prescription drug plans under this subsection shall be
28 the same as the terms and conditions of contracts
29 under this part for prescription drug plans.

30 “(B) PERIOD OF CONTRACT.—

31 “(i) IN GENERAL.—Subject to clause (ii), a
32 contract approved for a fallback prescription drug
33 plan for fallback service areas for a PDP region
34 under this section shall be for a period of 3 years
35 (except as may be renewed after a subsequent bid-
36 ding process).

1 “(ii) LIMITATION.—A fallback prescription
2 drug plan may be offered under a contract in an
3 area for a year only if that area is a fallback serv-
4 ice area for that year.

5 “(C) ENTITY NOT PERMITTED TO MARKET OR
6 BRAND FALLBACK PRESCRIPTION DRUG PLANS.—An el-
7 igible fallback entity with a contract under this sub-
8 section may not engage in any marketing or branding
9 of a fallback prescription drug plan.

10 “(h) ANNUAL REPORT ON USE OF LIMITED RISK PLANS
11 AND FALLBACK PLANS.—The Secretary shall submit to Con-
12 gress an annual report that describes instances in which limited
13 risk plans and fallback prescription drug plans were offered
14 under subsections (f) and (g). The Secretary shall include in
15 such report such recommendations as may be appropriate to
16 limit the need for the provision of such plans and to maximize
17 the assumption of financial risk under section subsection (f).

18 “(i) NONINTERFERENCE.—In order to promote competi-
19 tion under this part and in carrying out this part, the
20 Secretary—

21 “(1) may not interfere with the negotiations between
22 drug manufacturers and pharmacies and PDP sponsors;
23 and

24 “(2) may not require a particular formulary or insti-
25 tute a price structure for the reimbursement of covered
26 part D drugs.

27 “(j) COORDINATION OF BENEFITS.—A PDP sponsor offer-
28 ing a prescription drug plan shall permit State Pharmaceutical
29 Assistance Programs and Rx plans under sections 1860D–23
30 and 1860D–24 to coordinate benefits with the plan and, in con-
31 nection with such coordination with such a Program, not to im-
32 pose fees that are unrelated to the cost of coordination.

33 “REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION
34 DRUG PLAN (PDP) SPONSORS

35 “SEC. 1860D–12. (a) GENERAL REQUIREMENTS.—Each
36 PDP sponsor of a prescription drug plan shall meet the fol-
37 lowing requirements:

1 “(1) LICENSURE.—Subject to subsection (c), the spon-
2 sor is organized and licensed under State law as a risk-
3 bearing entity eligible to offer health insurance or health
4 benefits coverage in each State in which it offers a pre-
5 scription drug plan.

6 “(2) ASSUMPTION OF FINANCIAL RISK FOR UNSUB-
7 SIDIZED COVERAGE.—

8 “(A) IN GENERAL.—Subject to subparagraph (B),
9 to the extent that the entity is at risk the entity as-
10 sumes financial risk on a prospective basis for benefits
11 that it offers under a prescription drug plan and that
12 is not covered under section 1860D–15(b).

13 “(B) REINSURANCE PERMITTED.—The plan spon-
14 sor may obtain insurance or make other arrangements
15 for the cost of coverage provided to any enrollee to the
16 extent that the sponsor is at risk for providing such
17 coverage.

18 “(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the
19 case of a PDP sponsor that is not described in paragraph
20 (1) and for which a waiver has been approved under sub-
21 section (c), such sponsor shall meet solvency standards es-
22 tablished by the Secretary under subsection (d).

23 “(b) CONTRACT REQUIREMENTS.—

24 “(1) IN GENERAL.—The Secretary shall not permit
25 the enrollment under section 1860D–1 in a prescription
26 drug plan offered by a PDP sponsor under this part, and
27 the sponsor shall not be eligible for payments under section
28 1860D–14 or 1860D–15, unless the Secretary has entered
29 into a contract under this subsection with the sponsor with
30 respect to the offering of such plan. Such a contract with
31 a sponsor may cover more than one prescription drug plan.
32 Such contract shall provide that the sponsor agrees to com-
33 ply with the applicable requirements and standards of this
34 part and the terms and conditions of payment as provided
35 for in this part.

36 “(2) LIMITATION ON ENTITIES OFFERING FALLBACK
37 PRESCRIPTION DRUG PLANS.—The Secretary shall not

1 enter into a contract with a PDP sponsor for the offering
 2 of a prescription drug plan (other than a fallback prescrip-
 3 tion drug plan) in a PDP region for a year if the sponsor—

4 “(A) submitted a bid under section 1860D–11(g)
 5 for such year (as the first year of a contract period
 6 under such section) to offer a fallback prescription
 7 drug plan in any PDP region;

8 “(B) offers a fallback prescription drug plan in
 9 any PDP region during the year; or

10 “(C) offered a fallback prescription drug plan in
 11 that PDP region during the previous year.

12 For purposes of this paragraph, an entity shall be treated
 13 as submitting a bid with respect to a prescription drug plan
 14 or offering a fallback prescription drug plan if the entity
 15 is acting as a subcontractor of a PDP sponsor that is offer-
 16 ing such a plan. The previous sentence shall not apply to
 17 entities that are subcontractors of an MA organization ex-
 18 cept insofar as such organization is acting as a PDP spon-
 19 sor with respect to a prescription drug plan.

20 “(3) INCORPORATION OF CERTAIN MEDICARE ADVAN-
 21 TAGE CONTRACT REQUIREMENTS.—Except as otherwise
 22 provided, the following provisions of section 1857 shall
 23 apply to contracts under this section in the same manner
 24 as they apply to contracts under section 1857(a):

25 “(A) MINIMUM ENROLLMENT.—Paragraphs (1)
 26 and (3) of section 1857(b), except that—

27 “(i) the Secretary may increase the minimum
 28 number of enrollees required under such paragraph
 29 (1) as the Secretary determines appropriate; and

30 “(ii) the requirement of such paragraph (1)
 31 shall be waived during the first contract year with
 32 respect to an organization in a region.

33 “(B) CONTRACT PERIOD AND EFFECTIVENESS.—
 34 Section 1857(c), except that in applying paragraph
 35 (4)(B) of such section any reference to payment
 36 amounts under section 1853 shall be deemed payment
 37 amounts under section 1860D–15.

1 “(C) PROTECTIONS AGAINST FRAUD AND BENE-
2 FICIARY PROTECTIONS.—Section 1857(d).

3 “(D) ADDITIONAL CONTRACT TERMS.—Section
4 1857(e); except that section 1857(e)(2) shall apply as
5 specified to PDP sponsors and payments under this
6 part to an MA–PD plan shall be treated as expendi-
7 tures made under part D.

8 “(E) INTERMEDIATE SANCTIONS.—Section
9 1857(g) (other than paragraph (1)(F) of such section),
10 except that in applying such section the reference in
11 section 1857(g)(1)(B) to section 1854 is deemed a ref-
12 erence to this part.

13 “(F) PROCEDURES FOR TERMINATION.—Section
14 1857(h).

15 “(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND
16 CHOICE.—

17 “(1) AUTHORIZING WAIVER.—

18 “(A) IN GENERAL.—In the case of an entity that
19 seeks to offer a prescription drug plan in a State, the
20 Secretary shall waive the requirement of subsection
21 (a)(1) that the entity be licensed in that State if the
22 Secretary determines, based on the application and
23 other evidence presented to the Secretary, that any of
24 the grounds for approval of the application described in
25 paragraph (2) have been met.

26 “(B) APPLICATION OF REGIONAL PLAN WAIVER
27 RULE.—In addition to the waiver available under sub-
28 paragraph (A), the provisions of section 1858(d) shall
29 apply to PDP sponsors under this part in a manner
30 similar to the manner in which such provisions apply
31 to MA organizations under part C, except that no ap-
32 plication shall be required under paragraph (1)(B) of
33 such section in the case of a State that does not pro-
34 vide a licensing process for such a sponsor.

35 “(2) GROUNDS FOR APPROVAL.—

36 “(A) IN GENERAL.—The grounds for approval
37 under this paragraph are—

1 “(i) subject to subparagraph (B), the grounds
2 for approval described in subparagraphs (B), (C),
3 and (D) of section 1855(a)(2); and

4 “(ii) the application by a State of any grounds
5 other than those required under Federal law.

6 “(B) SPECIAL RULES.—In applying subparagraph
7 (A)(i)—

8 “(i) the ground of approval described in sec-
9 tion 1855(a)(2)(B) is deemed to have been met if
10 the State does not have a licensing process in effect
11 with respect to the PDP sponsor; and

12 “(ii) for plan years beginning before January
13 1, 2008, if the State does have such a licensing
14 process in effect, such ground for approval de-
15 scribed in such section is deemed to have been met
16 upon submission of an application described in
17 such section.

18 “(3) APPLICATION OF WAIVER PROCEDURES.—With
19 respect to an application for a waiver (or a waiver granted)
20 under paragraph (1)(A) of this subsection, the provisions
21 of subparagraphs (E), (F), and (G) of section 1855(a)(2)
22 shall apply, except that clauses (i) and (ii) of such subpara-
23 graph (E) shall not apply in the case of a State that does
24 not have a licensing process described in paragraph
25 (2)(B)(i) in effect.

26 “(4) REFERENCES TO CERTAIN PROVISIONS.—In ap-
27 plying provisions of section 1855(a)(2) under paragraphs
28 (2) and (3) of this subsection to prescription drug plans
29 and PDP sponsors—

30 “(A) any reference to a waiver application under
31 section 1855 shall be treated as a reference to a waiver
32 application under paragraph (1)(A) of this subsection;
33 and

34 “(B) any reference to solvency standards shall be
35 treated as a reference to solvency standards established
36 under subsection (d) of this section.

1 “(d) SOLVENCY STANDARDS FOR NON-LICENSED ENTI-
2 TIES.—

3 “(1) ESTABLISHMENT AND PUBLICATION.—The Sec-
4 retary, in consultation with the National Association of In-
5 surance Commissioners, shall establish and publish, by not
6 later than January 1, 2005, financial solvency and capital
7 adequacy standards for entities described in paragraph (2).

8 “(2) COMPLIANCE WITH STANDARDS.—A PDP spon-
9 sor that is not licensed by a State under subsection (a)(1)
10 and for which a waiver application has been approved
11 under subsection (c) shall meet solvency and capital ade-
12 quacy standards established under paragraph (1). The Sec-
13 retary shall establish certification procedures for such spon-
14 sors with respect to such solvency standards in the manner
15 described in section 1855(c)(2).

16 “(e) LICENSURE DOES NOT SUBSTITUTE FOR OR CON-
17 STITUTE CERTIFICATION.—The fact that a PDP sponsor is li-
18 censed in accordance with subsection (a)(1) or has a waiver ap-
19 plication approved under subsection (c) does not deem the
20 sponsor to meet other requirements imposed under this part for
21 a sponsor.

22 “(f) PERIODIC REVIEW AND REVISION OF STANDARDS.—

23 “(1) IN GENERAL.—Subject to paragraph (2), the Sec-
24 retary may periodically review the standards established
25 under this section and, based on such review, may revise
26 such standards if the Secretary determines such revision to
27 be appropriate.

28 “(2) PROHIBITION OF MIDYEAR IMPLEMENTATION OF
29 SIGNIFICANT NEW REGULATORY REQUIREMENTS.—The
30 Secretary may not implement, other than at the beginning
31 of a calendar year, regulations under this section that im-
32 pose new, significant regulatory requirements on a PDP
33 sponsor or a prescription drug plan.

34 “(g) PROHIBITION OF STATE IMPOSITION OF PREMIUM
35 TAXES; RELATION TO STATE LAWS.—The provisions of sec-
36 tions 1854(g) and 1856(b)(3) shall apply with respect to PDP
37 sponsors and prescription drug plans under this part in the

1 same manner as such sections apply to MA organizations and
2 MA plans under part C.

3 “PREMIUMS; LATE ENROLLMENT PENALTY

4 “SEC. 1860D–13. (a) MONTHLY BENEFICIARY PRE-
5 MIUM.—

6 “(1) COMPUTATION.—

7 “(A) IN GENERAL.—The monthly beneficiary pre-
8 mium for a prescription drug plan is the base bene-
9 ficiary premium computed under paragraph (2) as ad-
10 justed under this paragraph.

11 “(B) ADJUSTMENT TO REFLECT DIFFERENCE BE-
12 TWEEN BID AND NATIONAL AVERAGE BID.—

13 “(i) ABOVE AVERAGE BID.—If for a month the
14 amount of the standardized bid amount (as defined
15 in paragraph (5)) exceeds the amount of the ad-
16 justed national average monthly bid amount (as de-
17 fined in clause (iii)), the base beneficiary premium
18 for the month shall be increased by the amount of
19 such excess.

20 “(ii) BELOW AVERAGE BID.—If for a month
21 the amount of the adjusted national average
22 monthly bid amount for the month exceeds the
23 standardized bid amount, the base beneficiary pre-
24 mium for the month shall be decreased by the
25 amount of such excess.

26 “(iii) ADJUSTED NATIONAL AVERAGE MONTH-
27 LY BID AMOUNT DEFINED.—For purposes of this
28 subparagraph, the term ‘adjusted national average
29 monthly bid amount’ means the national average
30 monthly bid amount computed under paragraph
31 (4), as adjusted under section 1860D–15(e)(2).

32 “(C) INCREASE FOR SUPPLEMENTAL PRESCRIP-
33 TION DRUG BENEFITS.—The base beneficiary premium
34 shall be increased by the portion of the PDP approved
35 bid that is attributable to supplemental prescription
36 drug benefits.

1 “(D) INCREASE FOR LATE ENROLLMENT PEN-
2 ALTY.—The base beneficiary premium shall be in-
3 creased by the amount of any late enrollment penalty
4 under subsection (b).

5 “(E) DECREASE FOR LOW-INCOME ASSISTANCE.—
6 The monthly beneficiary premium is subject to decrease
7 in the case of a subsidy eligible individual under section
8 1860D–14.

9 “(F) UNIFORM PREMIUM.—Except as provided in
10 subparagraphs (D) and (E), the monthly beneficiary
11 premium for a prescription drug plan in a PDP region
12 is the same for all part D eligible individuals enrolled
13 in the plan.

14 “(2) BASE BENEFICIARY PREMIUM.—The base bene-
15 ficiary premium under this paragraph for a prescription
16 drug plan for a month is equal to the product—

17 “(A) the beneficiary premium percentage (as spec-
18 ified in paragraph (3)); and

19 “(B) the national average monthly bid amount
20 (computed under paragraph (4)) for the month.

21 “(3) BENEFICIARY PREMIUM PERCENTAGE.—For pur-
22 poses of this subsection, the beneficiary premium percent-
23 age for any year is the percentage equal to a fraction—

24 “(A) the numerator of which is 25.5 percent; and

25 “(B) the denominator of which is 100 percent
26 minus a percentage equal to—

27 “(i) the total reinsurance payments which the
28 Secretary estimates are payable under section
29 1860D–15(b) with respect to the coverage year; di-
30 vided by

31 “(ii) the sum of—

32 “(I) the amount estimated under clause (i)
33 for the year; and

34 “(II) the total payments which the Sec-
35 retary estimates will be paid to prescription
36 drug plans and MA–PD plans that are attrib-
37 utable to the standardized bid amount during

1 the year, taking into account amounts paid by
2 the Secretary and enrollees.

3 “(4) COMPUTATION OF NATIONAL AVERAGE MONTHLY
4 BID AMOUNT.—

5 “(A) IN GENERAL.—For each year (beginning
6 with 2006) the Secretary shall compute a national av-
7 erage monthly bid amount equal to the average of the
8 standardized bid amounts (as defined in paragraph (5))
9 for each prescription drug plan and for each MA–PD
10 plan described in section 1851(a)(2)(A)(i). Such aver-
11 age does not take into account the bids submitted for
12 MSA plans, MA private fee-for-service plan, and spe-
13 cialized MA plans for special needs individuals, PACE
14 programs under section 1894 (pursuant to section
15 1860D–21(f)), and under reasonable cost reimburse-
16 ment contracts under section 1876(h) (pursuant to sec-
17 tion 1860D–21(e)).

18 “(B) WEIGHTED AVERAGE.—

19 “(i) IN GENERAL.—The monthly national av-
20 erage monthly bid amount computed under sub-
21 paragraph (A) for a year shall be a weighted aver-
22 age, with the weight for each plan being equal to
23 the average number of part D eligible individuals
24 enrolled in such plan in the reference month (as de-
25 fined in section 1858(f)(4)).

26 “(ii) SPECIAL RULE FOR 2006.—For purposes
27 of applying this paragraph for 2006, the Secretary
28 shall establish procedures for determining the
29 weighted average under clause (i) for 2005.

30 “(5) STANDARDIZED BID AMOUNT DEFINED.—For
31 purposes of this subsection, the term ‘standardized bid
32 amount’ means the following:

33 “(A) PRESCRIPTION DRUG PLANS.—

34 “(i) BASIC COVERAGE.—In the case of a pre-
35 scription drug plan that provides basic prescription
36 drug coverage, the PDP approved bid (as defined
37 in paragraph (6)).

1 “(ii) SUPPLEMENTAL COVERAGE.—In the case
2 of a prescription drug plan that provides supple-
3 mental prescription drug coverage, the portion of
4 the PDP approved bid that is attributable to basic
5 prescription drug coverage.

6 “(B) MA–PD PLANS.—In the case of an MA–PD
7 plan, the portion of the accepted bid amount that is at-
8 tributable to basic prescription drug coverage.

9 “(6) PDP APPROVED BID DEFINED.—For purposes of
10 this part, the term ‘PDP approved bid’ means, with respect
11 to a prescription drug plan, the bid amount approved for
12 the plan under this part.

13 “(b) LATE ENROLLMENT PENALTY.—

14 “(1) IN GENERAL.—Subject to the succeeding provi-
15 sions of this subsection, in the case of a part D eligible in-
16 dividual described in paragraph (2) with respect to a con-
17 tinuous period of eligibility, there shall be an increase in
18 the monthly beneficiary premium established under sub-
19 section (a) in an amount determined under paragraph (3).

20 “(2) INDIVIDUALS SUBJECT TO PENALTY.—A part D
21 eligible individual described in this paragraph is, with re-
22 spect to a continuous period of eligibility, an individual for
23 whom there is a continuous period of 63 days or longer (all
24 of which in such continuous period of eligibility) beginning
25 on the day after the last date of the individual’s initial en-
26 rollment period under section 1860D–1(b)(2) and ending
27 on the date of enrollment under a prescription drug plan
28 or MA–PD plan during all of which the individual was not
29 covered under any creditable prescription drug coverage.

30 “(3) AMOUNT OF PENALTY.—

31 “(A) IN GENERAL.—The amount determined
32 under this paragraph for a part D eligible individual
33 for a continuous period of eligibility is the greater of—

34 “(i) an amount that the Secretary determines
35 is actuarially sound for each uncovered month (as
36 defined in subparagraph (B)) in the same contin-
37 uous period of eligibility; or

1 “(ii) 1 percent of the base beneficiary pre-
2 mium (computed under subsection (a)(2)) for each
3 such uncovered month in such period.

4 “(B) UNCOVERED MONTH DEFINED.—For pur-
5 poses of this subsection, the term ‘uncovered month’
6 means, with respect to a part D eligible individual, any
7 month beginning after the end of the initial enrollment
8 period under section 1860D–1(b)(2) unless the indi-
9 vidual can demonstrate that the individual had cred-
10 itable prescription drug coverage (as defined in para-
11 graph (4)) for any portion of such month.

12 “(4) CREDITABLE PRESCRIPTION DRUG COVERAGE DE-
13 FINED.—For purposes of this part, the term ‘creditable
14 prescription drug coverage’ means any of the following cov-
15 erage, but only if the coverage meets the requirement of
16 paragraph (5):

17 “(A) COVERAGE UNDER PRESCRIPTION DRUG
18 PLAN OR MA–PD PLAN.—Coverage under a prescription
19 drug plan or under an MA–PD plan.

20 “(B) MEDICAID.—Coverage under a medicaid plan
21 under title XIX or under a waiver under section 1115.

22 “(C) GROUP HEALTH PLAN.—Coverage under a
23 group health plan, including a health benefits plan
24 under chapter 89 of title 5, United States Code (com-
25 monly known as the Federal employees health benefits
26 program), and a qualified retiree prescription drug plan
27 (as defined in section 1860D–22(a)(2)).

28 “(D) STATE PHARMACEUTICAL ASSISTANCE PRO-
29 GRAM.—Coverage under a State pharmaceutical assist-
30 ance program described in section 1860D–23(b)(1).

31 “(E) VETERANS’ COVERAGE OF PRESCRIPTION
32 DRUGS.—Coverage for veterans, and survivors and de-
33 pendents of veterans, under chapter 17 of title 38,
34 United States Code.

35 “(F) PRESCRIPTION DRUG COVERAGE UNDER
36 MEDIGAP POLICIES.—Coverage under a medicare sup-
37 plemental policy under section 1882 that provides bene-

1 fits for prescription drugs (whether or not such cov-
 2 erage conforms to the standards for packages of bene-
 3 fits under section 1882(p)(1)).

4 “(G) MILITARY COVERAGE (INCLUDING
 5 TRICARE).—Coverage under chapter 55 of title 10,
 6 United States Code.

7 “(H) OTHER COVERAGE.—Such other coverage as
 8 the Secretary determines appropriate.

9 “(5) ACTUARIAL EQUIVALENCE REQUIREMENT.—Cov-
 10 erage meets the requirement of this paragraph only if the
 11 coverage is determined (in a manner specified by the Sec-
 12 retary) to provide coverage of the cost of prescription drugs
 13 the actuarial value of which (as defined by the Secretary)
 14 to the individual equals or exceeds the actuarial value of
 15 standard prescription drug coverage (as determined under
 16 section 1860D–11(c)).

17 “(6) PROCEDURES TO DOCUMENT CREDITABLE PRE-
 18 SCRIPTON DRUG COVERAGE.—

19 “(A) IN GENERAL.—The Secretary shall establish
 20 procedures (including the form, manner, and time) for
 21 the documentation of creditable prescription drug cov-
 22 erage, including procedures to assist in determining
 23 whether coverage meets the requirement of paragraph
 24 (5).

25 “(B) DISCLOSURE BY ENTITIES OFFERING CRED-
 26 ITABLE PRESCRIPTION DRUG COVERAGE.—

27 “(i) IN GENERAL.—Each entity that offers
 28 prescription drug coverage of the type described in
 29 subparagraphs (B) through (H) of paragraph (4)
 30 shall provide for disclosure, in a form, manner, and
 31 time consistent with standards established by the
 32 Secretary, to the Secretary and part D eligible indi-
 33 viduals of whether the coverage meets the require-
 34 ment of paragraph (5) or whether such coverage is
 35 changed so it no longer meets such requirement.

36 “(ii) DISCLOSURE OF NON-CREDITABLE COV-
 37 ERAGE.—In the case of such coverage that does not

1 meet such requirement, the disclosure to part D eli-
 2 gible individuals under this subparagraph shall in-
 3 clude information regarding the fact that because
 4 such coverage does not meet such requirement
 5 there are limitations on the periods in a year in
 6 which the individuals may enroll under a prescrip-
 7 tion drug plan or an MA-PD plan and that any
 8 such enrollment is subject to a late enrollment pen-
 9 alty under this subsection.

10 “(C) WAIVER OF REQUIREMENT.—In the case of
 11 a part D eligible individual who was enrolled in pre-
 12 scription drug coverage of the type described in sub-
 13 paragraphs (B) through (H) of paragraph (4) which is
 14 not creditable prescription drug coverage because it
 15 does not meet the requirement of paragraph (5), the in-
 16 dividual may apply to the Secretary to have such cov-
 17 erage treated as creditable prescription drug coverage
 18 if the individual establishes that the individual was not
 19 adequately informed that such coverage did not meet
 20 such requirement.

21 “(7) CONTINUOUS PERIOD OF ELIGIBILITY.—

22 “(A) IN GENERAL.—Subject to subparagraph (B),
 23 for purposes of this subsection, the term ‘continuous
 24 period of eligibility’ means, with respect to a part D eli-
 25 gible individual, the period that begins with the first
 26 day on which the individual is eligible to enroll in a
 27 prescription drug plan under this part and ends with
 28 the individual’s death.

29 “(B) SEPARATE PERIOD.—Any period during all
 30 of which a part D eligible individual is entitled to hos-
 31 pital insurance benefits under part A and—

32 “(i) which terminated in or before the month
 33 preceding the month in which the individual at-
 34 tained age 65; or

35 “(ii) for which the basis for eligibility for such
 36 entitlement changed between section 226(b) and

1 section 226(a), between 226(b) and section 226A,
 2 or between section 226A and section 226(a),
 3 shall be a separate continuous period of eligibility with
 4 respect to the individual (and each such period which
 5 terminates shall be deemed not to have existed for pur-
 6 poses of subsequently applying this paragraph).

7 “(c) COLLECTION OF MONTHLY BENEFICIARY PRE-
 8 MIUMS.—

9 “(1) IN GENERAL.—Subject to paragraphs (2) and
 10 (3), the provisions of section 1854(d) shall apply to PDP
 11 sponsors and premiums (and any late enrollment penalty)
 12 under this part in the same manner as they apply to MA
 13 organizations and beneficiary premiums under part C, ex-
 14 cept that any reference to a Trust Fund is deemed for this
 15 purpose a reference to the Medicare Prescription Drug Ac-
 16 count.

17 “(2) CREDITING OF LATE ENROLLMENT PENALTY.—

18 “(A) PORTION ATTRIBUTABLE TO INCREASED AC-
 19 TUARIAL COSTS.—With respect to late enrollment pen-
 20 alties imposed under subsection (b), the Secretary shall
 21 specify the portion of such a penalty that the Secretary
 22 estimates is attributable to increased actuarial costs as-
 23 sumed by the PDP sponsor or MA organization (and
 24 not taken into account through risk adjustment pro-
 25 vided under section 1860D–15(c)(1) or through rein-
 26 surance payments under section 1860D–15(b)) as a re-
 27 sult of such late enrollment.

28 “(B) COLLECTION THROUGH WITHHOLDING.—In
 29 the case of a late enrollment penalty that is collected
 30 from a part D eligible individual in the manner de-
 31 scribed in section 1854(d)(2)(A), the Secretary shall
 32 provide that only the portion of such penalty estimated
 33 under subparagraph (A) shall be paid to the PDP
 34 sponsor or MA organization offering the part D plan
 35 in which the individual is enrolled.

36 “(C) COLLECTION BY PLAN.—In the case of a late
 37 enrollment penalty that is collected from a part D eligi-

1 posed for that individual, and 100 percent of any
2 such penalties for any subsequent month.

3 “(B) ELIMINATION OF DEDUCTIBLE.—A reduction
4 in the annual deductible applicable under section
5 1860D–2(b)(1) to \$0.

6 “(C) CONTINUATION OF COVERAGE ABOVE THE
7 INITIAL COVERAGE LIMIT.—The continuation of cov-
8 erage from the initial coverage limit (under paragraph
9 (3) of section 1860D–2(b)) for expenditures incurred
10 through the total amount of expenditures at which ben-
11 efits are available under paragraph (4) of such section,
12 subject to the reduced cost-sharing described in sub-
13 paragraph (D).

14 “(D) REDUCTION IN COST-SHARING BELOW OUT-
15 OF-POCKET THRESHOLD.—

16 “(i) INSTITUTIONALIZED INDIVIDUALS.—In
17 the case of an individual who is a full-benefit dual
18 eligible individual and who is an institutionalized
19 individual or couple (as defined in section
20 1902(q)(1)(B)), the elimination of any beneficiary
21 coinsurance described in section 1860D–2(b)(2)
22 (for all amounts through the total amount of ex-
23 penditures at which benefits are available under
24 section 1860D–2(b)(4)).

25 “(ii) LOWEST INCOME DUAL ELIGIBLE INDI-
26 VIDUALS.—In the case of an individual not de-
27 scribed in clause (i) who is a full-benefit dual eligi-
28 ble individual and whose income does not exceed
29 100 percent of the poverty line applicable to a fam-
30 ily of the size involved, the substitution for the ben-
31 efiary coinsurance described in section 1860D–
32 2(b)(2) (for all amounts through the total amount
33 of expenditures at which benefits are available
34 under section 1860D–2(b)(4)) of a copayment
35 amount that does not exceed \$1 for a generic drug
36 or a preferred drug that is a multiple source drug
37 (as defined in section 1927(k)(7)(A)(i)) and \$3 for

1 any other drug, or, if less, the copayment amount
2 applicable to an individual under clause (iii).

3 “(iii) OTHER INDIVIDUALS.—In the case of an
4 individual not described in clause (i) or (ii), the
5 substitution for the beneficiary coinsurance de-
6 scribed in section 1860D–2(b)(2) (for all amounts
7 through the total amount of expenditures at which
8 benefits are available under section 1860D–
9 2(b)(4)) of a copayment amount that does not ex-
10 ceed the copayment amount specified under section
11 1860D–2(b)(4)(A)(i)(I) for the drug and year in-
12 volved.

13 “(E) ELIMINATION OF COST-SHARING ABOVE AN-
14 NUAL OUT-OF-POCKET THRESHOLD.—The elimination
15 of any cost-sharing imposed under section 1860D–
16 2(b)(4)(A).

17 “(2) OTHER INDIVIDUALS WITH INCOME BELOW 150
18 PERCENT OF POVERTY LINE.—In the case of a subsidy eli-
19 gible individual who is not described in paragraph (1), the
20 individual is entitled under this section to the following:

21 “(A) SLIDING SCALE PREMIUM SUBSIDY.—An in-
22 come-related premium subsidy determined on a linear
23 sliding scale ranging from 100 percent of the amount
24 described in paragraph (1)(A) for individuals with in-
25 comes at or below 135 percent of such level to 0 per-
26 cent of such amount for individuals with incomes at
27 150 percent of such level.

28 “(B) REDUCTION OF DEDUCTIBLE.—A reduction
29 in the annual deductible applicable under section
30 1860D–2(b)(1) to \$50.

31 “(C) CONTINUATION OF COVERAGE ABOVE THE
32 INITIAL COVERAGE LIMIT.—The continuation of cov-
33 erage from the initial coverage limit (under paragraph
34 (3) of section 1860D–2(b)) for expenditures incurred
35 through the total amount of expenditures at which ben-
36 efits are available under paragraph (4) of such section,

1 subject to the reduced coinsurance described in sub-
2 paragraph (D).

3 “(D) REDUCTION IN COST-SHARING BELOW OUT-
4 OF-POCKET THRESHOLD.—The substitution for the
5 beneficiary coinsurance described in section 1860D–
6 2(b)(2) (for all amounts above the deductible under
7 subparagraph (B) through the total amount of expendi-
8 tures at which benefits are available under section
9 1860D–2(b)(4)) of coinsurance of ‘15 percent’ instead
10 of coinsurance of ‘25 percent’ in section 1860D–
11 2(b)(2).

12 “(E) REDUCTION OF COST-SHARING ABOVE AN-
13 NUAL OUT-OF-POCKET THRESHOLD.—Subject to sub-
14 section (c), the substitution for the cost-sharing im-
15 posed under section 1860D–2(b)(4)(A) of a copayment
16 or coinsurance not to exceed the copayment or coinsur-
17 ance amount specified under section 1860D–
18 2(b)(4)(A)(i)(I) for the drug and year involved.

19 “(3) DETERMINATION OF ELIGIBILITY.—

20 “(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—
21 For purposes of this part, subject to subparagraph (F),
22 the term ‘subsidy eligible individual’ means a part D el-
23 igible individual who—

24 “(i) is enrolled in a prescription drug plan or
25 MA–PD plan;

26 “(ii) has income below 150 percent of the pov-
27 erty line applicable to a family of the size involved;
28 and

29 “(iii) meets the resources requirement de-
30 scribed in subparagraph (D) or (E).

31 “(B) DETERMINATIONS.—

32 “(i) IN GENERAL.—The determination of
33 whether a part D eligible individual residing in a
34 State is a subsidy eligible individual and whether
35 the individual is described in paragraph (1) shall be
36 determined under the State plan under title XIX
37 for the State under section 1935(a) or by the Com-

1 missioner of Social Security. There are authorized
2 to be appropriated to the Social Security Adminis-
3 tration such sums as may be necessary for the de-
4 termination of eligibility under this subparagraph.

5 “(ii) EFFECTIVE PERIOD.—Determinations
6 under this subparagraph shall be effective begin-
7 ning with the month in which the individual applies
8 for a determination that the individual is a subsidy
9 eligible individual and shall remain in effect for a
10 period specified by the Secretary, but not to exceed
11 1 year.

12 “(iii) REDETERMINATIONS AND APPEALS
13 THROUGH MEDICAID.—Redeterminations and ap-
14 peals, with respect to eligibility determinations
15 under clause (i) made under a State plan under
16 title XIX, shall be made in accordance with the fre-
17 quency of, and manner in which, redeterminations
18 and appeals of eligibility are made under such plan
19 for purposes of medical assistance under such title.

20 “(iv) REDETERMINATIONS AND APPEALS
21 THROUGH COMMISSIONER.—With respect to eligi-
22 bility determinations under clause (i) made by the
23 Commissioner of Social Security—

24 “(I) redeterminations shall be made at
25 such time or times as may be provided by the
26 Commissioner; and

27 “(II) the Commissioner shall establish pro-
28 cedures for appeals of such determinations that
29 are similar to the procedures described in the
30 third sentence of section 1631(c)(1)(A).

31 “(v) TREATMENT OF MEDICAID BENE-
32 FICIARIES.—Subject to subparagraph (F), the
33 Secretary—

34 “(I) shall provide that part D eligible indi-
35 viduals who are full-benefit dual eligible indi-
36 viduals (as defined in section 1935(c)(6)) or
37 who are recipients of supplemental security in-

1 come benefits under title XVI shall be treated
2 as subsidy eligible individuals described in
3 paragraph (1); and

4 “(II) may provide that part D eligible in-
5 dividuals not described in subclause (I) who are
6 determined for purposes of the State plan
7 under title XIX to be eligible for medical as-
8 sistance under clause (i), (iii), or (iv) of section
9 1902(a)(10)(E) are treated as being deter-
10 mined to be subsidy eligible individuals de-
11 scribed in paragraph (1).

12 Insofar as the Secretary determines that the eligi-
13 bility requirements under the State plan for med-
14 ical assistance referred to in subclause (II) are sub-
15 stantially the same as the requirements for being
16 treated as a subsidy eligible individual described in
17 paragraph (1), the Secretary shall provide for the
18 treatment described in such subclause.

19 “(C) INCOME DETERMINATIONS.—For purposes of
20 applying this section—

21 “(i) in the case of a part D eligible individual
22 who is not treated as a subsidy eligible individual
23 under subparagraph (B)(v), income shall be deter-
24 mined in the manner described in section
25 1905(p)(1)(B), without regard to the application of
26 section 1902(r)(2); and

27 “(ii) the term ‘poverty line’ has the meaning
28 given such term in section 673(2) of the Commu-
29 nity Services Block Grant Act (42 U.S.C. 9902(2)),
30 including any revision required by such section.

31 Nothing in clause (i) shall be construed to affect the
32 application of section 1902(r)(2) for the determination
33 of eligibility for medical assistance under title XIX.

34 “(D) RESOURCE STANDARD APPLIED TO FULL
35 LOW-INCOME SUBSIDY TO BE BASED ON THREE TIMES
36 SSI RESOURCE STANDARD.—The resources requirement
37 of this subparagraph is that an individual’s resources

1 (as determined under section 1613 for purposes of the
 2 supplemental security income program) do not
 3 exceed—

4 “(i) for 2006 three times the maximum
 5 amount of resources that an individual may have
 6 and obtain benefits under that program; and

7 “(ii) for a subsequent year the resource limita-
 8 tion established under this clause for the previous
 9 year increased by the annual percentage increase in
 10 the consumer price index (all items; U.S. city aver-
 11 age) as of September of such previous year.

12 Any resource limitation established under clause (ii)
 13 that is not a multiple of \$10 shall be rounded to the
 14 nearest multiple of \$10.

15 “(E) ALTERNATIVE RESOURCE STANDARD.—

16 “(i) IN GENERAL.—The resources requirement
 17 of this subparagraph is that an individual’s re-
 18 sources (as determined under section 1613 for pur-
 19 poses of the supplemental security income pro-
 20 gram) do not exceed—

21 “(I) for 2006, \$10,000 (or \$20,000 in the
 22 case of the combined value of the individual’s
 23 assets or resources and the assets or resources
 24 of the individual’s spouse); and

25 “(II) for a subsequent year the dollar
 26 amounts specified in this subclause (or sub-
 27 clause (I)) for the previous year increased by
 28 the annual percentage increase in the consumer
 29 price index (all items; U.S. city average) as of
 30 September of such previous year.

31 Any dollar amount established under subclause (II)
 32 that is not a multiple of \$10 shall be rounded to
 33 the nearest multiple of \$10.

34 “(ii) USE OF SIMPLIFIED APPLICATION FORM
 35 AND PROCESS.—The Secretary, jointly with the
 36 Commissioner of Social Security, shall—

1 “(I) develop a model, simplified applica-
 2 tion form and process consistent with clause
 3 (iii) for the determination and verification of a
 4 part D eligible individual’s assets or resources
 5 under this subparagraph; and

6 “(II) provide such form to States.

7 “(iii) DOCUMENTATION AND SAFEGUARDS.—
 8 Under such process—

9 “(I) the application form shall consist of
 10 an attestation under penalty of perjury regard-
 11 ing the level of assets or resources (or com-
 12 bined assets and resources in the case of a
 13 married part D eligible individual) and valu-
 14 ations of general classes of assets or resources;

15 “(II) such form shall be accompanied by
 16 copies of recent statements (if any) from finan-
 17 cial institutions in support of the application;
 18 and

19 “(III) matters attested to in the applica-
 20 tion shall be subject to appropriate methods of
 21 verification.

22 “(iv) METHODOLOGY FLEXIBILITY.—The Sec-
 23 retary may permit a State in making eligibility de-
 24 terminations for premium and cost-sharing sub-
 25 sidies under this section to use the same asset or
 26 resource methodologies that are used with respect
 27 to eligibility for medical assistance for medicare
 28 cost-sharing described in section 1905(p) so long as
 29 the Secretary determines that the use of such
 30 methodologies will not result in any significant dif-
 31 ferences in the number of individuals determined to
 32 be subsidy eligible individuals.

33 “(F) TREATMENT OF TERRITORIAL RESIDENTS.—
 34 In the case of a part D eligible individual who is not
 35 a resident of the 50 States or the District of Columbia,
 36 the individual is not eligible to be a subsidy eligible in-
 37 dividual under this section but may be eligible for fi-

1 nancial assistance with prescription drug expenses
2 under section 1935(e).

3 “(4) INDEXING DOLLAR AMOUNTS.—

4 “(A) COPAYMENT FOR LOWEST INCOME DUAL ELI-
5 GIBLE INDIVIDUALS.—The dollar amounts applied
6 under paragraph (1)(D)(ii)—

7 “(i) for 2007 shall be the dollar amounts spec-
8 ified in such paragraph increased by the annual
9 percentage increase in the consumer price index (all
10 items; U.S. city average) as of September of such
11 previous year; or

12 “(ii) for a subsequent year shall be the dollar
13 amounts specified in this clause (or clause (i)) for
14 the previous year increased by the annual percent-
15 age increase in the consumer price index (all items;
16 U.S. city average) as of September of such previous
17 year.

18 Any amount established under clause (i) or (ii), that is
19 based on an increase of \$1 or \$3, that is not a multiple
20 of 5 cents or 10 cents, respectively, shall be rounded
21 to the nearest multiple of 5 cents or 10 cents, respec-
22 tively.

23 “(B) REDUCED DEDUCTIBLE.—The dollar amount
24 applied under paragraph (2)(B)—

25 “(i) for 2007 shall be the dollar amount speci-
26 fied in such paragraph increased by the annual per-
27 centage increase described in section 1860D-
28 2(b)(6) for 2007; or

29 “(ii) for a subsequent year shall be the dollar
30 amount specified in this clause (or clause (i)) for
31 the previous year increased by the annual percent-
32 age increase described in section 1860D-2(b)(6)
33 for the year involved.

34 Any amount established under clause (i) or (ii) that is
35 not a multiple of \$1 shall be rounded to the nearest
36 multiple of \$1.

37 “(b) PREMIUM SUBSIDY AMOUNT.—

1 “(1) IN GENERAL.—The premium subsidy amount de-
 2 scribed in this subsection for a subsidy eligible individual
 3 residing in a PDP region and enrolled in a prescription
 4 drug plan or MA–PD plan is the low-income benchmark
 5 premium amount (as defined in paragraph (2)) for the
 6 PDP region in which the individual resides or, if greater,
 7 the amount specified in paragraph (3).

8 “(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DE-
 9 FINED.—

10 “(A) IN GENERAL.—For purposes of this sub-
 11 section, the term ‘low-income benchmark premium
 12 amount’ means, with respect to a PDP region in
 13 which—

14 “(i) all prescription drug plans are offered by
 15 the same PDP sponsor, the weighted average of the
 16 amounts described in subparagraph (B)(i) for such
 17 plans; or

18 “(ii) there are prescription drug plans offered
 19 by more than one PDP sponsor, the weighted aver-
 20 age of amounts described in subparagraph (B) for
 21 prescription drug plans and MA–PD plans de-
 22 scribed in section 1851(a)(2)(A)(i) offered in such
 23 region.

24 “(B) PREMIUM AMOUNTS DESCRIBED.—The pre-
 25 mium amounts described in this subparagraph are, in
 26 the case of—

27 “(i) a prescription drug plan that is a basic
 28 prescription drug plan, the monthly beneficiary pre-
 29 mium for such plan;

30 “(ii) a prescription drug plan that provides al-
 31 ternative prescription drug coverage the actuarial
 32 value of which is greater than that of standard pre-
 33 scription drug coverage, the portion of the monthly
 34 beneficiary premium that is attributable to basic
 35 prescription drug coverage; and

36 “(iii) an MA–PD plan, the portion of the MA
 37 monthly prescription drug beneficiary premium

1 that is attributable to basic prescription drug bene-
2 fits (described in section 1852(a)(6)(B)(ii)).

3 The premium amounts described in this subparagraph
4 do not include any amounts attributable to late enroll-
5 ment penalties under section 1860D-13(b).

6 “(3) ACCESS TO 0 PREMIUM PLAN.—In no case shall
7 the premium subsidy amount under this subsection for a
8 PDP region be less than the lowest monthly beneficiary
9 premium for a prescription drug plan that offers basic pre-
10 scription drug coverage in the region.

11 “(c) ADMINISTRATION OF SUBSIDY PROGRAM.—

12 “(1) IN GENERAL.—The Secretary shall provide a
13 process whereby, in the case of a part D eligible individual
14 who is determined to be a subsidy eligible individual and
15 who is enrolled in a prescription drug plan or is enrolled
16 in an MA-PD plan—

17 “(A) the Secretary provides for a notification of
18 the PDP sponsor or the MA organization offering the
19 plan involved that the individual is eligible for a sub-
20 sidy and the amount of the subsidy under subsection
21 (a);

22 “(B) the sponsor or organization involved reduces
23 the premiums or cost-sharing otherwise imposed by the
24 amount of the applicable subsidy and submits to the
25 Secretary information on the amount of such reduction;

26 “(C) the Secretary periodically and on a timely
27 basis reimburses the sponsor or organization for the
28 amount of such reductions; and

29 “(D) the Secretary ensures the confidentiality of
30 individually identifiable information.

31 In applying subparagraph (C), the Secretary shall compute
32 reductions based upon imposition under subsections
33 (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts
34 applied under such subsections.

35 “(2) USE OF CAPITATED FORM OF PAYMENT.—The re-
36 imbursement under this section with respect to cost-sharing
37 subsidies may be computed on a capitated basis, taking

1 into account the actuarial value of the subsidies and with
 2 appropriate adjustments to reflect differences in the risks
 3 actually involved.

4 “(d) RELATION TO MEDICAID PROGRAM.—For special
 5 provisions under the medicaid program relating to medicare
 6 prescription drug benefits, see section 1935.

7 “SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR
 8 QUALIFIED PRESCRIPTION DRUG COVERAGE

9 “SEC. 1860D–15. (a) SUBSIDY PAYMENT.—In order to re-
 10 duce premium levels applicable to qualified prescription drug
 11 coverage for part D eligible individuals consistent with an over-
 12 all subsidy level of 74.5 percent for basic prescription drug cov-
 13 erage, to reduce adverse selection among prescription drug
 14 plans and MA–PD plans, and to promote the participation of
 15 PDP sponsors under this part and MA organizations under
 16 part C, the Secretary shall provide for payment to a PDP spon-
 17 sor that offers a prescription drug plan and an MA organiza-
 18 tion that offers an MA–PD plan of the following subsidies in
 19 accordance with this section:

20 “(1) DIRECT SUBSIDY.—A direct subsidy for each part
 21 D eligible individual enrolled in a prescription drug plan or
 22 MA–PD plan for a month equal to—

23 “(A) the amount of the plan’s standardized bid
 24 amount (as defined in section 1860D–13(a)(5)), ad-
 25 justed under subsection (c)(1), reduced by

26 “(B) the base beneficiary premium (as computed
 27 under paragraph (2) of section 1860D–13(a) and as
 28 adjusted under paragraph (1)(B) of such section).

29 “(2) SUBSIDY THROUGH REINSURANCE.—The reinsur-
 30 ance payment amount (as defined in subsection (b)).

31 This section constitutes budget authority in advance of appro-
 32 priations Acts and represents the obligation of the Secretary to
 33 provide for the payment of amounts provided under this sec-
 34 tion.

35 “(b) REINSURANCE PAYMENT AMOUNT.—

36 “(1) IN GENERAL.—The reinsurance payment amount
 37 under this subsection for a part D eligible individual en-

1 rolled in a prescription drug plan or MA–PD plan for a
2 coverage year is an amount equal to 80 percent of the al-
3 lowable reinsurance costs (as specified in paragraph (2))
4 attributable to that portion of gross covered prescription
5 drug costs as specified in paragraph (3) incurred in the
6 coverage year after such individual has incurred costs that
7 exceed the annual out-of-pocket threshold specified in sec-
8 tion 1860D–2(b)(4)(B).

9 “(2) ALLOWABLE REINSURANCE COSTS.—For pur-
10 poses of this section, the term ‘allowable reinsurance costs’
11 means, with respect to gross covered prescription drug
12 costs under a prescription drug plan offered by a PDP
13 sponsor or an MA–PD plan offered by an MA organization,
14 the part of such costs that are actually paid (net of dis-
15 counts, chargebacks, and average percentage rebates) by
16 the sponsor or organization or by (or on behalf of) an en-
17 rollee under the plan, but in no case more than the part
18 of such costs that would have been paid under the plan if
19 the prescription drug coverage under the plan were basic
20 prescription drug coverage, or, in the case of a plan pro-
21 viding supplemental prescription drug coverage, if such cov-
22 erage were standard prescription drug coverage.

23 “(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—
24 For purposes of this section, the term ‘gross covered pre-
25 scription drug costs’ means, with respect to a part D eligi-
26 ble individual enrolled in a prescription drug plan or MA–
27 PD plan during a coverage year, the costs incurred under
28 the plan, not including administrative costs, but including
29 costs directly related to the dispensing of covered part D
30 drugs during the year and costs relating to the deductible.
31 Such costs shall be determined whether they are paid by
32 the individual or under the plan, regardless of whether the
33 coverage under the plan exceeds basic prescription drug
34 coverage.

35 “(4) COVERAGE YEAR DEFINED.—For purposes of this
36 section, the term ‘coverage year’ means a calendar year in
37 which covered part D drugs are dispensed if the claim for

1 such drugs (and payment on such claim) is made not later
2 than such period after the end of such year as the Sec-
3 retary specifies.

4 “(c) ADJUSTMENTS RELATING TO BIDS.—

5 “(1) HEALTH STATUS RISK ADJUSTMENT.—

6 “(A) ESTABLISHMENT OF RISK ADJUSTORS.—The
7 Secretary shall establish an appropriate methodology
8 for adjusting the standardized bid amount under sub-
9 section (a)(1)(A) to take into account variation in costs
10 for basic prescription drug coverage among prescription
11 drug plans and MA–PD plans based on the differences
12 in actuarial risk of different enrollees being served. Any
13 such risk adjustment shall be designed in a manner so
14 as not to result in a change in the aggregate amounts
15 payable to such plans under subsection (a)(1) and
16 through that portion of the monthly beneficiary pre-
17 scription drug premiums described in subsection
18 (a)(1)(B) and MA monthly prescription drug bene-
19 ficiary premiums.

20 “(B) CONSIDERATIONS.—In establishing the meth-
21 odology under subparagraph (A), the Secretary may
22 take into account the similar methodologies used under
23 section 1853(a)(3) to adjust payments to MA organiza-
24 tions for benefits under the original medicare fee-for-
25 service program option.

26 “(C) DATA COLLECTION.—In order to carry out
27 this paragraph, the Secretary shall require—

28 “(i) PDP sponsors to submit data regarding
29 drug claims that can be linked at the individual
30 level to part A and part B data and such other in-
31 formation as the Secretary determines necessary;
32 and

33 “(ii) MA organizations that offer MA–PD
34 plans to submit data regarding drug claims that
35 can be linked at the individual level to other data
36 that such organizations are required to submit to

1 the Secretary and such other information as the
2 Secretary determines necessary.

3 “(D) PUBLICATION.—At the time of publication of
4 risk adjustment factors under section
5 1853(b)(1)(B)(i)(II), the Secretary shall publish the
6 risk adjusters established under this paragraph for the
7 succeeding year.

8 “(2) GEOGRAPHIC ADJUSTMENT.—

9 “(A) IN GENERAL.—Subject to subparagraph (B),
10 for purposes of section 1860D–13(a)(1)(B)(iii), the
11 Secretary shall establish an appropriate methodology
12 for adjusting the national average monthly bid amount
13 (computed under section 1860D–13(a)(4)) to take into
14 account differences in prices for covered part D drugs
15 among PDP regions.

16 “(B) DE MINIMIS RULE.—If the Secretary deter-
17 mines that the price variations described in subpara-
18 graph (A) among PDP regions are de minimis, the Sec-
19 retary shall not provide for adjustment under this para-
20 graph.

21 “(C) BUDGET NEUTRAL ADJUSTMENT.—Any ad-
22 justment under this paragraph shall be applied in a
23 manner so as to not result in a change in the aggregate
24 payments made under this part that would have been
25 made if the Secretary had not applied such adjustment.

26 “(d) PAYMENT METHODS.—

27 “(1) IN GENERAL.—Payments under this section shall
28 be based on such a method as the Secretary determines.
29 The Secretary may establish a payment method by which
30 interim payments of amounts under this section are made
31 during a year based on the Secretary’s best estimate of
32 amounts that will be payable after obtaining all of the in-
33 formation.

34 “(2) REQUIREMENT FOR PROVISION OF INFORMA-
35 TION.—

36 “(A) REQUIREMENT.—Payments under this sec-
37 tion to a PDP sponsor or MA organization are condi-

1 tioned upon the furnishing to the Secretary, in a form
2 and manner specified by the Secretary, of such infor-
3 mation as may be required to carry out this section.

4 “(B) RESTRICTION ON USE OF INFORMATION.—
5 Information disclosed or obtained pursuant to subpara-
6 graph (A) may be used by officers, employees, and con-
7 tractors of the Department of Health and Human
8 Services only for the purposes of, and to the extent
9 necessary in, carrying out this section.

10 “(3) SOURCE OF PAYMENTS.—Payments under this
11 section shall be made from the Medicare Prescription Drug
12 Account.

13 “(4) APPLICATION OF ENROLLEE ADJUSTMENT.—The
14 provisions of section 1853(a)(2) shall apply to payments to
15 PDP sponsors under this section in the same manner as
16 they apply to payments to MA organizations under section
17 1853(a).

18 “(e) PORTION OF TOTAL PAYMENTS TO A SPONSOR OR
19 ORGANIZATION SUBJECT TO RISK (APPLICATION OF RISK
20 CORRIDORS).—

21 “(1) COMPUTATION OF ADJUSTED ALLOWABLE RISK
22 CORRIDOR COSTS.—

23 “(A) IN GENERAL.—For purposes of this sub-
24 section, the term ‘adjusted allowable risk corridor costs’
25 means, for a plan for a coverage year (as defined in
26 subsection (b)(4))—

27 “(i) the allowable risk corridor costs (as de-
28 fined in subparagraph (B)) for the plan for the
29 year, reduced by

30 “(ii) the sum of (I) the total reinsurance pay-
31 ments made under subsection (b) to the sponsor of
32 the plan for the year, and (II) the total subsidy
33 payments made under section 1860D–14 to the
34 sponsor of the plan for the year.

35 “(B) ALLOWABLE RISK CORRIDOR COSTS.—For
36 purposes of this subsection, the term ‘allowable risk
37 corridor costs’ means, with respect to a prescription

1 drug plan offered by a PDP sponsor or an MA-PD
2 plan offered by an MA organization, the part of costs
3 (not including administrative costs, but including costs
4 directly related to the dispensing of covered part D
5 drugs during the year) incurred by the sponsor or orga-
6 nization under the plan that are actually paid (net of
7 discounts, chargebacks, and average percentage re-
8 bates) by the sponsor or organization under the plan,
9 but in no case more than the part of such costs that
10 would have been paid under the plan if the prescription
11 drug coverage under the plan were basic prescription
12 drug coverage, or, in the case of a plan providing sup-
13 plemental prescription drug coverage, if such coverage
14 were basic prescription drug coverage taking into ac-
15 count the adjustment under section 1860D-11(c)(2).
16 In computing allowable costs under this paragraph, the
17 Secretary shall compute such costs based upon imposi-
18 tion under paragraphs (1)(D) and (2)(E) of section
19 1860D-14(a) of the maximum amount of copayments
20 permitted under such paragraphs.

21 “(2) ADJUSTMENT OF PAYMENT.—

22 “(A) NO ADJUSTMENT IF ADJUSTED ALLOWABLE
23 RISK CORRIDOR COSTS WITHIN RISK CORRIDOR.—If the
24 adjusted allowable risk corridor costs (as defined in
25 paragraph (1)) for the plan for the year are at least
26 equal to the first threshold lower limit of the risk cor-
27 ridor (specified in paragraph (3)(A)(i)), but not greater
28 than the first threshold upper limit of the risk corridor
29 (specified in paragraph (3)(A)(iii)) for the plan for the
30 year, then no payment adjustment shall be made under
31 this subsection.

32 “(B) INCREASE IN PAYMENT IF ADJUSTED AL-
33 LOWABLE RISK CORRIDOR COSTS ABOVE UPPER LIMIT
34 OF RISK CORRIDOR.—

35 “(i) COSTS BETWEEN FIRST AND SECOND
36 THRESHOLD UPPER LIMITS.—If the adjusted allow-
37 able risk corridor costs for the plan for the year are

1 greater than the first threshold upper limit, but not
2 greater than the second threshold upper limit, of
3 the risk corridor for the plan for the year, the Sec-
4 retary shall increase the total of the payments
5 made to the sponsor or organization offering the
6 plan for the year under this section by an amount
7 equal to 50 percent (or, for 2006 and 2007, 75
8 percent or 90 percent if the conditions described in
9 clause (iii) are met for the year) of the difference
10 between such adjusted allowable risk corridor costs
11 and the first threshold upper limit of the risk cor-
12 ridor.

13 “(ii) COSTS ABOVE SECOND THRESHOLD
14 UPPER LIMITS.—If the adjusted allowable risk cor-
15 ridor costs for the plan for the year are greater
16 than the second threshold upper limit of the risk
17 corridor for the plan for the year, the Secretary
18 shall increase the total of the payments made to
19 the sponsor or organization offering the plan for
20 the year under this section by an amount equal to
21 the sum of—

22 “(I) 50 percent (or, for 2006 and 2007,
23 75 percent or 90 percent if the conditions de-
24 scribed in clause (iii) are met for the year) of
25 the difference between the second threshold
26 upper limit and the first threshold upper limit;
27 and

28 “(II) 80 percent of the difference between
29 such adjusted allowable risk corridor costs and
30 the second threshold upper limit of the risk
31 corridor.

32 “(iii) CONDITIONS FOR APPLICATION OF HIGH-
33 ER PERCENTAGE FOR 2006 AND 2007.—The condi-
34 tions described in this clause are met for 2006 or
35 2007 if the Secretary determines with respect to
36 such year that—

1 “(I) at least 60 percent of prescription
2 drug plans and MA–PD plans to which this
3 subsection applies have adjusted allowable risk
4 corridor costs for the plan for the year that are
5 more than the first threshold upper limit of the
6 risk corridor for the plan for the year; and

7 “(II) such plans represent at least 60 per-
8 cent of part D eligible individuals enrolled in
9 any prescription drug plan or MA–PD plan.

10 “(C) REDUCTION IN PAYMENT IF ADJUSTED AL-
11 LOWABLE RISK CORRIDOR COSTS BELOW LOWER LIMIT
12 OF RISK CORRIDOR.—

13 “(i) COSTS BETWEEN FIRST AND SECOND
14 THRESHOLD LOWER LIMITS.—If the adjusted al-
15 lowable risk corridor costs for the plan for the year
16 are less than the first threshold lower limit, but not
17 less than the second threshold lower limit, of the
18 risk corridor for the plan for the year, the Sec-
19 retary shall reduce the total of the payments made
20 to the sponsor or organization offering the plan for
21 the year under this section by an amount (or other-
22 wise recover from the sponsor or organization an
23 amount) equal to 50 percent (or, for 2006 and
24 2007, 75 percent) of the difference between the
25 first threshold lower limit of the risk corridor and
26 such adjusted allowable risk corridor costs.

27 “(ii) COSTS BELOW SECOND THRESHOLD
28 LOWER LIMIT.—If the adjusted allowable risk cor-
29 ridor costs for the plan for the year are less the
30 second threshold lower limit of the risk corridor for
31 the plan for the year, the Secretary shall reduce
32 the total of the payments made to the sponsor or
33 organization offering the plan for the year under
34 this section by an amount (or otherwise recover
35 from the sponsor or organization an amount) equal
36 to the sum of—

1 “(I) 50 percent (or, for 2006 and 2007,
2 75 percent) of the difference between the first
3 threshold lower limit and the second threshold
4 lower limit; and

5 “(II) 80 percent of the difference between
6 the second threshold upper limit of the risk
7 corridor and such adjusted allowable risk cor-
8 ridor costs.

9 “(3) ESTABLISHMENT OF RISK CORRIDORS.—

10 “(A) IN GENERAL.—For each plan year the Sec-
11 retary shall establish a risk corridor for each prescrip-
12 tion drug plan and each MA–PD plan. The risk cor-
13 ridor for a plan for a year shall be equal to a range
14 as follows:

15 “(i) FIRST THRESHOLD LOWER LIMIT.—The
16 first threshold lower limit of such corridor shall be
17 equal to—

18 “(I) the target amount described in sub-
19 paragraph (B) for the plan; minus

20 “(II) an amount equal to the first thresh-
21 old risk percentage for the plan (as determined
22 under subparagraph (C)(i)) of such target
23 amount.

24 “(ii) SECOND THRESHOLD LOWER LIMIT.—
25 The second threshold lower limit of such corridor
26 shall be equal to—

27 “(I) the target amount described in sub-
28 paragraph (B) for the plan; minus

29 “(II) an amount equal to the second
30 threshold risk percentage for the plan (as de-
31 termined under subparagraph (C)(ii)) of such
32 target amount.

33 “(iii) FIRST THRESHOLD UPPER LIMIT.—The
34 first threshold upper limit of such corridor shall be
35 equal to the sum of—

36 “(I) such target amount; and

1 “(II) the amount described in clause
2 (i)(II).

3 “(iv) SECOND THRESHOLD UPPER LIMIT.—
4 The second threshold upper limit of such corridor
5 shall be equal to the sum of—

6 “(I) such target amount; and

7 “(II) the amount described in clause
8 (ii)(II).

9 “(B) TARGET AMOUNT DESCRIBED.—The target
10 amount described in this paragraph is, with respect to
11 a prescription drug plan or an MA–PD plan in a year,
12 the total amount of payments paid to the PDP sponsor
13 or MA–PD organization for the plan for the year, tak-
14 ing into account amounts paid by the Secretary and en-
15 rollees, based upon the standardized bid amount (as de-
16 fined in section 1860D–13(a)(5) and as risk adjusted
17 under subsection (c)(1)), reduced by the total amount
18 of administrative expenses for the year assumed in
19 such standardized bid.

20 “(C) FIRST AND SECOND THRESHOLD RISK PER-
21 CENTAGE DEFINED.—

22 “(i) FIRST THRESHOLD RISK PERCENTAGE.—
23 Subject to clause (iii), for purposes of this section,
24 the first threshold risk percentage is—

25 “(I) for 2006 and 2007, and 2.5 percent;

26 “(II) for 2008 through 2011, 5 percent;

27 and

28 “(III) for 2012 and subsequent years, a
29 percentage established by the Secretary, but in
30 no case less than 5 percent.

31 “(ii) SECOND THRESHOLD RISK PERCENT-
32 AGE.—Subject to clause (iii), for purposes of this
33 section, the second threshold risk percentage is—

34 “(I) for 2006 and 2007, 5 percent;

35 “(II) for 2008 through 2011, 10 percent;

36 and

1 “(III) for 2012 and subsequent years, a
2 percentage established by the Secretary that is
3 greater than the percent established for the
4 year under clause (i)(III), but in no case less
5 than 10 percent.

6 “(iii) REDUCTION OF RISK PERCENTAGE TO
7 ENSURE 2 PLANS IN AN AREA.—Pursuant to sec-
8 tion 1860D–11(b)(2)(E)(ii), a PDP sponsor may
9 submit a bid that requests a decrease in the appli-
10 cable first or second threshold risk percentages or
11 an increase in the percents applied under para-
12 graph (2).

13 “(4) PLANS AT RISK FOR ENTIRE AMOUNT OF SUP-
14 PLEMENTAL PRESCRIPTION DRUG COVERAGE.—A PDP
15 sponsor and MA organization that offers a plan that pro-
16 vides supplemental prescription drug benefits shall be at
17 full financial risk for the provision of such supplemental
18 benefits.

19 “(5) NO EFFECT ON MONTHLY PREMIUM.—No adjust-
20 ment in payments made by reason of this subsection shall
21 affect the monthly beneficiary premium or the MA monthly
22 prescription drug beneficiary premium.

23 “(f) DISCLOSURE OF INFORMATION.—

24 “(1) IN GENERAL.—Each contract under this part and
25 under part C shall provide that—

26 “(A) the PDP sponsor offering a prescription drug
27 plan or an MA organization offering an MA–PD plan
28 shall provide the Secretary with such information as
29 the Secretary determines is necessary to carry out this
30 section; and

31 “(B) the Secretary shall have the right in accord-
32 ance with section 1857(d)(2)(B) (as applied under sec-
33 tion 1860D–12(b)(3)(C)) to inspect and audit any
34 books and records of a PDP sponsor or MA organiza-
35 tion that pertain to the information regarding costs
36 provided to the Secretary under subparagraph (A).

1 “(2) RESTRICTION ON USE OF INFORMATION.—Infor-
 2 mation disclosed or obtained pursuant to the provisions of
 3 this section may be used by officers, employees, and con-
 4 tractors of the Department of Health and Human Services
 5 only for the purposes of, and to the extent necessary in,
 6 carrying out this section.

7 “(g) PAYMENT FOR FALLBACK PRESCRIPTION DRUG
 8 PLANS.—In lieu of the amounts otherwise payable under this
 9 section to a PDP sponsor offering a fallback prescription drug
 10 plan (as defined in section 1860D–3(c)(4)), the amount payable
 11 shall be the amounts determined under the contract for such
 12 plan pursuant to section 1860D–11(g)(5).

13 “MEDICARE PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL
 14 SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND
 15 “SEC. 1860D–16. (a) ESTABLISHMENT AND OPERATION
 16 OF ACCOUNT.—

17 “(1) ESTABLISHMENT.—There is created within the
 18 Federal Supplementary Medical Insurance Trust Fund es-
 19 tablished by section 1841 an account to be known as the
 20 ‘Medicare Prescription Drug Account’ (in this section re-
 21 ferred to as the ‘Account’).

22 “(2) FUNDING.—The Account shall consist of such
 23 gifts and bequests as may be made as provided in section
 24 201(i)(1), accrued interest on balances in the Account, and
 25 such amounts as may be deposited in, or appropriated to,
 26 such Account as provided in this part.

27 “(3) SEPARATE FROM REST OF TRUST FUND.—Funds
 28 provided under this part to the Account shall be kept sepa-
 29 rate from all other funds within the Federal Supplementary
 30 Medical Insurance Trust Fund, but shall be invested, and
 31 such investments redeemed, in the same manner as all
 32 other funds and investments within such Trust Fund.

33 “(b) PAYMENTS FROM ACCOUNT.—

34 “(1) IN GENERAL.—The Managing Trustee shall pay
 35 from time to time from the Account such amounts as the
 36 Secretary certifies are necessary to make payments to oper-
 37 ate the program under this part, including—

1 “(A) payments under section 1860D–14 (relating
2 to low-income subsidy payments);

3 “(B) payments under section 1860D–15 (relating
4 to subsidy payments and payments for fallback plans);

5 “(C) payments to sponsors of qualified retiree pre-
6 scription drug plans under section 1860D–22(a); and

7 “(D) payments with respect to administrative ex-
8 penses under this part in accordance with section
9 201(g).

10 “(2) TRANSFERS TO MEDICAID ACCOUNT FOR IN-
11 CREASED ADMINISTRATIVE COSTS.—The Managing Trustee
12 shall transfer from time to time from the Account to the
13 Grants to States for Medicaid account amounts the Sec-
14 retary certifies are attributable to increases in payment re-
15 sulting from the application of section 1935(b).

16 “(3) PAYMENTS OF PREMIUMS WITHHELD.—The Man-
17 aging Trustee shall make payment to the PDP sponsor or
18 MA organization involved of the premiums (and the portion
19 of late enrollment penalties) that are collected in the man-
20 ner described in section 1854(d)(2)(A) and that are pay-
21 able under a prescription drug plan or MA–PD plan offered
22 by such sponsor or organization.

23 “(4) TREATMENT IN RELATION TO PART B PRE-
24 MIUM.—Amounts payable from the Account shall not be
25 taken into account in computing actuarial rates or pre-
26 mium amounts under section 1839.

27 “(c) DEPOSITS INTO ACCOUNT.—

28 “(1) LOW-INCOME TRANSFER.—Amounts paid under
29 section 1935(c) (and any amounts collected or offset under
30 paragraph (1)(C) of such section) are deposited into the
31 Account.

32 “(2) AMOUNTS WITHHELD.—Pursuant to sections
33 1860D–13(c) and 1854(d) (as applied under this part),
34 amounts that are withheld (and allocated) to the Account
35 are deposited into the Account.

36 “(3) APPROPRIATIONS TO COVER GOVERNMENT CON-
37 TRIBUTIONS.—There are authorized to be appropriated

1 from time to time, out of any moneys in the Treasury not
 2 otherwise appropriated, to the Account, an amount equiva-
 3 lent to the amount of payments made from the Account
 4 under subsection (b) plus such amounts as the Managing
 5 Trustee certifies is necessary to maintain an appropriate
 6 contingency margin, reduced by the amounts deposited
 7 under paragraph (1) or subsection (a)(2).

8 “(4) INITIAL FUNDING AND RESERVE.—In order to
 9 assure prompt payment of benefits provided under this part
 10 and the administrative expenses thereunder during the
 11 early months of the program established by this part and
 12 to provide an initial contingency reserve, there are author-
 13 ized to be appropriated to the Account, out of any moneys
 14 in the Treasury not otherwise appropriated, such amount
 15 as the Secretary certifies are required, but not to exceed 10
 16 percent of the estimated total expenditures from such Ac-
 17 count in 2006.

18 “(5) TRANSFER OF ANY REMAINING BALANCE FROM
 19 TRANSITIONAL ASSISTANCE ACCOUNT.—Any balance in the
 20 Transitional Assistance Account that is transferred under
 21 section 1860D–31(k)(5) shall be deposited into the Ac-
 22 count.

23 “Subpart 3—Application to Medicare Advantage Program and
 24 Treatment of Employer-Sponsored Programs and Other Pre-
 25 scription Drug Plans

26 “APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND
 27 RELATED MANAGED CARE PROGRAMS

28 “SEC. 1860D–21. (a) SPECIAL RULES RELATING TO OF-
 29 FERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—

30 “(1) IN GENERAL.—An MA organization on and after
 31 January 1, 2006—

32 “(A) may not offer an MA plan described in sec-
 33 tion 1851(a)(2)(A) in an area unless either that plan
 34 (or another MA plan offered by the organization in
 35 that same service area) includes required prescription
 36 drug coverage (as defined in paragraph (2)); and

1 “(B) may not offer prescription drug coverage
2 (other than that required under parts A and B) to an
3 enrollee—

4 “(i) under an MSA plan; or

5 “(ii) under another MA plan unless such drug
6 coverage under such other plan provides qualified
7 prescription drug coverage and unless the require-
8 ments of this section with respect to such coverage
9 are met.

10 “(2) QUALIFYING COVERAGE.—For purposes of para-
11 graph (1)(A), the term ‘required coverage’ means with re-
12 spect to an MA–PD plan—

13 “(A) basic prescription drug coverage; or

14 “(B) qualified prescription drug coverage that pro-
15 vides supplemental prescription drug coverage, so long
16 as there is no MA monthly supplemental beneficiary
17 premium applied under the plan (due to the application
18 of a credit against such premium of a rebate under sec-
19 tion 1854(b)(1)(C)).

20 “(b) APPLICATION OF DEFAULT ENROLLMENT RULES.—

21 “(1) SEAMLESS CONTINUATION.—In applying section
22 1851(c)(3)(A)(ii), an individual who is enrolled in a health
23 benefits plan shall not be considered to have been deemed
24 to make an election into an MA–PD plan unless such
25 health benefits plan provides any prescription drug cov-
26 erage.

27 “(2) MA CONTINUATION.—In applying section
28 1851(c)(3)(B), an individual who is enrolled in an MA plan
29 shall not be considered to have been deemed to make an
30 election into an MA–PD plan unless—

31 “(A) for purposes of the election as of January 1,
32 2006, the MA plan provided as of December 31, 2005,
33 any prescription drug coverage; or

34 “(B) for periods after January 1, 2006, such MA
35 plan is an MA–PD plan.

36 “(3) DISCONTINUANCE OF MA–PD ELECTION DURING
37 FIRST YEAR OF ELIGIBILITY.—In applying the second sen-

1 tence of section 1851(e)(4) in the case of an individual who
 2 is electing to discontinue enrollment in an MA–PD plan,
 3 the individual shall be permitted to enroll in a prescription
 4 drug plan under part D at the time of the election of cov-
 5 erage under the original medicare fee-for-service program.

6 “(4) RULES REGARDING ENROLLEES IN MA PLANS
 7 NOT PROVIDING QUALIFIED PRESCRIPTION DRUG COV-
 8 ERAGE.—In the case of an individual who is enrolled in an
 9 MA plan (other than an MSA plan) that does not provide
 10 qualified prescription drug coverage, if the organization of-
 11 fering such coverage discontinues the offering with respect
 12 to the individual of all MA plans that do not provide such
 13 coverage—

14 “(i) the individual is deemed to have elected
 15 the original medicare fee-for-service program op-
 16 tion, unless the individual affirmatively elects to en-
 17 roll in an MA–PD plan; and

18 “(ii) in the case of such a deemed election, the
 19 disenrollment shall be treated as an involuntary
 20 termination of the MA plan described in subpara-
 21 graph (B)(ii) of section 1882(s)(3) for purposes of
 22 applying such section.

23 The information disclosed under section 1852(c)(1) for in-
 24 dividuals who are enrolled in such an MA plan shall include
 25 information regarding such rules.

26 “(c) APPLICATION OF PART D RULES FOR PRESCRIPTION
 27 DRUG COVERAGE.—With respect to the offering of qualified
 28 prescription drug coverage by an MA organization under this
 29 part on and after January 1, 2006—

30 “(1) IN GENERAL.—Except as otherwise provided, the
 31 provisions of this part shall apply under part C with re-
 32 spect to prescription drug coverage provided under MA–PD
 33 plans in lieu of the other provisions of part C that would
 34 apply to such coverage under such plans.

35 “(2) WAIVER.—The Secretary shall waive the provi-
 36 sions referred to in paragraph (1) to the extent the Sec-
 37 retary determines that such provisions duplicate, or are in

1 conflict with, provisions otherwise applicable to the organi-
2 zation or plan under part C or as may be necessary in
3 order to improve coordination of this part with the benefits
4 under this part.

5 “(3) TREATMENT OF MA OWNED AND OPERATED
6 PHARMACIES.—The Secretary may waive the requirement
7 of section 1860D–4(b)(1)(C) in the case of an MA–PD
8 plan that provides access (other than mail order) to quali-
9 fied prescription drug coverage through pharmacies owned
10 and operated by the MA organization, if the Secretary de-
11 termines that the organization’s pharmacy network is suffi-
12 cient to provide comparable access for enrollees under the
13 plan.

14 “(d) SPECIAL RULES FOR PRIVATE FEE-FOR-SERVICE
15 PLANS THAT OFFER PRESCRIPTION DRUG COVERAGE.—With
16 respect to an MA plan described in section 1851(a)(2)(C) that
17 offers qualified prescription drug coverage, on and after Janu-
18 ary 1, 2006, the following rules apply:

19 “(1) REQUIREMENTS REGARDING NEGOTIATED
20 PRICES.—Subsections (a)(1) and (d)(1) of section 1860D–
21 2 and section 1860D–4(b)(2)(A) shall not be construed to
22 require the plan to provide negotiated prices (described in
23 subsection (d)(1)(B) of such section), but shall apply to the
24 extent the plan does so.

25 “(2) MODIFICATION OF PHARMACY ACCESS STANDARD
26 AND DISCLOSURE REQUIREMENT.—If the plan provides
27 coverage for drugs purchased from all pharmacies, without
28 charging additional cost-sharing, and without regard to
29 whether they are participating pharmacies in a network or
30 have entered into contracts or agreements with pharmacies
31 to provide drugs to enrollees covered by the plan, sub-
32 sections (b)(1)(C) and (k) of section 1860D–4 shall not
33 apply to the plan.

34 “(3) DRUG UTILIZATION MANAGEMENT PROGRAM AND
35 MEDICATION THERAPY MANAGEMENT PROGRAM NOT RE-
36 QUIRED.—The requirements of subparagraphs (A) and (C)
37 of section 1860D–4(c)(1) shall not apply to the plan.

1 “(4) APPLICATION OF REINSURANCE.—The Secretary
2 shall determine the amount of reinsurance payments under
3 section 1860D–15(b) using a methodology that—

4 “(A) bases such amount on the Secretary’s esti-
5 mate of the amount of such payments that would be
6 payable if the plan were an MA–PD plan described in
7 section 1851(a)(2)(A)(i) and the previous provisions of
8 this subsection did not apply; and

9 “(B) takes into account the average reinsurance
10 payments made under section 1860D–15(b) for popu-
11 lations of similar risk under MA–PD plans described in
12 such section.

13 “(5) EXEMPTION FROM RISK CORRIDOR PROVI-
14 SIONS.—The provisions of section 1860D–15(e) shall not
15 apply.

16 “(6) EXEMPTION FROM NEGOTIATIONS.—Subsections
17 (d) and (e)(2)(C) of section 1860D–11 shall not apply and
18 the provisions of section 1854(a)(5)(B) prohibiting the re-
19 view, approval, or disapproval of amounts described in such
20 section shall apply to the proposed bid and terms and con-
21 ditions described in section 1860D–11(d).

22 “(7) TREATMENT OF INCURRED COSTS WITHOUT RE-
23 GARD TO FORMULARY.—The exclusion of costs incurred for
24 covered part D drugs which are not included (or treated as
25 being included) in a plan’s formulary under section 1860D–
26 2(b)(4)(B)(i) shall not apply insofar as the plan does not
27 utilize a formulary.

28 “(e) APPLICATION TO REASONABLE COST REIMBURSE-
29 MENT CONTRACTORS.—

30 “(1) IN GENERAL.—Subject to paragraphs (2) and (3)
31 and rules established by the Secretary, in the case of an
32 organization that is providing benefits under a reasonable
33 cost reimbursement contract under section 1876(h) and
34 that elects to provide qualified prescription drug coverage
35 to a part D eligible individual who is enrolled under such
36 a contract, the provisions of this part (and related provi-
37 sions of part C) shall apply to the provision of such cov-

1 erage to such enrollee in the same manner as such provi-
2 sions apply to the provision of such coverage under an MA-
3 PD local plan described in section 1851(a)(2)(A)(i) and
4 coverage under such a contract that so provides qualified
5 prescription drug coverage shall be deemed to be an MA-
6 PD local plan.

7 “(2) LIMITATION ON ENROLLMENT.—In applying
8 paragraph (1), the organization may not enroll part D eli-
9 gible individuals who are not enrolled under the reasonable
10 cost reimbursement contract involved.

11 “(3) BIDS NOT INCLUDED IN DETERMINING NATIONAL
12 AVERAGE MONTHLY BID AMOUNT.—The bid of an organiza-
13 tion offering prescription drug coverage under this sub-
14 section shall not be taken into account in computing the
15 national average monthly bid amount and low-income
16 benchmark premium amount under this part.

17 “(f) APPLICATION TO PACE.—

18 “(1) IN GENERAL.—Subject to paragraphs (2) and (3)
19 and rules established by the Secretary, in the case of a
20 PACE program under section 1894 that elects to provide
21 qualified prescription drug coverage to a part D eligible in-
22 dividual who is enrolled under such program, the provisions
23 of this part (and related provisions of part C) shall apply
24 to the provision of such coverage to such enrollee in a man-
25 ner that is similar to the manner in which such provisions
26 apply to the provision of such coverage under an MA-PD
27 local plan described in section 1851(a)(2)(A)(ii) and a
28 PACE program that so provides such coverage may be
29 deemed to be an MA-PD local plan.

30 “(2) LIMITATION ON ENROLLMENT.—In applying
31 paragraph (1), the organization may not enroll part D eli-
32 gible individuals who are not enrolled under the PACE pro-
33 gram involved.

34 “(3) BIDS NOT INCLUDED IN DETERMINING STAND-
35 ARDIZED BID AMOUNT.—The bid of an organization offer-
36 ing prescription drug coverage under this subsection is not
37 be taken into account in computing any average benchmark

1 bid amount and low-income benchmark premium amount
2 under this part.

3 “SPECIAL RULES FOR EMPLOYER-SPONSORED PROGRAMS

4 “SEC. 1860D–22. (a) SUBSIDY PAYMENT.—

5 “(1) IN GENERAL.—The Secretary shall provide in ac-
6 cordance with this subsection for payment to the sponsor
7 of a qualified retiree prescription drug plan (as defined in
8 paragraph (2)) of a special subsidy payment equal to the
9 amount specified in paragraph (3) for each qualified cov-
10 ered retiree under the plan (as defined in paragraph (4)).
11 This subsection constitutes budget authority in advance of
12 appropriations Acts and represents the obligation of the
13 Secretary to provide for the payment of amounts provided
14 under this section.

15 “(2) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN
16 DEFINED.—For purposes of this subsection, the term
17 ‘qualified retiree prescription drug plan’ means employ-
18 ment-based retiree health coverage (as defined in sub-
19 section (c)(1)) if, with respect to a part D eligible indi-
20 vidual who is a participant or beneficiary under such cov-
21 erage, the following requirements are met:

22 “(A) ATTESTATION OF ACTUARIAL EQUIVALENCE
23 TO STANDARD COVERAGE.—The sponsor of the plan
24 provides the Secretary, annually or at such other time
25 as the Secretary may require, with an attestation that
26 the actuarial value of prescription drug coverage under
27 the plan (as determined using the processes and meth-
28 ods described in section 1860D–11(c)) is at least equal
29 to the actuarial value of standard prescription drug
30 coverage.

31 “(B) AUDITS.—The sponsor of the plan, or an ad-
32 ministrator of the plan designated by the sponsor, shall
33 maintain (and afford the Secretary access to) such
34 records as the Secretary may require for purposes of
35 audits and other oversight activities necessary to en-
36 sure the adequacy of prescription drug coverage and
37 the accuracy of payments made under this section. The

1 provisions of section 1860D–2(d)(3) shall apply to such
 2 information under this section (including such actuarial
 3 value and attestation) in a manner similar to the man-
 4 ner in which they apply to financial records of PDP
 5 sponsors and MA organizations.

6 “(C) PROVISION OF DISCLOSURE REGARDING PRE-
 7 SCRIPTIION DRUG COVERAGE.—The sponsor of the plan
 8 shall provide for disclosure of information regarding
 9 prescription drug coverage in accordance with section
 10 1860D–13(b)(6)(B).

11 “(3) EMPLOYER AND UNION SPECIAL SUBSIDY
 12 AMOUNTS.—

13 “(A) IN GENERAL.—For purposes of this sub-
 14 section, the special subsidy payment amount under this
 15 paragraph for a qualifying covered retiree for a cov-
 16 erage year enrolled with the sponsor of a qualified re-
 17 tiree prescription drug plan is, for the portion of the
 18 retiree’s gross covered retiree plan-related prescription
 19 drug costs (as defined in subparagraph (C)(ii)) for such
 20 year that exceeds the cost threshold amount specified
 21 in subparagraph (B) and does not exceed the cost limit
 22 under such subparagraph, an amount equal to 28 per-
 23 cent of the allowable retiree costs (as defined in sub-
 24 paragraph (C)(i)) attributable to such gross covered
 25 prescription drug costs.

26 “(B) COST THRESHOLD AND COST LIMIT APPLICA-
 27 BLE.—

28 “(i) IN GENERAL.—Subject to clause (ii)—

29 “(I) the cost threshold under this subpara-
 30 graph is equal to \$250 for plan years that end
 31 in 2006; and

32 “(II) the cost limit under this subpara-
 33 graph is equal to \$5,000 for plan years that
 34 end in 2006.

35 “(ii) INDEXING.—The cost threshold and cost
 36 limit amounts specified in subclauses (I) and (II)
 37 of clause (i) for a plan year that ends after 2006

1 shall be adjusted in the same manner as the annual
2 deductible and the annual out-of-pocket threshold,
3 respectively, are annually adjusted under para-
4 graphs (1) and (4)(B) of section 1860D–2(b).

5 “(C) DEFINITIONS.—For purposes of this para-
6 graph:

7 “(i) ALLOWABLE RETIREE COSTS.—The term
8 ‘allowable retiree costs’ means, with respect to
9 gross covered prescription drug costs under a quali-
10 fied retiree prescription drug plan by a plan spon-
11 sor, the part of such costs that are actually paid
12 (net of discounts, chargebacks, and average per-
13 centage rebates) by the sponsor or by or on behalf
14 of a qualifying covered retiree under the plan.

15 “(ii) GROSS COVERED RETIREE PLAN-RE-
16 LATED PRESCRIPTION DRUG COSTS.—For purposes
17 of this section, the term ‘gross covered retiree plan-
18 related prescription drug costs’ means, with respect
19 to a qualifying covered retiree enrolled in a quali-
20 fied retiree prescription drug plan during a cov-
21 erage year, the costs incurred under the plan, not
22 including administrative costs, but including costs
23 directly related to the dispensing of covered part D
24 drugs during the year. Such costs shall be deter-
25 mined whether they are paid by the retiree or
26 under the plan.

27 “(iii) COVERAGE YEAR.—The term ‘coverage year’
28 has the meaning given such term in section 1860D–
29 15(b)(4).

30 “(4) QUALIFYING COVERED RETIREE DEFINED.—For
31 purposes of this subsection, the term ‘qualifying covered re-
32 tiree’ means a part D eligible individual who is not enrolled
33 in a prescription drug plan or an MA–PD plan but is cov-
34 ered under a qualified retiree prescription drug plan.

35 “(5) PAYMENT METHODS, INCLUDING PROVISION OF
36 NECESSARY INFORMATION.—The provisions of section
37 1860D–15(d) (including paragraph (2), relating to require-

1 ment for provision of information) shall apply to payments
2 under this subsection in a manner similar to the manner
3 in which they apply to payment under section 1860D-
4 15(b).

5 “(6) CONSTRUCTION.—Nothing in this subsection
6 shall be construed as—

7 “(A) precluding a part D eligible individual who is
8 covered under employment-based retiree health cov-
9 erage from enrolling in a prescription drug plan or in
10 an MA–PD plan;

11 “(B) precluding such employment-based retiree
12 health coverage or an employer or other person from
13 paying all or any portion of any premium required for
14 coverage under a prescription drug plan or MA–PD
15 plan on behalf of such an individual;

16 “(C) preventing such employment-based retiree
17 health coverage from providing coverage—

18 “(i) that is better than standard prescription
19 drug coverage to retirees who are covered under a
20 qualified retiree prescription drug plan; or

21 “(ii) that is supplemental to the benefits pro-
22 vided under a prescription drug plan or an MA–PD
23 plan, including benefits to retirees who are not cov-
24 ered under a qualified retiree prescription drug
25 plan but who are enrolled in such a prescription
26 drug plan or MA–PD plan; or

27 “(D) preventing employers to provide for flexibility
28 in benefit design and pharmacy access provisions, with-
29 out regard to the requirements for basic prescription
30 drug coverage, so long as the actuarial equivalence re-
31 quirement of paragraph (2)(A) is met.

32 “(b) APPLICATION OF MA WAIVER AUTHORITY.—The
33 provisions of section 1857(i) shall apply with respect to pre-
34 scription drug plans in relation to employment-based retiree
35 health coverage in a manner similar to the manner in which
36 they apply to an MA plan in relation to employers, including
37 authorizing the establishment of separate premium amounts for

1 enrollees in a prescription drug plan by reason of such coverage
2 and limitations on enrollment to part D eligible individuals en-
3 rolled under such coverage.

4 “(c) DEFINITIONS.—For purposes of this section:

5 “(1) EMPLOYMENT-BASED RETIREE HEALTH COV-
6 ERAGE.—The term ‘employment-based retiree health cov-
7 erage’ means health insurance or other coverage of health
8 care costs (whether provided by voluntary insurance cov-
9 erage or pursuant to statutory or contractual obligation)
10 for part D eligible individuals (or for such individuals and
11 their spouses and dependents) under a group health plan
12 based on their status as retired participants in such plan.

13 “(2) SPONSOR.—The term ‘sponsor’ means a plan
14 sponsor, as defined in section 3(16)(B) of the Employee
15 Retirement Income Security Act of 1974, in relation to a
16 group health plan, except that, in the case of a plan main-
17 tained jointly by one employer and an employee organiza-
18 tion and with respect to which the employer is the primary
19 source of financing, such term means such employer.

20 “(3) GROUP HEALTH PLAN.—The term ‘group health
21 plan’ includes such a plan as defined in section 607(1) of
22 the Employee Retirement Income Security Act of 1974 and
23 also includes the following:

24 “(A) FEDERAL AND STATE GOVERNMENTAL
25 PLANS.—Such a plan established or maintained for its
26 employees by the Government of the United States, by
27 the government of any State or political subdivision
28 thereof, or by any agency or instrumentality of any of
29 the foregoing, including a health benefits plan offered
30 under chapter 89 of title 5, United States Code.

31 “(B) COLLECTIVELY BARGAINED PLANS.—Such a
32 plan established or maintained under or pursuant to
33 one or more collective bargaining agreements.

34 “(C) CHURCH PLANS.—Such a plan established
35 and maintained for its employees (or their bene-
36 ficiaries) by a church or by a convention or association

1 of churches which is exempt from tax under section
2 501 of the Internal Revenue Code of 1986.

3 “STATE PHARMACEUTICAL ASSISTANCE PROGRAMS

4 “SEC. 1860D–23. (a) REQUIREMENTS FOR BENEFIT CO-
5 ORDINATION.—

6 “(1) IN GENERAL.—Before July 1, 2005, the Sec-
7 retary shall establish consistent with this section require-
8 ments for prescription drug plans to ensure the effective
9 coordination between a part D plan (as defined in para-
10 graph (5)) and a State Pharmaceutical Assistance Program
11 (as defined in subsection (b)) with respect to—

12 “(A) payment of premiums and coverage; and

13 “(B) payment for supplemental prescription drug
14 benefits,

15 for part D eligible individuals enrolled under both types of
16 plans.

17 “(2) COORDINATION ELEMENTS.—The requirements
18 under paragraph (1) shall include requirements relating to
19 coordination of each of the following:

20 “(A) Enrollment file sharing.

21 “(B) The processing of claims, including electronic
22 processing.

23 “(C) Claims payment.

24 “(D) Claims reconciliation reports.

25 “(E) Application of the protection against high
26 out-of-pocket expenditures under section 1860D–
27 2(b)(4).

28 “(F) Other administrative processes specified by
29 the Secretary.

30 Such requirements shall be consistent with applicable law
31 to safeguard the privacy of any individually identifiable
32 beneficiary information.

33 “(3) USE OF LUMP SUM PER CAPITA METHOD.—Such
34 requirements shall include a method for the application by
35 a part D plan of specified funding amounts from a State
36 Pharmaceutical Assistance Program for enrolled individuals
37 for supplemental prescription drug benefits.

1 “(4) CONSULTATION.—In establishing requirements
2 under this subsection, the Secretary shall consult with
3 State Pharmaceutical Assistance Programs, MA organiza-
4 tions, States, pharmaceutical benefit managers, employers,
5 representatives of part D eligible individuals, the data proc-
6 essing experts, pharmacists, pharmaceutical manufacturers,
7 and other experts.

8 “(5) PART D PLAN DEFINED.—For purposes of this
9 section and section 1860D–24, the term ‘part D plan’
10 means a prescription drug plan and an MA–PD plan.

11 “(b) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—
12 For purposes of this part, the term ‘State Pharmaceutical As-
13 sistance Program’ means a State program—

14 “(1) which provides financial assistance for the pur-
15 chase or provision of supplemental prescription drug cov-
16 erage or benefits on behalf of part D eligible individuals;

17 “(2) which, in determining eligibility and the amount
18 of assistance to part D eligible individuals under the Pro-
19 gram, provides assistance to such individuals in all part D
20 plans and does not discriminate based upon the part D
21 plan in which the individual is enrolled; and

22 “(3) which satisfies the requirements of subsections
23 (a) and (c).

24 “(c) RELATION TO OTHER PROVISIONS.—

25 “(1) MEDICARE AS PRIMARY PAYOR.—The require-
26 ments of this section shall not change or affect the primary
27 payor status of a part D plan.

28 “(2) USE OF A SINGLE CARD.—A card that is issued
29 under section 1860D–4(b)(2)(A) for use under a part D
30 plan may also be used in connection with coverage of bene-
31 fits provided under a State Pharmaceutical Assistance Pro-
32 gram and, in such case, may contain an emblem or symbol
33 indicating such connection.

34 “(3) OTHER PROVISIONS.—The provisions of section
35 1860D–24(c) shall apply to the requirements under this
36 section.

1 “(4) SPECIAL TREATMENT UNDER OUT-OF-POCKET
2 RULE.—In applying section 1860D–2(b)(4)(C)(ii), expenses
3 incurred under a State Pharmaceutical Assistance Program
4 may be counted toward the annual out-of-pocket threshold.

5 “(5) CONSTRUCTION.—Nothing in this section shall be
6 construed as requiring a State Pharmaceutical Assistance
7 Program to coordinate or provide financial assistance with
8 respect to any part D plan.

9 “(d) FACILITATION OF TRANSITION AND COORDINATION
10 WITH STATE PHARMACEUTICAL ASSISTANCE PROGRAMS.—

11 “(1) TRANSITIONAL GRANT PROGRAM.—The Secretary
12 shall provide payments to State Pharmaceutical Assistance
13 Programs with an application approved under this sub-
14 section.

15 “(2) USE OF FUNDS.—Payments under this section
16 may be used by a Program for any of the following:

17 “(A) Educating part D eligible individuals enrolled
18 in the Program about the prescription drug coverage
19 available through part D plans under this part.

20 “(B) Providing technical assistance, phone sup-
21 port, and counseling for such enrollees to facilitate se-
22 lection and enrollment in such plans.

23 “(C) Other activities designed to promote the ef-
24 fective coordination of enrollment, coverage, and pay-
25 ment between such Program and such plans.

26 “(3) ALLOCATION OF FUNDS.—Of the amount appro-
27 priated to carry out this subsection for a fiscal year, the
28 Secretary shall allocate payments among Programs that
29 have applications approved under paragraph (4) for such
30 fiscal year in proportion to the number of enrollees enrolled
31 in each such Program as of October 1, 2003.

32 “(4) APPLICATION.—No payments may be made under
33 this subsection except pursuant to an application that is
34 submitted and approved in a time, manner, and form speci-
35 fied by the Secretary.

36 “(5) FUNDING.—Out of any funds in the Treasury not
37 otherwise appropriated, there are appropriated for each of

1 fiscal years 2005 and 2006, \$62,500,000 to carry out this
 2 subsection.

3 “COORDINATION REQUIREMENTS FOR PLANS PROVIDING
 4 PRESCRIPTION DRUG COVERAGE

5 “SEC. 1860D–24. (a) APPLICATION OF BENEFIT COORDI-
 6 NATION REQUIREMENTS TO ADDITIONAL PLANS.—

7 “(1) IN GENERAL.—The Secretary shall apply the co-
 8 ordination requirements established under section 1860D–
 9 23(a) to Rx plans described in subsection (b) in the same
 10 manner as such requirements apply to a State Pharma-
 11 ceutical Assistance Program.

12 “(2) APPLICATION TO TREATMENT OF CERTAIN OUT-
 13 OF-POCKET EXPENDITURES.—To the extent specified by
 14 the Secretary, the requirements referred to in paragraph
 15 (1) shall apply to procedures established under section
 16 1860D–2(b)(4)(D).

17 “(3) USER FEES.—

18 “(A) IN GENERAL.—The Secretary may impose
 19 user fees for the transmittal of information necessary
 20 for benefit coordination under section 1860D–
 21 2(b)(4)(D) in a manner similar to the manner in which
 22 user fees are imposed under section 1842(h)(3)(B), ex-
 23 cept that the Secretary may retain a portion of such
 24 fees to defray the Secretary’s costs in carrying out pro-
 25 cedures under section 1860D–2(b)(4)(D).

26 “(B) APPLICATION.—A user fee may not be im-
 27 posed under subparagraph (A) with respect to a State
 28 Pharmaceutical Assistance Program.

29 “(b) RX PLAN.—An Rx plan described in this subsection
 30 is any of the following:

31 “(1) MEDICAID PROGRAMS.—A State plan under title
 32 XIX, including such a plan operating under a waiver under
 33 section 1115, if it meets the requirements of section
 34 1860D–23(b)(2).

35 “(2) GROUP HEALTH PLANS.—An employer group
 36 health plan.

1 “(A) IMPLEMENTATION DEADLINE.—The Sec-
2 retary shall implement the program under this section
3 so that discount cards and transitional assistance are
4 first available by not later than 6 months after the date
5 of the enactment of this section.

6 “(B) EXPEDITING IMPLEMENTATION.—The Sec-
7 retary shall promulgate regulations to carry out the
8 program under this section which may be effective and
9 final immediately on an interim basis as of the date of
10 publication of the interim final regulation. If the Sec-
11 retary provides for an interim final regulation, the Sec-
12 retary shall provide for a period of public comments on
13 such regulation after the date of publication. The Sec-
14 retary may change or revise such regulation after com-
15 pletion of the period of public comment.

16 “(C) TERMINATION AND TRANSITION.—

17 “(i) IN GENERAL.—Subject to clause (ii)—

18 “(I) the program under this section shall
19 not apply to covered discount card drugs dis-
20 pensed after December 31, 2005; and

21 “(II) transitional assistance shall be avail-
22 able after such date to the extent the assistance
23 relates to drugs dispensed on or before such
24 date.

25 “(ii) TRANSITION.—In the case of an indi-
26 vidual who is enrolled in an endorsed discount card
27 program as of December 31, 2005, during the indi-
28 vidual’s transition period (if any) under clause (iii),
29 in accordance with transition rules specified by the
30 Secretary—

31 “(I) such endorsed program may continue
32 to apply to covered discount card drugs dis-
33 pensed to the individual under the program
34 during such transition period;

35 “(II) no annual enrollment fee shall be ap-
36 plicable during the transition period;

1 “(III) during such period the individual
2 may not change the endorsed program plan in
3 which the individual is enrolled; and

4 “(IV) the balance of any transitional as-
5 sistance remaining on January 1, 2006, shall
6 remain available for drugs dispensed during the
7 individual’s transition period.

8 “(iii) TRANSITION PERIOD.—The transition
9 period under this clause for an individual is the pe-
10 riod beginning on January 1, 2006, and ending in
11 the case of an individual who—

12 “(I) is enrolled in a prescription drug plan
13 or an MA–PD plan before the last date of the
14 initial enrollment period under section 1860D–
15 1(b)(2)(A), on the effective date of the individ-
16 ual’s coverage under such part; or

17 “(II) is not so enrolled, on the last day of
18 such initial period.

19 “(3) VOLUNTARY NATURE OF PROGRAM.—Nothing in
20 this section shall be construed as requiring a discount card
21 eligible individual to enroll in an endorsed discount card
22 program under this section.

23 “(4) GLOSSARY AND DEFINITIONS OF TERMS.—For
24 purposes of this section:

25 “(A) COVERED DISCOUNT CARD DRUG.—The term
26 ‘covered discount card drug’ has the meaning given the
27 term ‘covered part D drug’ in section 1860D–2(e).

28 “(B) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—
29 The term ‘discount card eligible individual’ is defined
30 in subsection (b)(1)(A).

31 “(C) ENDORSED DISCOUNT CARD PROGRAM; EN-
32 DORSED PROGRAM.—The terms ‘endorsed discount card
33 program’ and ‘endorsed program’ mean a prescription
34 drug discount card program that is endorsed (and for
35 which the sponsor has a contract with the Secretary)
36 under this section.

1 “(D) NEGOTIATED PRICE.—Negotiated prices are
2 described in subsection (e)(1)(A)(ii).

3 “(E) PRESCRIPTION DRUG CARD SPONSOR; SPON-
4 SOR.—The terms ‘prescription drug card sponsor’ and
5 ‘sponsor’ are defined in subsection (h)(1)(A).

6 “(F) STATE.—The term ‘State’ has the meaning
7 given such term for purposes of title XIX.

8 “(G) TRANSITIONAL ASSISTANCE ELIGIBLE INDI-
9 VIDUAL.—The term ‘transitional assistance eligible in-
10 dividual’ is defined in subsection (b)(2).

11 “(b) ELIGIBILITY FOR DISCOUNT CARD AND FOR TRANSI-
12 TIONAL ASSISTANCE.—For purposes of this section:

13 “(1) DISCOUNT CARD ELIGIBLE INDIVIDUAL.—

14 “(A) IN GENERAL.—The term ‘discount card eligi-
15 ble individual’ means an individual who—

16 “(i) is entitled to benefits, or enrolled, under
17 part A or enrolled under part B; and

18 “(ii) subject to paragraph (4), is not an indi-
19 vidual described in subparagraph (B).

20 “(B) INDIVIDUAL DESCRIBED.—An individual de-
21 scribed in this subparagraph is an individual described
22 in subparagraph (A)(i) who is enrolled under title XIX
23 (or under a waiver under section 1115 of the require-
24 ments of such title) and is entitled to any medical as-
25 sistance for outpatient prescribed drugs described in
26 section 1905(a)(12).

27 “(2) TRANSITIONAL ASSISTANCE ELIGIBLE INDI-
28 VIDUAL.—

29 “(A) IN GENERAL.—Subject to subparagraph (B),
30 the term ‘transitional assistance eligible individual’
31 means a discount card eligible individual who resides in
32 one of the 50 States or the District of Columbia and
33 whose income (as determined under subsection
34 (f)(1)(B)) is not more than 135 percent of the poverty
35 line (as defined in section 673(2) of the Community
36 Services Block Grant Act, 42 U.S.C. 9902(2), including
37 any revision required by such section) applicable to the

1 family size involved (as determined under subsection
2 (f)(1)(B)).

3 “(B) EXCLUSION OF INDIVIDUALS WITH CERTAIN
4 PRESCRIPTION DRUG COVERAGE.—Such term does not
5 include an individual who has coverage of, or assistance
6 for, covered discount card drugs under any of the fol-
7 lowing:

8 “(i) A group health plan or health insurance
9 coverage (as such terms are defined in section 2791
10 of the Public Health Service Act), other than cov-
11 erage under a plan under part C and other than
12 coverage consisting only of excepted benefits (as de-
13 fined in such section).

14 “(ii) Chapter 55 of title 10, United States
15 Code (relating to medical and dental care for mem-
16 bers of the uniformed services).

17 “(iii) A plan under chapter 89 of title 5,
18 United States Code (relating to the Federal em-
19 ployees’ health benefits program).

20 “(3) SPECIAL TRANSITIONAL ASSISTANCE ELIGIBLE
21 INDIVIDUAL.—The term ‘special transitional assistance eli-
22 gible individual’ means a transitional assistance eligible in-
23 dividual whose income (as determined under subsection
24 (f)(1)(B)) is not more than 100 percent of the poverty line
25 (as defined in section 673(2) of the Community Services
26 Block Grant Act, 42 U.S.C. 9902(2), including any revision
27 required by such section) applicable to the family size in-
28 volved (as determined under subsection (f)(1)(B)).

29 “(4) TREATMENT OF MEDICAID MEDICALLY NEEDY.—
30 For purposes of this section, the Secretary shall provide for
31 appropriate rules for the treatment of medically needy indi-
32 viduals described in section 1902(a)(10)(C) as discount
33 card eligible individuals and as transitional assistance eligi-
34 ble individuals.

35 “(c) ENROLLMENT AND ENROLLMENT FEES.—

36 “(1) ENROLLMENT PROCESS.—The Secretary shall es-
37 tablish a process through which a discount card eligible in-

1 individual is enrolled and disenrolled in an endorsed discount
2 card program under this section consistent with the fol-
3 lowing:

4 “(A) CONTINUOUS OPEN ENROLLMENT.—Subject
5 to the succeeding provisions of this paragraph and sub-
6 section (h)(9), a discount card eligible individual who
7 is not enrolled in an endorsed discount card program
8 and is residing in a State may enroll in any such en-
9 dored program—

10 “(i) that serves residents of the State; and

11 “(ii) at any time beginning on the initial en-
12 rollment date, specified by the Secretary, and be-
13 fore January 1, 2006.

14 “(B) USE OF STANDARD ENROLLMENT FORM.—
15 An enrollment in an endorsed program shall only be ef-
16 fected through completion of a standard enrollment
17 form specified by the Secretary. Each sponsor of an en-
18 dored program shall transmit to the Secretary (in a
19 form and manner specified by the Secretary) informa-
20 tion on individuals who complete such enrollment forms
21 and, to the extent provided under subsection (f), infor-
22 mation regarding certification as a transitional assist-
23 ance eligible individual.

24 “(C) ENROLLMENT ONLY IN ONE PROGRAM.—

25 “(i) IN GENERAL.—Subject to clauses (ii) and
26 (iii), a discount card eligible individual may be en-
27 rolled in only one endorsed discount card program
28 under this section.

29 “(ii) CHANGE IN ENDORSED PROGRAM PER-
30 MITTED FOR 2005.—The Secretary shall establish a
31 process, similar to (and coordinated with) the proc-
32 ess for annual, coordinated elections under section
33 1851(e)(3) during 2004, under which an individual
34 enrolled in an endorsed discount card program may
35 change the endorsed program in which the indi-
36 vidual is enrolled for 2005.

1 “(iii) ADDITIONAL EXCEPTIONS.—The Sec-
2 retary shall permit an individual to change the en-
3 dorsed discount card program in which the indi-
4 vidual is enrolled in the case of an individual who
5 changes residence to be outside the service area of
6 such program and in such other exceptional cases
7 as the Secretary may provide (taking into account
8 the circumstances for special election periods under
9 section 1851(e)(4)). Under the previous sentence,
10 the Secretary may consider a change in residential
11 setting (such as placement in a nursing facility) or
12 enrollment in or disenrollment from a plan under
13 part C through which the individual was enrolled in
14 an endorsed program to be an exceptional cir-
15 cumstance.

16 “(D) DISENROLLMENT.—

17 “(i) VOLUNTARY.—An individual may volun-
18 tarily disenroll from an endorsed discount card pro-
19 gram at any time. In the case of such a voluntary
20 disenrollment, the individual may not enroll in an-
21 other endorsed program, except under such excep-
22 tional circumstances as the Secretary may recog-
23 nize under subparagraph (C)(iii) or during the an-
24 nual coordinated enrollment period provided under
25 subparagraph (C)(ii).

26 “(ii) INVOLUNTARY.—An individual who is en-
27 rolled in an endorsed discount card program and
28 not a transitional assistance eligible individual may
29 be disenrolled by the sponsor of the program if the
30 individual fails to pay any annual enrollment fee
31 required under the program.

32 “(E) APPLICATION TO CERTAIN ENROLLEES.—In
33 the case of a discount card eligible individual who is en-
34 rolled in a plan described in section 1851(a)(2)(A) or
35 under a reasonable cost reimbursement contract under
36 section 1876(h) that is offered by an organization that
37 also is a prescription discount card sponsor that offers

1 an endorsed discount card program under which the in-
2 dividual may be enrolled and that has made an election
3 to apply the special rules under subsection (h)(9)(B)
4 for such an endorsed program, the individual may only
5 enroll in such an endorsed discount card program of-
6 fered by that sponsor.

7 “(2) ENROLLMENT FEES.—

8 “(A) IN GENERAL.—Subject to the succeeding pro-
9 visions of this paragraph, a prescription drug card
10 sponsor may charge an annual enrollment fee for each
11 discount card eligible individual enrolled in an endorsed
12 discount card program offered by such sponsor. The
13 annual enrollment fee for either 2004 or 2005 shall not
14 be prorated for portions of a year. There shall be no
15 annual enrollment fee for a year after 2005.

16 “(B) AMOUNT.—No annual enrollment fee
17 charged under subparagraph (A) may exceed \$30.

18 “(C) UNIFORM ENROLLMENT FEE.—A prescrip-
19 tion drug card sponsor shall ensure that the annual en-
20 rollment fee (if any) for an endorsed discount card pro-
21 gram is the same for all discount card eligible individ-
22 uals enrolled in the program and residing in the State.

23 “(D) COLLECTION.—The annual enrollment fee (if
24 any) charged for enrollment in an endorsed program
25 shall be collected by the sponsor of the program.

26 “(E) PAYMENT OF FEE FOR TRANSITIONAL AS-
27 SISTANCE ELIGIBLE INDIVIDUALS.—Under subsection
28 (g)(1)(A), the annual enrollment fee (if any) otherwise
29 charged under this paragraph with respect to a transi-
30 tional assistance eligible individual shall be paid by the
31 Secretary on behalf of such individual.

32 “(F) OPTIONAL PAYMENT OF FEE BY STATE.—

33 “(i) IN GENERAL.—The Secretary shall estab-
34 lish an arrangement under which a State may pro-
35 vide for payment of some or all of the enrollment
36 fee for some or all enrollees who are not transi-
37 tional assistance eligible individuals in the State, as

1 specified by the State under the arrangement. Inso-
2 far as such a payment arrangement is made with
3 respect to an enrollee, the amount of the enroll-
4 ment fee shall be paid directly by the State to the
5 sponsor.

6 “(ii) NO FEDERAL MATCHING AVAILABLE
7 UNDER MEDICAID OR SCHIP.—Expenditures made
8 by a State for enrollment fees described in clause
9 (i) shall not be treated as State expenditures for
10 purposes of Federal matching payments under title
11 XIX or XXI.

12 “(G) RULES IN CASE OF CHANGES IN PROGRAM
13 ENROLLMENT DURING A YEAR.—The Secretary shall
14 provide special rules in the case of payment of an an-
15 nual enrollment fee for a discount card eligible indi-
16 vidual who changes the endorsed program in which the
17 individual is enrolled during a year.

18 “(3) ISSUANCE OF DISCOUNT CARD.—Each prescrip-
19 tion drug card sponsor of an endorsed discount card pro-
20 gram shall issue, in a standard format specified by the Sec-
21 retary, to each discount card eligible individual enrolled in
22 such program a card that establishes proof of enrollment
23 and that can be used in a coordinated manner to identify
24 the sponsor, program, and individual for purposes of the
25 program under this section.

26 “(4) PERIOD OF ACCESS.—In the case of a discount
27 card eligible individual who enrolls in an endorsed program,
28 access to negotiated prices and transitional assistance, if
29 any, under such endorsed program shall take effect on such
30 date as the Secretary shall specify.

31 “(d) PROVISION OF INFORMATION ON ENROLLMENT AND
32 PROGRAM FEATURES.—

33 “(1) SECRETARIAL RESPONSIBILITIES.—

34 “(A) IN GENERAL.—The Secretary shall provide
35 for activities under this subsection to broadly dissemi-
36 nate information to discount card eligible individuals
37 (and prospective eligible individuals) regarding—

1 “(i) enrollment in endorsed discount card pro-
2 grams; and

3 “(ii) the features of the program under this
4 section, including the availability of transitional as-
5 sistance.

6 “(B) PROMOTION OF INFORMED CHOICE.—In
7 order to promote informed choice among endorsed pre-
8 scription drug discount card programs, the Secretary
9 shall provide for the dissemination of information
10 which—

11 “(i) compares the annual enrollment fee and
12 other features of such programs, which may include
13 comparative prices for covered discount card drugs;
14 and

15 “(ii) includes educational materials on the var-
16 iability of discounts on prices of covered discount
17 card drugs under an endorsed program.

18 The dissemination of information under clause (i) shall,
19 to the extent practicable, be coordinated with the dis-
20 semination of educational information on other medi-
21 care options.

22 “(C) SPECIAL RULE FOR INITIAL ENROLLMENT
23 DATE UNDER THE PROGRAM.—To the extent prac-
24 ticable, the Secretary shall ensure, through the activi-
25 ties described in subparagraphs (A) and (B), that dis-
26 count card eligible individuals are provided with such
27 information at least 30 days prior to the initial enroll-
28 ment date specified under subsection (c)(1)(A)(ii).

29 “(D) USE OF MEDICARE TOLL-FREE NUMBER.—
30 The Secretary shall provide through the toll-free tele-
31 phone number 1-800-MEDICARE for the receipt and
32 response to inquiries and complaints concerning the
33 program under this section and endorsed programs.

34 “(2) PRESCRIPTION DRUG CARD SPONSOR RESPON-
35 SIBILITIES.—

36 “(A) IN GENERAL.—Each prescription drug card
37 sponsor that offers an endorsed discount card program

1 shall make available to discount card eligible individ-
2 uals (through the Internet and otherwise) information
3 that the Secretary identifies as being necessary to pro-
4 mote informed choice among endorsed discount card
5 programs by such individuals, including information on
6 enrollment fees and negotiated prices for covered dis-
7 count card drugs charged to such individuals.

8 “(B) RESPONSE TO ENROLLEE QUESTIONS.—
9 Each sponsor offering an endorsed discount card pro-
10 gram shall have a mechanism (including a toll-free tele-
11 phone number) for providing upon request specific in-
12 formation (such as negotiated prices and the amount of
13 transitional assistance remaining available through the
14 program) to discount card eligible individuals enrolled
15 in the program. The sponsor shall inform transitional
16 assistance eligible individuals enrolled in the program
17 of the availability of such toll-free telephone number to
18 provide information on the amount of available transi-
19 tional assistance.

20 “(C) INFORMATION ON BALANCE OF TRANSI-
21 TIONAL ASSISTANCE AVAILABLE AT POINT-OF-SALE.—
22 Each sponsor offering an endorsed discount card pro-
23 gram shall have a mechanism so that information on
24 the amount of transitional assistance remaining under
25 subsection (g)(1)(B) is available (electronically or by
26 telephone) at the point-of-sale of covered discount card
27 drugs.

28 “(3) PUBLIC DISCLOSURE OF PHARMACEUTICAL
29 PRICES FOR EQUIVALENT DRUGS.—

30 “(A) IN GENERAL.—A prescription drug card
31 sponsor offering an endorsed discount card program
32 shall provide that each pharmacy that dispenses a cov-
33 ered discount card drug shall inform a discount card el-
34 igible individual enrolled in the program of any dif-
35 ferential between the price of the drug to the enrollee
36 and the price of the lowest priced generic covered dis-
37 count card drug under the program that is therapeuti-

1 cally equivalent and bioequivalent and available at such
2 pharmacy.

3 “(B) TIMING OF NOTICE.—

4 “(i) IN GENERAL.—Subject to clause (ii), the
5 information under subparagraph (A) shall be pro-
6 vided at the time of purchase of the drug involved,
7 or, in the case of dispensing by mail order, at the
8 time of delivery of such drug.

9 “(ii) WAIVER.—The Secretary may waive
10 clause (i) in such circumstances as the Secretary
11 may specify.

12 “(e) DISCOUNT CARD FEATURES.—

13 “(1) SAVINGS TO ENROLLEES THROUGH NEGOTIATED
14 PRICES.—

15 “(A) ACCESS TO NEGOTIATED PRICES.—

16 “(i) IN GENERAL.—Each prescription drug
17 card sponsor that offers an endorsed discount card
18 program shall provide each discount card eligible
19 individual enrolled in the program with access to
20 negotiated prices.

21 “(ii) NEGOTIATED PRICES.—For purposes of
22 this section, negotiated prices shall take into ac-
23 count negotiated price concessions, such as dis-
24 counts, direct or indirect subsidies, rebates, and di-
25 rect or indirect remunerations, for covered discount
26 card drugs, and include any dispensing fees for
27 such drugs.

28 “(B) ENSURING PHARMACY ACCESS.—Each pre-
29 scription drug card sponsor offering an endorsed dis-
30 count card program shall secure the participation in its
31 network of a sufficient number of pharmacies that dis-
32 pense (other than solely by mail order) drugs directly
33 to enrollees to ensure convenient access to covered dis-
34 count card drugs at negotiated prices (consistent with
35 rules established by the Secretary). The Secretary shall
36 establish convenient access rules under this clause that
37 are no less favorable to enrollees than the standards for

1 convenient access to pharmacies included in the state-
2 ment of work of solicitation (#MDA906-03-R-0002)
3 of the Department of Defense under the TRICARE
4 Retail Pharmacy (TRRx) as of March 13, 2003.

5 “(C) PROHIBITION ON CHARGES FOR REQUIRED
6 SERVICES.—

7 “(i) IN GENERAL.—Subject to clause (ii), a
8 prescription drug card sponsor (and any pharmacy
9 contracting with such sponsor for the provision of
10 covered discount card drugs to individuals enrolled
11 in such sponsor’s endorsed discount card program)
12 may not charge an enrollee any amount for any
13 items and services required to be provided by the
14 sponsor under this section.

15 “(ii) CONSTRUCTION.—Nothing in clause (i)
16 shall be construed to prevent—

17 “(I) the sponsor from charging the annual
18 enrollment fee (except in the case of a transi-
19 tional assistance eligible individual); and

20 “(II) the pharmacy dispensing the covered
21 discount card drug, from imposing a charge
22 (consistent with the negotiated price) for the
23 covered discount card drug dispensed, reduced
24 by the amount of any transitional assistance
25 made available.

26 “(D) INAPPLICABILITY OF MEDICAID BEST PRICE
27 RULES.—The prices negotiated from drug manufactur-
28 ers for covered discount card drugs under an endorsed
29 discount card program under this section shall (not-
30 withstanding any other provision of law) not be taken
31 into account for the purposes of establishing the best
32 price under section 1927(c)(1)(C).

33 “(2) REDUCTION OF MEDICATION ERRORS AND AD-
34 VERSE DRUG INTERACTIONS.—Each endorsed discount card
35 program shall implement a system to reduce the likelihood
36 of medication errors and adverse drug interactions and to
37 improve medication use.

1 “(f) ELIGIBILITY PROCEDURES FOR ENDORSED PRO-
2 GRAMS AND TRANSITIONAL ASSISTANCE.—

3 “(1) DETERMINATIONS.—

4 “(A) PROCEDURES.—The determination of wheth-
5 er an individual is a discount card eligible individual or
6 a transitional assistance eligible individual or a special
7 transitional assistance eligible individual (as defined in
8 subsection (b)) shall be determined under procedures
9 specified by the Secretary consistent with this sub-
10 section.

11 “(B) INCOME AND FAMILY SIZE DETERMINA-
12 TIONS.—For purposes of this section, the Secretary
13 shall define the terms ‘income’ and ‘family size’ and
14 shall specify the methods and period for which they are
15 determined. If under such methods income or family
16 size is determined based on the income or family size
17 for prior periods of time, the Secretary shall permit
18 (whether through a process of reconsideration or other-
19 wise) an individual whose income or family size has
20 changed to elect to have eligibility for transitional as-
21 sistance determined based on income or family size for
22 a more recent period.

23 “(2) USE OF SELF-CERTIFICATION FOR TRANSITIONAL
24 ASSISTANCE.—

25 “(A) IN GENERAL.—Under the procedures speci-
26 fied under paragraph (1)(A) an individual who wishes
27 to be treated as a transitional assistance eligible indi-
28 vidual or a special transitional assistance eligible indi-
29 vidual under this section (or another qualified person
30 on such individual’s behalf) shall certify on the enroll-
31 ment form under subsection (c)(1)(B) (or similar form
32 specified by the Secretary), through a simplified means
33 specified by the Secretary and under penalty of perjury
34 or similar sanction for false statements, as to the
35 amount of the individual’s income, family size, and in-
36 dividual’s prescription drug coverage (if any) insofar as
37 they relate to eligibility to be a transitional assistance

1 eligible individual or a special transitional assistance el-
2 igible individual. Such certification shall be deemed as
3 consent to verification of respective eligibility under
4 paragraph (3). A certification under this paragraph
5 may be provided before, on, or after the time of enroll-
6 ment under an endorsed program.

7 “(B) TREATMENT OF SELF-CERTIFICATION.—The
8 Secretary shall treat a certification under subparagraph
9 (A) that is verified under paragraph (3) as a deter-
10 mination that the individual involved is a transitional
11 assistance eligible individual or special transitional as-
12 sistance eligible individual (as the case may be) for the
13 entire period of the enrollment of the individual in any
14 endorsed program.

15 “(3) VERIFICATION.—

16 “(A) IN GENERAL.—The Secretary shall establish
17 methods (which may include the use of sampling and
18 the use of information described in subparagraph (B))
19 to verify eligibility for individuals who seek to enroll in
20 an endorsed program and for individuals who provide
21 a certification under paragraph (2).

22 “(B) INFORMATION DESCRIBED.—The information
23 described in this subparagraph is as follows:

24 “(i) MEDICAID-RELATED INFORMATION.—In-
25 formation on eligibility under title XIX and pro-
26 vided to the Secretary under arrangements between
27 the Secretary and States in order to verify the eli-
28 gibility of individuals who seek to enroll in an en-
29 dorsed program and of individuals who provide cer-
30 tification under paragraph (2).

31 “(ii) SOCIAL SECURITY INFORMATION.—Fi-
32 nancial information made available to the Secretary
33 under arrangements between the Secretary and the
34 Commissioner of Social Security in order to verify
35 the eligibility of individuals who provide such cer-
36 tification.

1 “(iii) INFORMATION FROM SECRETARY OF THE
2 TREASURY.—Financial information made available
3 to the Secretary under section 6103(l)(19) of the
4 Internal Revenue Code of 1986 in order to verify
5 the eligibility of individuals who provide such cer-
6 tification.

7 “(C) VERIFICATION IN CASES OF MEDICAID EN-
8 ROLLEES.—

9 “(i) IN GENERAL.—Nothing in this section
10 shall be construed as preventing the Secretary from
11 finding that a discount card eligible individual
12 meets the income requirements under subsection
13 (b)(2)(A) if the individual is within a category of
14 discount card eligible individuals who are enrolled
15 under title XIX (such as qualified medicare bene-
16 ficiaries (QMBs), specified low-income medicare
17 beneficiaries (SLMBs), and certain qualified indi-
18 viduals (QI-1s)).

19 “(ii) AVAILABILITY OF INFORMATION FOR
20 VERIFICATION PURPOSES.—As a condition of provi-
21 sion of Federal financial participation to a State
22 that is one of the 50 States or the District of Co-
23 lumbia under title XIX, for purposes of carrying
24 out this section, the State shall provide the infor-
25 mation it submits to the Secretary relating to such
26 title in a manner specified by the Secretary that
27 permits the Secretary to identify individuals who
28 are described in subsection (b)(1)(B) or are transi-
29 tional assistance eligible individuals or special tran-
30 sitional assistance eligible individuals.

31 “(4) RECONSIDERATION.—

32 “(A) IN GENERAL.—The Secretary shall establish
33 a process under which a discount card eligible indi-
34 vidual, who is determined through the certification and
35 verification methods under paragraphs (2) and (3) not
36 to be a transitional assistance eligible individual or a

1 special transitional assistance eligible individual, may
2 request a reconsideration of the determination.

3 “(B) CONTRACT AUTHORITY.—The Secretary may
4 enter into a contract to perform the reconsiderations
5 requested under subparagraph (A).

6 “(C) COMMUNICATION OF RESULTS.—Under the
7 process under subparagraph (A) the results of such re-
8 consideration shall be communicated to the individual
9 and the prescription drug card sponsor involved.

10 “(g) TRANSITIONAL ASSISTANCE.—

11 “(1) PROVISION OF TRANSITIONAL ASSISTANCE.—An
12 individual who is a transitional assistance eligible individual
13 (as determined under this section) and who is enrolled with
14 an endorsed program is entitled—

15 “(A) to have payment made of any annual enroll-
16 ment fee charged under subsection (c)(2) for enroll-
17 ment under the program; and

18 “(B) to have payment made, up to the amount
19 specified in paragraph (2), under such endorsed pro-
20 gram of 90 percent (or 95 percent in the case of a spe-
21 cial transitional assistance eligible individual) of the
22 costs incurred for covered discount card drugs obtained
23 through the program taking into account the nego-
24 tiated price (if any) for the drug under the program.

25 “(2) LIMITATION ON DOLLAR AMOUNT.—

26 “(A) IN GENERAL.—Subject to subparagraph (B),
27 the amount specified in this paragraph for a transi-
28 tional assistance eligible individual—

29 “(i) for costs incurred during 2004, is \$600;

30 or

31 “(ii) for costs incurred during 2005, is—

32 “(I) \$600, plus

33 “(II) except as provided in subparagraph
34 (E), the amount by which the amount available
35 under this paragraph for 2004 for that indi-
36 vidual exceeds the amount of payment made

1 under paragraph (1)(B) for that individual for
2 costs incurred during 2004.

3 “(B) PRORATION.—

4 “(i) IN GENERAL.—In the case of an indi-
5 vidual not described in clause (ii) with respect to
6 a year, the Secretary may prorate the amount spec-
7 ified in subparagraph (A) for the balance of the
8 year involved in a manner specified by the Sec-
9 retary.

10 “(ii) INDIVIDUAL DESCRIBED.—An individual
11 described in this clause is a transitional assistance
12 eligible individual who—

13 “(I) with respect to 2004, enrolls in an en-
14 dorsed program, and provides a certification
15 under subsection (f)(2), before the initial imple-
16 mentation date of the program under this sec-
17 tion; and

18 “(II) with respect to 2005, is enrolled in
19 an endorsed program, and has provided such a
20 certification, before February 1, 2005.

21 “(C) ACCOUNTING FOR AVAILABLE BALANCES IN
22 CASES OF CHANGES IN PROGRAM ENROLLMENT.—In
23 the case of a transitional assistance eligible individual
24 who changes the endorsed discount card program in
25 which the individual is enrolled under this section, the
26 Secretary shall provide a process under which the Sec-
27 retary provides to the sponsor of the endorsed program
28 in which the individual enrolls information concerning
29 the balance of amounts available on behalf of the indi-
30 vidual under this paragraph.

31 “(D) LIMITATION ON USE OF FUNDS.—Pursuant
32 to subsection (a)(2)(C), no assistance shall be provided
33 under paragraph (1)(B) with respect to covered dis-
34 count card drugs dispensed after December 31, 2005.

35 “(E) NO ROLLOVER PERMITTED IN CASE OF VOL-
36 UNTARY DISENROLLMENT.—Except in such exceptional
37 cases as the Secretary may provide, in the case of a

1 transitional assistance eligible individual who volun-
2 tarily disenrolls from an endorsed plan, the provisions
3 of subclause (II) of subparagraph (A)(ii) shall not
4 apply.

5 “(3) PAYMENT.—The Secretary shall provide a meth-
6 od for the reimbursement of prescription drug card spon-
7 sors for assistance provided under this subsection.

8 “(4) COVERAGE OF COINSURANCE.—

9 “(A) WAIVER PERMITTED BY PHARMACY.—Notth-
10 ing in this section shall be construed as precluding a
11 pharmacy from reducing or waiving the application of
12 coinsurance imposed under paragraph (1)(B) in accord-
13 ance with section 1128B(b)(3)(G).

14 “(B) OPTIONAL PAYMENT OF COINSURANCE BY
15 STATE.—

16 “(i) IN GENERAL.—The Secretary shall estab-
17 lish an arrangement under which a State may pro-
18 vide for payment of some or all of the coinsurance
19 under paragraph (1)(B) for some or all enrollees in
20 the State, as specified by the State under the ar-
21 rangement. Insofar as such a payment arrange-
22 ment is made with respect to an enrollee, the
23 amount of the coinsurance shall be paid directly by
24 the State to the pharmacy involved.

25 “(ii) NO FEDERAL MATCHING AVAILABLE
26 UNDER MEDICAID OR SCHIP.—Expenditures made
27 by a State for coinsurance described in clause (i)
28 shall not be treated as State expenditures for pur-
29 poses of Federal matching payments under title
30 XIX or XXI.

31 “(iii) NOT TREATED AS MEDICARE COST-SHAR-
32 ING.—Coinsurance described in paragraph (1)(B)
33 shall not be treated as coinsurance under this title
34 for purposes of section 1905(p)(3)(B).

35 “(C) TREATMENT OF COINSURANCE.—The
36 amount of any coinsurance imposed under paragraph
37 (1)(B), whether paid or waived under this paragraph,

1 shall not be taken into account in applying the limita-
2 tion in dollar amount under paragraph (2).

3 “(5) ENSURING ACCESS TO TRANSITIONAL ASSIST-
4 ANCE FOR QUALIFIED RESIDENTS OF LONG-TERM CARE FA-
5 CILITIES AND AMERICAN INDIANS.—

6 “(A) RESIDENTS OF LONG-TERM CARE FACILI-
7 TIES.—The Secretary shall establish procedures and
8 may waive requirements of this section as necessary to
9 negotiate arrangements with sponsors to provide ar-
10 rangements with pharmacies that support long-term
11 care facilities in order to ensure access to transitional
12 assistance for transitional assistance eligible individuals
13 who reside in long-term care facilities.

14 “(B) AMERICAN INDIANS.—The Secretary shall es-
15 tablish procedures and may waive requirements of this
16 section to ensure that, for purposes of providing transi-
17 tional assistance, pharmacies operated by the Indian
18 Health Service, Indian tribes and tribal organizations,
19 and urban Indian organizations (as defined in section
20 4 of the Indian Health Care Improvement Act) have
21 the opportunity to participate in the pharmacy net-
22 works of at least two endorsed programs in each of the
23 50 States and the District of Columbia where such a
24 pharmacy operates.

25 “(6) NO IMPACT ON BENEFITS UNDER OTHER PRO-
26 GRAMS.—The availability of negotiated prices or transi-
27 tional assistance under this section shall not be treated as
28 benefits or otherwise taken into account in determining an
29 individual’s eligibility for, or the amount of benefits under,
30 any other Federal program.

31 “(7) DISREGARD FOR PURPOSES OF PART C.—Nonuni-
32 formity of benefits resulting from the implementation of
33 this section (including the provision or nonprovision of
34 transitional assistance and the payment or waiver of any
35 enrollment fee under this section) shall not be taken into
36 account in applying section 1854(f).

1 “(h) QUALIFICATION OF PRESCRIPTION DRUG CARD
2 SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PRO-
3 GRAMS; BENEFICIARY PROTECTIONS.—

4 “(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALI-
5 FICATIONS.—

6 “(A) PRESCRIPTION DRUG CARD SPONSOR AND
7 SPONSOR DEFINED.—For purposes of this section, the
8 terms ‘prescription drug card sponsor’ and ‘sponsor’
9 mean any nongovernmental entity that the Secretary
10 determines to be appropriate to offer an endorsed dis-
11 count card program under this section, which may
12 include—

13 “(i) a pharmaceutical benefit management
14 company;

15 “(ii) a wholesale or retail pharmacy delivery
16 system;

17 “(iii) an insurer (including an insurer that of-
18 fers medicare supplemental policies under section
19 1882);

20 “(iv) an organization offering a plan under
21 part C; or

22 “(v) any combination of the entities described
23 in clauses (i) through (iv).

24 “(B) ADMINISTRATIVE QUALIFICATIONS.—Each
25 endorsed discount card program shall be operated di-
26 rectly, or through arrangements with an affiliated orga-
27 nization (or organizations), by one or more entities that
28 have demonstrated experience and expertise in oper-
29 ating such a program or a similar program and that
30 meets such business stability and integrity require-
31 ments as the Secretary may specify.

32 “(C) ACCOUNTING FOR TRANSITIONAL ASSIST-
33 ANCE.—The sponsor of an endorsed discount card pro-
34 gram shall have arrangements satisfactory to the Sec-
35 retary to account for the assistance provided under
36 subsection (g) on behalf of transitional assistance eligi-
37 ble individuals.

1 “(2) APPLICATIONS FOR PROGRAM ENDORSEMENT.—

2 “(A) SUBMISSION.—Each prescription drug card
3 sponsor that seeks endorsement of a prescription drug
4 discount card program under this section shall submit
5 to the Secretary, at such time and in such manner as
6 the Secretary may specify, an application containing
7 such information as the Secretary may require.

8 “(B) APPROVAL; COMPLIANCE WITH APPLICABLE
9 REQUIREMENTS.—The Secretary shall review the appli-
10 cation submitted under subparagraph (A) and shall de-
11 termine whether to endorse the prescription drug dis-
12 count card program. The Secretary may not endorse
13 such a program unless—

14 “(i) the program and prescription drug card
15 sponsor offering the program comply with the ap-
16 plicable requirements under this section; and

17 “(ii) the sponsor has entered into a contract
18 with the Secretary to carry out such requirements.

19 “(C) TERMINATION OF ENDORSEMENT AND CON-
20 TRACTS.—An endorsement of an endorsed program and
21 a contract under subparagraph (B) shall be for the du-
22 ration of the program under this section (including any
23 transition applicable under subsection (a)(2)(C)(ii)), ex-
24 cept that the Secretary may, with notice and for cause
25 (as defined by the Secretary), terminate such endorse-
26 ment and contract.

27 “(D) ENSURING CHOICE OF PROGRAMS.—

28 “(i) IN GENERAL.—The Secretary shall ensure
29 that there is available to each discount card eligible
30 individual a choice of at least 2 endorsed programs
31 (each offered by a different sponsor).

32 “(ii) LIMITATION ON NUMBER.—The Sec-
33 retary may limit (but not below 2) the number of
34 sponsors in a State that are awarded contracts
35 under this paragraph.

36 “(3) SERVICE AREA ENCOMPASSING ENTIRE
37 STATES.—Except as provided in paragraph (9), if a pre-

1 prescription drug card sponsor that offers an endorsed pro-
2 gram enrolls in the program individuals residing in any
3 part of a State, the sponsor must permit any discount card
4 eligible individual residing in any portion of the State to
5 enroll in the program.

6 “(4) SAVINGS TO MEDICARE BENEFICIARIES.—Each
7 prescription drug card sponsor that offers an endorsed dis-
8 count card program shall pass on to discount card eligible
9 individuals enrolled in the program negotiated prices on
10 covered discount card drugs, including discounts negotiated
11 with pharmacies and manufacturers, to the extent disclosed
12 under subsection (i)(1).

13 “(5) GRIEVANCE MECHANISM.—Each prescription
14 drug card sponsor shall provide meaningful procedures for
15 hearing and resolving grievances between the sponsor (in-
16 cluding any entity or individual through which the sponsor
17 carries out the endorsed discount card program) and enroll-
18 ees in endorsed discount card programs of the sponsor
19 under this section in a manner similar to that required
20 under section 1852(f).

21 “(6) CONFIDENTIALITY OF ENROLLEE RECORDS.—

22 “(A) IN GENERAL.—For purposes of the program
23 under this section, the operations of an endorsed pro-
24 gram are covered functions and a prescription drug
25 card sponsor is a covered entity for purposes of apply-
26 ing part C of title XI and all regulatory provisions pro-
27 mulgated thereunder, including regulations (relating to
28 privacy) adopted pursuant to the authority of the Sec-
29 retary under section 264(c) of the Health Insurance
30 Portability and Accountability Act of 1996 (42 U.S.C.
31 1320d–2 note).

32 “(B) WAIVER AUTHORITY.—In order to promote
33 participation of sponsors in the program under this sec-
34 tion, the Secretary may waive such relevant portions of
35 regulations relating to privacy referred to in subpara-
36 graph (A), for such appropriate, limited period of time,
37 as the Secretary specifies.

1 “(7) LIMITATION ON PROVISION AND MARKETING OF
2 PRODUCTS AND SERVICES.—The sponsor of an endorsed
3 discount card program—

4 “(A) may provide under the program—

5 “(i) a product or service only if the product or
6 service is directly related to a covered discount card
7 drug; or

8 “(ii) a discount price for nonprescription
9 drugs; and

10 “(B) may, to the extent otherwise permitted under
11 paragraph (6) (relating to application of HIPAA re-
12 quirements), market a product or service under the
13 program only if the product or service is directly re-
14 lated to—

15 “(i) a covered discount card drug; or

16 “(ii) a drug described in subparagraph (A)(ii)
17 and the marketing consists of information on the
18 discounted price made available for the drug in-
19 volved.

20 “(8) ADDITIONAL PROTECTIONS.—Each endorsed dis-
21 count card program shall meet such additional require-
22 ments as the Secretary identifies to protect and promote
23 the interest of discount card eligible individuals, including
24 requirements that ensure that discount card eligible indi-
25 viduals enrolled in endorsed discount card programs are
26 not charged more than the lower of the price based on ne-
27 gotiated prices or the usual and customary price.

28 “(9) SPECIAL RULES FOR CERTAIN ORGANIZATIONS.—

29 “(A) IN GENERAL.—In the case of an organization
30 that is offering a plan under part C or enrollment
31 under a reasonable cost reimbursement contract under
32 section 1876(h) that is seeking to be a prescription
33 drug card sponsor under this section, the organization
34 may elect to apply the special rules under subpara-
35 graph (B) with respect to enrollees in any plan de-
36 scribed in section 1851(a)(2)(A) that it offers or under
37 such contract and an endorsed discount card program

1 it offers, but only if it limits enrollment under such
2 program to individuals enrolled in such plan or under
3 such contract.

4 “(B) SPECIAL RULES.—The special rules under
5 this subparagraph are as follows:

6 “(i) LIMITATION ON ENROLLMENT.—The
7 sponsor limits enrollment under this section under
8 the endorsed discount card program to discount
9 card eligible individuals who are enrolled in the
10 part C plan involved or under the reasonable cost
11 reimbursement contract involved and is not re-
12 quired nor permitted to enroll other individuals
13 under such program.

14 “(ii) PHARMACY ACCESS.—Pharmacy access
15 requirements under subsection (e)(1)(B) are
16 deemed to be met if the access is made available
17 through a pharmacy network (and not only through
18 mail order) and the network used by the sponsor
19 is approved by the Secretary.

20 “(iii) SPONSOR REQUIREMENTS.—The Sec-
21 retary may waive the application of such require-
22 ments for a sponsor as the Secretary determines to
23 be duplicative or to conflict with a requirement of
24 the organization under part C or section 1876 (as
25 the case may be) or to be necessary in order to im-
26 prove coordination of this section with the benefits
27 under such part or section.

28 “(i) DISCLOSURE AND OVERSIGHT.—

29 “(1) DISCLOSURE.—Each prescription drug card spon-
30 sor offering an endorsed discount card program shall dis-
31 close to the Secretary (in a manner specified by the Sec-
32 retary) information relating to program performance, use
33 of prescription drugs by discount card eligible individuals
34 enrolled in the program, the extent to which negotiated
35 price concessions described in subsection (e)(1)(A)(ii) made
36 available to the entity by a manufacturer are passed
37 through to enrollees through pharmacies or otherwise, and

1 such other information as the Secretary may specify. The
2 provisions of section 1927(b)(3)(D) shall apply to drug
3 pricing data reported under the previous sentence (other
4 than data in aggregate form).

5 “(2) OVERSIGHT; AUDIT AND INSPECTION AUTHOR-
6 ITY.—The Secretary shall provide appropriate oversight to
7 ensure compliance of endorsed discount card programs and
8 their sponsors with the requirements of this section. The
9 Secretary shall have the right to audit and inspect any
10 books and records of a prescription discount card sponsor
11 (and of any affiliated organization referred to in subsection
12 (h)(1)(B)) that pertain to the endorsed discount card pro-
13 gram under this section, including amounts payable to the
14 sponsor under this section.

15 “(3) SANCTIONS FOR ABUSIVE PRACTICES.—The Sec-
16 retary may implement intermediate sanctions or may re-
17 voke the endorsement of a program offered by a sponsor
18 under this section if the Secretary determines that the
19 sponsor or the program no longer meets the applicable re-
20 quirements of this section or that the sponsor has engaged
21 in false or misleading marketing practices. The Secretary
22 may impose a civil money penalty in an amount not to ex-
23 ceed \$10,000 for conduct that a party knows or should
24 know is a violation of this section. The provisions of section
25 1128A (other than subsections (a) and (b) and the second
26 sentence of subsection (f)) shall apply to a civil money pen-
27 alty under the previous sentence in the same manner as
28 such provisions apply to a penalty or proceeding under sec-
29 tion 1128A(a).

30 “(j) TREATMENT OF TERRITORIES.—

31 “(1) IN GENERAL.—The Secretary may waive any pro-
32 vision of this section (including subsection (h)(2)(D)) in the
33 case of a resident of a State (other than the 50 States and
34 the District of Columbia) insofar as the Secretary deter-
35 mines it is necessary to secure access to negotiated prices
36 for discount card eligible individuals (or, at the option of

1 the Secretary, individuals described in subsection
2 (b)(1)(A)(i)).

3 “(2) TRANSITIONAL ASSISTANCE.—

4 “(A) IN GENERAL.—In the case of a State, other
5 than the 50 States and the District of Columbia, if the
6 State establishes a plan described in subparagraph (B)
7 (for providing transitional assistance with respect to
8 the provision of prescription drugs to some or all indi-
9 viduals residing in the State who are described in sub-
10 subparagraph (B)(i)), the Secretary shall pay to the State
11 for the entire period of the operation of this section an
12 amount equal to the amount allotted to the State under
13 subparagraph (C).

14 “(B) PLAN.—The plan described in this subpara-
15 graph is a plan that—

16 “(i) provides transitional assistance with re-
17 spect to the provision of covered discount card
18 drugs to some or all individuals who are entitled to
19 benefits under part A or enrolled under part B,
20 who reside in the State, and who have income
21 below 135 percent of the poverty line; and

22 “(ii) assures that amounts received by the
23 State under this paragraph are used only for such
24 assistance.

25 “(C) ALLOTMENT LIMIT.—The amount described
26 in this subparagraph for a State is equal to
27 \$35,000,000 multiplied by the ratio (as estimated by
28 the Secretary) of—

29 “(i) the number of individuals who are entitled
30 to benefits under part A or enrolled under part B
31 and who reside in the State (as determined by the
32 Secretary as of July 1, 2003), to

33 “(ii) the sum of such numbers for all States
34 to which this paragraph applies.

35 “(D) CONTINUED AVAILABILITY OF FUNDS.—
36 Amounts made available to a State under this para-
37 graph which are not used under this paragraph shall be

1 added to the amount available to that State for pur-
2 poses of carrying out section 1935(e).

3 “(k) FUNDING.—

4 “(1) ESTABLISHMENT OF TRANSITIONAL ASSISTANCE
5 ACCOUNT.—

6 “(A) IN GENERAL.—There is created within the
7 Federal Supplementary Medical Insurance Trust Fund
8 established by section 1841 an account to be known as
9 the ‘Transitional Assistance Account’ (in this sub-
10 section referred to as the ‘Account’).

11 “(B) FUNDS.—The Account shall consist of such
12 gifts and bequests as may be made as provided in sec-
13 tion 201(i)(1), accrued interest on balances in the Ac-
14 count, and such amounts as may be deposited in, or
15 appropriated to, the Account as provided in this sub-
16 section.

17 “(C) SEPARATE FROM REST OF TRUST FUND.—
18 Funds provided under this subsection to the Account
19 shall be kept separate from all other funds within the
20 Federal Supplementary Medical Insurance Trust Fund,
21 but shall be invested, and such investments redeemed,
22 in the same manner as all other funds and investments
23 within such Trust Fund.

24 “(2) PAYMENTS FROM ACCOUNT.—

25 “(A) IN GENERAL.—The Managing Trustee shall
26 pay from time to time from the Account such amounts
27 as the Secretary certifies are necessary to make pay-
28 ments for transitional assistance provided under sub-
29 sections (g) and (j)(2).

30 “(B) TREATMENT IN RELATION TO PART B PRE-
31 MIUM.—Amounts payable from the Account shall not
32 be taken into account in computing actuarial rates or
33 premium amounts under section 1839.

34 “(3) APPROPRIATIONS TO COVER BENEFITS.—There
35 are appropriated to the Account in a fiscal year, out of any
36 moneys in the Treasury not otherwise appropriated, an

1 amount equal to the payments made from the Account in
2 the year.

3 “(4) FOR ADMINISTRATIVE EXPENSES.—There are au-
4 thorized to be appropriated to the Secretary such sums as
5 may be necessary to carry out the Secretary’s responsibil-
6 ities under this section.

7 “(5) TRANSFER OF ANY REMAINING BALANCE TO
8 MEDICARE PRESCRIPTION DRUG ACCOUNT.—Any balance
9 remaining in the Account after the Secretary determines
10 that funds in the Account are no longer necessary to carry
11 out the program under this section shall be transferred and
12 deposited into the Medicare Prescription Drug Account
13 under section 1860D–16.

14 “(6) CONSTRUCTION.—Nothing in this section shall be
15 construed as authorizing the Secretary to provide for pay-
16 ment (other than payment of an enrollment fee on behalf
17 of a transitional assistance eligible individual under sub-
18 section (g)(1)(A)) to a sponsor for administrative expenses
19 incurred by the sponsor in carrying out this section (includ-
20 ing in administering the transitional assistance provisions
21 of subsections (f) and (g)).

22 “Subpart 5—Definitions and Miscellaneous Provisions

23 “DEFINITIONS; TREATMENT OF REFERENCES TO PROVISIONS
24 IN PART C

25 “SEC. 1860D–41. (a) DEFINITIONS.—For purposes of this
26 part:

27 “(1) BASIC PRESCRIPTION DRUG COVERAGE.—The
28 term ‘basic prescription drug coverage’ is defined in section
29 1860D–2(a)(3).

30 “(2) COVERED PART D DRUG.—The term ‘covered
31 part D drug’ is defined in section 1860D–2(e).

32 “(3) CREDITABLE PRESCRIPTION DRUG COVERAGE.—
33 The term ‘creditable prescription drug coverage’ has the
34 meaning given such term in section 1860D–13(b)(4).

35 “(4) PART D ELIGIBLE INDIVIDUAL.—The term ‘part
36 D eligible individual’ has the meaning given such term in
37 section 1860D–1(a)(4)(A).

1 “(5) FALLBACK PRESCRIPTION DRUG PLAN.—The
2 term ‘fallback prescription drug plan’ has the meaning
3 given such term in section 1860D–11(g)(4).

4 “(6) INITIAL COVERAGE LIMIT.—The term ‘initial cov-
5 erage limit’ means such limit as established under section
6 1860D–2(b)(3), or, in the case of coverage that is not
7 standard prescription drug coverage, the comparable limit
8 (if any) established under the coverage.

9 “(7) INSURANCE RISK.—The term ‘insurance risk’
10 means, with respect to a participating pharmacy, risk of
11 the type commonly assumed only by insurers licensed by a
12 State and does not include payment variations designed to
13 reflect performance-based measures of activities within the
14 control of the pharmacy, such as formulary compliance and
15 generic drug substitution.

16 “(8) MA PLAN.—The term ‘MA plan’ has the meaning
17 given such term in section 1860D–1(a)(4)(B).

18 “(9) MA–PD PLAN.—The term ‘MA–PD plan’ has the
19 meaning given such term in section 1860D–1(a)(4)(C).

20 “(10) MEDICARE PRESCRIPTION DRUG ACCOUNT.—
21 The term ‘Medicare Prescription Drug Account’ means the
22 Account created under section 1860D–16(a).

23 “(11) PDP APPROVED BID.—The term ‘PDP ap-
24 proved bid’ has the meaning given such term in section
25 1860D–13(a)(6).

26 “(12) PDP REGION.—The term ‘PDP region’ means
27 such a region as provided under section 1860D–11(a)(2).

28 “(13) PDP SPONSOR.—The term ‘PDP sponsor’
29 means a nongovernmental entity that is certified under this
30 part as meeting the requirements and standards of this
31 part for such a sponsor.

32 “(14) PRESCRIPTION DRUG PLAN.—The term ‘pre-
33 scription drug plan’ means prescription drug coverage that
34 is offered—

35 “(A) under a policy, contract, or plan that has
36 been approved under section 1860D–11(e); and

1 “(B) by a PDP sponsor pursuant to, and in ac-
2 cordance with, a contract between the Secretary and
3 the sponsor under section 1860D–12(b).

4 “(15) QUALIFIED PRESCRIPTION DRUG COVERAGE.—
5 The term ‘qualified prescription drug coverage’ is defined
6 in section 1860D–2(a)(1).

7 “(16) STANDARD PRESCRIPTION DRUG COVERAGE.—
8 The term ‘standard prescription drug coverage’ is defined
9 in section 1860D–2(b).

10 “(17) STATE PHARMACEUTICAL ASSISTANCE PRO-
11 GRAM.—The term ‘State Pharmaceutical Assistance Pro-
12 gram’ has the meaning given such term in section 1860D–
13 23(b).

14 “(18) SUBSIDY ELIGIBLE INDIVIDUAL.—The term
15 ‘subsidy eligible individual’ has the meaning given such
16 term in section 1860D–14(a)(3)(A).

17 “(b) APPLICATION OF PART C PROVISIONS UNDER THIS
18 PART.—For purposes of applying provisions of part C under
19 this part with respect to a prescription drug plan and a PDP
20 sponsor, unless otherwise provided in this part such provisions
21 shall be applied as if—

22 “(1) any reference to an MA plan included a reference
23 to a prescription drug plan;

24 “(2) any reference to an MA organization or a pro-
25 vider-sponsored organization included a reference to a PDP
26 sponsor;

27 “(3) any reference to a contract under section 1857
28 included a reference to a contract under section 1860D–
29 12(b);

30 “(4) any reference to part C included a reference to
31 this part; and

32 “(5) any reference to an election period under section
33 1851 were a reference to an enrollment period under sec-
34 tion 1860D–1.

35 “MISCELLANEOUS PROVISIONS

36 “SEC. 1860D–42. (a) ACCESS TO COVERAGE IN TERRI-
37 TORIES.—The Secretary may waive such requirements of this

1 part, including section 1860D–3(a)(1), insofar as the Secretary
2 determines it is necessary to secure access to qualified prescrip-
3 tion drug coverage for part D eligible individuals residing in a
4 State (other than the 50 States and the District of Columbia).

5 “(b) APPLICATION OF DEMONSTRATION AUTHORITY.—
6 The provisions of section 402 of the Social Security Amend-
7 ments of 1967 (Public Law 90–248) shall apply with respect
8 to this part and part C in the same manner it applies with re-
9 spect to parts A and B, except that any reference with respect
10 to a Trust Fund in relation to an experiment or demonstration
11 project relating to prescription drug coverage under this part
12 shall be deemed a reference to the Medicare Prescription Drug
13 Account within the Federal Supplementary Medical Insurance
14 Trust Fund.”.

15 (b) SUBMISSION OF LEGISLATIVE PROPOSAL.—Not later
16 than 6 months after the date of the enactment of this Act, the
17 Secretary shall submit to the appropriate committees of Con-
18 gress a legislative proposal providing for such technical and
19 conforming amendments in the law as are required by the pro-
20 visions of this title and title II.

21 (c) STUDY ON TRANSITIONING PART B PRESCRIPTION
22 DRUG COVERAGE.—Not later than January 1, 2005, the Sec-
23 retary shall submit a report to Congress that makes rec-
24 ommendations regarding methods for providing benefits under
25 subpart 1 of part D of title XVIII of the Social Security Act
26 for outpatient prescription drugs for which benefits are pro-
27 vided under part B of such title.

28 (d) REPORT ON PROGRESS IN IMPLEMENTATION OF PRE-
29 SCRIPTIION DRUG BENEFIT.—Not later than March 1, 2005,
30 the Secretary shall submit a report to Congress on the progress
31 that has been made in implementing the prescription drug ben-
32 efit under this title. The Secretary shall include in the report
33 specific steps that have been taken, and that need to be taken,
34 to ensure a timely start of the program on January 1, 2006.
35 The report shall include recommendations regarding an appro-
36 priate transition from the program under section 1860D–31 of

1 the Social Security Act to prescription drug benefits under sub-
2 part 1 of part D of title XVIII of such Act.

3 (e) ADDITIONAL CONFORMING CHANGES.—

4 (1) CONFORMING REFERENCES TO PREVIOUS PART
5 D.—Any reference in law (in effect before the date of the
6 enactment of this Act) to part D of title XVIII of the So-
7 cial Security Act is deemed a reference to part E of such
8 title (as in effect after such date).

9 (2) CONFORMING AMENDMENT PERMITTING WAIVER
10 OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C.
11 1320a–7b(b)(3)) is amended—

12 (A) by striking “and” at the end of subparagraph
13 (E);

14 (B) by striking the period at the end of subpara-
15 graph (F) and inserting “; and”; and

16 (C) by adding at the end the following new sub-
17 paragraph:

18 “(G) the waiver or reduction by pharmacies (including
19 pharmacies of the Indian Health Service, Indian tribes,
20 tribal organizations, and urban Indian organizations) of
21 any cost-sharing imposed under part D of title XVIII, if
22 the conditions described in clauses (i) through (iii) of sec-
23 tion 1128A(i)(6)(A) are met with respect to the waiver or
24 reduction (except that, in the case of such a waiver or re-
25 duction on behalf of a subsidy eligible individual (as defined
26 in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall
27 be applied without regard to clauses (ii) and (iii) of that
28 section).”.

29 (3) MEDICARE PRESCRIPTION DRUG ACCOUNT.—

30 (A) Section 201(g) (42 U.S.C. 401(g)) is
31 amended—

32 (i) in paragraph (1)(B)(i)(V), by inserting
33 “(and, of such portion, the portion of such costs
34 which should have been borne by the Medicare Pre-
35 scription Drug Account in such Trust Fund)” after
36 “Trust Fund”; and

1 (ii) in paragraph (1)(B)(ii)(III), by inserting
 2 “(and, of such portion, the portion of such costs
 3 which should have been borne by the Medicare Pre-
 4 scription Drug Account in such Trust Fund)” after
 5 “Trust Fund”.

6 (B) Section 201(i)(1) (42 U.S.C. 401(i)(1)) is
 7 amended by inserting “(and for the Medicare Prescrip-
 8 tion Drug Account and the Transitional Assistance Ac-
 9 count in such Trust Fund)” after “Federal Supple-
 10 mentary Medical Insurance Trust Fund”.

11 (C) Section 1841 (42 U.S.C. 1395t) is amended—

12 (i) in the last sentence of subsection (a)—

13 (I) by striking “and” before “such
 14 amounts”; and

15 (II) by inserting before the period the fol-
 16 lowing: “, and such amounts as may be depos-
 17 ited in, or appropriated to, the Medicare Pre-
 18 scription Drug Account established by section
 19 1860D–16”;

20 (ii) in subsection (g), by adding at the end the
 21 following: “The payments provided for under part
 22 D, other than under section 1860D–31(k)(2), shall
 23 be made from the Medicare Prescription Drug Ac-
 24 count in the Trust Fund.”;

25 (iii) in subsection (h), by inserting “or pursu-
 26 ant to section 1860D–13(c)(1) or 1854(d)(2)(A)
 27 (in which case payments shall be made in appro-
 28 priate part from the Medicare Prescription Drug
 29 Account in the Trust Fund)” after “1840(d)”; and

30 (iv) in subsection (i), by inserting after “and
 31 section 1842(g)” the following: “and pursuant to
 32 sections 1860D–13(c)(1) and 1854(d)(2)(A) (in
 33 which case payments shall be made in appropriate
 34 part from the Medicare Prescription Drug Account
 35 in the Trust Fund)”.

36 (D) Section 1853(f) (42 U.S.C. 1395w–23(f)) is
 37 amended—

1 (i) in the heading by striking “TRUST FUND”
2 and inserting “TRUST FUNDS”; and

3 (ii) by inserting after the first sentence the fol-
4 lowing: “Payments to MA organizations for statu-
5 tory drug benefits provided under this title are
6 made from the Medicare Prescription Drug Ac-
7 count in the Federal Supplementary Medical Insur-
8 ance Trust Fund.”.

9 (4) APPLICATION OF CONFIDENTIALITY FOR DRUG
10 PRICING DATA.—Section 1927(b)(3)(D) (42 U.S.C. 1396r-
11 8(b)(3)(D)) is amended by adding after and below clause
12 (iii) the following:

13 “The previous sentence shall also apply to information
14 disclosed under section 1860D–2(d)(2) or 1860D–
15 4(c)(2)(E).”.

16 (5) CLARIFICATION OF TREATMENT OF PART A EN-
17 ROLLEES.—Section 1818(a) (42 U.S.C. 1395i–2(a)) is
18 amended by adding at the end the following: “Except as
19 otherwise provided, any reference to an individual entitled
20 to benefits under this part includes an individual entitled
21 to benefits under this part pursuant to an enrollment under
22 this section or section 1818A.”.

23 (6) DISCLOSURE.—Section 6103(l)(7)(D)(ii) of the In-
24 ternal Revenue Code of 1986 is amended by inserting “or
25 subsidies provided under section 1860D–14 of such Act”
26 after “Social Security Act”.

27 (7) EXTENSION OF STUDY AUTHORITY.—Section
28 1875(b) (42 U.S.C. 1395ll(b)) is amended by striking “the
29 insurance programs under parts A and B” and inserting
30 “this title”.

31 (8) CONFORMING AMENDMENTS RELATING TO FACILI-
32 TATION OF ELECTRONIC PRESCRIBING.—

33 (A) Section 1128B(b)(3)(C) (42 U.S.C. 1320a-
34 7b(b)(3)(C)) is amended by inserting “or in regulations
35 under section 1860D–3(e)(6)” after “1987”.

1 (B) Section 1877(b) (42 U.S.C. 1395nn(b)) is
 2 amended by adding at the end the following new para-
 3 graph:

4 “(5) ELECTRONIC PRESCRIBING.—An exception estab-
 5 lished by regulation under section 1860D–3(e)(6).”.

6 (9) OTHER CHANGES.—Section 1927(g)(1)(B)(i) (42
 7 U.S.C. 1396r–8(g)(1)(B)(i)) is amended—

8 (A) by adding “and” at the end of subclause (II);
 9 and

10 (B) by striking subclause (IV).

11 **SEC. 102. MEDICARE ADVANTAGE CONFORMING AMEND-**
 12 **MENTS.**

13 (a) CONFORMING AMENDMENTS TO ENROLLMENT PROC-
 14 ESS.—

15 (1) EXTENDING OPEN ENROLLMENT PERIODS.—Sec-
 16 tion 1851(e) (42 U.S.C. 1395w–21(e)) is amended—

17 (A) in paragraph (2), by striking “2004” and
 18 “2005” and inserting “2005” and “2006” each place
 19 it appears; and

20 (B) in paragraph (4), by striking “2005” and in-
 21 serting “2006” each place it appears.

22 (2) ESTABLISHMENT OF SPECIAL ANNUAL, COORDI-
 23 NATED ELECTION PERIOD FOR 6 MONTHS BEGINNING NO-
 24 VEMBER 15, 2005.—Section 1851(e)(3)(B) (42 U.S.C.
 25 1395w–21(e)(3)(B)) is amended to read as follows:

26 “(B) ANNUAL, COORDINATED ELECTION PE-
 27 RIOD.—For purposes of this section, the term ‘annual,
 28 coordinated election period’ means—

29 “(i) with respect to a year before 2002, the
 30 month of November before such year;

31 “(ii) with respect to 2002, 2003, 2004, and
 32 2005, the period beginning on November 15 and
 33 ending on December 31 of the year before such
 34 year;

35 “(iii) with respect to 2006, the period begin-
 36 ning on November 15, 2005, and ending on May
 37 15, 2006; and

1 “(iv) with respect to 2007 and succeeding
2 years, the period beginning on November 15 and
3 ending on December 31 of the year before such
4 year.”.

5 (3) SPECIAL INFORMATION CAMPAIGN.—Section
6 1851(e)(3) (42 U.S.C. 1395w-21(e)(3)) is amended—

7 (A) in subparagraph (C), by inserting “and during
8 the period described in subparagraph (B)(iii)” after
9 “(beginning with 1999)”; and

10 (B) in subparagraph (D)—

11 (i) in the heading by striking “CAMPAIGN IN
12 1998” and inserting “CAMPAIGNS”; and

13 (ii) by adding at the end the following: “Dur-
14 ing the period described in subparagraph (B)(iii),
15 the Secretary shall provide for an educational and
16 publicity campaign to inform MA eligible individ-
17 uals about the availability of MA plans (including
18 MA-PD plans) offered in different areas and the
19 election process provided under this section.”.

20 (4) COORDINATING INITIAL ENROLLMENT PERIODS.—
21 Section 1851(e)(1) (42 U.S.C. 1395w-21(e)(1)) is amend-
22 ed by adding at the end the following new sentence: “If any
23 portion of an individual’s initial enrollment period under
24 part B occurs after the end of the annual, coordinated elec-
25 tion period described in paragraph (3)(B)(iii), the initial
26 enrollment period under this part shall further extend
27 through the end of the individual’s initial enrollment period
28 under part B.”.

29 (5) COORDINATION OF EFFECTIVENESS OF ELECTIONS
30 DURING ANNUAL COORDINATED ELECTION PERIOD FOR
31 2006.—Section 1851(f)(3) (42 U.S.C. 1395w-21(f)(3)) is
32 amended by inserting “, other than the period described in
33 clause (iii) of such subsection” after “subsection
34 (e)(3)(B)”.

35 (6) LIMITATION ON ONE-CHANGE RULE TO SAME TYPE
36 OF PLAN.—Section 1851(e)(2) (42 U.S.C. 1395w-21(e)(2))
37 is amended—

1 (A) in subparagraph (B)(i), by inserting “, sub-
2 paragraph (C)(iii),” after “clause (ii)”;

3 (B) in subparagraph (C)(i), by striking “clause
4 (ii)” and inserting “clauses (ii) and (iii)”;

5 (C) by adding at the end of subparagraph (C) the
6 following new clause:

7 “(iii) LIMITATION ON EXERCISE OF RIGHT
8 WITH RESPECT TO PRESCRIPTION DRUG COV-
9 ERAGE.—Effective for plan years beginning on or
10 after January 1, 2006, in applying clause (i) (and
11 clause (i) of subparagraph (B)) in the case of an
12 individual who—

13 “(I) is enrolled in an MA plan that does
14 provide qualified prescription drug coverage,
15 the individual may exercise the right under
16 such clause only with respect to coverage under
17 the original fee-for-service plan or coverage
18 under another MA plan that does not provide
19 such coverage and may not exercise such right
20 to obtain coverage under an MA–PD plan or
21 under a prescription drug plan under part D;
22 or

23 “(II) is enrolled in an MA–PD plan, the
24 individual may exercise the right under such
25 clause only with respect to coverage under an-
26 other MA–PD plan (and not an MA plan that
27 does not provide qualified prescription drug
28 coverage) or under the original fee-for-service
29 plan and coverage under a prescription drug
30 plan under part D.”.

31 (b) PROMOTION OF E-PRESCRIBING BY MA PLANS.—Sec-
32 tion 1852(j) (42 U.S.C. 1395w–22(j)) is amended by adding at
33 the end the following new paragraph:

34 “(7) PROMOTION OF E-PRESCRIBING BY MA
35 PLANS.—

36 “(A) IN GENERAL.—An MA–PD plan may provide
37 for a separate payment or otherwise provide for a dif-

1 ferential payment for a participating physician that
 2 prescribes covered part D drugs in accordance with an
 3 electronic prescription drug program that meets stand-
 4 ards established under section 1860D–4(e).

5 “(B) CONSIDERATIONS.—Such payment may take
 6 into consideration the costs of the physician in imple-
 7 menting such a program and may also be increased for
 8 those participating physicians who significantly
 9 increase—

10 “(i) formulary compliance;

11 “(ii) lower cost, therapeutically equivalent al-
 12 ternatives;

13 “(iii) reductions in adverse drug interactions;
 14 and

15 “(iv) efficiencies in filing prescriptions through
 16 reduced administrative costs.

17 “(C) STRUCTURE.—Additional or increased pay-
 18 ments under this subsection may be structured in the
 19 same manner as medication therapy management fees
 20 are structured under section 1860D–4(c)(2)(E).”.

21 (c) OTHER CONFORMING AMENDMENTS.—

22 (1) Section 1851(a)(1) (42 U.S.C. 1395w–21(a)(1)) is
 23 amended—

24 (A) by inserting “(other than qualified prescrip-
 25 tion drug benefits)” after “benefits”;

26 (B) by striking the period at the end of subpara-
 27 graph (B) and inserting a comma; and

28 (C) by adding after and below subparagraph (B)
 29 the following:

30 “and may elect qualified prescription drug coverage in ac-
 31 cordance with section 1860D–1.”.

32 (2) EFFECTIVE DATE.—The amendments made by
 33 this subsection shall apply on and after January 1, 2006.

34 **SEC. 103. MEDICAID AMENDMENTS.**

35 (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME
 36 SUBSIDIES.—

1 (1) REQUIREMENT.—Section 1902(a) (42 U.S.C.
2 1396a(a)) is amended—

3 (A) by striking “and” at the end of paragraph
4 (64);

5 (B) by striking the period at the end of paragraph
6 (65) and inserting “; and”; and

7 (C) by inserting after paragraph (65) the following
8 new paragraph:

9 “(66) provide for making eligibility determinations
10 under section 1935(a).”.

11 (2) NEW SECTION.—Title XIX is further amended—

12 (A) by redesignating section 1935 as section 1936;
13 and

14 (B) by inserting after section 1934 the following
15 new section:

16 “SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION
17 DRUG BENEFIT

18 “SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE
19 PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE
20 TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a con-
21 dition of its State plan under this title under section
22 1902(a)(66) and receipt of any Federal financial assistance
23 under section 1903(a), a State shall do the following:

24 “(1) INFORMATION FOR TRANSITIONAL PRESCRIPTION
25 DRUG ASSISTANCE VERIFICATION.—The State shall provide
26 the Secretary with information to carry out section 1860D-
27 31(f)(3)(B)(i).

28 “(2) ELIGIBILITY DETERMINATIONS FOR LOW-INCOME
29 SUBSIDIES.—The State shall—

30 “(A) make determinations of eligibility for pre-
31 mium and cost-sharing subsidies under and in accord-
32 ance with section 1860D-14;

33 “(B) inform the Secretary of such determinations
34 in cases in which such eligibility is established; and

35 “(C) otherwise provide the Secretary with such in-
36 formation as may be required to carry out part D,

1 other than subpart 4, of title XVIII (including section
2 1860D–14).

3 “(3) SCREENING FOR ELIGIBILITY, AND ENROLLMENT
4 OF, BENEFICIARIES FOR MEDICARE COST-SHARING.—As
5 part of making an eligibility determination required under
6 paragraph (2) for an individual, the State shall make a de-
7 termination of the individual’s eligibility for medical assist-
8 ance for any medicare cost-sharing described in section
9 1905(p)(3) and, if the individual is eligible for any such
10 medicare cost-sharing, offer enrollment to the individual
11 under the State plan (or under a waiver of such plan).

12 “(b) REGULAR FEDERAL SUBSIDY OF ADMINISTRATIVE
13 COSTS.—The amounts expended by a State in carrying out
14 subsection (a) are expenditures reimbursable under the appro-
15 priate paragraph of section 1903(a).

16 (b) PHASED-IN FEDERAL ASSUMPTION OF MEDICAID RE-
17 SPONSIBILITY FOR PREMIUM AND COST-SHARING SUBSIDIES
18 FOR DUALY ELIGIBLE INDIVIDUALS.—Section 1935, as in-
19 serted by subsection (a)(2), is amended by adding at the end
20 the following new subsection:

21 “(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION
22 DRUG COSTS FOR DUALY ELIGIBLE INDIVIDUALS.—

23 “(1) PHASED-DOWN STATE CONTRIBUTION.—

24 “(A) IN GENERAL.—Each of the 50 States and
25 the District of Columbia for each month beginning with
26 January 2006 shall provide for payment under this
27 subsection to the Secretary of the product of—

28 “(i) the amount computed under paragraph
29 (2)(A) for the State and month;

30 “(ii) the total number of full-benefit dual eligi-
31 ble individuals (as defined in paragraph (6)) for
32 such State and month; and

33 “(iii) the factor for the month specified in
34 paragraph (5).

35 “(B) FORM AND MANNER OF PAYMENT.—Payment
36 under subparagraph (A) shall be made in a manner
37 specified by the Secretary that is similar to the manner

1 in which State payments are made under an agreement
2 entered into under section 1843, except that all such
3 payments shall be deposited into the Medicare Prescrip-
4 tion Drug Account in the Federal Supplementary Med-
5 ical Insurance Trust Fund.

6 “(C) COMPLIANCE.—If a State fails to pay to the
7 Secretary an amount required under subparagraph (A),
8 interest shall accrue on such amount at the rate pro-
9 vided under section 1903(d)(5). The amount so owed
10 and applicable interest shall be immediately offset
11 against amounts otherwise payable to the State under
12 section 1903(a), in accordance with the Federal Claims
13 Collection Act of 1996 and applicable regulations.

14 “(D) DATA MATCH.—The Secretary shall perform
15 such periodic data matches as may be necessary to
16 identify and compute the number of full-benefit dual el-
17 igible individuals for purposes of computing the amount
18 under subparagraph (A).

19 “(2) AMOUNT.—

20 “(A) IN GENERAL.—The amount computed under
21 this paragraph for a State described in paragraph (1)
22 and for a month in a year is equal to—

23 “(i) $\frac{1}{12}$ of the product of—

24 “(I) the base year state medicaid per cap-
25 ita expenditures for covered part D drugs for
26 full-benefit dual eligible individuals (as com-
27 puted under paragraph (3)); and

28 “(II) a proportion equal to 100 percent
29 minus the Federal medical assistance percent-
30 age (as defined in section 1905(b)) applicable
31 to the State for the fiscal year in which the
32 month occurs; and

33 “(ii) increased for each year (beginning with
34 2004 up to and including the year involved) by the
35 applicable growth factor specified in paragraph (4)
36 for that year.

1 “(B) NOTICE.—The Secretary shall notify each
2 State described in paragraph (1) not later than October
3 15 before the beginning of each year (beginning with
4 2006) of the amount computed under subparagraph
5 (A) for the State for that year.

6 “(3) BASE YEAR STATE MEDICAID PER CAPITA EX-
7 PENDITURES FOR COVERED PART D DRUGS FOR FULL-
8 BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

9 “(A) IN GENERAL.—For purposes of paragraph
10 (2)(A), the ‘base year State medicaid per capita ex-
11 penditures for covered part D drugs for full-benefit
12 dual eligible individuals’ for a State is equal to the
13 weighted average (as weighted under subparagraph
14 (C)) of—

15 “(i) the gross per capita medicaid expenditures
16 for prescription drugs for 2003, determined under
17 subparagraph (B); and

18 “(ii) the estimated actuarial value of prescrip-
19 tion drug benefits provided under a capitated man-
20 aged care plan per full-benefit dual eligible indi-
21 vidual for 2003, as determined using such data as
22 the Secretary determines appropriate.

23 “(B) GROSS PER CAPITA MEDICAID EXPENDI-
24 TURES FOR PRESCRIPTION DRUGS.—

25 “(i) IN GENERAL.—The gross per capita med-
26 icaid expenditures for prescription drugs for 2003
27 under this subparagraph is equal to the expendi-
28 tures, including dispensing fees, for the State
29 under this title during 2003 for covered outpatient
30 drugs, determined per full-benefit-dual-eligible-indi-
31 vidual for such individuals not receiving medical as-
32 sistance for such drugs through a medicaid man-
33 aged care plan.

34 “(ii) DETERMINATION.—In determining the
35 amount under clause (i), the Secretary shall—

1 “(I) use data from the Medicaid Statistical
2 Information System (MSIS) and other available
3 data;

4 “(II) exclude expenditures attributable to
5 covered outpatient prescription drugs that are
6 not covered part D drugs (as defined in section
7 1860D–2(e)); and

8 “(III) reduce such expenditures by the
9 product of such portion and the adjustment
10 factor (described in clause (iii)).

11 “(iii) ADJUSTMENT FACTOR.—The adjustment
12 factor described in this clause for a State is equal
13 to the ratio for the State for 2003 of—

14 “(I) aggregate payments under agree-
15 ments under section 1927; to

16 “(II) the gross expenditures under this
17 title for covered outpatient drugs referred to in
18 clause (i).

19 Such factor shall be determined based on informa-
20 tion reported by the State in the medicaid financial
21 management reports (form CMS–64) for the 4
22 quarters of calendar year 2003 and such other data
23 as the Secretary may require.

24 “(C) WEIGHTED AVERAGE.—The weighted aver-
25 age under subparagraph (A) shall be determined taking
26 into account—

27 “(i) with respect to subparagraph (A)(i), the
28 average number of full-benefit dual eligible individ-
29 uals in 2003 who are not described in clause (ii);
30 and

31 “(ii) with respect to subparagraph (A)(ii), the
32 average number of full-benefit dual eligible individ-
33 uals in such year who received in 2003 medical as-
34 sistance for covered outpatient drugs through a
35 medicaid managed care plan.

36 “(4) APPLICABLE GROWTH FACTOR.—The applicable
37 growth factor under this paragraph for—

1 “(A) each of 2004, 2005, and 2006, is the average
2 annual percent change (to that year from the previous
3 year) of the per capita amount of prescription drug ex-
4 penditures (as determined based on the most recent
5 National Health Expenditure projections for the years
6 involved); and

7 “(B) a succeeding year, is the annual percentage
8 increase specified in section 1860D–2(b)(6) for the
9 year.

10 “(5) FACTOR.—The factor under this paragraph for a
11 month—

12 “(A) in 2006 is 90 percent;

13 “(B) in 2007 is 88- $\frac{1}{3}$ percent;

14 “(C) in 2008 is 86- $\frac{2}{3}$ percent;

15 “(D) in 2009 is 85 percent;

16 “(E) in 2010 is 83- $\frac{1}{3}$ percent;

17 “(F) in 2011 is 81- $\frac{2}{3}$ percent;

18 “(G) in 2012 is 80 percent;

19 “(H) in 2013 is 78- $\frac{1}{3}$ percent;

20 “(I) in 2014 is 76- $\frac{2}{3}$ percent; or

21 “(J) after December 2014, is 75 percent.

22 “(6) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL DE-
23 FINED.—

24 “(A) IN GENERAL.—For purposes of this section,
25 the term ‘full-benefit dual eligible individual’ means for
26 a State for a month an individual who—

27 “(i) has coverage for the month for covered
28 part D drugs under a prescription drug plan under
29 part D of title XVIII, or under an MA–PD plan
30 under part C of such title; and

31 “(ii) is determined eligible by the State for
32 medical assistance for full benefits under this title
33 for such month under section 1902(a)(10)(A) or
34 1902(a)(10)(C), by reason of section 1902(f), or
35 under any other category of eligibility for medical
36 assistance for full benefits under this title, as de-
37 termined by the Secretary.

1 “(B) TREATMENT OF MEDICALLY NEEDY AND
 2 OTHER INDIVIDUALS REQUIRED TO SPEND DOWN.—In
 3 applying subparagraph (A) in the case of an individual
 4 determined to be eligible by the State for medical as-
 5 sistance under section 1902(a)(10)(C) or by reason of
 6 section 1902(f), the individual shall be treated as meet-
 7 ing the requirement of subparagraph (A)(ii) for any
 8 month if such medical assistance is provided for in any
 9 part of the month.”.

10 (c) MEDICAID COORDINATION WITH MEDICARE PRE-
 11 SCRIPTION DRUG BENEFITS.—Section 1935, as so inserted and
 12 amended, is further amended by adding at the end the fol-
 13 lowing new subsection:

14 “(d) COORDINATION OF PRESCRIPTION DRUG BENE-
 15 FITS.—

16 “(1) MEDICARE AS PRIMARY PAYOR.—In the case of
 17 a part D eligible individual (as defined in section 1860D-
 18 1(a)(3)(A)) who is described in subsection (c)(6)(A)(ii),
 19 notwithstanding any other provision of this title, medical
 20 assistance is not available under this title for such drugs
 21 (or for any cost-sharing respecting such drugs), and the
 22 rules under this title relating to the provision of medical as-
 23 sistance for such drugs shall not apply. The provision of
 24 benefits with respect to such drugs shall not be considered
 25 as the provision of care or services under the plan under
 26 this title. No payment may be made under section 1903(a)
 27 for prescribed drugs for which medical assistance is not
 28 available pursuant to this paragraph.

29 “(2) COVERAGE OF CERTAIN EXCLUDABLE DRUGS.—
 30 In the case of medical assistance under this title with re-
 31 spect to a covered outpatient drug (other than a covered
 32 part D drug) furnished to an individual who is enrolled in
 33 a prescription drug plan under part D of title XVIII or an
 34 MA-PD plan under part C of such title, the State may
 35 elect to provide such medical assistance in the manner oth-
 36 erwise provided in the case of individuals who are not full-

1 benefit dual eligible individuals or through an arrangement
2 with such plan.”.

3 (d) TREATMENT OF TERRITORIES.—

4 (1) IN GENERAL.—Section 1935, as so inserted and
5 amended, is further amended—

6 (A) in subsection (a) in the matter preceding para-
7 graph (1), by inserting “subject to subsection (e)” after
8 “section 1903(a)”;

9 (B) in subsection (c)(1), by inserting “subject to
10 subsection (e)” after “1903(a)(1)”; and

11 (C) by adding at the end the following new sub-
12 section:

13 “(e) TREATMENT OF TERRITORIES.—

14 “(1) IN GENERAL.—In the case of a State, other than
15 the 50 States and the District of Columbia—

16 “(A) the previous provisions of this section shall
17 not apply to residents of such State; and

18 “(B) if the State establishes and submits to the
19 Secretary a plan described in paragraph (2) (for pro-
20 viding medical assistance with respect to the provision
21 of prescription drugs to part D eligible individuals), the
22 amount otherwise determined under section 1108(f) (as
23 increased under section 1108(g)) for the State shall be
24 increased by the amount for the fiscal period specified
25 in paragraph (3).

26 “(2) PLAN.—The Secretary shall determine that a
27 plan is described in this paragraph if the plan—

28 “(A) provides medical assistance with respect to
29 the provision of covered part D drugs (as defined in
30 section 1860D–2(e)) to low-income part D eligible indi-
31 viduals;

32 “(B) provides assurances that additional amounts
33 received by the State that are attributable to the oper-
34 ation of this subsection shall be used only for such as-
35 sistance and related administrative expenses and that
36 no more than 10 percent of the amount specified in

1 paragraph (3)(A) for the State for any fiscal period
2 shall be used for such administrative expenses; and

3 “(C) meets such other criteria as the Secretary
4 may establish.

5 “(3) INCREASED AMOUNT.—

6 “(A) IN GENERAL.—The amount specified in this
7 paragraph for a State for a year is equal to the product
8 of—

9 “(i) the aggregate amount specified in sub-
10 paragraph (B); and

11 “(ii) the ratio (as estimated by the Secretary)
12 of—

13 “(I) the number of individuals who are en-
14 titled to benefits under part A or enrolled
15 under part B and who reside in the State (as
16 determined by the Secretary based on the most
17 recent available data before the beginning of
18 the year); to

19 “(II) the sum of such numbers for all
20 States that submit a plan described in para-
21 graph (2).

22 “(B) AGGREGATE AMOUNT.—The aggregate
23 amount specified in this subparagraph for—

24 “(i) the last 3 quarters of fiscal year 2006, is
25 equal to \$28,125,000;

26 “(ii) fiscal year 2007, is equal to \$37,500,000;
27 or

28 “(iii) a subsequent year, is equal to the aggre-
29 gate amount specified in this subparagraph for the
30 previous year increased by annual percentage in-
31 crease specified in section 1860D–2(b)(6) for the
32 year involved.

33 “(4) REPORT.—The Secretary shall submit to Con-
34 gress a report on the application of this subsection and
35 may include in the report such recommendations as the
36 Secretary deems appropriate.”

1 (2) CONFORMING AMENDMENT.—Section 1108(f) (42
 2 U.S.C. 1308(f)) is amended by inserting “and section
 3 1935(e)(1)(B)” after “Subject to subsection (g)”.

4 (e) AMENDMENT TO BEST PRICE.—

5 (1) IN GENERAL.—Section 1927(c)(1)(C)(i) (42
 6 U.S.C. 1396r–8(c)(1)(C)(i)) is amended—

7 (A) by striking “and” at the end of subclause
 8 (III);

9 (B) by striking the period at the end of subclause
 10 (IV) and inserting a semicolon; and

11 (C) by adding at the end the following new sub-
 12 clauses:

13 “(V) the prices negotiated from drug man-
 14 ufacturers for covered discount card drugs
 15 under an endorsed discount card program
 16 under section 1860D–31; and

17 “(VI) any prices charged which are nego-
 18 tiated by a prescription drug plan under part
 19 D of title XVIII, by an MA–PD plan under
 20 part C of such title with respect to covered part
 21 D drugs or by a qualified retiree prescription
 22 drug plan (as defined in section 1860D–
 23 22(a)(2)) with respect to such drugs on behalf
 24 of individuals entitled to benefits under part A
 25 or enrolled under part B of such title.”.

26 (2) IN GENERAL.—Section 1927(c)(1)(C)(i)(VI) of the
 27 Social Security Act, as added by paragraph (1), shall apply
 28 to prices charged for drugs dispensed on or after January
 29 1, 2006.

30 (f) EXTENSION OF MEDICARE COST-SHARING FOR PART
 31 B PREMIUM FOR QUALIFYING INDIVIDUALS THROUGH SEP-
 32 TEMBER 2004.—

33 (1) IN GENERAL.—Section 1902(a)(10)(E)(iv) (42
 34 U.S.C. 1396a(a)(10)(E)(iv)), as amended by section 401(a)
 35 of Public Law 108–89, is amended by striking “ending
 36 with March 2004” and inserting “ending with September
 37 2004”.

1 (2) TOTAL AMOUNT AVAILABLE FOR ALLOCATION.—
 2 Section 1933(g) (42 U.S.C. 1396u–3(g)), as added by sec-
 3 tion 401(c) of Public Law 108–89, is amended—

4 (A) in the matter preceding paragraph (1), by
 5 striking “March 31, 2004” and inserting “September
 6 30, 2004”; and

7 (B) in paragraph (2), by striking “\$100,000,000”
 8 and inserting “\$300,000,000”.

9 (3) EFFECTIVE DATE.—The amendments made by
 10 this subsection shall apply to calendar quarters beginning
 11 on or after April 1, 2004.

12 (g) OUTREACH BY THE COMMISSIONER OF SOCIAL SECUR-
 13 ITY.—Section 1144 (42 U.S.C. 1320b–14) is amended—

14 (1) in the section heading, by inserting “AND SUB-
 15 SIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE
 16 XVIII” after “COST-SHARING”;

17 (2) in subsection (a)—

18 (A) in paragraph (1)—

19 (i) in subparagraph (A), by inserting “for the
 20 transitional assistance under section 1860D–31(f),
 21 or for premium and cost-sharing subsidies under
 22 section 1860D–14” before the semicolon; and

23 (ii) in subparagraph (B), by inserting “, pro-
 24 gram, and subsidies” after “medical assistance”;
 25 and

26 (B) in paragraph (2)—

27 (i) in the matter preceding subparagraph (A),
 28 by inserting “, the transitional assistance under
 29 section 1860D–31(f), or premium and cost-sharing
 30 subsidies under section 1860D–14” after “assist-
 31 ance”; and

32 (ii) in subparagraph (A), by striking “such eli-
 33 gibility” and inserting “eligibility for medicare cost-
 34 sharing under the medicaid program”; and

35 (3) in subsection (b)—

36 (A) in paragraph (1)(A), by inserting “, for transi-
 37 tional assistance under section 1860D–31(f), or for

1 premium and cost-sharing subsidies for low-income in-
 2 dividuals under section 1860D-14” after “1933”; and
 3 (B) in paragraph (2), by inserting “, program,
 4 and subsidies” after “medical assistance”.

5 **SEC. 104. MEDIGAP AMENDMENTS.**

6 (a) RULES RELATING TO MEDIGAP POLICIES THAT PRO-
 7 VIDE PRESCRIPTION DRUG COVERAGE.—

8 (1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is
 9 amended by adding at the end the following new sub-
 10 section:

11 “(v) RULES RELATING TO MEDIGAP POLICIES THAT PRO-
 12 VIDE PRESCRIPTION DRUG COVERAGE.—

13 “(1) PROHIBITION ON SALE, ISSUANCE, AND RENEWAL
 14 OF NEW POLICIES THAT PROVIDE PRESCRIPTION DRUG
 15 COVERAGE.—

16 “(A) IN GENERAL.—Notwithstanding any other
 17 provision of law, on or after January 1, 2006, a
 18 medigap Rx policy (as defined in paragraph (6)(A))
 19 may not be sold, issued, or renewed under this
 20 section—

21 “(i) to an individual who is a part D enrollee
 22 (as defined in paragraph (6)(B)); or

23 “(ii) except as provided in subparagraph (B),
 24 to an individual who is not a part D enrollee.

25 “(B) CONTINUATION PERMITTED FOR NON-PART
 26 D ENROLLEES.—Subparagraph (A)(ii) shall not apply
 27 to the renewal of a medigap Rx policy that was issued
 28 before January 1, 2006.

29 “(C) CONSTRUCTION.—Nothing in this subsection
 30 shall be construed as preventing the offering on and
 31 after January 1, 2006, of ‘H’, ‘I’, and ‘J’ policies de-
 32 scribed in paragraph (2)(D)(i) if the benefit packages
 33 are modified in accordance with paragraph (2)(C).

34 “(2) ELIMINATION OF DUPLICATIVE COVERAGE UPON
 35 PART D ENROLLMENT.—

1 “(A) IN GENERAL.—In the case of an individual
2 who is covered under a medigap Rx policy and enrolls
3 under a part D plan—

4 “(i) before the end of the initial part D enroll-
5 ment period, the individual may—

6 “(I) enroll in a medicare supplemental poli-
7 cy without prescription drug coverage under
8 paragraph (3); or

9 “(II) continue the policy in effect subject
10 to the modification described in subparagraph
11 (C)(i); or

12 “(ii) after the end of such period, the indi-
13 vidual may continue the policy in effect subject to
14 such modification.

15 “(B) NOTICE REQUIRED TO BE PROVIDED TO
16 CURRENT POLICYHOLDERS WITH MEDIGAP RX POL-
17 ICY.—No medicare supplemental policy of an issuer
18 shall be deemed to meet the standards in subsection (c)
19 unless the issuer provides written notice (in accordance
20 with standards of the Secretary established in consulta-
21 tion with the National Association of Insurance Com-
22 missioners) during the 60-day period immediately pre-
23 ceding the initial part D enrollment period, to each in-
24 dividual who is a policyholder or certificate holder of a
25 medigap Rx policy (at the most recent available address
26 of that individual) of the following:

27 “(i) If the individual enrolls in a plan under
28 part D during the initial enrollment period under
29 section 1860D–1(b)(2)(A), the individual has the
30 option of—

31 “(I) continuing enrollment in the individ-
32 ual’s current plan, but the plan’s coverage of
33 prescription drugs will be modified under sub-
34 paragraph (C)(i); or

35 “(II) enrolling in another medicare supple-
36 mental policy pursuant to paragraph (3).

1 “(ii) If the individual does not enroll in a plan
2 under part D during such period, the individual
3 may continue enrollment in the individual’s current
4 plan without change, but—

5 “(I) the individual will not be guaranteed
6 the option of enrollment in another medicare
7 supplemental policy pursuant to paragraph (3);
8 and

9 “(II) if the current plan does not provide
10 creditable prescription drug coverage (as de-
11 fined in section 1860D–13(b)(4)), notice of
12 such fact and that there are limitations on the
13 periods in a year in which the individual may
14 enroll under a part D plan and any such enroll-
15 ment is subject to a late enrollment penalty.

16 “(iii) Such other information as the Secretary
17 may specify (in consultation with the National As-
18 sociation of Insurance Commissioners), including
19 the potential impact of such election on premiums
20 for medicare supplemental policies.

21 “(C) MODIFICATION.—

22 “(i) IN GENERAL.—The policy modification
23 described in this subparagraph is the elimination of
24 prescription coverage for expenses of prescription
25 drugs incurred after the effective date of the indi-
26 vidual’s coverage under a part D plan and the ap-
27 propriate adjustment of premiums to reflect such
28 elimination of coverage.

29 “(ii) CONTINUATION OF RENEWABILITY AND
30 APPLICATION OF MODIFICATION.—No medicare
31 supplemental policy of an issuer shall be deemed to
32 meet the standards in subsection (c) unless the
33 issuer—

34 “(I) continues renewability of medigap Rx
35 policies that it has issued, subject to subclause
36 (II); and

1 “(II) applies the policy modification de-
 2 scribed in clause (i) in the cases described in
 3 clauses (i)(II) and (ii) of subparagraph (A).

4 “(D) REFERENCES TO RX POLICIES.—

5 “(i) H, I, AND J POLICIES.—Any reference to
 6 a benefit package classified as ‘H’, ‘I’, or ‘J’ (in-
 7 cluding the benefit package classified as ‘J’ with a
 8 high deductible feature, as described in subsection
 9 (p)(11)) under the standards established under
 10 subsection (p)(2) shall be construed as including a
 11 reference to such a package as modified under sub-
 12 subparagraph (C) and such packages as modified shall
 13 not be counted as a separate benefit package under
 14 such subsection.

15 “(ii) APPLICATION IN WAIVERED STATES.—
 16 Except for the modification provided under sub-
 17 subparagraph (C), the waivers previously in effect
 18 under subsection (p)(2) shall continue in effect.

19 “(3) AVAILABILITY OF SUBSTITUTE POLICIES WITH
 20 GUARANTEED ISSUE.—

21 “(A) IN GENERAL.—The issuer of a medicare sup-
 22 plemental policy—

23 “(i) may not deny or condition the issuance or
 24 effectiveness of a medicare supplemental policy that
 25 has a benefit package classified as ‘A’, ‘B’, ‘C’, or
 26 ‘F’ (including the benefit package classified as ‘F’
 27 with a high deductible feature, as described in sub-
 28 section (p)(11)), under the standards established
 29 under subsection (p)(2), or a benefit package de-
 30 scribed in subparagraph (A) or (B) of subsection
 31 (w)(2) and that is offered and is available for
 32 issuance to new enrollees by such issuer;

33 “(ii) may not discriminate in the pricing of
 34 such policy, because of health status, claims experi-
 35 ence, receipt of health care, or medical condition;
 36 and

1 “(iii) may not impose an exclusion of benefits
2 based on a pre-existing condition under such policy,
3 in the case of an individual described in subparagraph
4 (B) who seeks to enroll under the policy not later than
5 63 days after the effective date of the individual’s cov-
6 erage under a part D plan.

7 “(B) INDIVIDUAL COVERED.—An individual de-
8 scribed in this subparagraph with respect to the issuer
9 of a medicare supplemental policy is an individual
10 who—

11 “(i) enrolls in a part D plan during the initial
12 part D enrollment period;

13 “(ii) at the time of such enrollment was en-
14 rolled in a medigap Rx policy issued by such issuer;
15 and

16 “(iii) terminates enrollment in such policy and
17 submits evidence of such termination along with
18 the application for the policy under subparagraph
19 (A).

20 “(C) SPECIAL RULE FOR WAIVERED STATES.—For
21 purposes of applying this paragraph in the case of a
22 State that provides for offering of benefit packages
23 other than under the classification referred to in sub-
24 paragraph (A)(i), the references to benefit packages in
25 such subparagraph are deemed references to com-
26 parable benefit packages offered in such State.

27 “(4) ENFORCEMENT.—

28 “(A) PENALTIES FOR DUPLICATION.—The pen-
29 alties described in subsection (d)(3)(A)(ii) shall apply
30 with respect to a violation of paragraph (1)(A).

31 “(B) GUARANTEED ISSUE.—The provisions of
32 paragraph (4) of subsection (s) shall apply with respect
33 to the requirements of paragraph (3) in the same man-
34 ner as they apply to the requirements of such sub-
35 section.

36 “(5) CONSTRUCTION.—Any provision in this section or
37 in a medicare supplemental policy relating to guaranteed

1 renewability of coverage shall be deemed to have been met
 2 with respect to a part D enrollee through the continuation
 3 of the policy subject to modification under paragraph
 4 (2)(C) or the offering of a substitute policy under para-
 5 graph (3). The previous sentence shall not be construed to
 6 affect the guaranteed renewability of such a modified or
 7 substitute policy.

8 “(6) DEFINITIONS.—For purposes of this subsection:

9 “(A) MEDIGAP RX POLICY.—The term ‘medigap
 10 Rx policy’ means a medicare supplemental policy—

11 “(i) which has a benefit package classified as
 12 ‘H’, ‘I’, or ‘J’ (including the benefit package classi-
 13 fied as ‘J’ with a high deductible feature, as de-
 14 scribed in subsection (p)(11)) under the standards
 15 established under subsection (p)(2), without regard
 16 to this subsection; and

17 “(ii) to which such standards do not apply (or
 18 to which such standards have been waived under
 19 subsection (p)(6)) but which provides benefits for
 20 prescription drugs.

21 Such term does not include a policy with a benefit
 22 package as classified under clause (i) which has been
 23 modified under paragraph (2)(C)(i).

24 “(B) PART D ENROLLEE.—The term ‘part D en-
 25 rollee’ means an individual who is enrolled in a part D
 26 plan.

27 “(C) PART D PLAN.—The term ‘part D plan’
 28 means a prescription drug plan or an MA–PD plan (as
 29 defined for purposes of part D).

30 “(D) INITIAL PART D ENROLLMENT PERIOD.—The
 31 term ‘initial part D enrollment period’ means the initial
 32 enrollment period described in section 1860D–
 33 1(b)(2)(A).”.

34 (2) CONFORMING CURRENT GUARANTEED ISSUE PROVI-
 35 SIONS.—

36 (A) EXTENDING GUARANTEED ISSUE POLICY FOR
 37 INDIVIDUALS ENROLLED IN MEDIGAP RX POLICIES

1 WHO TRY MEDICARE ADVANTAGE.—Subsection
2 (s)(3)(C)(ii) of such section is amended—

3 (i) by striking “(ii) Only” and inserting
4 “(ii)(I) Subject to subclause (II), only”; and

5 (ii) by adding at the end the following new
6 subclause:

7 “(II) If the medicare supplemental policy referred to in
8 subparagraph (B)(v) was a medigap Rx policy (as defined in
9 subsection (v)(6)(A)), a medicare supplemental policy described
10 in this subparagraph is such policy in which the individual was
11 most recently enrolled as modified under subsection (v)(2)(C)(i)
12 or, at the election of the individual, a policy referred to in sub-
13 section (v)(3)(A)(i).”.

14 (B) CONFORMING AMENDMENT.—Section
15 1882(s)(3)(C)(iii) is amended by inserting “and subject
16 to subsection (v)(1)” after “subparagraph (B)(vi)”.

17 (b) DEVELOPMENT OF NEW STANDARDS FOR MEDIGAP
18 POLICIES.—

19 (1) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is
20 further amended by adding at the end the following new
21 subsection:

22 “(w) DEVELOPMENT OF NEW STANDARDS FOR MEDICARE
23 SUPPLEMENTAL POLICIES.—

24 “(1) IN GENERAL.—The Secretary shall request the
25 National Association of Insurance Commissioners to review
26 and revise the standards for benefit packages under sub-
27 section (p)(1), taking into account the changes in benefits
28 resulting from enactment of the Medicare Prescription
29 Drug, Improvement, and Modernization Act of 2003 and to
30 otherwise update standards to reflect other changes in law
31 included in such Act. Such revision shall incorporate the in-
32 clusion of the 2 benefit packages described in paragraph
33 (2). Such revisions shall be made consistent with the rules
34 applicable under subsection (p)(1)(E) with the reference to
35 the ‘1991 NAIC Model Regulation’ deemed a reference to
36 the NAIC Model Regulation as published in the Federal
37 Register on December 4, 1998, and as subsequently up-

1 dated by the National Association of Insurance Commis-
2 sioners to reflect previous changes in law (and subsection
3 (v)) and the reference to ‘date of enactment of this sub-
4 section’ deemed a reference to the date of enactment of the
5 Medicare Prescription Drug, Improvement, and Moderniza-
6 tion Act of 2003. To the extent practicable, such revision
7 shall provide for the implementation of revised standards
8 for benefit packages as of January 1, 2006.

9 “(2) NEW BENEFIT PACKAGES.—The benefit packages
10 described in this paragraph are the following (notwith-
11 standing any other provision of this section relating to a
12 core benefit package):

13 “(A) FIRST NEW BENEFIT PACKAGE.—A benefit
14 package consisting of the following:

15 “(i) Subject to clause (ii), coverage of 50 per-
16 cent of the cost-sharing otherwise applicable under
17 parts A and B, except there shall be no coverage
18 of the part B deductible and coverage of 100 per-
19 cent of any cost-sharing otherwise applicable for
20 preventive benefits.

21 “(ii) Coverage for all hospital inpatient coin-
22 surance and 365 extra lifetime days of coverage of
23 inpatient hospital services (as in the current core
24 benefit package).

25 “(iii) A limitation on annual out-of-pocket ex-
26 penditures under parts A and B to \$4,000 in 2006
27 (or, in a subsequent year, to such limitation for the
28 previous year increased by an appropriate inflation
29 adjustment specified by the Secretary).

30 “(B) SECOND NEW BENEFIT PACKAGE.—A benefit
31 package consisting of the benefit package described in
32 subparagraph (A), except as follows:

33 “(i) Substitute ‘75 percent’ for ‘50 percent’ in
34 clause (i) of such subparagraph.

35 “(ii) Substitute ‘\$2,000’ for ‘\$4,000’ in clause
36 (iii) of such subparagraph.”

1 (2) CONFORMING AMENDMENTS.—Section 1882 (42
2 U.S.C. 1395ss) is amended—

3 (A) in subsection (g)(1), by inserting “a prescrip-
4 tion drug plan under part D or” after “but does not
5 include”; and

6 (B) in subsection (o)(1), by striking “subsection
7 (p)” and inserting “subsections (p), (v), and (w)”.

8 (c) RULE OF CONSTRUCTION.—

9 (1) IN GENERAL.—Nothing in this Act shall be con-
10 strued to require an issuer of a medicare supplemental pol-
11 icy under section 1882 of the Social Security Act (42
12 U.S.C. 1395rr) to participate as a PDP sponsor under part
13 D of title XVIII of such Act, as added by section 101, as
14 a condition for issuing such policy.

15 (2) PROHIBITION ON STATE REQUIREMENT.—A State
16 may not require an issuer of a medicare supplemental pol-
17 icy under section 1882 of the Social Security Act (42
18 U.S.C. 1395rr) to participate as a PDP sponsor under
19 such part D as a condition for issuing such policy.

20 **SEC. 105. ADDITIONAL PROVISIONS RELATING TO MEDI-**
21 **CARE PRESCRIPTION DRUG DISCOUNT CARD**
22 **AND TRANSITIONAL ASSISTANCE PROGRAM.**

23 (a) EXCLUSION OF COSTS FROM DETERMINATION OF
24 PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C.
25 1395r(g)) is amended—

26 (1) by striking “attributable to the application of sec-
27 tion” and inserting “attributable to—

28 “(1) the application of section”;

29 (2) by striking the period and inserting “; and”; and

30 (3) by adding at the end the following new paragraph:

31 “(2) the medicare prescription drug discount card and
32 transitional assistance program under section 1860D–31.”.

33 (b) APPLICATION OF CONFIDENTIALITY FOR DRUG PRIC-
34 ING DATA.—The last sentence of section 1927(b)(3)(D) (42
35 U.S.C. 1396r–8(b)(3)(D)), as added by section 101(e)(4), is
36 amended by inserting “and drug pricing data reported under

1 the first sentence of section 1860D–31(i)(1)” after “section
2 1860D–4(c)(2)(E)”.

3 (c) RULES FOR IMPLEMENTATION.—The following rules
4 shall apply to the medicare prescription drug discount card and
5 transitional assistance program under section 1860D–31 of the
6 Social Security Act, as added by section 101(a):

7 (1) In promulgating regulations pursuant to sub-
8 section (a)(2)(B) of such section 1860D–31—

9 (A) section 1871(a)(3) of the Social Security Act
10 (42 U.S.C. 1395hh(a)(3)), as added by section
11 902(a)(1), shall not apply;

12 (B) chapter 35 of title 44, United States Code,
13 shall not apply; and

14 (C) sections 553(d) and 801(a)(3)(A) of title 5,
15 United States Code, shall not apply.

16 (2) Section 1857(c)(5) of the Social Security Act (42
17 U.S.C. 1395w–27(c)(5)) shall apply with respect to section
18 1860D–31 of such Act, as added by section 101(a), in the
19 same manner as it applies to part C of title XVIII of such
20 Act.

21 (3) The administration of such program shall be made
22 without regard to chapter 35 of title 44, United States
23 Code.

24 (4)(A) There shall be no judicial review of a deter-
25 mination not to endorse, or enter into a contract, with a
26 prescription drug card sponsor under section 1860D–31 of
27 the Social Security Act.

28 (B) In the case of any order issued to enjoin any pro-
29 vision of section 1860D–31 of the Social Security Act (or
30 of any provision of this section), such order shall not affect
31 any other provision of such section (or of this section) and
32 all such provisions shall be treated as severable.

33 (d) CONFORMING AMENDMENTS TO FEDERAL SMI TRUST
34 FUND FOR TRANSITIONAL ASSISTANCE ACCOUNT.—Section
35 1841 (42 U.S.C. 1395t), as amended by section 101(e)(3)(C),
36 is amended—

1 (1) in the last sentence of subsection (a), by inserting
 2 after “section 1860D–16” the following: “or the Transi-
 3 tional Assistance Account established by section 1860D–
 4 31(k)(1)”; and

5 (2) in subsection (g), by adding at the end the fol-
 6 lowing: “The payments provided for under section 1860D–
 7 31(k)(2) shall be made from the Transitional Assistance
 8 Account in the Trust Fund.”.

9 (e) DISCLOSURE OF RETURN INFORMATION FOR PUR-
 10 POSSES OF PROVIDING TRANSITIONAL ASSISTANCE UNDER
 11 MEDICARE DISCOUNT CARD PROGRAM.—

12 (1) IN GENERAL.—Subsection (l) of section 6103 of
 13 the Internal Revenue Code of 1986 (relating to disclosure
 14 of returns and return information for purposes other than
 15 tax administration) is amended by adding at the end the
 16 following new paragraph:

17 “(19) DISCLOSURE OF RETURN INFORMATION FOR
 18 PURPOSES OF PROVIDING TRANSITIONAL ASSISTANCE
 19 UNDER MEDICARE DISCOUNT CARD PROGRAM.—

20 “(A) IN GENERAL.—The Secretary, upon written
 21 request from the Secretary of Health and Human Serv-
 22 ices pursuant to carrying out section 1860D–31 of the
 23 Social Security Act, shall disclose to officers, employ-
 24 ees, and contractors of the Department of Health and
 25 Human Services with respect to a taxpayer for the ap-
 26 plicable year—

27 “(i)(I) whether the adjusted gross income, as
 28 modified in accordance with specifications of the
 29 Secretary of Health and Human Services for pur-
 30 poses of carrying out such section, of such taxpayer
 31 and, if applicable, such taxpayer’s spouse, for the
 32 applicable year, exceeds the amounts specified by
 33 the Secretary of Health and Human Services in
 34 order to apply the 100 and 135 percent of the pov-
 35 erty lines under such section, (II) whether the re-
 36 turn was a joint return, and (III) the applicable
 37 year, or

1 “(ii) if applicable, the fact that there is no re-
2 turn filed for such taxpayer for the applicable year.

3 “(B) DEFINITION OF APPLICABLE YEAR.—For the
4 purposes of this subsection, the term ‘applicable year’
5 means the most recent taxable year for which informa-
6 tion is available in the Internal Revenue Service’s tax-
7 payer data information systems, or, if there is no re-
8 turn filed for such taxpayer for such year, the prior
9 taxable year.

10 “(C) RESTRICTION ON USE OF DISCLOSED INFOR-
11 MATION.—Return information disclosed under this
12 paragraph may be used only for the purposes of deter-
13 mining eligibility for and administering transitional as-
14 sistance under section 1860D–31 of the Social Security
15 Act.”

16 (2) CONFIDENTIALITY.—Paragraph (3) of section
17 6103(a) of such Code is amended by striking “or (16)” and
18 inserting “(16), or (19)”.

19 (3) PROCEDURES AND RECORDKEEPING RELATED TO
20 DISCLOSURES.—Subsection (p)(4) of section 6103 of such
21 Code is amended by striking “(l)(16) or (17)” each place
22 it appears and inserting “(l)(16), (17), or (19)”.

23 (4) UNAUTHORIZED DISCLOSURE OR INSPECTION.—
24 Paragraph (2) of section 7213(a) of such Code is amended
25 by striking “or (16)” and inserting “(16), or (19)”.

26 **SEC. 106. STATE PHARMACEUTICAL ASSISTANCE TRAN-**
27 **SITION COMMISSION.**

28 (a) ESTABLISHMENT.—

29 (1) IN GENERAL.—There is established, as of the first
30 day of the third month beginning after the date of the en-
31 actment of this Act, a State Pharmaceutical Assistance
32 Transition Commission (in this section referred to as the
33 “Commission”) to develop a proposal for addressing the
34 unique transitional issues facing State pharmaceutical as-
35 sistance programs, and program participants, due to the
36 implementation of the voluntary prescription drug benefit

1 program under part D of title XVIII of the Social Security
2 Act, as added by section 101.

3 (2) DEFINITIONS.—For purposes of this section:

4 (A) STATE PHARMACEUTICAL ASSISTANCE PRO-
5 GRAM DEFINED.—The term “State pharmaceutical as-
6 sistance program” means a program (other than the
7 medicaid program) operated by a State (or under con-
8 tract with a State) that provides as of the date of the
9 enactment of this Act financial assistance to medicare
10 beneficiaries for the purchase of prescription drugs.

11 (B) PROGRAM PARTICIPANT.—The term “program
12 participant” means a low-income medicare beneficiary
13 who is a participant in a State pharmaceutical assist-
14 ance program.

15 (b) COMPOSITION.—The Commission shall include the fol-
16 lowing:

17 (1) A representative of each Governor of each State
18 that the Secretary identifies as operating on a statewide
19 basis a State pharmaceutical assistance program that pro-
20 vides for eligibility and benefits that are comparable or
21 more generous than the low-income assistance eligibility
22 and benefits offered under section 1860D–14 of the Social
23 Security Act.

24 (2) Representatives from other States that the Sec-
25 retary identifies have in operation other State pharma-
26 ceutical assistance programs, as appointed by the Sec-
27 retary.

28 (3) Representatives of organizations that have an in-
29 herent interest in program participants or the program
30 itself, as appointed by the Secretary but not to exceed the
31 number of representatives under paragraphs (1) and (2).

32 (4) Representatives of Medicare Advantage organiza-
33 tions, pharmaceutical benefit managers, and other private
34 health insurance plans, as appointed by the Secretary.

35 (5) The Secretary (or the Secretary’s designee) and
36 such other members as the Secretary may specify.

1 The Secretary shall designate a member to serve as Chair of
2 the Commission and the Commission shall meet at the call of
3 the Chair.

4 (c) DEVELOPMENT OF PROPOSAL.—The Commission shall
5 develop the proposal described in subsection (a) in a manner
6 consistent with the following principles:

7 (1) Protection of the interests of program participants
8 in a manner that is the least disruptive to such participants
9 and that includes a single point of contact for enrollment
10 and processing of benefits.

11 (2) Protection of the financial and flexibility interests
12 of States so that States are not financially worse off as a
13 result of the enactment of this title.

14 (3) Principles of medicare modernization under this
15 Act.

16 (d) REPORT.—By not later than January 1, 2005, the
17 Commission shall submit to the President and Congress a re-
18 port that contains a detailed proposal (including specific legis-
19 lative or administrative recommendations, if any) and such
20 other recommendations as the Commission deems appropriate.

21 (e) SUPPORT.—The Secretary shall provide the Commis-
22 sion with the administrative support services necessary for the
23 Commission to carry out its responsibilities under this section.

24 (f) TERMINATION.—The Commission shall terminate 30
25 days after the date of submission of the report under sub-
26 section (d).

27 **SEC. 107. STUDIES AND REPORTS.**

28 (a) STUDY REGARDING REGIONAL VARIATIONS IN PRE-
29 SCRIPTIION DRUG SPENDING.—

30 (1) IN GENERAL.—The Secretary shall conduct a
31 study that examines variations in per capita spending for
32 covered part D drugs under part D of title XVIII of the
33 Social Security Act among PDP regions and, with respect
34 to such spending, the amount of such variation that is at-
35 tributable to—

36 (A) price variations (described in section 1860D-
37 15(c)(2) of such Act); and

1 (B) differences in per capita utilization that is not
2 taken into account in the health status risk adjustment
3 provided under section 1860D–15(c)(1) of such Act.

4 (2) REPORT AND RECOMMENDATIONS.—Not later than
5 January 1, 2009, the Secretary shall submit to Congress
6 a report on the study conducted under paragraph (1). Such
7 report shall include—

8 (A) information regarding the extent of geographic
9 variation described in paragraph (1)(B);

10 (B) an analysis of the impact on direct subsidies
11 under section 1860D–15(a)(1) of the Social Security
12 Act in different PDP regions if such subsidies were ad-
13 justed to take into account the variation described in
14 subparagraph (A); and

15 (C) recommendations regarding the appropriate-
16 ness of applying an additional geographic adjustment
17 factor under section 1860D–15(c)(2) that reflects some
18 or all of the variation described in subparagraph (A).

19 (b) REVIEW AND REPORT ON CURRENT STANDARDS OF
20 PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS
21 IN NURSING FACILITIES.—

22 (1) REVIEW.—

23 (A) IN GENERAL.—Not later than 12 months after
24 the date of the enactment of this Act, the Secretary
25 shall conduct a thorough review of the current stand-
26 ards of practice for pharmacy services provided to pa-
27 tients in nursing facilities.

28 (B) SPECIFIC MATTERS REVIEWED.—In con-
29 ducting the review under subparagraph (A), the Sec-
30 retary shall—

31 (i) assess the current standards of practice,
32 clinical services, and other service requirements
33 generally used for pharmacy services in long-term
34 care settings; and

35 (ii) evaluate the impact of those standards
36 with respect to patient safety, reduction of medica-
37 tion errors and quality of care.

1 (2) REPORT.—

2 (A) IN GENERAL.—Not later than the date that is
3 18 months after the date of the enactment of this Act,
4 the Secretary shall submit a report to Congress on the
5 study conducted under paragraph (1)(A).

6 (B) CONTENTS.—The report submitted under sub-
7 paragraph (A) shall contain—

8 (i) a description of the plans of the Secretary
9 to implement the provisions of this Act in a manner
10 consistent with applicable State and Federal laws
11 designed to protect the safety and quality of care
12 of nursing facility patients; and

13 (ii) recommendations regarding necessary ac-
14 tions and appropriate reimbursement to ensure the
15 provision of prescription drugs to medicare bene-
16 ficiaries residing in nursing facilities in a manner
17 consistent with existing patient safety and quality
18 of care standards under applicable State and Fed-
19 eral laws.

20 (c) IOM STUDY ON DRUG SAFETY AND QUALITY.—

21 (1) IN GENERAL.—The Secretary shall enter into a
22 contract with the Institutes of Medicine of the National
23 Academies of Science (such Institutes referred to in this
24 subsection as the “IOM”) to carry out a comprehensive
25 study (in this subsection referred to as the “study”) of
26 drug safety and quality issues in order to provide a blue-
27 print for system-wide change.

28 (2) OBJECTIVES.—

29 (A) The study shall develop a full understanding
30 of drug safety and quality issues through an evidence-
31 based review of literature, case studies, and analysis.
32 This review will consider the nature and causes of
33 medication errors, their impact on patients, the dif-
34 ferences in causation, impact, and prevention across
35 multiple dimensions of health care delivery-including
36 patient populations, care settings, clinicians, and insti-
37 tutional cultures.

1 (B) The study shall attempt to develop credible es-
2 timates of the incidence, severity, costs of medication
3 errors that can be useful in prioritizing resources for
4 national quality improvement efforts and influencing
5 national health care policy.

6 (C) The study shall evaluate alternative ap-
7 proaches to reducing medication errors in terms of
8 their efficacy, cost-effectiveness, appropriateness in dif-
9 ferent settings and circumstances, feasibility, institu-
10 tional barriers to implementation, associated risks, and
11 the quality of evidence supporting the approach.

12 (D) The study shall provide guidance to con-
13 sumers, providers, payers, and other key stakeholders
14 on high-priority strategies to achieve both short-term
15 and long-term drug safety goals, to elucidate the goals
16 and expected results of such initiatives and support the
17 business case for them, and to identify critical success
18 factors and key levers for achieving success.

19 (E) The study shall assess the opportunities and
20 key impediments to broad nationwide implementation
21 of medication error reductions, and to provide guidance
22 to policy-makers and government agencies (including
23 the Food and Drug Administration, the Centers for
24 Medicare & Medicaid Services, and the National Insti-
25 tutes of Health) in promoting a national agenda for
26 medication error reduction.

27 (F) The study shall develop an applied research
28 agenda to evaluate the health and cost impacts of alter-
29 native interventions, and to assess collaborative public
30 and private strategies for implementing the research
31 agenda through AHRQ and other government agencies.

32 (3) CONDUCT OF STUDY.—

33 (A) EXPERT COMMITTEE.—In conducting the
34 study, the IOM shall convene a committee of leading
35 experts and key stakeholders in pharmaceutical man-
36 agement and drug safety, including clinicians, health

1 services researchers, pharmacists, system administra-
2 tors, payer representatives, and others.

3 (B) COMPLETION.—The study shall be completed
4 within an 18-month period.

5 (4) REPORT.—A report on the study shall be sub-
6 mitted to Congress upon the completion of the study.

7 (5) AUTHORIZATION OF APPROPRIATIONS.—There are
8 authorized to be appropriated to carry out this section such
9 sums as may be necessary.

10 (d) STUDY OF MULTI-YEAR CONTRACTS.—

11 (1) IN GENERAL.—The Secretary shall provide for a
12 study on the feasibility and advisability of providing for
13 contracting with PDP sponsors and MA organizations
14 under parts C and D of title XVIII on a multi-year basis.

15 (2) REPORT.—Not later than January 1, 2007, the
16 Secretary shall submit to Congress a report on the study
17 under paragraph (1). The report shall include such rec-
18 ommendations as the Secretary deems appropriate.

19 (e) GAO STUDY REGARDING IMPACT OF ASSETS TEST
20 FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

21 (1) STUDY.—The Comptroller General of the United
22 States shall conduct a study to determine the extent to
23 which drug utilization and access to covered part D drugs
24 under part D of title XVIII of the Social Security Act by
25 subsidy eligible individuals differs from such utilization and
26 access for individuals who would qualify as such subsidy el-
27 igible individuals but for the application of section 1860D-
28 14(a)(3)(A)(iii) of such Act.

29 (2) REPORT.—Not later than September 30, 2007, the
30 Comptroller General shall submit a report to Congress on
31 the study conducted under paragraph (1) that includes
32 such recommendations for legislation as the Comptroller
33 General determines are appropriate.

34 (f) STUDY ON MAKING PRESCRIPTION PHARMACEUTICAL
35 INFORMATION ACCESSIBLE FOR BLIND AND VISUALLY-IM-
36 PAIRED INDIVIDUALS.—

37 (1) STUDY.—

1 (A) IN GENERAL.—The Secretary shall undertake
2 a study of how to make prescription pharmaceutical in-
3 formation, including drug labels and usage instructions,
4 accessible to blind and visually-impaired individuals.

5 (B) STUDY TO INCLUDE EXISTING AND EMERGING
6 TECHNOLOGIES.—The study under subparagraph (A)
7 shall include a review of existing and emerging tech-
8 nologies, including assistive technology, that makes es-
9 sential information on the content and prescribed use
10 of pharmaceutical medicines available in a usable for-
11 mat for blind and visually-impaired individuals.

12 (2) REPORT.—

13 (A) IN GENERAL.—Not later than 18 months after
14 the date of the enactment of this Act, the Secretary
15 shall submit a report to Congress on the study required
16 under paragraph (1).

17 (B) CONTENTS OF REPORT.—The report required
18 under paragraph (1) shall include recommendations for
19 the implementation of usable formats for making pre-
20 scription pharmaceutical information available to blind
21 and visually-impaired individuals and an estimate of
22 the costs associated with the implementation of each
23 format.

24 **SEC. 108. GRANTS TO PHYSICIANS TO IMPLEMENT ELEC-**
25 **TRONIC PRESCRIPTION DRUG PROGRAMS.**

26 (a) IN GENERAL.—The Secretary is authorized to make
27 grants to physicians for the purpose of assisting such physi-
28 cians to implement electronic prescription drug programs that
29 comply with the standards promulgated or modified under sec-
30 tion 1860D–4(e) of the Social Security Act, as inserted by sec-
31 tion 101(a).

32 (b) AWARDING OF GRANTS.—

33 (1) APPLICATION.—No grant may be made under this
34 section except pursuant to a grant application that is sub-
35 mitted and approved in a time, manner, and form specified
36 by the Secretary.

1 (2) CONSIDERATIONS AND PREFERENCES.—In award-
2 ing grants under this section, the Secretary shall—

3 (A) give special consideration to physicians who
4 serve a disproportionate number of medicare patients;
5 and

6 (B) give preference to physicians who serve a rural
7 or underserved area.

8 (3) LIMITATION ON GRANTS.—Only 1 grant may be
9 awarded under this section with respect to any physician or
10 group practice of physicians.

11 (c) TERMS AND CONDITIONS.—

12 (1) IN GENERAL.—Grants under this section shall be
13 made under such terms and conditions as the Secretary
14 specifies consistent with this section.

15 (2) USE OF GRANT FUNDS.—Funds provided under
16 grants under this section may be used for any of the fol-
17 lowing:

18 (A) For purchasing, leasing, and installing com-
19 puter software and hardware, including handheld com-
20 puter technologies.

21 (B) Making upgrades and other improvements to
22 existing computer software and hardware to enable e-
23 prescribing.

24 (C) Providing education and training to eligible
25 physician staff on the use of technology to implement
26 the electronic transmission of prescription and patient
27 information.

28 (3) PROVISION OF INFORMATION.—As a condition for
29 the awarding of a grant under this section, an applicant
30 shall provide to the Secretary such information as the Sec-
31 retary may require in order to—

32 (A) evaluate the project for which the grant is
33 made; and

34 (B) ensure that funding provided under the grant
35 is expended only for the purposes for which it is made.

36 (4) AUDIT.—The Secretary shall conduct appropriate
37 audits of grants under this section.

1 this part and title XVIII, the functions described in this
2 paragraph shall be treated as a review function.”.

3 (c) EFFECTIVE DATE.—The amendments made by this
4 section shall apply on and after January 1, 2004.

5 (d) IOM STUDY OF QIOS.—

6 (1) IN GENERAL.—The Secretary shall request the In-
7 stitute of Medicine of the National Academy of Sciences to
8 conduct an evaluation of the program under part B of title
9 XI of the Social Security Act. The study shall include a re-
10 view of the following:

11 (A) An overview of the program under such part.

12 (B) The duties of organizations with contracts
13 with the Secretary under such part.

14 (C) The extent to which quality improvement orga-
15 nizations improve the quality of care for medicare bene-
16 ficiaries.

17 (D) The extent to which other entities could per-
18 form such quality improvement functions as well as, or
19 better than, quality improvement organizations.

20 (E) The effectiveness of reviews and other actions
21 conducted by such organizations in carrying out those
22 duties.

23 (F) The source and amount of funding for such
24 organizations.

25 (G) The conduct of oversight of such organiza-
26 tions.

27 (2) REPORT TO CONGRESS.—Not later than June 1,
28 2006, the Secretary shall submit to Congress a report on
29 the results of the study described in paragraph (1), includ-
30 ing any recommendations for legislation.

31 (3) INCREASED COMPETITION.—If the Secretary finds
32 based on the study conducted under paragraph (1) that
33 other entities could improve quality in the medicare pro-
34 gram as well as, or better than, the current quality im-
35 provement organizations, then the Secretary shall provide
36 for such increased competition through the addition of new

1 types of entities which may perform quality improvement
2 functions.

3 **SEC. 110. CONFLICT OF INTEREST STUDY.**

4 (a) STUDY.—The Federal Trade Commission shall conduct
5 a study of differences in payment amounts for pharmacy serv-
6 ices provided to enrollees in group health plans that utilize
7 pharmacy benefit managers. Such study shall include the fol-
8 lowing:

9 (1) An assessment of the differences in costs incurred
10 by such enrollees and plans for prescription drugs dis-
11 pensed by mail-order pharmacies owned by pharmaceutical
12 benefit managers compared to mail-order pharmacies not
13 owned by pharmaceutical benefit managers, and community
14 pharmacies.

15 (2) Whether such plans are acting in a manner that
16 maximizes competition and results in lower prescription
17 drug prices for enrollees.

18 (b) REPORT.—Not later than 18 months after the date of
19 the enactment of this Act, the Commission shall submit to Con-
20 gress a report on the study conducted under subsection (a).
21 Such report shall include recommendations regarding any need
22 for legislation to ensure the fiscal integrity of the voluntary
23 prescription drug benefit program under part D of title XVIII,
24 as added by section 101, that may be appropriated as the re-
25 sult of such study.

26 (c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—
27 Chapter 35 of title 44, United States Code, shall not apply to
28 the collection of information under subsection (a).

29 **SEC. 111. STUDY ON EMPLOYMENT-BASED RETIREE**
30 **HEALTH COVERAGE.**

31 (a) STUDY.—The Comptroller General of the United
32 States shall conduct an initial and final study under this sub-
33 section to examine trends in employment-based retiree health
34 coverage (as defined in 1860D–22(e)(1) of the Social Security
35 Act, as added by section 101), including coverage under the
36 Federal Employees Health Benefits Program (FEHBP), and

1 the options and incentives available under this Act which may
2 have an effect on the voluntary provision of such coverage.

3 (b) CONTENT OF INITIAL STUDY.—The initial study under
4 this section shall consider the following:

5 (1) Trends in employment-based retiree health cov-
6 erage prior to the date of the enactment of this Act.

7 (2) The opinions of sponsors of employment-based re-
8 tiree health coverage concerning which of the options avail-
9 able under this Act they are most likely to utilize for the
10 provision of health coverage to their medicare-eligible retir-
11 ees, including an assessment of the administrative burdens
12 associated with the available options.

13 (3) The likelihood of sponsors of employment-based re-
14 tiree health coverage to maintain or adjust their levels of
15 retiree health benefits beyond coordination with medicare,
16 including for prescription drug coverage, provided to medi-
17 care-eligible retirees after the date of the enactment of this
18 Act.

19 (4) The factors that sponsors of employment-based re-
20 tiree health coverage expect to consider in making decisions
21 about any changes they may make in the health coverage
22 provided to medicare-eligible retirees.

23 (5) Whether the prescription drug plan options avail-
24 able, or the health plan options available under the Medi-
25 care Advantage program, are likely to cause employers and
26 other entities that did not provide health coverage to retir-
27 ees prior to the date of the enactment of this Act to provide
28 supplemental coverage or contributions toward premium ex-
29 penses for medicare-eligible retirees who may enroll in such
30 options in the future.

31 (c) CONTENTS OF FINAL STUDY.—The final study under
32 this section shall consider the following:

33 (1) Changes in the trends in employment-based retiree
34 health coverage since the completion of the initial study by
35 the Comptroller General.

36 (2) Factors contributing to any changes in coverage
37 levels.

1 (3) The number and characteristics of sponsors of em-
2 ployment-based retiree health coverage who receive the spe-
3 cial subsidy payments under section 1860D–22 of the So-
4 cial Security Act, as added by section 101, for the provision
5 of prescription drug coverage to their medicare-eligible re-
6 tirees that is the same or greater actuarial value as the
7 prescription drug coverage available to other medicare
8 beneficiaries without employment-based retiree health cov-
9 erage.

10 (4) The extent to which sponsors of employment-based
11 retiree health coverage provide supplemental health cov-
12 erage or contribute to the premiums for medicare-eligible
13 retirees who enroll in a prescription drug plan or an MA–
14 PD plan.

15 (5) Other coverage options, including tax-preferred re-
16 tirement or health savings accounts, consumer-directed
17 health plans, or other vehicles that sponsors of employ-
18 ment-based retiree health coverage believe would assist re-
19 tirees with their future health care needs and their willing-
20 ness to sponsor such alternative plan designs.

21 (6) The extent to which employers or other entities
22 that did not provide employment-based retiree health cov-
23 erage prior to the date of the enactment of this Act pro-
24 vided some form of coverage or financial assistance for re-
25 tiree health care needs after the date of the enactment of
26 this Act.

27 (7) Recommendations by employers, benefits experts,
28 academics, and others on ways that the voluntary provision
29 of employment-based retiree health coverage may be im-
30 proved and expanded.

31 (d) REPORTS.—The Comptroller General shall submit a
32 report to Congress on—

33 (1) the initial study under subsection (b) not later
34 than 1 year after the date of the enactment of this Act;
35 and

36 (2) the final study under subsection (c) not later than
37 January 1, 2007.

1 (e) CONSULTATION.—The Comptroller General shall con-
 2 sult with sponsors of employment-based retiree health coverage,
 3 benefits experts, human resources professionals, employee bene-
 4 fits consultants, and academics with experience in health bene-
 5 fits and survey research in the development and design of the
 6 initial and final studies under this section.

7 **TITLE II—MEDICARE ADVANTAGE**
 8 **Subtitle A—Implementation of**
 9 **Medicare Advantage Program**

10 **SEC. 201. IMPLEMENTATION OF MEDICARE ADVANTAGE**
 11 **PROGRAM.**

12 (a) IN GENERAL.—There is hereby established the Medi-
 13 care Advantage program. The Medicare Advantage program
 14 shall consist of the program under part C of title XVIII of the
 15 Social Security Act (as amended by this Act).

16 (b) REFERENCES.—Subject to subsection (c), any ref-
 17 erence to the program under part C of title XVIII of the Social
 18 Security Act shall be deemed a reference to the Medicare Ad-
 19 vantage program and, with respect to such part, any reference
 20 to “Medicare+Choice” is deemed a reference to “Medicare Ad-
 21 vantage” and “MA”.

22 (c) TRANSITION.—In order to provide for an orderly tran-
 23 sition and avoid beneficiary and provider confusion, the Sec-
 24 retary shall provide for an appropriate transition in the use of
 25 the terms “Medicare+Choice” and “Medicare Advantage” (or
 26 “MA”) in reference to the program under part C of title XVIII
 27 of the Social Security Act. Such transition shall be fully com-
 28 pleted for all materials for plan years beginning not later than
 29 January 1, 2006. Before the completion of such transition, any
 30 reference to “Medicare Advantage” or “MA” shall be deemed
 31 to include a reference to “Medicare+Choice”.

32 **Subtitle B—Immediate Improvements**

33 **SEC. 211. IMMEDIATE IMPROVEMENTS.**

34 (a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.—

1 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
2 1395w-23(c)(1)) is amended by adding at the end the fol-
3 lowing:

4 “(D) 100 PERCENT OF FEE-FOR-SERVICE
5 COSTS.—

6 “(i) IN GENERAL.—For each year specified in
7 clause (ii), the adjusted average per capita cost for
8 the year involved, determined under section
9 1876(a)(4) and adjusted as appropriate for the
10 purpose of risk adjustment, for the MA payment
11 area for individuals who are not enrolled in an MA
12 plan under this part for the year, but adjusted to
13 exclude costs attributable to payments under sec-
14 tion 1886(h).

15 “(ii) PERIODIC REBASING.—The provisions of
16 clause (i) shall apply for 2004 and for subsequent
17 years as the Secretary shall specify (but not less
18 than once every 3 years).

19 “(iii) INCLUSION OF COSTS OF VA AND DOD
20 MILITARY FACILITY SERVICES TO MEDICARE-ELIGI-
21 BLE BENEFICIARIES.—In determining the adjusted
22 average per capita cost under clause (i) for a year,
23 such cost shall be adjusted to include the Sec-
24 retary’s estimate, on a per capita basis, of the
25 amount of additional payments that would have
26 been made in the area involved under this title if
27 individuals entitled to benefits under this title had
28 not received services from facilities of the Depart-
29 ment of Defense or the Department of Veterans
30 Affairs.”.

31 (2) CONFORMING AMENDMENT.—Such section is fur-
32 ther amended, in the matter before subparagraph (A), by
33 striking “or (C)” and inserting “(C), or (D)”.

34 (b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Sec-
35 tion 1853(c) (42 U.S.C. 1395w-23(c)) is amended—

36 (1) in paragraph (1)(A), by inserting “(for a year
37 other than 2004)” after “multiplied”; and

1 (2) in paragraph (5), by inserting “(other than 2004)”
 2 after “for each year”.

3 (c) INCREASING MINIMUM PERCENTAGE INCREASE TO
 4 NATIONAL GROWTH RATE.—

5 (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C.
 6 1395w-23(c)(1)) is amended—

7 (A) in subparagraph (A), by striking “The sum”
 8 and inserting “For a year before 2005, the sum”;

9 (B) in subparagraph (B)(iv), by striking “and
 10 each succeeding year” and inserting “, 2003, and
 11 2004”;

12 (C) in subparagraph (C)(iv), by striking “and each
 13 succeeding year” and inserting “and 2003”; and

14 (D) by adding at the end of subparagraph (C) the
 15 following new clause:

16 “(v) For 2004 and each succeeding year, the
 17 greater of—

18 “(I) 102 percent of the annual MA capita-
 19 tion rate under this paragraph for the area for
 20 the previous year; or

21 “(II) the annual MA capitation rate under
 22 this paragraph for the area for the previous
 23 year increased by the national per capita MA
 24 growth percentage, described in paragraph (6)
 25 for that succeeding year, but not taking into
 26 account any adjustment under paragraph
 27 (6)(C) for a year before 2004.”.

28 (2) CONFORMING AMENDMENT.—Section
 29 1853(c)(6)(C) (42 U.S.C. 1395w-23(c)(6)(C)) is amended
 30 by inserting before the period at the end the following: “,
 31 except that for purposes of paragraph (1)(C)(v)(II), no
 32 such adjustment shall be made for a year before 2004”.

33 (d) INCLUSION OF COSTS OF DOD AND VA MILITARY FA-
 34 CILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES IN
 35 CALCULATION OF PAYMENT RATES.—Section 1853(c)(3) (42
 36 U.S.C. 1395w-23(c)(3)) is amended—

1 (1) in subparagraph (A), by striking “subparagraph
2 (B)” and inserting “subparagraphs (B) and (E)”; and

3 (2) by adding at the end the following new subpara-
4 graph:

5 “(E) INCLUSION OF COSTS OF DOD AND VA MILI-
6 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
7 BENEFICIARIES.—In determining the area-specific MA
8 capitation rate under subparagraph (A) for a year (be-
9 ginning with 2004), the annual per capita rate of pay-
10 ment for 1997 determined under section 1876(a)(1)(C)
11 shall be adjusted to include in the rate the Secretary’s
12 estimate, on a per capita basis, of the amount of addi-
13 tional payments that would have been made in the area
14 involved under this title if individuals entitled to bene-
15 fits under this title had not received services from fa-
16 cilities of the Department of Defense or the Depart-
17 ment of Veterans Affairs.”.

18 (e) EXTENDING SPECIAL RULE FOR CERTAIN INPATIENT
19 HOSPITAL STAYS TO REHABILITATION HOSPITALS AND LONG-
20 TERM CARE HOSPITALS.—

21 (1) IN GENERAL.—Section 1853(g) (42 U.S.C.
22 1395w-23(g)) is amended—

23 (A) in the matter preceding paragraph (1), by in-
24 serting “, a rehabilitation hospital described in section
25 1886(d)(1)(B)(ii) or a distinct part rehabilitation unit
26 described in the matter following clause (v) of section
27 1886(d)(1)(B), or a long-term care hospital (described
28 in section 1886(d)(1)(B)(iv))” after “1886(d)(1)(B)”;
29 and

30 (B) in paragraph (2)(B), by inserting “or other
31 payment provision under this title for inpatient services
32 for the type of facility, hospital, or unit involved, de-
33 scribed in the matter preceding paragraph (1), as the
34 case may be,” after “1886(d)”.

35 (2) EFFECTIVE DATE.—The amendments made by
36 paragraph (1) shall apply to contract years beginning on or
37 after January 1, 2004.

1 (f) MEDPAC STUDY OF AAPCC.—

2 (1) STUDY.—The Medicare Payment Advisory Com-
3 mission shall conduct a study that assesses the method
4 used for determining the adjusted average per capita cost
5 (AAPCC) under section 1876(a)(4) of the Social Security
6 Act (42 U.S.C. 1395mm(a)(4)) as applied under section
7 1853(c)(1)(A) of such Act (as amended by subsection (a)).
8 Such study shall include an examination of—

9 (A) the bases for variation in such costs between
10 different areas, including differences in input prices,
11 utilization, and practice patterns;

12 (B) the appropriate geographic area for payment
13 of MA local plans under the Medicare Advantage pro-
14 gram under part C of title XVIII of such Act; and

15 (C) the accuracy of risk adjustment methods in re-
16 flecting differences in costs of providing care to dif-
17 ferent groups of beneficiaries served under such pro-
18 gram.

19 (2) REPORT.—Not later than 18 months after the
20 date of the enactment of this Act, the Commission shall
21 submit to Congress a report on the study conducted under
22 paragraph (1).

23 (g) REPORT ON IMPACT OF INCREASED FINANCIAL AS-
24 SISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than
25 July 1, 2006, the Secretary shall submit to Congress a report
26 that describes the impact of additional financing provided
27 under this Act and other Acts (including the Medicare, Med-
28 icaid, and SCHIP Balanced Budget Refinement Act of 1999
29 and BIPA) on the availability of Medicare Advantage plans in
30 different areas and its impact on lowering premiums and in-
31 creasing benefits under such plans.

32 (h) MEDPAC STUDY AND REPORT ON CLARIFICATION OF
33 AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE
34 BENEFICIARY COST-SHARING.—

35 (1) STUDY.—The Medicare Payment Advisory Com-
36 mission, in consultation with beneficiaries, consumer
37 groups, employers, and organizations offering plans under

1 part C of title XVIII of the Social Security Act, shall con-
2 duct a study to determine the extent to which the cost-
3 sharing structures under such plans affect access to cov-
4 ered services or select enrollees based on the health status
5 of eligible individuals described in section 1851(a)(3) of the
6 Social Security Act (42 U.S.C. 1395w-21(a)(3)).

7 (2) REPORT.—Not later than December 31, 2004, the
8 Commission shall submit a report to Congress on the study
9 conducted under paragraph (1) together with recommenda-
10 tions for such legislation and administrative actions as the
11 Commission considers appropriate.

12 (i) IMPLEMENTATION OF PROVISIONS.—

13 (1) ANNOUNCEMENT OF REVISED MEDICARE ADVAN-
14 TAGE PAYMENT RATES.—Within 6 weeks after the date of
15 the enactment of this Act, the Secretary shall determine,
16 and shall announce (in a manner intended to provide notice
17 to interested parties) MA capitation rates under section
18 1853 of the Social Security Act (42 U.S.C. 1395w-23) for
19 2004, revised in accordance with the provisions of this sec-
20 tion.

21 (2) TRANSITION TO REVISED PAYMENT RATES.—The
22 provisions of section 604 of BIPA (114 Stat. 2763A-555)
23 (other than subsection (a)) shall apply to the provisions of
24 subsections (a) through (d) of this section for 2004 in the
25 same manner as the provisions of such section 604 applied
26 to the provisions of BIPA for 2001.

27 (3) SPECIAL RULE FOR PAYMENT RATES IN 2004.—

28 (A) JANUARY AND FEBRUARY.—Notwithstanding
29 the amendments made by subsections (a) through (d),
30 for purposes of making payments under section 1853
31 of the Social Security Act (42 U.S.C. 1395w-23) for
32 January and February 2004, the annual capitation
33 rate for a payment area shall be calculated and the ex-
34 cess amount under section 1854(f)(1)(B) of such Act
35 (42 U.S.C. 1395w-24(f)(1)(B)) shall be determined as
36 if such amendments had not been enacted.

1 (B) MARCH THROUGH DECEMBER.—Notwith-
2 standing the amendments made by subsections (a)
3 through (d), for purposes of making payments under
4 section 1853 of the Social Security Act (42 U.S.C.
5 1395w–23) for March through December 2004, the an-
6 nual capitation rate for a payment area shall be cal-
7 culated and the excess amount under section
8 1854(f)(1)(B) of such Act (42 U.S.C. 1395w–
9 24(f)(1)(B)) shall be determined, in such manner as
10 the Secretary estimates will ensure that the total of
11 such payments with respect to 2004 is the same as the
12 amounts that would have been if subparagraph (A) had
13 not been enacted.

14 (C) CONSTRUCTION.—Subparagraphs (A) and (B)
15 shall not be taken into account in computing such capi-
16 tation rate for 2005 and subsequent years.

17 (4) PLANS REQUIRED TO PROVIDE NOTICE OF
18 CHANGES IN PLAN BENEFITS.—In the case of an organiza-
19 tion offering a plan under part C of title XVIII of the So-
20 cial Security Act that revises its submission of the informa-
21 tion described in section 1854(a)(1) of such Act (42 U.S.C.
22 1395w–23(a)(1)) for a plan pursuant to the application of
23 paragraph (2), if such revision results in changes in bene-
24 ficiary premiums, beneficiary cost-sharing, or benefits
25 under the plan, then by not later than 3 weeks after the
26 date the Secretary approves such submission, the organiza-
27 tion offering the plan shall provide each beneficiary enrolled
28 in the plan with written notice of such changes.

29 (5) LIMITATION ON REVIEW.—There shall be no ad-
30 ministrative or judicial review under section 1869 or sec-
31 tion 1878 of the Social Security Act (42 U.S.C. 1395ff and
32 1395oo), or otherwise of any determination made by the
33 Secretary under this subsection or the application of the
34 payment rates determined pursuant to this subsection.

35 (j) ADDITIONAL AMENDMENTS.—Section 1852(d)(4) (42
36 U.S.C. 1395w–22(d)(4)) is amended—

1 (1) in subparagraph (B), by inserting “(other than
2 deemed contracts or agreements under subsection (j)(6))”
3 after “the plan has contracts or agreements”; and

4 (2) in the last sentence, by inserting before the period
5 at the end the following: “, except that, if a plan entirely
6 meets such requirement with respect to a category of health
7 care professional or provider on the basis of subparagraph
8 (B), it may provide for a higher beneficiary copayment in
9 the case of health care professionals and providers of that
10 category who do not have contracts or agreements (other
11 than deemed contracts or agreements under subsection
12 (j)(6)) to provide covered services under the terms of the
13 plan”.

14 **Subtitle C—Offering of Medicare Ad-**
15 **vantage (MA) Regional Plans; Medi-**
16 **care Advantage Competition**

17 **SEC. 221. ESTABLISHMENT OF MA REGIONAL PLANS.**

18 (a) OFFERING OF MA REGIONAL PLANS.—

19 (1) IN GENERAL.—Section 1851(a)(2)(A) is
20 amended—

21 (A) by striking “COORDINATED CARE PLANS.—Co-
22 ordinated” and inserting the following: “COORDINATED
23 CARE PLANS (INCLUDING REGIONAL PLANS).—

24 “(i) IN GENERAL.—Coordinated”;

25 (B) by inserting “regional or local” before “pre-
26 ferred provider organization plans”; and

27 (C) by inserting “ (including MA regional plans)”
28 after “preferred provider organization plans”.

29 (2) MORATORIUM ON NEW LOCAL PREFERRED PRO-
30 VIDER ORGANIZATION PLANS.—The Secretary shall not
31 permit the offering of a local preferred provider organiza-
32 tion plan under part C of title XVIII of the Social Security
33 Act during 2006 or 2007 in a service area unless such plan
34 was offered under such part (including under a demonstra-
35 tion project under such part) in such area as of December
36 31, 2005.

1 (b) DEFINITION OF MA REGIONAL PLAN; MA LOCAL
2 PLAN.—

3 (1) IN GENERAL.—Section 1859(b) (42 U.S.C.
4 1395w-29(b)) is amended by adding at the end the fol-
5 lowing new paragraphs:

6 “(4) MA REGIONAL PLAN.—The term ‘MA regional
7 plan’ means an MA plan described in section
8 1851(a)(2)(A)(i)—

9 “(A) that has a network of providers that have
10 agreed to a contractually specified reimbursement for
11 covered benefits with the organization offering the plan;

12 “(B) that provides for reimbursement for all cov-
13 ered benefits regardless of whether such benefits are
14 provided within such network of providers; and

15 “(C) the service area of which is one or more en-
16 tire MA regions.

17 “(5) MA LOCAL PLAN.—The term ‘MA local plan’
18 means an MA plan that is not an MA regional plan.”.

19 (2) CONSTRUCTION.—Nothing in part C of title XVIII
20 of the Social Security Act shall be construed as preventing
21 an MSA plan or MA private fee-for-service plan from hav-
22 ing a service area that covers one or more MA regions or
23 the entire nation.

24 (c) RULES FOR MA REGIONAL PLANS.—Part C of title
25 XVIII (42 U.S.C. 1395w-21 et seq.) is amended by inserting
26 after section 1857 the following new section:

27 “SPECIAL RULES FOR MA REGIONAL PLANS

28 “SEC. 1858. (a) REGIONAL SERVICE AREA; ESTABLISH-
29 MENT OF MA REGIONS.—

30 “(1) COVERAGE OF ENTIRE MA REGION.—The service
31 area for an MA regional plan shall consist of an entire MA
32 region established under paragraph (2) and the provisions
33 of section 1854(h) shall not apply to such a plan.

34 “(2) ESTABLISHMENT OF MA REGIONS.—

35 “(A) MA REGION.—For purposes of this title, the
36 term ‘MA region’ means such a region within the 50

1 States and the District of Columbia as established by
2 the Secretary under this paragraph.

3 “(B) ESTABLISHMENT.—

4 “(i) INITIAL ESTABLISHMENT.—Not later than
5 January 1, 2005, the Secretary shall first establish
6 and publish MA regions.

7 “(ii) PERIODIC REVIEW AND REVISION OF
8 SERVICE AREAS.—The Secretary may periodically
9 review MA regions under this paragraph and, based
10 on such review, may revise such regions if the Sec-
11 retary determines such revision to be appropriate.

12 “(C) REQUIREMENTS FOR MA REGIONS.—The Sec-
13 retary shall establish, and may revise, MA regions
14 under this paragraph in a manner consistent with the
15 following:

16 “(i) NUMBER OF REGIONS.—There shall be no
17 fewer than 10 regions, and no more than 50 re-
18 gions.

19 “(ii) MAXIMIZING AVAILABILITY OF PLANS.—
20 The regions shall maximize the availability of MA
21 regional plans to all MA eligible individuals without
22 regard to health status, especially those residing in
23 rural areas.

24 “(D) MARKET SURVEY AND ANALYSIS.—Before
25 establishing MA regions, the Secretary shall conduct a
26 market survey and analysis, including an examination
27 of current insurance markets, to determine how the re-
28 gions should be established.

29 “(3) NATIONAL PLAN.—Nothing in this subsection
30 shall be construed as preventing an MA regional plan from
31 being offered in more than one MA region (including all re-
32 gions).

33 “(b) APPLICATION OF SINGLE DEDUCTIBLE AND CATA-
34 STROPHIC LIMIT ON OUT-OF-POCKET EXPENSES.—An MA re-
35 gional plan shall include the following:

36 “(1) SINGLE DEDUCTIBLE.—Any deductible for bene-
37 fits under the original medicare fee-for-service program op-

1 tion shall be a single deductible (instead of a separate inpa-
 2 tient hospital deductible and a part B deductible) and may
 3 be applied differentially for in-network services and may be
 4 waived for preventive or other items and services.

5 “(2) CATASTROPHIC LIMIT.—

6 “(A) IN-NETWORK.—A catastrophic limit on out-
 7 of-pocket expenditures for in-network benefits under
 8 the original medicare fee-for-service program option.

9 “(B) TOTAL.—A catastrophic limit on out-of-pock-
 10 et expenditures for all benefits under the original medi-
 11 care fee-for-service program option.

12 “(c) PORTION OF TOTAL PAYMENTS TO AN ORGANIZA-
 13 TION SUBJECT TO RISK FOR 2006 AND 2007.—

14 “(1) APPLICATION OF RISK CORRIDORS.—

15 “(A) IN GENERAL.—This subsection shall only
 16 apply to MA regional plans offered during 2006 or
 17 2007.

18 “(B) NOTIFICATION OF ALLOWABLE COSTS UNDER
 19 THE PLAN.—In the case of an MA organization that of-
 20 fers an MA regional plan in an MA region in 2006 or
 21 2007, the organization shall notify the Secretary, be-
 22 fore such date in the succeeding year as the Secretary
 23 specifies, of—

24 “(i) its total amount of costs that the organi-
 25 zation incurred in providing benefits covered under
 26 the original medicare fee-for-service program option
 27 for all enrollees under the plan in the region in the
 28 year and the portion of such costs that is attrib-
 29 utable to administrative expenses described in sub-
 30 paragraph (C); and

31 “(ii) its total amount of costs that the organi-
 32 zation incurred in providing rebatable integrated
 33 benefits (as defined in subparagraph (D)) and with
 34 respect to such benefits the portion of such costs
 35 that is attributable to administrative expenses de-
 36 scribed in subparagraph (C) and not described in
 37 clause (i) of this subparagraph.

1 “(C) ALLOWABLE COSTS DEFINED.—For purposes
2 of this subsection, the term ‘allowable costs’ means,
3 with respect to an MA regional plan for a year, the
4 total amount of costs described in subparagraph (B)
5 for the plan and year, reduced by the portion of such
6 costs attributable to administrative expenses incurred
7 in providing the benefits described in such subpara-
8 graph.

9 “(D) REBATABLE INTEGRATED BENEFITS.—For
10 purposes of this subsection, the term ‘rebata-
11 ble integrated benefits’ means such non-drug supplemental
12 benefits under subclause (I) of section
13 1854(b)(1)(C)(ii) pursuant to a rebate under such sec-
14 tion that the Secretary determines are integrated with
15 the benefits described in subparagraph (B)(i).

16 “(2) ADJUSTMENT OF PAYMENT.—

17 “(A) NO ADJUSTMENT IF ALLOWABLE COSTS
18 WITHIN 3 PERCENT OF TARGET AMOUNT.—If the allow-
19 able costs for the plan for the year are at least 97 per-
20 cent, but do not exceed 103 percent, of the target
21 amount for the plan and year, there shall be no pay-
22 ment adjustment under this subsection for the plan and
23 year.

24 “(B) INCREASE IN PAYMENT IF ALLOWABLE
25 COSTS ABOVE 103 PERCENT OF TARGET AMOUNT.—

26 “(i) COSTS BETWEEN 103 AND 108 PERCENT
27 OF TARGET AMOUNT.—If the allowable costs for
28 the plan for the year are greater than 103 percent,
29 but not greater than 108 percent, of the target
30 amount for the plan and year, the Secretary shall
31 increase the total of the monthly payments made to
32 the organization offering the plan for the year
33 under section 1853(a) by an amount equal to 50
34 percent of the difference between such allowable
35 costs and 103 percent of such target amount.

36 “(ii) COSTS ABOVE 108 PERCENT OF TARGET
37 AMOUNT.—If the allowable costs for the plan for

1 the year are greater than 108 percent of the target
2 amount for the plan and year, the Secretary shall
3 increase the total of the monthly payments made to
4 the organization offering the plan for the year
5 under section 1853(a) by an amount equal to the
6 sum of—

7 “(I) 2.5 percent of such target amount;

8 and

9 “(II) 80 percent of the difference between
10 such allowable costs and 108 percent of such
11 target amount.

12 “(C) REDUCTION IN PAYMENT IF ALLOWABLE
13 COSTS BELOW 97 PERCENT OF TARGET AMOUNT.—

14 “(i) COSTS BETWEEN 92 AND 97 PERCENT OF
15 TARGET AMOUNT.—If the allowable costs for the
16 plan for the year are less than 97 percent, but
17 greater than or equal to 92 percent, of the target
18 amount for the plan and year, the Secretary shall
19 reduce the total of the monthly payments made to
20 the organization offering the plan for the year
21 under section 1853(a) by an amount (or otherwise
22 recover from the plan an amount) equal to 50 per-
23 cent of the difference between 97 percent of the
24 target amount and such allowable costs.

25 “(ii) COSTS BELOW 92 PERCENT OF TARGET
26 AMOUNT.—If the allowable costs for the plan for
27 the year are less than 92 percent of the target
28 amount for the plan and year, the Secretary shall
29 reduce the total of the monthly payments made to
30 the organization offering the plan for the year
31 under section 1853(a) by an amount (or otherwise
32 recover from the plan an amount) equal to the sum
33 of—

34 “(I) 2.5 percent of such target amount;

35 and

1 “(II) 80 percent of the difference between
2 92 percent of such target amount and such al-
3 lowable costs.

4 “(D) TARGET AMOUNT DESCRIBED.—For pur-
5 poses of this paragraph, the term ‘target amount’
6 means, with respect to an MA regional plan offered by
7 an organization in a year, an amount equal to—

8 “(i) the sum of—

9 “(I) the total monthly payments made to
10 the organization for enrollees in the plan for
11 the year that are attributable to benefits under
12 the original medicare fee-for-service program
13 option (as defined in section 1852(a)(1)(B));

14 “(II) the total of the MA monthly basic
15 beneficiary premium collectable for such enroll-
16 ees for the year; and

17 “(III) the total amount of the rebates
18 under section 1854(b)(1)(C)(ii) that are attrib-
19 utable to rebatable integrated benefits; reduced
20 by

21 “(ii) the amount of administrative expenses
22 assumed in the bid insofar as the bid is attrib-
23 utable to benefits described in clause (i)(I) or
24 (i)(III).

25 “(3) DISCLOSURE OF INFORMATION.—

26 “(A) IN GENERAL.—Each contract under this part
27 shall provide—

28 “(i) that an MA organization offering an MA
29 regional plan shall provide the Secretary with such
30 information as the Secretary determines is nec-
31 essary to carry out this subsection; and

32 “(ii) that, pursuant to section 1857(d)(2)(B),
33 the Secretary has the right to inspect and audit
34 any books and records of the organization that per-
35 tain to the information regarding costs provided to
36 the Secretary under paragraph (1)(B).

1 “(B) RESTRICTION ON USE OF INFORMATION.—
 2 Information disclosed or obtained pursuant to the pro-
 3 visions of this subsection may be used by officers, em-
 4 ployees, and contractors of the Department of Health
 5 and Human Services only for the purposes of, and to
 6 the extent necessary in, carrying out this subsection.

7 “(d) ORGANIZATIONAL AND FINANCIAL REQUIRE-
 8 MENTS.—

9 “(1) IN GENERAL.—In the case of an MA organization
 10 that is offering an MA regional plan in an MA region
 11 and—

12 “(A) meets the requirements of section 1855(a)(1)
 13 with respect to at least one such State in such region;
 14 and

15 “(B) with respect to each other State in such re-
 16 gion in which it does not meet requirements, it dem-
 17 onstrates to the satisfaction of the Secretary that it has
 18 filed the necessary application to meet such require-
 19 ments,

20 the Secretary may waive such requirement with respect to
 21 each State described in subparagraph (B) for such period
 22 of time as the Secretary determines appropriate for the
 23 timely processing of such an application by the State (and,
 24 if such application is denied, through the end of such plan
 25 year as the Secretary determines appropriate to provide for
 26 a transition).

27 “(2) SELECTION OF APPROPRIATE STATE.—In apply-
 28 ing paragraph (1) in the case of an MA organization that
 29 meets the requirements of section 1855(a)(1) with respect
 30 to more than one State in a region, the organization shall
 31 select, in a manner specified by the Secretary among such
 32 States, one State the rules of which shall apply in the case
 33 of the States described in paragraph (1)(B).

34 “(e) STABILIZATION FUND.—

35 “(1) ESTABLISHMENT.—The Secretary shall establish
 36 under this subsection an MA Regional Plan Stabilization

1 Fund (in this subsection referred to as the ‘Fund’) which
2 shall be available for 2 purposes:

3 “(A) PLAN ENTRY.—To provide incentives to have
4 MA regional plans offered in each MA region under
5 paragraph (3).

6 “(B) PLAN RETENTION.—To provide incentives to
7 retain MA regional plans in certain MA regions with
8 below-national-average MA market penetration under
9 paragraph (4).

10 “(2) FUNDING.—

11 “(A) INITIAL FUNDING.—

12 “(i) IN GENERAL.—There shall be available to
13 the Fund, for expenditures from the Fund during
14 the period beginning on January 1, 2007, and end-
15 ing on December 31, 2013, a total of
16 \$10,000,000,000.

17 “(ii) PAYMENT FROM TRUST FUNDS.—Such
18 amount shall be available to the Fund, as expendi-
19 tures are made from the Fund, from the Federal
20 Hospital Insurance Trust Fund and the Federal
21 Supplementary Medical Insurance Trust Fund in
22 the proportion specified in section 1853(f).

23 “(B) ADDITIONAL FUNDING FROM SAVINGS.—

24 “(i) IN GENERAL.—There shall also be made
25 available to the Fund, 50 percent of savings de-
26 scribed in clause (ii).

27 “(ii) SAVINGS.—The savings described in this
28 clause are 25 percent of the average per capita sav-
29 ings described in section 1854(b)(4)(C) for which
30 monthly rebates are provided under section
31 1854(b)(1)(C) in the fiscal year involved that are
32 attributable to MA regional plans.

33 “(iii) AVAILABILITY.—Funds made available
34 under this subparagraph shall be transferred into a
35 special account in the Treasury from the Federal
36 Hospital Insurance Trust Fund and the Federal
37 Supplementary Medical Insurance Trust Fund in

1 the proportion specified in section 1853(f) on a
2 monthly basis.

3 “(C) OBLIGATIONS.—Amounts in the Fund shall
4 be available in advance of appropriations to MA re-
5 gional plans in qualifying MA regions only in accord-
6 ance with paragraph (5).

7 “(D) ORDERING.—Expenditures from the Fund
8 shall first be made from amounts made available under
9 subparagraph (A).

10 “(3) PLAN ENTRY FUNDING.—

11 “(A) IN GENERAL.—Funding is available under
12 this paragraph for a year only as follows:

13 “(i) NATIONAL PLAN.—For a national bonus
14 payment described in subparagraph (B) for the of-
15 fering by a single MA organization of an MA re-
16 gional plan in each MA region in the year, but only
17 if there was not such a plan offered in each such
18 region in the previous year. Funding under this
19 clause is only available with respect to any indi-
20 vidual MA organization for a single year, but may
21 be made available to more than one such organiza-
22 tion in the same year.

23 “(ii) REGIONAL PLANS.—Subject to clause
24 (iii), for an increased amount under subparagraph
25 (C) for an MA regional plan offered in an MA re-
26 gion which did not have any MA regional plan of-
27 fered in the prior year.

28 “(iii) LIMITATION ON REGIONAL PLAN FUND-
29 ING IN CASE OF NATIONAL PLAN.—In no case shall
30 there be any payment adjustment under subpara-
31 graph (C) for a year for which a national payment
32 adjustment is made under subparagraph (B).

33 “(B) NATIONAL BONUS PAYMENT.—The national
34 bonus payment under this subparagraph shall—

35 “(i) be available to an MA organization only if
36 the organization offers MA regional plans in every
37 MA region;

1 “(ii) be available with respect to all MA re-
2 gional plans of the organization regardless of
3 whether any other MA regional plan is offered in
4 any region; and

5 “(iii) subject to amounts available under para-
6 graph (5) for a year, be equal to 3 percent of the
7 benchmark amount otherwise applicable for each
8 MA regional plan offered by the organization.

9 “(C) REGIONAL PAYMENT ADJUSTMENT.—

10 “(i) IN GENERAL.—The increased amount
11 under this subparagraph for an MA regional plan
12 in an MA region for a year shall be an amount, de-
13 termined by the Secretary, based on the bid sub-
14 mitted for such plan (or plans) and shall be avail-
15 able to all MA regional plans offered in such region
16 and year. Such amount may be based on the mean,
17 mode, or median, or other measure of such bids
18 and may vary from region to region. The Secretary
19 may not limit the number of plans or bids in a re-
20 gion.

21 “(ii) MULTI-YEAR FUNDING.—

22 “(I) IN GENERAL.—Subject to amounts
23 available under paragraph (5), funding under
24 this subparagraph shall be available for a pe-
25 riod determined by the Secretary.

26 “(II) REPORT.—If the Secretary deter-
27 mines that funding will be provided for a sec-
28 ond consecutive year with respect to an MA re-
29 gion, the Secretary shall submit to the Con-
30 gress a report that describes the underlying
31 market dynamics in the region and that in-
32 cludes recommendations concerning changes in
33 the payment methodology otherwise provided
34 for MA regional plans under this part.

35 “(iii) APPLICATION TO ALL PLANS IN A RE-
36 GION.—Funding under this subparagraph with re-
37 spect to an MA region shall be made available with

1 respect to all MA regional plans offered in the re-
2 gion.

3 “(iv) LIMITATION ON AVAILABILITY OF PLAN
4 RETENTION FUNDING IN NEXT YEAR.—If an in-
5 creased amount is made available under this sub-
6 paragraph with respect to an MA region for a pe-
7 riod determined by the Secretary under clause
8 (ii)(I), in no case shall funding be available under
9 paragraph (4) with respect to MA regional plans
10 offered in the region in the year following such pe-
11 riod.

12 “(D) APPLICATION.—Any additional payment
13 under this paragraph provided for an MA regional plan
14 for a year shall be treated as if it were an addition to
15 the benchmark amount otherwise applicable to such
16 plan and year, but shall not be taken into account in
17 the computation of any benchmark amount for any
18 subsequent year.

19 “(4) PLAN RETENTION FUNDING.—

20 “(A) IN GENERAL.—Funding is available under
21 this paragraph for a year with respect to MA regional
22 plans offered in an MA region for the increased amount
23 specified in subparagraph (B) but only if the region
24 meets the requirements of subparagraphs (C) and (E).

25 “(B) PAYMENT INCREASE.—The increased amount
26 under this subparagraph for an MA regional plan in an
27 MA region for a year shall be an amount, determined
28 by the Secretary, that does not exceed the greater of—

29 “(i) 3 percent of the benchmark amount appli-
30 cable in the region; or

31 “(ii) such amount as (when added to the
32 benchmark amount applicable to the region) will re-
33 sult in the ratio of—

34 “(I) such additional amount plus the
35 benchmark amount computed under section
36 1854(b)(4)(B)(i) for the region and year, to the
37 adjusted average per capita cost for the region

1 and year, as estimated by the Secretary under
 2 section 1876(a)(4) and adjusted as appropriate
 3 for the purpose of risk adjustment; being equal
 4 to

5 “(II) the weighted average of such bench-
 6 mark amounts for all the regions and such
 7 year, to the average per capita cost for the
 8 United States and such year, as estimated by
 9 the Secretary under section 1876(a)(4) and ad-
 10 justed as appropriate for the purpose of risk
 11 adjustment.

12 “(C) REGIONAL REQUIREMENTS.—The require-
 13 ments of this subparagraph for an MA region for a
 14 year are as follows:

15 “(i) NOTIFICATION OF PLAN EXIT.—The Sec-
 16 retary has received notice (in such form and man-
 17 ner as the Secretary specifies) before a year that
 18 one or more MA regional plans that were offered
 19 in the region in the previous year will not be of-
 20 fered in the succeeding year.

21 “(ii) REGIONAL PLANS AVAILABLE FROM
 22 FEWER THAN 2 MA ORGANIZATIONS IN THE RE-
 23 GION.—The Secretary determines that if the plans
 24 referred to in clause (i) are not offered in the year,
 25 fewer than 2 MA organizations will be offering MA
 26 regional plans in the region in the year involved.

27 “(iii) PERCENTAGE ENROLLMENT IN MA RE-
 28 GIONAL PLANS BELOW NATIONAL AVERAGE.—For
 29 the previous year, the Secretary determines that
 30 the average percentage of MA eligible individuals
 31 residing in the region who are enrolled in MA re-
 32 gional plans is less than the average percentage of
 33 such individuals in the United States enrolled in
 34 such plans.

35 “(D) APPLICATION.—Any additional payment
 36 under this paragraph provided for an MA regional plan
 37 for a year shall be treated as if it were an addition to

1 the benchmark amount otherwise applicable to such
2 plan and year, but shall not be taken into account in
3 the computation of any benchmark amount for any
4 subsequent year.

5 “(E) 2-CONSECUTIVE-YEAR LIMITATION.—

6 “(i) IN GENERAL.—In no case shall any fund-
7 ing be available under this paragraph in an MA re-
8 gion in a period of consecutive years that exceeds
9 2 years.

10 “(ii) REPORT.—If the Secretary determines
11 that funding will be provided under this paragraph
12 for a second consecutive year with respect to an
13 MA region, the Secretary shall submit to the Con-
14 gress a report that describes the underlying market
15 dynamics in the region and that includes rec-
16 ommendations concerning changes in the payment
17 methodology otherwise provided for MA regional
18 plans under this part.

19 “(5) FUNDING LIMITATION.—

20 “(A) IN GENERAL.—The total amount expended
21 from the Fund as a result of the application of this
22 subsection through the end of a calendar year may not
23 exceed the amount available to the Fund as of the first
24 day of such year. For purposes of this subsection,
25 amounts that are expended under this title insofar as
26 such amounts would not have been expended but for
27 the application of this subsection shall be counted as
28 amounts expended as a result of such application.

29 “(B) APPLICATION OF LIMITATION.—The Sec-
30 retary may obligate funds from the Fund for a year
31 only if the Secretary determines (and the Chief Actuary
32 of the Centers for Medicare & Medicaid Services and
33 the appropriate budget officer certify) that there are
34 available in the Fund at the beginning of the year suf-
35 ficient amounts to cover all such obligations incurred
36 during the year consistent with subparagraph (A). The
37 Secretary shall take such steps, in connection with

1 computing additional payment amounts under para-
2 graphs (3) and (4) and including limitations on enroll-
3 ment in MA regional plans receiving such payments, as
4 will ensure that sufficient funds are available to make
5 such payments for the entire year. Funds shall only be
6 made available from the Fund pursuant to an appor-
7 tionment made in accordance with applicable proce-
8 dures.

9 “(6) SECRETARY REPORTS.—Not later than April 1 of
10 each year (beginning in 2008), the Secretary shall submit
11 a report to Congress and the Comptroller General of the
12 United States that includes—

13 “(A) a detailed description of—

14 “(i) the total amount expended as a result of
15 the application of this subsection in the previous
16 year compared to the total amount that would have
17 been expended under this title in the year if this
18 subsection had not been enacted;

19 “(ii) the projections of the total amount that
20 will be expended as a result of the application of
21 this subsection in the year in which the report is
22 submitted compared to the total amount that would
23 have been expended under this title in the year if
24 this subsection had not been enacted;

25 “(iii) amounts remaining within the funding
26 limitation specified in paragraph (5); and

27 “(iv) the steps that the Secretary will take
28 under paragraph (5)(B) to ensure that the applica-
29 tion of this subsection will not cause expenditures
30 to exceed the amount available in the Fund; and

31 “(B) a certification from the Chief Actuary of the
32 Centers for Medicare & Medicaid Services that the de-
33 scription provided under subparagraph (A) is reason-
34 able, accurate, and based on generally accepted actu-
35 arial principles and methodologies.

36 “(7) BIENNIAL GAO REPORTS.—Not later than Janu-
37 ary 1 of 2009, 2011, 2013, and 2015, the Comptroller

1 General of the United States shall submit to the Secretary
 2 and Congress a report on the application of additional pay-
 3 ments under this subsection. Each report shall include—

4 “(A) an evaluation of—

5 “(i) the quality of care provided to individuals
 6 enrolled in MA regional plans for which additional
 7 payments were made under this subsection;

8 “(ii) the satisfaction of such individuals with
 9 benefits under such a plan;

10 “(iii) the costs to the medicare program for
 11 payments made to such plans; and

12 “(iv) any improvements in the delivery of
 13 health care services under such a plan;

14 “(B) a comparative analysis of the performance of
 15 MA regional plans receiving payments under this sub-
 16 section with MA regional plans not receiving such pay-
 17 ments; and

18 “(C) recommendations for such legislation or ad-
 19 ministrative action as the Comptroller General deter-
 20 mines to be appropriate.

21 “(f) COMPUTATION OF APPLICABLE MA REGION-SPECIFIC
 22 NON-DRUG MONTHLY BENCHMARK AMOUNTS.—

23 “(1) COMPUTATION FOR REGIONS.—For purposes of
 24 section 1853(j)(2) and this section, subject to subsection
 25 (e), the term ‘MA region-specific non-drug monthly bench-
 26 mark amount’ means, with respect to an MA region for a
 27 month in a year, the sum of the 2 components described
 28 in paragraph (2) for the region and year. The Secretary
 29 shall compute such benchmark amount for each MA region
 30 before the beginning of each annual, coordinated election
 31 period under section 1851(e)(3)(B) for each year (begin-
 32 ning with 2006).

33 “(2) 2 COMPONENTS.—For purposes of paragraph (1),
 34 the 2 components described in this paragraph for an MA
 35 region and a year are the following:

36 “(A) STATUTORY COMPONENT.—The product of
 37 the following:

1 “(i) STATUTORY REGION-SPECIFIC NON-DRUG
2 AMOUNT.—The statutory region-specific non-drug
3 amount (as defined in paragraph (3)) for the re-
4 gion and year.

5 “(ii) STATUTORY NATIONAL MARKET
6 SHARE.—The statutory national market share per-
7 centage, determined under paragraph (4) for the
8 year.

9 “(B) PLAN-BID COMPONENT.—The product of the
10 following:

11 “(i) WEIGHTED AVERAGE OF MA PLAN BIDS
12 IN REGION.—The weighted average of the plan bids
13 for the region and year (as determined under para-
14 graph (5)(A)).

15 “(ii) NON-STATUTORY MARKET SHARE.—1
16 minus the statutory national market share percent-
17 age, determined under paragraph (4) for the year.

18 “(3) STATUTORY REGION-SPECIFIC NON-DRUG
19 AMOUNT.—For purposes of paragraph (2)(A)(i), the term
20 ‘statutory region-specific non-drug amount’ means, for an
21 MA region and year, an amount equal the sum (for each
22 MA local area within the region) of the product of—

23 “(A) MA area-specific non-drug monthly bench-
24 mark amount under section 1853(j)(1)(A) for that area
25 and year; and

26 “(B) the number of MA eligible individuals resid-
27 ing in the local area, divided by the total number of
28 MA eligible individuals residing in the region.

29 “(4) COMPUTATION OF STATUTORY MARKET SHARE
30 PERCENTAGE.—

31 “(A) IN GENERAL.—The Secretary shall determine
32 for each year a statutory national market share per-
33 centage that is equal to the proportion of MA eligible
34 individuals nationally who were not enrolled in an MA
35 plan during the reference month.

36 “(B) REFERENCE MONTH DEFINED.—For pur-
37 poses of this part, the term ‘reference month’ means,

1 with respect to a year, the most recent month during
 2 the previous year for which the Secretary determines
 3 that data are available to compute the percentage spec-
 4 ified in subparagraph (A) and other relevant percent-
 5 ages under this part.

6 “(5) DETERMINATION OF WEIGHTED AVERAGE MA
 7 BIDS FOR A REGION.—

8 “(A) IN GENERAL.—For purposes of paragraph
 9 (2)(B)(i), the weighted average of plan bids for an MA
 10 region and a year is the sum, for MA regional plans
 11 described in subparagraph (D) in the region and year,
 12 of the products (for each such plan) of the following:

13 “(i) MONTHLY MA STATUTORY NON-DRUG BID
 14 AMOUNT.—The unadjusted MA statutory non-drug
 15 monthly bid amount for the plan.

16 “(ii) PLAN’S SHARE OF MA ENROLLMENT IN
 17 REGION.—The factor described in subparagraph
 18 (B) for the plan.

19 “(B) PLAN’S SHARE OF MA ENROLLMENT IN RE-
 20 GION.—

21 “(i) IN GENERAL.—Subject to the succeeding
 22 provisions of this subparagraph, the factor de-
 23 scribed in this subparagraph for a plan is equal to
 24 the number of individuals described in subpara-
 25 graph (C) for such plan, divided by the total num-
 26 ber of such individuals for all MA regional plans
 27 described in subparagraph (D) for that region and
 28 year.

29 “(ii) SINGLE PLAN RULE.—In the case of an
 30 MA region in which only a single MA regional plan
 31 is being offered, the factor described in this sub-
 32 paragraph shall be equal to 1.

33 “(iii) EQUAL DIVISION AMONG MULTIPLE
 34 PLANS IN YEAR IN WHICH PLANS ARE FIRST AVAIL-
 35 ABLE.—In the case of an MA region in the first
 36 year in which any MA regional plan is offered, if
 37 more than one MA regional plan is offered in such

1 year, the factor described in this subparagraph for
 2 a plan shall (as specified by the Secretary) be equal
 3 to—

4 “(I) 1 divided by the number of such plans
 5 offered in such year; or

6 “(II) a factor for such plan that is based
 7 upon the organization’s estimate of projected
 8 enrollment, as reviewed and adjusted by the
 9 Secretary to ensure reasonableness and as is
 10 certified by the Chief Actuary of the Centers
 11 for Medicare & Medicaid Services.

12 “(C) COUNTING OF INDIVIDUALS.—For purposes
 13 of subparagraph (B)(i), the Secretary shall count for
 14 each MA regional plan described in subparagraph (D)
 15 for an MA region and year, the number of individuals
 16 who reside in the region and who were enrolled under
 17 such plan under this part during the reference month.

18 “(D) PLANS COVERED.—For an MA region and
 19 year, an MA regional plan described in this subpara-
 20 graph is an MA regional plan that is offered in the re-
 21 gion and year and was offered in the region in the re-
 22 ference month.

23 “(g) ELECTION OF UNIFORM COVERAGE DETERMINA-
 24 TION.—Instead of applying section 1852(a)(2)(C) with respect
 25 to an MA regional plan, the organization offering the plan may
 26 elect to have a local coverage determination for the entire MA
 27 region be the local coverage determination applied for any part
 28 of such region (as selected by the organization).

29 “(h) ASSURING NETWORK ADEQUACY.—

30 “(1) IN GENERAL.—For purposes of enabling MA or-
 31 ganizations that offer MA regional plans to meet applicable
 32 provider access requirements under section 1852 with re-
 33 spect to such plans, the Secretary may provide for payment
 34 under this section to an essential hospital that provides in-
 35 patient hospital services to enrollees in such a plan where
 36 the MA organization offering the plan certifies to the Sec-
 37 retary that the organization was unable to reach an agree-

1 ment between the hospital and the organization regarding
 2 provision of such services under the plan. Such payment
 3 shall be available only if—

4 “(A) the organization provides assurances satisfac-
 5 tory to the Secretary that the organization will make
 6 payment to the hospital for inpatient hospital services
 7 of an amount that is not less than the amount that
 8 would be payable to the hospital under section 1886
 9 with respect to such services; and

10 “(B) with respect to specific inpatient hospital
 11 services provided to an enrollee, the hospital dem-
 12 onstrates to the satisfaction of the Secretary that the
 13 hospital’s costs of such services exceed the payment
 14 amount described in subparagraph (A).

15 “(2) PAYMENT AMOUNTS.—The payment amount
 16 under this subsection for inpatient hospital services pro-
 17 vided by a subsection (d) hospital to an enrollee in an MA
 18 regional plan shall be, subject to the limitation of funds
 19 under paragraph (3), the amount (if any) by which—

20 “(A) the amount of payment that would have been
 21 paid for such services under this title if the enrollees
 22 were covered under the original medicare fee-for-service
 23 program option and the hospital were a critical access
 24 hospital; exceeds

25 “(B) the amount of payment made for such serv-
 26 ices under paragraph (1)(A).

27 “(3) AVAILABLE AMOUNTS.—There shall be available
 28 for payments under this subsection—

29 “(A) in 2006, \$25,000,000; and

30 “(B) in each succeeding year the amount specified
 31 in this paragraph for the preceding year increased by
 32 the market basket percentage increase (as defined in
 33 section 1886(b)(3)(B)(iii)) for the fiscal year ending in
 34 such succeeding year.

35 Payments under this subsection shall be made from the
 36 Federal Hospital Insurance Trust Fund.

1 “(4) ESSENTIAL HOSPITAL.—In this subsection, the
2 term ‘essential hospital’ means, with respect to an MA re-
3 gional plan offered by an MA organization, a subsection (d)
4 hospital (as defined in section 1886(d)) that the Secretary
5 determines, based upon an application filed by the organi-
6 zation with the Secretary, is necessary to meet the require-
7 ments referred to in paragraph (1) for such plan.”.

8 (d) CONFORMING AMENDMENTS.—

9 (1) RELATING TO MA REGIONS.—Section 1853(d) (42
10 U.S.C. 1395w-23(d)) is amended—

11 (A) by amending the heading to read as follows:

12 “MA PAYMENT AREA; MA LOCAL AREA; MA REGION
13 DEFINED”;

14 (B) by redesignating paragraphs (2) and (3) as
15 paragraphs (3) and (4), respectively;

16 (C) by amending paragraph (1) to read as follows:

17 “(1) MA PAYMENT AREA.—In this part, except as pro-
18 vided in this subsection, the term ‘MA payment area’
19 means—

20 “(A) with respect to an MA local plan, an MA
21 local area (as defined in paragraph (2)); and

22 “(B) with respect to an MA regional plan, an MA
23 region (as established under section 1858(a)(2)).”;

24 (D) by inserting after paragraph (1) the following
25 new paragraph:

26 “(2) MA LOCAL AREA.—The term ‘MA local area’
27 means a county or equivalent area specified by the Sec-
28 retary.”; and

29 (E) in paragraph (4), as so redesignated—

30 (i) in subparagraph (A), by inserting “for MA
31 local plans” after “paragraph (1)”;

32 (ii) in subparagraph (A)(iii), by striking
33 “paragraph (1)” and inserting “paragraph (1)(A)”;
34 and

35 (iii) in subparagraph (B)—

36 (I) by inserting “with respect to MA local
37 plans” after “established under this section”;

1 (II) by inserting “for such plans” after
2 “payments under this section”; and

3 (III) by inserting “for such plans” after
4 “made under this section”.

5 (2) MA LOCAL AREA DEFINED.—Section 1859(c) (42
6 U.S.C. 1395w-29(c)) is amended by adding at the end the
7 following:

8 “(5) MA LOCAL AREA.—The term ‘MA local area’ is
9 defined in section 1853(d)(2).”.

10 (3) APPLICATION OF SPECIAL BENEFIT RULES TO
11 PPOS AND REGIONAL PLANS.—Section 1852(a) (42 U.S.C.
12 1395w-22(a)) is amended—

13 (A) in paragraph (1), by inserting “and except as
14 provided in paragraph (6) for MA regional plans” after
15 “MSA plans”; and

16 (B) by adding at the end the following new para-
17 graph:

18 “(6) SPECIAL BENEFIT RULES FOR REGIONAL
19 PLANS.—In the case of an MA plan that is an MA regional
20 plan, benefits under the plan shall include the benefits de-
21 scribed in paragraphs (1) and (2) of section 1858(b).”.

22 (4) APPLICATION OF CAPITATION RATES TO LOCAL
23 AREAS.—Section 1853(c)(1) (42 U.S.C. 1395w-23(c)(1)) is
24 amended by inserting “that is an MA local area” after “for
25 a Medicare+Choice payment area”.

26 (5) NETWORK ADEQUACY HOSPITAL PAYMENTS.—Sec-
27 tion 1851(i)(2) (42 U.S.C. 1395w-21(i)(2)) is amended by
28 inserting “1858(h),” after “1857(f)(2),”.

29 **SEC. 222. COMPETITION PROGRAM BEGINNING IN 2006.**

30 (a) SUBMISSION OF BIDDING AND REBATE INFORMATION
31 BEGINNING IN 2006.—

32 (1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w-
33 24) is amended—

34 (A) by amending paragraph (1) of subsection (a)
35 to read as follows:

36 “(1) IN GENERAL.—

1 “(A) INITIAL SUBMISSION.—Not later than the
 2 second Monday in September of 2002, 2003, and 2004
 3 (or the first Monday in June of each subsequent year),
 4 each MA organization shall submit to the Secretary, in
 5 a form and manner specified by the Secretary and for
 6 each MA plan for the service area (or segment of such
 7 an area if permitted under subsection (h)) in which it
 8 intends to be offered in the following year the fol-
 9 lowing:

10 “(i) The information described in paragraph
 11 (2), (3), (4), or (6)(A) for the type of plan and
 12 year involved.

13 “(ii) The plan type for each plan.

14 “(iii) The enrollment capacity (if any) in rela-
 15 tion to the plan and area.

16 “(B) BENEFICIARY REBATE INFORMATION.—In
 17 the case of a plan required to provide a monthly rebate
 18 under subsection (b)(1)(C) for a year, the MA organi-
 19 zation offering the plan shall submit to the Secretary,
 20 in such form and manner and at such time as the Sec-
 21 retary specifies, information on—

22 “(i) the manner in which such rebate will be
 23 provided under clause (ii) of such subsection; and

24 “(ii) the MA monthly prescription drug bene-
 25 ficiary premium (if any) and the MA monthly sup-
 26 plemental beneficiary premium (if any).

27 “(C) PAPERWORK REDUCTION FOR OFFERING OF
 28 MA REGIONAL PLANS NATIONALLY OR IN MULTI-RE-
 29 GION AREAS.—The Secretary shall establish require-
 30 ments for information submission under this subsection
 31 in a manner that promotes the offering of MA regional
 32 plans in more than one region (including all regions)
 33 through the filing of consolidated information.”; and

34 (B) by adding at the end of subsection (a) the fol-
 35 lowing:

36 “(6) SUBMISSION OF BID AMOUNTS BY MA ORGANIZA-
 37 TIONS BEGINNING IN 2006.—

1 “(A) INFORMATION TO BE SUBMITTED.—For an
2 MA plan (other than an MSA plan) for a plan year be-
3 ginning on or after January 1, 2006, the information
4 described in this subparagraph is as follows:

5 “(i) The monthly aggregate bid amount for
6 the provision of all items and services under the
7 plan, which amount shall be based on average rev-
8 enue requirements (as used for purposes of section
9 1302(8) of the Public Health Service Act) in the
10 payment area for an enrollee with a national aver-
11 age risk profile for the factors described in section
12 1853(a)(1)(C) (as specified by the Secretary).

13 “(ii) The proportions of such bid amount that
14 are attributable to—

15 “(I) the provision of benefits under the
16 original medicare fee-for-service program option
17 (as defined in section 1852(a)(1)(B));

18 “(II) the provision of basic prescription
19 drug coverage; and

20 “(III) the provision of supplemental health
21 care benefits.

22 “(iii) The actuarial basis for determining the
23 amount under clause (i) and the proportions de-
24 scribed in clause (ii) and such additional informa-
25 tion as the Secretary may require to verify such ac-
26 tuarial bases and the projected number of enrollees
27 in each MA local area.

28 “(iv) A description of deductibles, coinsurance,
29 and copayments applicable under the plan and the
30 actuarial value of such deductibles, coinsurance,
31 and copayments, described in subsection (e)(4)(A).

32 “(v) With respect to qualified prescription
33 drug coverage, the information required under sec-
34 tion 1860D-4, as incorporated under section
35 1860D-11(b)(2), with respect to such coverage.

36 In the case of a specialized MA plan for special needs
37 individuals, the information described in this subpara-

1 graph is such information as the Secretary shall speci-
2 fy.

3 “(B) ACCEPTANCE AND NEGOTIATION OF BID
4 AMOUNTS.—

5 “(i) AUTHORITY.—Subject to clauses (iii) and
6 (iv), the Secretary has the authority to negotiate
7 regarding monthly bid amounts submitted under
8 subparagraph (A) (and the proportions described in
9 subparagraph (A)(ii)), including supplemental ben-
10 efits provided under subsection (b)(1)(C)(ii)(I) and
11 in exercising such authority the Secretary shall
12 have authority similar to the authority of the Di-
13 rector of the Office of Personnel Management with
14 respect to health benefits plans under chapter 89
15 of title 5, United States Code.

16 “(ii) APPLICATION OF FEHBP STANDARD.—
17 Subject to clause (iv), the Secretary may only ac-
18 cept such a bid amount or proportion if the Sec-
19 retary determines that such amount and propor-
20 tions are supported by the actuarial bases provided
21 under subparagraph (A) and reasonably and equi-
22 tably reflects the revenue requirements (as used for
23 purposes of section 1302(8) of the Public Health
24 Service Act) of benefits provided under that plan.

25 “(iii) NONINTERFERENCE.—In order to pro-
26 mote competition under this part and part D and
27 in carrying out such parts, the Secretary may not
28 require any MA organization to contract with a
29 particular hospital, physician, or other entity or in-
30 dividual to furnish items and services under this
31 title or require a particular price structure for pay-
32 ment under such a contract to the extent consistent
33 with the Secretary’s authority under this part.

34 “(iv) EXCEPTION.—In the case of a plan de-
35 scribed in section 1851(a)(2)(C), the provisions of
36 clauses (i) and (ii) shall not apply and the provi-
37 sions of paragraph (5)(B), prohibiting the review,

1 approval, or disapproval of amounts described in
 2 such paragraph, shall apply to the negotiation and
 3 rejection of the monthly bid amounts and the pro-
 4 portions referred to in subparagraph (A).”.

5 (2) DEFINITION OF BENEFITS UNDER THE ORIGINAL
 6 MEDICARE FEE-FOR-SERVICE PROGRAM OPTION.—Section
 7 1852(a)(1) (42 U.S.C. 1395w-22(a)(1)) is amended—

8 (A) by striking “IN GENERAL.—Except” and in-
 9 serting “REQUIREMENT.—

10 “(A) IN GENERAL.—Except”; and

11 (B) by striking “title XI” and all that follows and
 12 inserting the following: “title XI, benefits under the
 13 original medicare fee-for-service program option (and,
 14 for plan years before 2006, additional benefits required
 15 under section 1854(f)(1)(A)).

16 “(B) BENEFITS UNDER THE ORIGINAL MEDICARE
 17 FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

18 “(i) IN GENERAL.—For purposes of this part,
 19 the term ‘benefits under the original medicare fee-
 20 for-service program option’ means those items and
 21 services (other than hospice care) for which bene-
 22 fits are available under parts A and B to individ-
 23 uals entitled to benefits under part A and enrolled
 24 under part B, with cost-sharing for those services
 25 as required under parts A and B or an actuarially
 26 equivalent level of cost-sharing as determined in
 27 this part.

28 “(ii) SPECIAL RULE FOR REGIONAL PLANS.—
 29 In the case of an MA regional plan in determining
 30 an actuarially equivalent level of cost-sharing with
 31 respect to benefits under the original medicare fee-
 32 for-service program option, there shall only be
 33 taken into account, with respect to the application
 34 of section 1858(b)(2), such expenses only with re-
 35 spect to subparagraph (A) of such section.”.

36 (3) CONFORMING AMENDMENT RELATING TO SUPPLE-
 37 MENTAL HEALTH BENEFITS.—Section 1852(a)(3) (42

1 U.S.C. 1395w-22(a)(3)) is amended by adding at the end
 2 the following: “Such benefits may include reductions in
 3 cost-sharing below the actuarial value specified in section
 4 1854(e)(4)(B).”.

5 (b) PROVIDING FOR BENEFICIARY SAVINGS FOR CERTAIN
 6 PLANS.—

7 (1) BENEFICIARY REBATES.—Section 1854(b)(1) (42
 8 U.S.C. 1395w-24(b)(1)) is amended—

9 (A) in subparagraph (A), by striking “The month-
 10 ly amount” and inserting “Subject to the rebate under
 11 subparagraph (C), the monthly amount (if any)”; and

12 (B) by adding at the end the following new sub-
 13 paragraph:

14 “(C) BENEFICIARY REBATE RULE.—

15 “(i) REQUIREMENT.—The MA plan shall pro-
 16 vide to the enrollee a monthly rebate equal to 75
 17 percent of the average per capita savings (if any)
 18 described in paragraph (3)(C) or (4)(C), as appli-
 19 cable to the plan and year involved.

20 “(ii) FORM OF REBATE.—A rebate required
 21 under this subparagraph shall be provided through
 22 the application of the amount of the rebate toward
 23 one or more of the following:

24 “(I) PROVISION OF SUPPLEMENTAL
 25 HEALTH CARE BENEFITS AND PAYMENT FOR
 26 PREMIUM FOR SUPPLEMENTAL BENEFITS.—

27 The provision of supplemental health care ben-
 28 efits described in section 1852(a)(3) in a man-
 29 ner specified under the plan, which may include
 30 the reduction of cost-sharing otherwise applica-
 31 ble as well as additional health care benefits
 32 which are not benefits under the original medi-
 33 care fee-for-service program option, or crediting
 34 toward an MA monthly supplemental bene-
 35 ficiary premium (if any).

36 “(II) PAYMENT FOR PREMIUM FOR PRE-
 37SCRIPTION DRUG COVERAGE.—Crediting to-

ward the MA monthly prescription drug beneficiary premium.

“(III) PAYMENT TOWARD PART B PREMIUM.—Crediting toward the premium imposed under part B (determined without regard to the application of subsections (b), (h), and (i) of section 1839).

“(iii) DISCLOSURE RELATING TO REBATES.—The plan shall disclose to the Secretary information on the form and amount of the rebate provided under this subparagraph or the actuarial value in the case of supplemental health care benefits.

“(iv) APPLICATION OF PART B PREMIUM REDUCTION.—Insofar as an MA organization elects to provide a rebate under this subparagraph under a plan as a credit toward the part B premium under clause (ii)(III), the Secretary shall apply such credit to reduce the premium under section 1839 of each enrollee in such plan as provided in section 1840(i).”.

(2) REVISION OF PREMIUM TERMINOLOGY.—Section 1854(b)(2) (42 U.S.C. 1395w-24(b)(2)) is amended—

(A) in the heading, by inserting “AND BID” after “PREMIUM”;

(B) by redesignating subparagraph (C) as subparagraph (D);

(C) by striking subparagraphs (A) and (B) and inserting the following:

“(A) MA MONTHLY BASIC BENEFICIARY PREMIUM.—The term ‘MA monthly basic beneficiary premium’ means, with respect to an MA plan—

“(i) described in section 1853(a)(1)(B)(i) (relating to plans providing rebates), zero; or

“(ii) described in section 1853(a)(1)(B)(ii), the amount (if any) by which the unadjusted MA statutory non-drug monthly bid amount (as defined in subparagraph (E)) exceeds the applicable

1 unadjusted MA area-specific non-drug monthly
2 benchmark amount (as defined in section 1853(j)).

3 “(B) MA MONTHLY PRESCRIPTION DRUG BENE-
4 FICIARY PREMIUM.—The term ‘MA monthly prescrip-
5 tion drug beneficiary premium’ means, with respect to
6 an MA plan, the base beneficiary premium (as deter-
7 mined under section 1860D–13(a)(2) and as adjusted
8 under section 1860D–13(a)(1)(B)), less the amount of
9 rebate credited toward such amount under section
10 1854(b)(1)(C)(ii)(II).

11 “(C) MA MONTHLY SUPPLEMENTAL BENEFICIARY
12 PREMIUM.—The term ‘MA monthly supplemental bene-
13 ficiary premium’ means, with respect to an MA plan,
14 the portion of the aggregate monthly bid amount sub-
15 mitted under clause (i) of subsection (a)(6)(A) for the
16 year that is attributable under clause (ii)(III) of such
17 subsection to the provision of supplemental health care
18 benefits, less the amount of rebate credited toward
19 such portion under section 1854(b)(1)(C)(ii)(I).”;

20 (D) by adding at the end the following:

21 “(E) UNADJUSTED MA STATUTORY NON-DRUG
22 MONTHLY BID AMOUNT.—The term ‘unadjusted MA
23 statutory non-drug monthly bid amount’ means the
24 portion of the bid amount submitted under clause (i)
25 of subsection (a)(6)(A) for the year that is attributable
26 under clause (ii)(I) of such subsection to the provision
27 of benefits under the original medicare fee-for-service
28 program option (as defined in section 1852(a)(1)(B)).”.

29 (3) COMPUTATION OF SAVINGS.—Section 1854(b) (42
30 U.S.C. 1395w–24(b)) is further amended by adding at the
31 end the following new paragraphs:

32 “(3) COMPUTATION OF AVERAGE PER CAPITA MONTH-
33 LY SAVINGS FOR LOCAL PLANS.—For purposes of para-
34 graph (1)(C)(i), the average per capita monthly savings re-
35 ferred to in such paragraph for an MA local plan and year
36 is computed as follows:

1 “(A) DETERMINATION OF STATEWIDE AVERAGE
2 RISK ADJUSTMENT FOR LOCAL PLANS.—

3 “(i) IN GENERAL.—Subject to clause (iii), the
4 Secretary shall determine, at the same time rates
5 are promulgated under section 1853(b)(1) (begin-
6 ning with 2006) for each State, the average of the
7 risk adjustment factors to be applied under section
8 1853(a)(1)(C) to payment for enrollees in that
9 State for MA local plans.

10 “(ii) TREATMENT OF STATES FOR FIRST YEAR
11 IN WHICH LOCAL PLAN OFFERED.—In the case of
12 a State in which no MA local plan was offered in
13 the previous year, the Secretary shall estimate such
14 average. In making such estimate, the Secretary
15 may use average risk adjustment factors applied to
16 comparable States or applied on a national basis.

17 “(iii) AUTHORITY TO DETERMINE RISK AD-
18 JUSTMENT FOR AREAS OTHER THAN STATES.—The
19 Secretary may provide for the determination and
20 application of risk adjustment factors under this
21 subparagraph on the basis of areas other than
22 States or on a plan-specific basis.

23 “(B) DETERMINATION OF RISK ADJUSTED BENCH-
24 MARK AND RISK-ADJUSTED BID FOR LOCAL PLANS.—
25 For each MA plan offered in a local area in a State,
26 the Secretary shall—

27 “(i) adjust the applicable MA area-specific
28 non-drug monthly benchmark amount (as defined
29 in section 1853(j)(1)) for the area by the average
30 risk adjustment factor computed under subpara-
31 graph (A); and

32 “(ii) adjust the unadjusted MA statutory non-
33 drug monthly bid amount by such applicable aver-
34 age risk adjustment factor.

35 “(C) DETERMINATION OF AVERAGE PER CAPITA
36 MONTHLY SAVINGS.—The average per capita monthly

1 savings described in this subparagraph for an MA local
2 plan is equal to the amount (if any) by which—

3 “(i) the risk-adjusted benchmark amount com-
4 puted under subparagraph (B)(i); exceeds

5 “(ii) the risk-adjusted bid computed under
6 subparagraph (B)(ii).

7 “(4) COMPUTATION OF AVERAGE PER CAPITA MONTH-
8 LY SAVINGS FOR REGIONAL PLANS.—For purposes of para-
9 graph (1)(C)(i), the average per capita monthly savings re-
10 ferred to in such paragraph for an MA regional plan and
11 year is computed as follows:

12 “(A) DETERMINATION OF REGIONWIDE AVERAGE
13 RISK ADJUSTMENT FOR REGIONAL PLANS.—

14 “(i) IN GENERAL.—The Secretary shall deter-
15 mine, at the same time rates are promulgated
16 under section 1853(b)(1) (beginning with 2006) for
17 each MA region the average of the risk adjustment
18 factors to be applied under section 1853(a)(1)(C)
19 to payment for enrollees in that region for MA re-
20 gional plans.

21 “(ii) TREATMENT OF REGIONS FOR FIRST
22 YEAR IN WHICH REGIONAL PLAN OFFERED.—In
23 the case of an MA region in which no MA regional
24 plan was offered in the previous year, the Secretary
25 shall estimate such average. In making such esti-
26 mate, the Secretary may use average risk adjust-
27 ment factors applied to comparable regions or ap-
28 plied on a national basis.

29 “(iii) AUTHORITY TO DETERMINE RISK AD-
30 JUSTMENT FOR AREAS OTHER THAN REGIONS.—
31 The Secretary may provide for the determination
32 and application of risk adjustment factors under
33 this subparagraph on the basis of areas other than
34 MA regions or on a plan-specific basis.

35 “(B) DETERMINATION OF RISK-ADJUSTED BENCH-
36 MARK AND RISK-ADJUSTED BID FOR REGIONAL

1 PLANS.—For each MA regional plan offered in a re-
 2 gion, the Secretary shall—

3 “(i) adjust the applicable MA area-specific
 4 non-drug monthly benchmark amount (as defined
 5 in section 1853(j)(2)) for the region by the average
 6 risk adjustment factor computed under subpara-
 7 graph (A); and

8 “(ii) adjust the unadjusted MA statutory non-
 9 drug monthly bid amount by such applicable aver-
 10 age risk adjustment factor.

11 “(C) DETERMINATION OF AVERAGE PER CAPITA
 12 MONTHLY SAVINGS.—The average per capita monthly
 13 savings described in this subparagraph for an MA re-
 14 gional plan is equal to the amount (if any) by which—

15 “(i) the risk-adjusted benchmark amount com-
 16 puted under subparagraph (B)(i); exceeds

17 “(ii) the risk-adjusted bid computed under
 18 subparagraph (B)(ii).”.

19 (c) COLLECTION OF PREMIUMS.—Section 1854(d) (42
 20 U.S.C. 1395w-24(d)) is amended—

21 (1) by striking “PREMIUMS.—Each” and inserting
 22 “PREMIUMS.—

23 “(1) IN GENERAL.—Each”; and

24 (2) by adding at the end the following new para-
 25 graphs:

26 “(2) BENEFICIARY’S OPTION OF PAYMENT THROUGH
 27 WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE
 28 OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In ac-
 29 cordance with regulations, an MA organization shall permit
 30 each enrollee, at the enrollee’s option, to make payment of
 31 premiums (if any) under this part to the organization
 32 through—

33 “(A) withholding from benefit payments in the
 34 manner provided under section 1840 with respect to
 35 monthly premiums under section 1839;

1 “(B) an electronic funds transfer mechanism (such
2 as automatic charges of an account at a financial insti-
3 tution or a credit or debit card account); or

4 “(C) such other means as the Secretary may speci-
5 fy, including payment by an employer or under employ-
6 ment-based retiree health coverage (as defined in sec-
7 tion 1860D–22(c)(1)) on behalf of an employee or
8 former employee (or dependent).

9 All premium payments that are withheld under subpara-
10 graph (A) shall be credited to the appropriate Trust Fund
11 (or Account thereof), as specified by the Secretary, under
12 this title and shall be paid to the MA organization involved.
13 No charge may be imposed under an MA plan with respect
14 to the election of the payment option described in subpara-
15 graph (A). The Secretary shall consult with the Commis-
16 sioner of Social Security and the Secretary of the Treasury
17 regarding methods for allocating premiums withheld under
18 subparagraph (A) among the appropriate Trust Funds and
19 Account.

20 “(3) INFORMATION NECESSARY FOR COLLECTION.—In
21 order to carry out paragraph (2)(A) with respect to an en-
22 rollee who has elected such paragraph to apply, the Sec-
23 retary shall transmit to the Commissioner of Social
24 Security—

25 “(A) by the beginning of each year, the name, so-
26 cial security account number, consolidated monthly
27 beneficiary premium described in paragraph (4) owed
28 by such enrollee for each month during the year, and
29 other information determined appropriate by the Sec-
30 retary, in consultation with the Commissioner of Social
31 Security; and

32 “(B) periodically throughout the year, information
33 to update the information previously transmitted under
34 this paragraph for the year.

35 “(4) CONSOLIDATED MONTHLY BENEFICIARY PRE-
36 MIUM.—In the case of an enrollee in an MA plan, the Sec-
37 retary shall provide a mechanism for the consolidation of—

1 “(A) the MA monthly basic beneficiary premium
2 (if any);

3 “(B) the MA monthly supplemental beneficiary
4 premium (if any); and

5 “(C) the MA monthly prescription drug bene-
6 ficiary premium (if any).”.

7 (d) COMPUTATION OF MA AREA-SPECIFIC NON-DRUG
8 BENCHMARK.—Section 1853 (42 U.S.C. 1395w-23) is amend-
9 ed by adding at the end the following new subsection:

10 “(j) COMPUTATION OF BENCHMARK AMOUNTS.—For pur-
11 poses of this part, the term ‘MA area-specific non-drug month-
12 ly benchmark amount’ means for a month in a year—

13 “(1) with respect to—

14 “(A) a service area that is entirely within an MA
15 local area, an amount equal to $\frac{1}{12}$ of the annual MA
16 capitation rate under section 1853(c)(1) for the area
17 for the year, adjusted as appropriate for the purpose of
18 risk adjustment; or

19 “(B) a service area that includes more than one
20 MA local area, an amount equal to the average of the
21 amounts described in subparagraph (A) for each such
22 local MA area, weighted by the projected number of en-
23 rollees in the plan residing in the respective local MA
24 areas (as used by the plan for purposes of the bid and
25 disclosed to the Secretary under section
26 1854(a)(6)(A)(iii)), adjusted as appropriate for the
27 purpose of risk adjustment; or

28 “(2) with respect to an MA region for a month in a
29 year, the MA region-specific non-drug monthly benchmark
30 amount, as defined in section 1858(f) for the region for the
31 year.”.

32 (e) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

33 (1) IN GENERAL.—Section 1853(a)(1) (42 U.S.C.
34 1395w-23(a)(1)) (42 U.S.C. 1395w-23) is amended—

35 (A) by redesignating subparagraph (B) as sub-
36 paragraph (H); and

1 (B) in subparagraph (A), by striking “in an
2 amount” and all that follows and inserting the fol-
3 lowing: “in an amount determined as follows:

4 “(i) PAYMENT BEFORE 2006.—For years be-
5 fore 2006, the payment amount shall be equal to
6 $\frac{1}{12}$ of the annual MA capitation rate (as calculated
7 under subsection (c)(1)) with respect to that indi-
8 vidual for that area, adjusted under subparagraph
9 (C) and reduced by the amount of any reduction
10 elected under section 1854(f)(1)(E).

11 “(ii) PAYMENT FOR ORIGINAL FEE-FOR-SERV-
12 ICE BENEFITS BEGINNING WITH 2006.—For years
13 beginning with 2006, the amount specified in sub-
14 paragraph (B).

15 “(B) PAYMENT AMOUNT FOR ORIGINAL FEE-FOR-
16 SERVICE BENEFITS BEGINNING WITH 2006.—

17 “(i) PAYMENT OF BID FOR PLANS WITH BIDS
18 BELOW BENCHMARK.—In the case of a plan for
19 which there are average per capita monthly savings
20 described in section 1854(b)(3)(C) or
21 1854(b)(4)(C), as the case may be, the amount
22 specified in this subparagraph is equal to the
23 unadjusted MA statutory non-drug monthly bid
24 amount, adjusted under subparagraph (C) and (if
25 applicable) under subparagraphs (F) and (G), plus
26 the amount (if any) of any rebate under subpara-
27 graph (E).

28 “(ii) PAYMENT OF BENCHMARK FOR PLANS
29 WITH BIDS AT OR ABOVE BENCHMARK.—In the
30 case of a plan for which there are no average per
31 capita monthly savings described in section
32 1854(b)(3)(C) or 1854(b)(4)(C), as the case may
33 be, the amount specified in this subparagraph is
34 equal to the MA area-specific non-drug monthly
35 benchmark amount, adjusted under subparagraph
36 (C) and (if applicable) under subparagraphs (F)
37 and (G).

1 “(iii) PAYMENT OF BENCHMARK FOR MSA
2 PLANS.—Notwithstanding clauses (i) and (ii), in
3 the case of an MSA plan, the amount specified in
4 this subparagraph is equal to the MA area-specific
5 non-drug monthly benchmark amount, adjusted
6 under subparagraph (C).

7 “(C) DEMOGRAPHIC ADJUSTMENT, INCLUDING AD-
8 JUSTMENT FOR HEALTH STATUS.—The Secretary shall
9 adjust the payment amount under subparagraph (A)(i)
10 and the amount specified under subparagraph (B)(i),
11 (B)(ii), and (B)(iii) for such risk factors as age, dis-
12 ability status, gender, institutional status, and such
13 other factors as the Secretary determines to be appro-
14 priate, including adjustment for health status under
15 paragraph (3), so as to ensure actuarial equivalence.
16 The Secretary may add to, modify, or substitute for
17 such adjustment factors if such changes will improve
18 the determination of actuarial equivalence.

19 “(D) SEPARATE PAYMENT FOR FEDERAL DRUG
20 SUBSIDIES.—In the case of an enrollee in an MA–PD
21 plan, the MA organization offering such plan also
22 receives—

23 “(i) subsidies under section 1860D–15 (other
24 than under subsection (g)); and

25 “(ii) reimbursement for premium and cost-
26 sharing reductions for low-income individuals under
27 section 1860D–14(c)(1)(C).

28 “(E) PAYMENT OF REBATE FOR PLANS WITH BIDS
29 BELOW BENCHMARK.—In the case of a plan for which
30 there are average per capita monthly savings described
31 in section 1854(b)(3)(C) or 1854(b)(4)(C), as the case
32 may be, the amount specified in this subparagraph is
33 the amount of the monthly rebate computed under sec-
34 tion 1854(b)(1)(C)(i) for that plan and year (as re-
35 duced by the amount of any credit provided under sec-
36 tion 1854(b)(1)(C)(iv)).

1 “(F) ADJUSTMENT FOR INTRA-AREA VARI-
2 ATIONS.—

3 “(i) INTRA-REGIONAL VARIATIONS.—In the
4 case of payment with respect to an MA regional
5 plan for an MA region, the Secretary shall also ad-
6 just the amounts specified under subparagraphs
7 (B)(i) and (B)(ii) in a manner to take into account
8 variations in MA local payment rates under this
9 part among the different MA local areas included
10 in such region.

11 “(ii) INTRA-SERVICE AREA VARIATIONS.—In
12 the case of payment with respect to an MA local
13 plan for a service area that covers more than one
14 MA local area, the Secretary shall also adjust the
15 amounts specified under subparagraphs (B)(i) and
16 (B)(ii) in a manner to take into account variations
17 in MA local payment rates under this part among
18 the different MA local areas included in such serv-
19 ice area.

20 “(G) ADJUSTMENT RELATING TO RISK ADJUST-
21 MENT.—The Secretary shall adjust payments with re-
22 spect to MA plans as necessary to ensure that—

23 “(i) the sum of—

24 “(I) the monthly payment made under
25 subparagraph (A)(ii); and

26 “(II) the MA monthly basic beneficiary
27 premium under section 1854(b)(2)(A); equals

28 “(ii) the unadjusted MA statutory non-drug
29 monthly bid amount, adjusted in the manner de-
30 scribed in subparagraph (C) and, for an MA re-
31 gional plan, subparagraph (F).”.

32 (f) CONFORMING CHANGES TO ANNUAL ANNOUNCEMENT
33 PROCESS.—Section 1853(b) (42 U.S.C. 1395w-23(b)(1)) is
34 amended—

35 (1) by amending paragraph (1) to read as follows:

36 “(1) ANNUAL ANNOUNCEMENTS.—

1 “(A) FOR 2005.—The Secretary shall determine,
2 and shall announce (in a manner intended to provide
3 notice to interested parties), not later than the second
4 Monday in May of 2004, with respect to each MA pay-
5 ment area, the following:

6 “(i) MA CAPITATION RATES.—The annual MA
7 capitation rate for each MA payment area for
8 2005.

9 “(ii) ADJUSTMENT FACTORS.—The risk and
10 other factors to be used in adjusting such rates
11 under subsection (a)(1)(C) for payments for
12 months in 2005.

13 “(B) FOR 2006 AND SUBSEQUENT YEARS.—For a
14 year after 2005—

15 “(i) INITIAL ANNOUNCEMENT.—The Secretary
16 shall determine, and shall announce (in a manner
17 intended to provide notice to interested parties),
18 not later than the first Monday in April before the
19 calendar year concerned, with respect to each MA
20 payment area, the following:

21 “(I) MA CAPITATION RATES; MA LOCAL
22 AREA BENCHMARK.—The annual MA capita-
23 tion rate for each MA payment area for the
24 year.

25 “(II) ADJUSTMENT FACTORS.—The risk
26 and other factors to be used in adjusting such
27 rates under subsection (a)(1)(C) for payments
28 for months in such year.

29 “(ii) REGIONAL BENCHMARK ANNOUNCE-
30 MENT.—The Secretary shall determine, and shall
31 announce (in a manner intended to provide notice
32 to interested parties), on a timely basis before the
33 calendar year concerned, with respect to each MA
34 region and each MA regional plan for which a bid
35 was submitted under section 1854, the MA region-
36 specific non-drug monthly benchmark amount for
37 that region for the year involved.”; and

1 (2) in paragraph (3), by striking “in the announce-
2 ment” and all that follows and inserting “in such an-
3 nouncement.”.

4 (g) OTHER AMENDMENTS RELATING TO PREMIUMS AND
5 BID AMOUNTS.—

6 (1) IN GENERAL.—Section 1854 (42 U.S.C. 1395w-
7 24) is amended—

8 (A) by amending the section heading to read as
9 follows:

10 “PREMIUMS AND BID AMOUNTS”;

11 (B) in the heading of subsection (a), by inserting
12 “, BID AMOUNTS,” after “PREMIUMS”;

13 (C) in subsection (a)(2)—

14 (i) by inserting “BEFORE 2006” after “FOR CO-
15 ORDINATED CARE PLANS”; and

16 (ii) by inserting “for a year before 2006” after
17 “section 1851(a)(2)(A)”;

18 (D) in subsection (a)(3), by striking “described”
19 and inserting “for any year”;

20 (E) in subsection (a)(4)—

21 (i) by inserting “BEFORE 2006” after “FOR
22 PRIVATE FEE-FOR-SERVICE PLANS”; and

23 (ii) by inserting “for a year before 2006” after
24 “section 1852(a)(1)(A)”;

25 (F) in subsection (a)(5)(A), by inserting “para-
26 graphs (2) and (4) of” after “filed under”;

27 (G) in subsection (a)(5)(B), by inserting after
28 “paragraph (3) or” the following: “, in the case of an
29 MA private fee-for-service plan,”; and

30 (H) in subsection (b)(1)(A) by striking “and” and
31 inserting a comma and by inserting before the period
32 at the end the following: “, and, if the plan provides
33 qualified prescription drug coverage, the MA monthly
34 prescription drug beneficiary premium”.

35 (2) UNIFORMITY.—Section 1854(c) (42 U.S.C.
36 1395w-24(c)) is amended to read as follows:

1 “(c) UNIFORM PREMIUM AND BID AMOUNTS.—Except as
2 permitted under section 1857(i), the MA monthly bid amount
3 submitted under subsection (a)(6), the amounts of the MA
4 monthly basic, prescription drug, and supplemental beneficiary
5 premiums, and the MA monthly MSA premium charged under
6 subsection (b) of an MA organization under this part may not
7 vary among individuals enrolled in the plan.”.

8 (3) PREMIUMS.—Section 1854(d)(1) (42 U.S.C.
9 1395w-24(d)(1)), as amended by subsection (c)(1), is
10 amended by inserting “, prescription drug,” after “basic”.

11 (4) LIMITATION ON ENROLLEE LIABILITY.—Section
12 1854(e) (42 U.S.C. 1395w-24(e)) is amended—

13 (A) in paragraph (1), by striking “.—In” and in-
14 serting “BEFORE 2006.—For periods before 2006, in”;

15 (B) in paragraph (2), by striking “.—If” and in-
16 sert “BEFORE 2006.—For periods before 2006, if”;

17 (C) in paragraph (3), by striking “or (2)” and in-
18 serting “, (2), or (4)”; and

19 (D) in paragraph (4)—

20 (i) by inserting “AND FOR BASIC BENEFITS
21 BEGINNING IN 2006” after “PLANS”;

22 (ii) in the matter before subparagraph (A), by
23 inserting “and for periods beginning with 2006,
24 with respect to an MA plan described in section
25 1851(a)(2)(A)” after “MSA plan”;

26 (iii) in subparagraph (A), by striking “re-
27 quired benefits described in section 1852(a)(1)”
28 and inserting “benefits under the original medicare
29 fee-for-service program option”; and

30 (iv) in subparagraph (B), by inserting “with
31 respect to such benefits” after “would be applica-
32 ble”.

33 (5) MODIFICATION OF ACR PROCESS.—Section 1854(f)
34 (42 U.S.C. 1395w-24(f)) is amended—

35 (A) in the heading, by inserting “BEFORE 2006”
36 after “ADDITIONAL BENEFITS”; and

1 (B) in paragraph (1)(A), by striking “Each” and
 2 inserting “For years before 2006, each”.

3 (h) PLAN INCENTIVES.—Section 1852(j)(4) (42 U.S.C.
 4 1395w–22(j)(4)) is amended—

5 (1) by inserting “the organization provides assurances
 6 satisfactory to the Secretary that” after “unless”;

7 (2) in clause (ii)—

8 (A) by striking “the organization—” and all that
 9 follows through “(I) provides” and inserting “the orga-
 10 nization provides”;

11 (B) by striking “, and” and inserting a period;
 12 and

13 (C) by striking subclause (II); and

14 (3) by striking clause (iii).

15 (i) CONTINUATION OF TREATMENT OF ENROLLEES WITH
 16 END-STAGE RENAL DISEASE.—Section 1853(a)(1)(H), as re-
 17 designated under subsection (d)(1)(A), is amended—

18 (1) by amending the second sentence to read as fol-
 19 lows: “Such rates of payment shall be actuarially equivalent
 20 to rates that would have been paid with respect to other
 21 enrollees in the MA payment area (or such other area as
 22 specified by the Secretary) under the provisions of this sec-
 23 tion as in effect before the date of the enactment of the
 24 Medicare Prescription Drug, Improvement, and Moderniza-
 25 tion Act of 2003.”; and

26 (2) by adding at the end the following new sentence:
 27 “The Secretary may apply the competitive bidding method-
 28 ology provided for in this section, with appropriate adjust-
 29 ments to account for the risk adjustment methodology ap-
 30 plied to end stage renal disease payments.”.

31 (j) FACILITATION OF EMPLOYER SPONSORSHIP OF MA
 32 PLANS.—Section 1857(i) (42 U.S.C. 1395w–27(i)) is
 33 amended—

34 (1) by designating the matter following the heading as
 35 a paragraph (1) with the heading “CONTRACTS WITH MA
 36 ORGANIZATIONS.—” and appropriate indentation; and

37 (2) by adding at the end the following new paragraph:

1 “(2) EMPLOYER SPONSORED MA PLANS.—To facilitate
 2 the offering of MA plans by employers, labor organizations,
 3 or the trustees of a fund established by one or more em-
 4 ployers or labor organizations (or combination thereof) to
 5 furnish benefits to the entity’s employees, former employees
 6 (or combination thereof) or members or former members
 7 (or combination thereof) of the labor organizations, the
 8 Secretary may waive or modify requirements that hinder
 9 the design of, the offering of, or the enrollment in such MA
 10 plans. Notwithstanding section 1851(g), an MA plan de-
 11 scribed in the previous sentence may restrict the enrollment
 12 of individuals under this part to individuals who are bene-
 13 ficiaries and participants in such plan.”.

14 (k) EXPANSION OF MEDICARE BENEFICIARY EDUCATION
 15 AND INFORMATION CAMPAIGN.—Section 1857(e)(2) (42 U.S.C.
 16 1395w–27(e)(2)) is amended—

17 (1) in subparagraph (A) by inserting “and a PDP
 18 sponsor under part D” after “organization”;

19 (2) in subparagraph (B)—

20 (A) by inserting “and each PDP sponsor with a
 21 contract under part D” after “contract under this
 22 part”;

23 (B) by inserting “or sponsor’s” after “organiza-
 24 tion’s”; and

25 (C) by inserting “, section 1860D–1(c),” after “in-
 26 formation”;

27 (3) in subparagraph (C)—

28 (A) by inserting “and ending with fiscal year
 29 2005” after “beginning with fiscal year 2001”;

30 (B) by inserting “and for each fiscal year begin-
 31 ning with fiscal year 2006 an amount equal to
 32 \$200,000,000,” after “\$100,000,000,”; and

33 (C) by inserting “and section 1860D–
 34 12(b)(3)(D)” after “under this paragraph”;

35 (4) in subparagraph (D)—

36 (A) in clause (i) by inserting “and section 1860D–
 37 1(c)” after “section 1851”;

1 (B) in clause (ii)(III), by striking “and” at the
2 end of subclause (III);

3 (C) in clause (ii)(IV), by striking “each succeeding
4 fiscal year.” and inserting “each succeeding fiscal year
5 before fiscal year 2006; and”; and

6 (D) in clause (ii), by adding at the end the fol-
7 lowing new subclause:

8 “(V) the applicable portion (as defined in sub-
9 paragraph (F)) of \$200,000,000 in fiscal year
10 2006 and each succeeding fiscal year.”; and

11 (5) by adding at the end the following new subpara-
12 graph:

13 “(F) APPLICABLE PORTION DEFINED.—In this
14 paragraph, the term ‘applicable portion’ means, for a
15 fiscal year—

16 “(i) with respect to MA organizations, the Sec-
17 retary’s estimate of the total proportion of expendi-
18 tures under this title that are attributable to ex-
19 penditures made under this part (including pay-
20 ments under part D that are made to such organi-
21 zations); or

22 “(ii) with respect to PDP sponsors, the Sec-
23 retary’s estimate of the total proportion of expendi-
24 tures under this title that are attributable to ex-
25 penditures made to such sponsors under part D.”.

26 (I) CONFORMING AMENDMENTS.—

27 (1) PROTECTION AGAINST BENEFICIARY SELECTION.—
28 Section 1852(b)(1)(A) (42 U.S.C. 1395w-22(b)(1)(A)) is
29 amended by adding at the end the following: “The Sec-
30 retary shall not approve a plan of an organization if the
31 Secretary determines that the design of the plan and its
32 benefits are likely to substantially discourage enrollment by
33 certain MA eligible individuals with the organization.”.

34 (2) RELATING TO REBATES.—

35 (A) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is
36 amended by striking “80 percent of any reduction
37 elected under section 1854(f)(1)(E)” and inserting

1 “any credit provided under section
2 1854(b)(1)(C)(ii)(III)”.

3 (B) The first sentence of section 1840(i) (42
4 U.S.C. 1395s(i)) is amended by inserting “and to re-
5 flect any credit provided under section
6 1854(b)(1)(C)(iv)” after “section 1854(f)(1)(E)”.

7 (C) Section 1844(c) (42 U.S.C. 1395w(e)) is
8 amended by inserting “or any credits provided under
9 section 1854(b)(1)(C)(iv)” after “section
10 1854(f)(1)(E)”.

11 (3) OTHER CONFORMING AND TECHNICAL AMEND-
12 MENTS.—

13 (A) Section 1851(b)(1) (42 U.S.C. 1395w-
14 21(b)(1)) is amended—

15 (i) in subparagraph (B), by striking “a plan”
16 and inserting “an MA local plan”;

17 (ii) in subparagraph (B), by striking “basic
18 benefits described in section 1852(a)(1)(A)” and
19 inserting “benefits under the original medicare fee-
20 for-service program option”; and

21 (iii) in subparagraph (C), by striking “in a
22 Medicare+Choice plan” and inserting “in an MA
23 local plan”.

24 (B) Section 1851(d) (42 U.S.C. 1395w-21(d)) is
25 amended—

26 (i) in paragraph (3), by adding at the end the
27 following new subparagraph:

28 “(F) CATASTROPHIC COVERAGE AND SINGLE DE-
29 DUCTIBLE.—In the case of an MA regional plan, a de-
30 scription of the catastrophic coverage and single de-
31 ductible applicable under the plan.”;

32 (ii) in paragraph (4)(A)(ii), by inserting “, in-
33 cluding information on the single deductible (if ap-
34 plicable) under section 1858(b)(1)” after “cost
35 sharing”;

36 (iii) in paragraph (4)(B)(i), by striking
37 “Medicare+Choice monthly basic” and all that fol-

1 lows and inserting “monthly amount of the pre-
2 mium charged to an individual.”; and

3 (iv) by amending subparagraph (E) of sub-
4 section (d)(4) to read as follows:

5 “(E) SUPPLEMENTAL BENEFITS.—Supplemental
6 health care benefits, including any reductions in cost-
7 sharing under section 1852(a)(3) and the terms and
8 conditions (including premiums) for such benefits.”.

9 (C) Section 1857(d)(1) (42 U.S.C. 1395w-
10 27(d)(1)) is amended by striking “, costs, and com-
11 putation of the adjusted community rate” and inserting
12 “and costs, including allowable costs under section
13 1858(c)”.

14 (D) Section 1851(a)(3)(B)(ii) (42 U.S.C. 1395w-
15 21(a)(3)(B)(ii)) is amended by striking “section
16 1851(e)(4)(A)” and inserting “subsection (e)(4)(A)”.

17 (E) Section 1851(f)(1) (42 U.S.C. 1395w-
18 21(f)(1)) is amended by striking “subsection (e)(1)(A)”
19 and inserting “subsection (e)(1)”.

20 **SEC. 223. EFFECTIVE DATE.**

21 (a) EFFECTIVE DATE.—The amendments made by this
22 subtitle shall apply with respect to plan years beginning on or
23 after January 1, 2006.

24 (b) ISSUANCE OF REGULATIONS.—The Secretary shall re-
25 vise the regulations previously promulgated to carry out part
26 C of title XVIII of the Social Security Act to carry out the pro-
27 visions of this Act.

28 **Subtitle D—Additional Reforms**

29 **SEC. 231. SPECIALIZED MA PLANS FOR SPECIAL NEEDS**
30 **INDIVIDUALS.**

31 (a) TREATMENT AS COORDINATED CARE PLAN.—Section
32 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)), as amended by
33 section 221(a), is amended by adding at the end the following
34 new clause:

35 “(ii) SPECIALIZED MA PLANS FOR SPECIAL
36 NEEDS INDIVIDUALS.—Specialized MA plans for
37 special needs individuals (as defined in section

1 1859(b)(6)) may be any type of coordinated care
2 plan.”.

3 (b) SPECIALIZED MA PLAN FOR SPECIAL NEEDS INDIVID-
4 UALS DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)),
5 as amended by section 221(b), is amended by adding at the end
6 the following new paragraph:

7 “(6) SPECIALIZED MA PLANS FOR SPECIAL NEEDS IN-
8 DIVIDUALS.—

9 “(A) IN GENERAL.—The term ‘specialized MA
10 plan for special needs individuals’ means an MA plan
11 that exclusively serves special needs individuals (as de-
12 fined in subparagraph (B)).

13 “(B) SPECIAL NEEDS INDIVIDUAL.—The term
14 ‘special needs individual’ means an MA eligible indi-
15 vidual who—

16 “(i) is institutionalized (as defined by the Sec-
17 retary);

18 “(ii) is entitled to medical assistance under a
19 State plan under title XIX; or

20 “(iii) meets such requirements as the Sec-
21 retary may determine would benefit from enroll-
22 ment in such a specialized MA plan described in
23 subparagraph (A) for individuals with severe or dis-
24 abling chronic conditions.

25 The Secretary may waive application of section
26 1851(a)(3)(B) in the case of an individual described in
27 clause (i), (ii), or (iii) of this subparagraph and may
28 apply rules similar to the rules of section 1894(c)(4)
29 for continued eligibility of special needs individuals.”.

30 (c) RESTRICTION ON ENROLLMENT PERMITTED.—Section
31 1859 (42 U.S.C. 1395w–29) is amended by adding at the end
32 the following new subsection:

33 “(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED
34 MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—In the case of
35 a specialized MA plan for special needs individuals (as defined
36 in subsection (b)(6)), notwithstanding any other provision of
37 this part and in accordance with regulations of the Secretary

1 and for periods before January 1, 2009, the plan may restrict
 2 the enrollment of individuals under the plan to individuals who
 3 are within one or more classes of special needs individuals.”.

4 (d) **AUTHORITY TO DESIGNATE OTHER PLANS AS SPE-**
 5 **CIALIZED MA PLANS.**—In promulgating regulations to carry
 6 out section 1851(a)(2)(A)(ii) of the Social Security Act (as
 7 added by subsection (a)) and section 1859(b)(6) of such Act
 8 (as added by subsection (b)), the Secretary may provide (not-
 9 withstanding section 1859(b)(6)(A) of such Act) for the offer-
 10 ing of specialized MA plans for special needs individuals by MA
 11 plans that disproportionately serve special needs individuals.

12 (e) **REPORT TO CONGRESS.**—Not later than December 31,
 13 2007, the Secretary shall submit to Congress a report that as-
 14 sesses the impact of specialized MA plans for special needs in-
 15 dividuals on the cost and quality of services provided to enroll-
 16 ees. Such report shall include an assessment of the costs and
 17 savings to the medicare program as a result of amendments
 18 made by subsections (a), (b), and (c).

19 (f) **EFFECTIVE DATES.**—

20 (1) **IN GENERAL.**—The amendments made by sub-
 21 sections (a), (b), and (c) shall take effect upon the date of
 22 the enactment of this Act.

23 (2) **DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR**
 24 **SPECIAL NEEDS INDIVIDUALS; TRANSITION.**—No later than
 25 1 year after the date of the enactment of this Act, the Sec-
 26 retary shall issue final regulations to establish requirements
 27 for special needs individuals under section
 28 1859(b)(6)(B)(iii) of the Social Security Act, as added by
 29 subsection (b).

30 **SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.**

31 (a) **IN GENERAL.**—Section 1856(b)(3) (42 U.S.C. 1395w-
 32 26(b)(3)) is amended to read as follows:

33 “(3) **RELATION TO STATE LAWS.**—The standards es-
 34 tablished under this part shall supersede any State law or
 35 regulation (other than State licensing laws or State laws
 36 relating to plan solvency) with respect to MA plans which
 37 are offered by MA organizations under this part.”.

1 (b) CONFORMING AMENDMENT.—Section 1854(g) (42
2 U.S.C. 1395w-24(g)) is amended by inserting “or premiums
3 paid to such organizations under this part” after “section
4 1853”.

5 (c) EFFECTIVE DATE.—The amendments made by this
6 subsection shall take effect on the date of the enactment of this
7 Act.

8 **SEC. 233. MEDICARE MSAS.**

9 (a) EXEMPTION FROM REPORTING REQUIREMENT.—

10 (1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C.
11 1395w-22(e)(1)) is amended by inserting “(other than
12 MSA plans)” after “plans”.

13 (2) CONFORMING AMENDMENTS.—Section 1852 (42
14 U.S.C. 1395w-22) is amended—

15 (A) in subsection (c)(1)(I), by inserting before the
16 period at the end the following: “, if required under
17 such section”; and

18 (B) in subsection (e)(2)(A), by striking “, a non-
19 network MSA plan,”; and

20 (C) in subsection (e)(2)(B), by striking “, NON-
21 NETWORK MSA PLANS,” and “, a non-network MSA
22 plan,”.

23 (3) EFFECTIVE DATE.—The amendments made by
24 this subsection shall apply on and after the date of the en-
25 actment of this Act but shall not apply to contract years
26 beginning on or after January 1, 2006.

27 (b) MAKING PROGRAM PERMANENT AND ELIMINATING
28 CAP.—Section 1851(b)(4) (42 U.S.C. 1395w-21(b)(4)) is
29 amended—

30 (1) in the heading, by striking “ON A DEMONSTRATION
31 BASIS”;

32 (2) by striking the first sentence of subparagraph (A);
33 and

34 (3) by striking the second sentence of subparagraph
35 (C).

36 (c) APPLYING LIMITATIONS ON BALANCE BILLING.—Sec-
37 tion 1852(k)(1) (42 U.S.C. 1395w-22(k)(1)) is amended by in-

1 serting “or with an organization offering an MSA plan” after
2 “section 1851(a)(2)(A)”.

3 (d) ADDITIONAL AMENDMENT.—Section 1851(e)(5)(A)
4 (42 U.S.C. 1395w-21(e)(5)(A)) is amended—

5 (1) by adding “or” at the end of clause (i);

6 (2) by striking “, or” at the end of clause (ii) and in-
7 serting a semicolon; and

8 (3) by striking clause (iii).

9 **SEC. 234. EXTENSION OF REASONABLE COST CON-**
10 **TRACTS.**

11 Subparagraph (C) of section 1876(h)(5) (42 U.S.C.
12 1395mm(h)(5)) is amended to read as follows:

13 “(C)(i) Subject to clause (ii), a reasonable cost reimburse-
14 ment contract under this subsection may be extended or re-
15 newed indefinitely.

16 “(ii) For any period beginning on or after January 1,
17 2008, a reasonable cost reimbursement contract under this sub-
18 section may not be extended or renewed for a service area inso-
19 far as such area during the entire previous year was within the
20 service area of—

21 “(I) 2 or more MA regional plans described in clause
22 (iii); or

23 “(II) 2 or more MA local plans described in clause
24 (iii).

25 “(iii) A plan described in this clause for a year for a serv-
26 ice area is a plan described in section 1851(a)(2)(A)(i) if the
27 service area for the year meets the following minimum enroll-
28 ment requirements:

29 “(I) With respect to any portion of the area involved
30 that is within a Metropolitan Statistical Area with a popu-
31 lation of more than 250,000 and counties contiguous to
32 such Metropolitan Statistical Area, 5,000 individuals.

33 “(II) With respect to any other portion of such area,
34 1,500 individuals.”

1 **SEC. 235. 2-YEAR EXTENSION OF MUNICIPAL HEALTH**
 2 **SERVICE DEMONSTRATION PROJECTS.**

3 The last sentence of section 9215(a) of the Consolidated
 4 Omnibus Budget Reconciliation Act of 1985 (42 U.S.C.
 5 1395b-1 note), as amended by section 6135 of the Omnibus
 6 Budget Reconciliation Act of 1989, section 13557 of the Omni-
 7 bus Budget Reconciliation Act of 1993, section 4017 of BBA,
 8 section 534 of BBRA (113 Stat. 1501A-390), and section 633
 9 of BIPA, is amended by striking “December 31, 2004” and in-
 10 serting “December 31, 2006”.

11 **SEC. 236. PAYMENT BY PACE PROVIDERS FOR MEDI-**
 12 **CARE AND MEDICAID SERVICES FURNISHED**
 13 **BY NONCONTRACT PROVIDERS.**

14 (a) MEDICARE SERVICES.—

15 (1) MEDICARE SERVICES FURNISHED BY PROVIDERS
 16 OF SERVICES.—Section 1866(a)(1)(O) (42 U.S.C.
 17 1395cc(a)(1)(O)) is amended—

18 (A) by striking “part C or” and inserting “part C,
 19 with a PACE provider under section 1894 or 1934,
 20 or”;

21 (B) by striking “(i)”;

22 (C) by striking “and (ii)”;

23 (D) by inserting “(or, in the case of a PACE pro-
 24 vider, contract or other agreement)” after “have a con-
 25 tract”; and

26 (E) by striking “members of the organization”
 27 and inserting “members of the organization or PACE
 28 program eligible individuals enrolled with the PACE
 29 provider,”.

30 (2) MEDICARE SERVICES FURNISHED BY PHYSICIANS
 31 AND OTHER ENTITIES.—Section 1894(b) (42 U.S.C.
 32 1395eee(b)) is amended by adding at the end the following
 33 new paragraphs:

34 “(3) TREATMENT OF MEDICARE SERVICES FURNISHED
 35 BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

36 “(A) APPLICATION OF MEDICARE ADVANTAGE RE-
 37 QUIREMENT WITH RESPECT TO MEDICARE SERVICES

1 FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER
 2 ENTITIES.—Section 1852(k)(1) (relating to limitations
 3 on balance billing against MA organizations for non-
 4 contract physicians and other entities with respect to
 5 services covered under this title) shall apply to PACE
 6 providers, PACE program eligible individuals enrolled
 7 with such PACE providers, and physicians and other
 8 entities that do not have a contract or other agreement
 9 establishing payment amounts for services furnished to
 10 such an individual in the same manner as such section
 11 applies to MA organizations, individuals enrolled with
 12 such organizations, and physicians and other entities
 13 referred to in such section.

14 “(B) REFERENCE TO RELATED PROVISION FOR
 15 NONCONTRACT PROVIDERS OF SERVICES.—For the pro-
 16 vision relating to limitations on balance billing against
 17 PACE providers for services covered under this title
 18 furnished by noncontract providers of services, see sec-
 19 tion 1866(a)(1)(O).

20 “(4) REFERENCE TO RELATED PROVISION FOR SERV-
 21 ICES COVERED UNDER TITLE XIX BUT NOT UNDER THIS
 22 TITLE.—For provisions relating to limitations on payments
 23 to providers participating under the State plan under title
 24 XIX that do not have a contract or other agreement with
 25 a PACE provider establishing payment amounts for serv-
 26 ices covered under such plan (but not under this title) when
 27 such services are furnished to enrollees of that PACE pro-
 28 vider, see section 1902(a)(66).”.

29 (b) MEDICAID SERVICES.—

30 (1) REQUIREMENT UNDER STATE PLAN.—Section
 31 1902(a) (42 U.S.C. 1396a(a)), as amended by section
 32 103(a), is amended—

33 (A) in paragraph (65), by striking “and” at the
 34 end;

35 (B) in paragraph (66), by striking the period at
 36 the end and inserting “; and”; and

1 (C) by inserting after paragraph (66) the following
2 new paragraph:

3 “(67) provide, with respect to services covered under
4 the State plan (but not under title XVIII) that are fur-
5 nished to a PACE program eligible individual enrolled with
6 a PACE provider by a provider participating under the
7 State plan that does not have a contract or other agree-
8 ment with the PACE provider that establishes payment
9 amounts for such services, that such participating provider
10 may not require the PACE provider to pay the partici-
11 pating provider an amount greater than the amount that
12 would otherwise be payable for the service to the partici-
13 pating provider under the State plan for the State where
14 the PACE provider is located (in accordance with regula-
15 tions issued by the Secretary).”.

16 (2) APPLICATION UNDER MEDICAID.—Section 1934(b)
17 (42 U.S.C. 1396u–4(b)) is amended by adding at the end
18 the following new paragraphs:

19 “(3) TREATMENT OF MEDICARE SERVICES FURNISHED
20 BY NONCONTRACT PHYSICIANS AND OTHER ENTITIES.—

21 “(A) APPLICATION OF MEDICARE ADVANTAGE RE-
22 QUIREMENT WITH RESPECT TO MEDICARE SERVICES
23 FURNISHED BY NONCONTRACT PHYSICIANS AND OTHER
24 ENTITIES.—Section 1852(k)(1) (relating to limitations
25 on balance billing against MA organizations for non-
26 contract physicians and other entities with respect to
27 services covered under title XVIII) shall apply to
28 PACE providers, PACE program eligible individuals
29 enrolled with such PACE providers, and physicians and
30 other entities that do not have a contract or other
31 agreement establishing payment amounts for services
32 furnished to such an individual in the same manner as
33 such section applies to MA organizations, individuals
34 enrolled with such organizations, and physicians and
35 other entities referred to in such section.

36 “(B) REFERENCE TO RELATED PROVISION FOR
37 NONCONTRACT PROVIDERS OF SERVICES.—For the pro-

1 vision relating to limitations on balance billing against
 2 PACE providers for services covered under title XVIII
 3 furnished by noncontract providers of services, see sec-
 4 tion 1866(a)(1)(O).

5 “(4) REFERENCE TO RELATED PROVISION FOR SERV-
 6 ICES COVERED UNDER THIS TITLE BUT NOT UNDER TITLE
 7 XVIII.—For provisions relating to limitations on payments
 8 to providers participating under the State plan under this
 9 title that do not have a contract or other agreement with
 10 a PACE provider establishing payment amounts for serv-
 11 ices covered under such plan (but not under title XVIII)
 12 when such services are furnished to enrollees of that PACE
 13 provider, see section 1902(a)(67).”.

14 (c) EFFECTIVE DATE.—The amendments made by this
 15 section shall apply to services furnished on or after January 1,
 16 2004.

17 **SEC. 237. REIMBURSEMENT FOR FEDERALLY QUALI-**
 18 **FIED HEALTH CENTERS PROVIDING SERV-**
 19 **ICES UNDER MA PLANS.**

20 (a) REIMBURSEMENT.—Section 1833(a)(3) (42 U.S.C.
 21 1395l(a)(3)) is amended to read as follows:

22 “(3) in the case of services described in section
 23 1832(a)(2)(D)—

24 “(A) except as provided in subparagraph (B), the
 25 costs which are reasonable and related to the cost of
 26 furnishing such services or which are based on such
 27 other tests of reasonableness as the Secretary may pre-
 28 scribe in regulations, including those authorized under
 29 section 1861(v)(1)(A), less the amount a provider may
 30 charge as described in clause (ii) of section
 31 1866(a)(2)(A), but in no case may the payment for
 32 such services (other than for items and services de-
 33 scribed in section 1861(s)(10)(A)) exceed 80 percent of
 34 such costs; or

35 “(B) with respect to the services described in
 36 clause (ii) of section 1832(a)(2)(D) that are furnished
 37 to an individual enrolled with a MA plan under part C

1 pursuant to a written agreement described in section
2 1853(a)(4), the amount (if any) by which—

3 “(i) the amount of payment that would have
4 otherwise been provided under subparagraph (A)
5 (calculated as if ‘100 percent’ were substituted for
6 ‘80 percent’ in such subparagraph) for such serv-
7 ices if the individual had not been so enrolled; ex-
8 ceeds

9 “(ii) the amount of the payments received
10 under such written agreement for such services
11 (not including any financial incentives provided for
12 in such agreement such as risk pool payments, bo-
13 nuses, or withholds),

14 less the amount the Federally qualified health center
15 may charge as described in section 1857(e)(3)(B);”.

16 (b) CONTINUATION OF MONTHLY PAYMENTS.—

17 (1) IN GENERAL.—Section 1853(a) (42 U.S.C.
18 1395w-23(a)) is amended by adding at the end the fol-
19 lowing new paragraph:

20 “(4) PAYMENT RULE FOR FEDERALLY QUALIFIED
21 HEALTH CENTER SERVICES.—If an individual who is en-
22 rolled with an MA plan under this part receives a service
23 from a Federally qualified health center that has a written
24 agreement with the MA organization that offers such plan
25 for providing such a service (including any agreement re-
26 quired under section 1857(e)(3))—

27 “(A) the Secretary shall pay the amount deter-
28 mined under section 1833(a)(3)(B) directly to the Fed-
29 erally qualified health center not less frequently than
30 quarterly; and

31 “(B) the Secretary shall not reduce the amount of
32 the monthly payments under this subsection as a result
33 of the application of subparagraph (A).”.

34 (2) CONFORMING AMENDMENTS.—

35 (A) Section 1851(i) (42 U.S.C. 1395w-21(i)) is
36 amended—

1 (i) in paragraph (1), by inserting
 2 “1853(a)(4),” after “Subject to sections
 3 1852(a)(5),”; and

4 (ii) in paragraph (2), by inserting
 5 “1853(a)(4),” after “Subject to sections”.

6 (B) Section 1853(c)(5) is amended by striking
 7 “subsections (a)(3)(C)(iii) and (i)” and inserting “sub-
 8 sections (a)(3)(C)(iii), (a)(4), and (i)”.

9 (c) ADDITIONAL CONTRACT REQUIREMENTS.—Section
 10 1857(e) (42 U.S.C. 1395w–27(e)) is amended by adding at the
 11 end the following new paragraph:

12 “(3) AGREEMENTS WITH FEDERALLY QUALIFIED
 13 HEALTH CENTERS.—

14 “(A) PAYMENT LEVELS AND AMOUNTS.—A con-
 15 tract under this section with an MA organization shall
 16 require the organization to provide, in any written
 17 agreement described in section 1853(a)(4) between the
 18 organization and a Federally qualified health center,
 19 for a level and amount of payment to the Federally
 20 qualified health center for services provided by such
 21 health center that is not less than the level and amount
 22 of payment that the plan would make for such services
 23 if the services had been furnished by a entity providing
 24 similar services that was not a Federally qualified
 25 health center.

26 “(B) COST-SHARING.—Under the written agree-
 27 ment referred to in subparagraph (A), a Federally
 28 qualified health center must accept the payment
 29 amount referred to in such subparagraph plus the Fed-
 30 eral payment provided for in section 1833(a)(3)(B) as
 31 payment in full for services covered by the agreement,
 32 except that such a health center may collect any
 33 amount of cost-sharing permitted under the contract
 34 under this section, so long as the amounts of any de-
 35 ductible, coinsurance, or copayment comply with the re-
 36 quirements under section 1854(e).”.

1 (d) SAFE HARBOR.—Section 1128B(b)(3) (42 U.S.C.
2 1320a–7b(b)(3)), as amended by section 101(f)(2), is
3 amended—

4 (1) in subparagraph (F), by striking “and” after the
5 semicolon at the end;

6 (2) in subparagraph (G), by striking the period at the
7 end and inserting “; and”; and

8 (3) by adding at the end the following new subpara-
9 graph:

10 “(H) any remuneration between a Federally quali-
11 fied health center (or an entity controlled by such a
12 health center) and an MA organization pursuant to a
13 written agreement described in section 1853(a)(4).”.

14 (e) EFFECTIVE DATE.—The amendments made by this
15 section shall apply to services provided on or after January 1,
16 2006, and contract years beginning on or after such date.

17 **SEC. 238. INSTITUTE OF MEDICINE EVALUATION AND**
18 **REPORT ON HEALTH CARE PERFORMANCE**
19 **MEASURES.**

20 (a) EVALUATION.—

21 (1) IN GENERAL.—Not later than the date that is 2
22 months after the date of the enactment of this Act, the
23 Secretary shall enter into an arrangement under which the
24 Institute of Medicine of the National Academy of Sciences
25 (in this section referred to as the “Institute”) shall conduct
26 an evaluation of leading health care performance measures
27 in the public and private sectors and options to implement
28 policies that align performance with payment under the
29 medicare program under title XVIII of the Social Security
30 Act (42 U.S.C. 1395 et seq.).

31 (2) SPECIFIC MATTERS EVALUATED.—In conducting
32 the evaluation under paragraph (1), the Institute shall—

33 (A) catalogue, review, and evaluate the validity of
34 leading health care performance measures;

35 (B) catalogue and evaluate the success and utility
36 of alternative performance incentive programs in public
37 or private sector settings; and

1 (C) identify and prioritize options to implement
2 policies that align performance with payment under the
3 medicare program that indicate—

4 (i) the performance measurement set to be
5 used and how that measurement set will be up-
6 dated;

7 (ii) the payment policy that will reward per-
8 formance; and

9 (iii) the key implementation issues (such as
10 data and information technology requirements) that
11 must be addressed.

12 (3) SCOPE OF HEALTH CARE PERFORMANCE MEAS-
13 URES.—The health care performance measures described in
14 paragraph (2)(A) shall encompass a variety of perspectives,
15 including physicians, hospitals, other health care providers,
16 health plans, purchasers, and patients.

17 (4) CONSULTATION WITH MEDPAC.—In evaluating the
18 matters described in paragraph (2)(C), the Institute shall
19 consult with the Medicare Payment Advisory Commission
20 established under section 1805 of the Social Security Act
21 (42 U.S.C. 1395b–6).

22 (b) REPORT.—Not later than the date that is 18 months
23 after the date of enactment of this Act, the Institute shall sub-
24 mit to the Secretary and appropriate committees of jurisdiction
25 of the Senate and House of Representatives a report on the
26 evaluation conducted under subsection (a)(1) describing the
27 findings of such evaluation and recommendations for an overall
28 strategy and approach for aligning payment with performance,
29 including options for updating performance measures, in the
30 original medicare fee-for-service program under parts A and B
31 of title XVIII of the Social Security Act, the Medicare Advan-
32 tage program under part C of such title, and any other pro-
33 grams under such title XVIII.

34 (c) AUTHORIZATION OF APPROPRIATIONS.—There are au-
35 thorized to be appropriated such sums as may be necessary for
36 purposes of conducting the evaluation and preparing the report
37 required by this section.

**Subtitle E—Comparative Cost
Adjustment (CCA) Program**

SEC. 241. COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM.

(a) IN GENERAL.—Part C of title XVIII is amended by adding at the end the following new section:

“COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM

“SEC. 1860C–1. (a) ESTABLISHMENT OF PROGRAM.—

“(1) IN GENERAL.—The Secretary shall establish a program under this section (in this section referred to as the ‘CCA program’) for the application of comparative cost adjustment in CCA areas selected under this section.

“(2) DURATION.—The CCA program shall begin January 1, 2010, and shall extend over a period of 6 years, and end on December 31, 2015.

“(3) REPORT.—Upon the completion of the CCA program, the Secretary shall submit a report to Congress. Such report shall include the following, with respect to both this part and the original medicare fee-for-service program:

“(A) An evaluation of the financial impact of the CCA program.

“(B) An evaluation of changes in access to physicians and other health care providers.

“(C) Beneficiary satisfaction.

“(D) Recommendations regarding any extension or expansion of the CCA program.

“(b) REQUIREMENTS FOR SELECTION OF CCA AREAS.—

“(1) CCA AREA DEFINED.—

“(A) IN GENERAL.—For purposes of this section, the term ‘CCA area’ means an MSA that meets the requirements of paragraph (2) and is selected by the Secretary under subsection (c).

“(B) MSA DEFINED.—For purposes of this section, the term ‘MSA’ means a Metropolitan Statistical Area (or such similar area as the Secretary recognizes).

1 “(2) REQUIREMENTS FOR CCA AREAS.—The require-
2 ments of this paragraph for an MSA to be a CCA area are
3 as follows:

4 “(A) MA ENROLLMENT REQUIREMENT.—For the
5 reference month (as defined under section
6 1858(f)(4)(B)) with respect to 2010, at least 25 per-
7 cent of the total number of MA eligible individuals who
8 reside in the MSA were enrolled in an MA local plan
9 described in section 1851(a)(2)(A)(i).

10 “(B) 2 PLAN REQUIREMENT.—There will be of-
11 fered in the MSA during the annual, coordinated elec-
12 tion period under section 1851(e)(3)(B) before the be-
13 ginning of 2010 at least 2 MA local plans described in
14 section 1851(a)(2)(A)(i) (in addition to the fee-for-serv-
15 ice program under parts A and B), each offered by a
16 different MA organization and each of which met the
17 minimum enrollment requirements of paragraph (1) of
18 section 1857(b) (as applied without regard to para-
19 graph (3) thereof) as of the reference month.

20 “(c) SELECTION OF CCA AREAS.—

21 “(1) GENERAL SELECTION CRITERIA.—The Secretary
22 shall select CCA areas from among those MSAs qualifying
23 under subsection (b) in a manner that—

24 “(A) seeks to maximize the opportunity to test the
25 application of comparative cost adjustment under this
26 title;

27 “(B) does not seek to maximize the number of MA
28 eligible individuals who reside in such areas; and

29 “(C) provides for geographic diversity consistent
30 with the criteria specified in paragraph (2).

31 “(2) SELECTION CRITERIA.—With respect to the selec-
32 tion of MSAs that qualify to be CCA areas under sub-
33 section (b), the following rules apply, to the maximum ex-
34 tent feasible:

35 “(A) MAXIMUM NUMBER.—The number of such
36 MSAs selected may not exceed the lesser of (i) 6, or

1 (ii) 25 percent of the number of MSAs that meet the
2 requirement of subsection (b)(2)(A).

3 “(B) ONE OF 4 LARGEST AREAS BY POPU-
4 LATION.—At least one such qualifying MSA shall be se-
5 lected from among the 4 such qualifying MSAs with
6 the largest total population of MA eligible individuals.

7 “(C) ONE OF 4 AREAS WITH LOWEST POPULATION
8 DENSITY.—At least one such qualifying MSA shall be
9 selected from among the 4 such qualifying MSAs with
10 the lowest population density (as measured by residents
11 per square mile or similar measure of density).

12 “(D) MULTISTATE AREA.—At least one such
13 qualifying MSA shall be selected that includes a multi-
14 State area. Such an MSA may be an MSA described
15 in subparagraph (B) or (C).

16 “(E) LIMITATION WITHIN SAME GEOGRAPHIC RE-
17 GION.—No more than 2 such MSAs shall be selected
18 that are, in whole or in part, within the same geo-
19 graphic region (as specified by the Secretary) of the
20 United States.

21 “(F) PRIORITY TO AREAS NOT WITHIN CERTAIN
22 DEMONSTRATION PROJECTS.—Priority shall be pro-
23 vided for those qualifying MSAs that do not have a
24 demonstration project in effect as of the date of the en-
25 actment of this section for medicare preferred provider
26 organization plans under this part.

27 “(d) APPLICATION OF COMPARATIVE COST ADJUST-
28 MENT.—

29 “(1) IN GENERAL.—In the case of a CCA area for a
30 year—

31 “(A) for purposes of applying this part with re-
32 spect to payment for MA local plans, any reference to
33 an MA area-specific non-drug monthly benchmark
34 amount shall be treated as a reference to such bench-
35 mark computed as if the CCA area-specific non-drug
36 monthly benchmark amount (as defined in subsection
37 (e)(1)) were substituted for the amount described in

1 section 1853(j)(1)(A) for the CCA area and year in-
 2 volved, as phased in under paragraph (3); and

3 “(B) with respect to months in the year for indi-
 4 viduals residing in the CCA area who are not enrolled
 5 in an MA plan, the amount of the monthly premium
 6 under section 1839 is subject to adjustment under sub-
 7 section (f).

8 “(2) EXCLUSION OF MA LOCAL AREAS WITH FEWER
 9 THAN 2 ORGANIZATIONS OFFERING MA PLANS.—

10 “(A) IN GENERAL.—In no case shall an MA local
 11 area that is within an MSA be included as part of a
 12 CCA area unless for 2010 (and, except as provided in
 13 subparagraph (B), for a subsequent year) there is of-
 14 fered in each part of such MA local area at least 2 MA
 15 local plans described in section 1851(a)(2)(A)(i) each
 16 of which is offered by a different MA organization.

17 “(B) CONTINUATION.—If an MA local area meets
 18 the requirement of subparagraph (A) and is included in
 19 a CCA area for 2010, such local area shall continue to
 20 be included in such CCA area for a subsequent year
 21 notwithstanding that it no longer meets such require-
 22 ment so long as there is at least one MA local plan de-
 23 scribed in section 1851(a)(2)(A)(i) that is offered in
 24 such local area.

25 “(3) PHASE-IN OF CCA BENCHMARK.—

26 “(A) IN GENERAL.—In applying this section for a
 27 year before 2013, paragraph (1)(A) shall be applied as
 28 if the phase-in fraction under subparagraph (B) of the
 29 CCA non-drug monthly benchmark amount for the year
 30 were substituted for such fraction of the MA area-spe-
 31 cific non-drug monthly benchmark amount.

32 “(B) PHASE-IN FRACTION.—The phase-in fraction
 33 under this subparagraph is—

34 “(i) for 2010 $\frac{1}{4}$; and

35 “(ii) for a subsequent year is the phase-in
 36 fraction under this subparagraph for the previous
 37 year increased by $\frac{1}{4}$, but in no case more than 1.

1 “(e) COMPUTATION OF CCA BENCHMARK AMOUNT.—

2 “(1) CCA NON-DRUG MONTHLY BENCHMARK
3 AMOUNT.—For purposes of this section, the term ‘CCA
4 non-drug monthly benchmark amount’ means, with respect
5 to a CCA area for a month in a year, the sum of the 2
6 components described in paragraph (2) for the area and
7 year. The Secretary shall compute such benchmark amount
8 for each such CCA area before the beginning of each an-
9 nual, coordinated election period under section
10 1851(e)(3)(B) for each year (beginning with 2010) in
11 which the CCA area is so selected.

12 “(2) 2 COMPONENTS.—For purposes of paragraph (1),
13 the 2 components described in this paragraph for a CCA
14 area and a year are the following:

15 “(A) MA LOCAL COMPONENT.—The product of the
16 following:

17 “(i) WEIGHTED AVERAGE OF MEDICARE AD-
18 VANTAGE PLAN BIDS IN AREA.—The weighted aver-
19 age of the plan bids for the area and year (as de-
20 termined under paragraph (3)(A)).

21 “(ii) NON-FFS MARKET SHARE.—1 minus the
22 fee-for-service market share percentage, determined
23 under paragraph (4) for the area and year.

24 “(B) FEE-FOR-SERVICE COMPONENT.—The prod-
25 uct of the following:

26 “(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-
27 DRUG AMOUNT.—The fee-for-service area-specific
28 non-drug amount (as defined in paragraph (5)) for
29 the area and year.

30 “(ii) FEE-FOR-SERVICE MARKET SHARE.—The
31 fee-for-service market share percentage, determined
32 under paragraph (4) for the area and year.

33 “(3) DETERMINATION OF WEIGHTED AVERAGE MA
34 BIDS FOR A CCA AREA.—

35 “(A) IN GENERAL.—For purposes of paragraph
36 (2)(A)(i), the weighted average of plan bids for a CCA
37 area and a year is, subject to subparagraph (D), the

1 sum of the following products for MA local plans de-
 2 scribed in subparagraph (C) in the area and year:

3 “(i) MONTHLY MEDICARE ADVANTAGE STATU-
 4 TORY NON-DRUG BID AMOUNT.—The accepted
 5 unadjusted MA statutory non-drug monthly bid
 6 amount.

7 “(ii) PLAN’S SHARE OF MEDICARE ADVANTAGE
 8 ENROLLMENT IN AREA.—The number of individ-
 9 uals described in subparagraph (B), divided by the
 10 total number of such individuals for all MA plans
 11 described in subparagraph (C) for that area and
 12 year.

13 “(B) COUNTING OF INDIVIDUALS.—The Secretary
 14 shall count, for each MA local plan described in sub-
 15 paragraph (C) for an area and year, the number of in-
 16 dividuals who reside in the area and who were enrolled
 17 under such plan under this part during the reference
 18 month for that year.

19 “(C) EXCLUSION OF PLANS NOT OFFERED IN PRE-
 20 VIOUS YEAR.—For an area and year, the MA local
 21 plans described in this subparagraph are MA local
 22 plans described in section 1851(a)(2)(A)(i) that are of-
 23 fered in the area and year and were offered in the CCA
 24 area in the reference month.

25 “(D) COMPUTATION OF WEIGHTED AVERAGE OF
 26 PLAN BIDS.—In calculating the weighted average of
 27 plan bids for a CCA area under subparagraph (A)—

28 “(i) in the case of an MA local plan that has
 29 a service area only part of which is within such
 30 CCA area, the MA organization offering such plan
 31 shall submit a separate bid for such plan for the
 32 portion within such CCA area; and

33 “(ii) the Secretary shall adjust such separate
 34 bid (or, in the case of an MA local plan that has
 35 a service area entirely within such CCA area, the
 36 plan bid) as may be necessary to take into account
 37 differences between the service area of such plan

1 within the CCA area and the entire CCA area and
 2 the distribution of plan enrollees of all MA local
 3 plans offered within the CCA area.

4 “(4) COMPUTATION OF FEE-FOR-SERVICE MARKET
 5 SHARE PERCENTAGE.—The Secretary shall determine, for a
 6 year and a CCA area, the proportion (in this subsection re-
 7 ferred to as the ‘fee-for-service market share percentage’)
 8 equal to—

9 “(A) the total number of MA eligible individuals
 10 residing in such area who during the reference month
 11 for the year were not enrolled in any MA plan; divided
 12 by

13 “(B) the sum of such number and the total num-
 14 ber of MA eligible individuals residing in such area who
 15 during such reference month were enrolled in an MA
 16 local plan described in section 1851(a)(2)(A)(i),
 17 or, if greater, such proportion determined for individuals
 18 nationally.

19 “(5) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG
 20 AMOUNT.—

21 “(A) IN GENERAL.—For purposes of paragraph
 22 (2)(B)(i) and subsection (f)(2)(A), subject to subpara-
 23 graph (C), the term ‘fee-for-service area-specific non-
 24 drug amount’ means, for a CCA area and a year, the
 25 adjusted average per capita cost for such area and year
 26 involved, determined under section 1876(a)(4) and ad-
 27 justed as appropriate for the purpose of risk adjust-
 28 ment for benefits under the original medicare fee-for-
 29 service program option for individuals entitled to bene-
 30 fits under part A and enrolled under part B who are
 31 not enrolled in an MA plan for the year, but adjusted
 32 to exclude costs attributable to payments under section
 33 1886(h).

34 “(B) USE OF FULL RISK ADJUSTMENT TO STAND-
 35 ARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENE-
 36 FICIARY.—In determining the adjusted average per
 37 capita cost for an area and year under subparagraph

1 (A), such costs shall be adjusted to fully take into ac-
 2 count the demographic and health status risk factors
 3 established under section 1853(a)(1)(A)(iv) so that
 4 such per capita costs reflect the average costs for a
 5 typical beneficiary residing in the CCA area.

6 “(C) INCLUSION OF COSTS OF VA AND DOD MILI-
 7 TARY FACILITY SERVICES TO MEDICARE-ELIGIBLE
 8 BENEFICIARIES.—In determining the adjusted average
 9 per capita cost under subparagraph (A) for a year,
 10 such cost shall be adjusted to include the Secretary’s
 11 estimate, on a per capita basis, of the amount of addi-
 12 tional payments that would have been made in the area
 13 involved under this title if individuals entitled to bene-
 14 fits under this title had not received services from fa-
 15 cilities of the Department of Veterans Affairs or the
 16 Department of Defense.

17 “(f) PREMIUM ADJUSTMENT.—

18 “(1) APPLICATION.—

19 “(A) IN GENERAL.—Except as provided in sub-
 20 paragraph (B), in the case of an individual who is en-
 21 rolled under part B, who resides in a CCA area, and
 22 who is not enrolled in an MA plan under this part, the
 23 monthly premium otherwise applied under part B (de-
 24 termined without regard to subsections (b), (f), and (i)
 25 of section 1839 or any adjustment under this sub-
 26 section) shall be adjusted in accordance with paragraph
 27 (2), but only in the case of premiums for months dur-
 28 ing the period in which the CCA program under this
 29 section for such area is in effect.

30 “(B) NO PREMIUM ADJUSTMENT FOR SUBSIDY EL-
 31 IGIBLE BENEFICIARIES.—No premium adjustment shall
 32 be made under this subsection for a premium for a
 33 month if the individual is determined to be a subsidy
 34 eligible individual (as defined in section 1860D-
 35 14(a)(3)(A)) for the month.

36 “(2) AMOUNT OF ADJUSTMENT.—

1 “(A) IN GENERAL.—Under this paragraph, subject
 2 to the exemption under paragraph (1)(B) and the limi-
 3 tation under subparagraph (B), if the fee-for-service
 4 area-specific non-drug amount (as defined in section
 5 (e)(5)) for a CCA area in which an individual resides
 6 for a month—

7 “(i) does not exceed the CCA non-drug month-
 8 ly benchmark amount (as determined under sub-
 9 section (e)(1)) for such area and month, the
 10 amount of the premium for the individual for the
 11 month shall be reduced, by an amount equal to 75
 12 percent of the amount by which such CCA bench-
 13 mark exceeds such fee-for-service area-specific non-
 14 drug amount; or

15 “(ii) exceeds such CCA non-drug benchmark,
 16 the amount of the premium for the individual for
 17 the month shall be adjusted to ensure, that—

18 “(I) the sum of the amount of the ad-
 19 justed premium and the CCA non-drug bench-
 20 mark for the area; is equal to

21 “(II) the sum of the unadjusted premium
 22 plus the amount of such fee-for-service area-
 23 specific non-drug amount for the area.

24 “(B) LIMITATION.—In no case shall the actual
 25 amount of an adjustment under subparagraph (A) for
 26 an area and month in a year result in an adjustment
 27 that exceeds the maximum adjustment permitted under
 28 subparagraph (C) for the area and year, or, if less, the
 29 maximum annual adjustment permitted under subpara-
 30 graph (D) for the area and year.

31 “(C) PHASE-IN OF ADJUSTMENT.—The amount of
 32 an adjustment under subparagraph (A) for a CCA area
 33 and year may not exceed the product of the phase-in
 34 fraction for the year under subsection (d)(3)(B) multi-
 35 plied by the amount of the adjustment otherwise com-
 36 puted under subparagraph (A) for the area and year,

1 determined without regard to this subparagraph and
 2 subparagraph (D).

3 “(D) 5-PERCENT LIMITATION ON ADJUSTMENT.—
 4 The amount of the adjustment under this subsection
 5 for months in a year shall not exceed 5 percent of the
 6 amount of the monthly premium amount determined
 7 for months in the year under section 1839 without re-
 8 gard to subsections (b), (f), and (i) of such section and
 9 this subsection.”.

10 (b) CONFORMING AMENDMENTS.—

11 (1) MA LOCAL PLANS.—

12 (A) Section 1853(j)(1)(A) (42 U.S.C. 1395w-
 13 23(j)(1)(A)), as added by section 222(d), is amended
 14 by inserting “subject to section 1860C–1(d)(2)(A),”
 15 after “within an MA local area,”.

16 (B) Section 1853(b)(1)(B), as amended by section
 17 222(f)(1), is amended by adding at the end the fol-
 18 lowing new clause:

19 “(iii) BENCHMARK ANNOUNCEMENT FOR CCA
 20 LOCAL AREAS.—The Secretary shall determine, and
 21 shall announce (in a manner intended to provide
 22 notice to interested parties), on a timely basis be-
 23 fore the calendar year concerned, with respect to
 24 each CCA area (as defined in section 1860C–
 25 1(b)(1)(A)), the CCA non-drug monthly benchmark
 26 amount under section 1860C–1(e)(1) for that area
 27 for the year involved.”.

28 (2) PREMIUM ADJUSTMENT.—

29 (A) Section 1839 (42 U.S.C. 1395r) is amended
 30 by adding at the end the following new subsection:

31 “(h) POTENTIAL APPLICATION OF COMPARATIVE COST
 32 ADJUSTMENT IN CCA AREAS.—

33 “(1) IN GENERAL.—Certain individuals who are resid-
 34 ing in a CCA area under section 1860C–1 who are not en-
 35 rolled in an MA plan under part C may be subject to a pre-
 36 mium adjustment under subsection (f) of such section for

1 months in which the CCA program under such section is
2 in effect in such area.

3 “(2) NO EFFECT ON LATE ENROLLMENT PENALTY OR
4 INCOME-RELATED ADJUSTMENT IN SUBSIDIES.—Nothing in
5 this subsection or section 1860C–1(f) shall be construed as
6 affecting the amount of any premium adjustment under
7 subsection (b) or (i). Subsection (f) shall be applied without
8 regard to any premium adjustment referred to in para-
9 graph (1).

10 “(3) IMPLEMENTATION.—In order to carry out a pre-
11 mium adjustment under this subsection and section
12 1860C–1(f) (insofar as it is effected through the manner
13 of collection of premiums under section 1840(a)), the Sec-
14 retary shall transmit to the Commissioner of Social
15 Security—

16 “(A) at the beginning of each year, the name, so-
17 cial security account number, and the amount of the
18 premium adjustment (if any) for each individual en-
19 rolled under this part for each month during the year;
20 and

21 “(B) periodically throughout the year, information
22 to update the information previously transmitted under
23 this paragraph for the year.”.

24 (B) Section 1844(c) (42 U.S.C. 1395w(c)) is
25 amended by inserting “and without regard to any pre-
26 mium adjustment effected under sections 1839(h) and
27 1860C–1(f)” before the period at the end.

28 (c) NO CHANGE IN MEDICARE’S DEFINED BENEFIT
29 PACKAGE.—Nothing in this part (or the amendments made by
30 this part) shall be construed as changing the entitlement to de-
31 fined benefits under parts A and B of title XVIII of the Social
32 Security Act.

1 **TITLE III—COMBATTING WASTE,**
 2 **FRAUD, AND ABUSE**

3 **SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVI-**
 4 **SIONS.**

5 (a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S
 6 AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CER-
 7 TAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—Section
 8 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—

9 (1) in subparagraph (A)(ii), by striking “promptly (as
 10 determined in accordance with regulations)”; and

11 (2) in subparagraph (B)—

12 (A) by redesignating clauses (i) through (v) as
 13 clauses (ii) through (vi), respectively; and

14 (B) by inserting before clause (ii), as so redesign-
 15 ated, the following new clause:

16 “(i) AUTHORITY TO MAKE CONDITIONAL PAY-
 17 MENT.—The Secretary may make payment under
 18 this title with respect to an item or service if a pri-
 19 mary plan described in subparagraph (A)(ii) has
 20 not made or cannot reasonably be expected to make
 21 payment with respect to such item or service
 22 promptly (as determined in accordance with regula-
 23 tions). Any such payment by the Secretary shall be
 24 conditioned on reimbursement to the appropriate
 25 Trust Fund in accordance with the succeeding pro-
 26 visions of this subsection.”.

27 (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAY-
 28 MENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C.
 29 1395y(b)(2)), as amended by subsection (a), is amended—

30 (1) in subparagraph (A), in the matter following
 31 clause (ii), by inserting the following sentence at the end:
 32 “An entity that engages in a business, trade, or profession
 33 shall be deemed to have a self-insured plan if it carries its
 34 own risk (whether by a failure to obtain insurance, or oth-
 35 erwise) in whole or in part.”;

1 (2) in subparagraph (B)(ii), as redesignated by sub-
2 section (a)(2)(A)—

3 (A) by striking the first sentence and inserting the
4 following: “A primary plan, and an entity that receives
5 payment from a primary plan, shall reimburse the ap-
6 propriate Trust Fund for any payment made by the
7 Secretary under this title with respect to an item or
8 service if it is demonstrated that such primary plan has
9 or had a responsibility to make payment with respect
10 to such item or service. A primary plan’s responsibility
11 for such payment may be demonstrated by a judgment,
12 a payment conditioned upon the recipient’s com-
13 promise, waiver, or release (whether or not there is a
14 determination or admission of liability) of payment for
15 items or services included in a claim against the pri-
16 mary plan or the primary plan’s insured, or by other
17 means.”; and

18 (B) in the final sentence, by striking “on the date
19 such notice or other information is received” and in-
20 serting “on the date notice of, or information related
21 to, a primary plan’s responsibility for such payment or
22 other information is received”; and

23 (3) in subparagraph (B)(iii), as redesignated by sub-
24 section (a)(2)(A), by striking the first sentence and insert-
25 ing the following: “In order to recover payment made under
26 this title for an item or service, the United States may
27 bring an action against any or all entities that are or were
28 required or responsible (directly, as an insurer or self-in-
29 surer, as a third-party administrator, as an employer that
30 sponsors or contributes to a group health plan, or large
31 group health plan, or otherwise) to make payment with re-
32 spect to the same item or service (or any portion thereof)
33 under a primary plan. The United States may, in accord-
34 ance with paragraph (3)(A) collect double damages against
35 any such entity. In addition, the United States may recover
36 under this clause from any entity that has received pay-

1 ment from a primary plan or from the proceeds of a pri-
2 mary plan’s payment to any entity.”.

3 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C.
4 1395y(b)) is amended—

5 (1) in paragraph (1)(A), by moving the indentation of
6 clauses (ii) through (v) 2 ems to the left; and

7 (2) in paragraph (3)(A), by striking “such” before
8 “paragraphs”.

9 (d) EFFECTIVE DATES.—The amendments made by this
10 section shall be effective—

11 (1) in the case of subsection (a), as if included in the
12 enactment of title III of the Medicare and Medicaid Budget
13 Reconciliation Amendments of 1984 (Public Law 98–369);
14 and

15 (2) in the case of subsections (b) and (c), as if in-
16 cluded in the enactment of section 953 of the Omnibus
17 Reconciliation Act of 1980 (Public Law 96–499; 94 Stat.
18 2647).

19 **SEC. 302. PAYMENT FOR DURABLE MEDICAL EQUIP-**
20 **MENT; COMPETITIVE ACQUISITION OF CER-**
21 **TAIN ITEMS AND SERVICES.**

22 (a) QUALITY ENHANCEMENT AND FRAUD REDUCTION.—

23 (1) ESTABLISHMENT OF QUALITY STANDARDS AND
24 ACCREDITATION REQUIREMENTS FOR DURABLE MEDICAL
25 EQUIPMENT SUPPLIERS.—Section 1834(a) (42 U.S.C.
26 1395m(a)) is amended—

27 (A) by transferring paragraph (17), as added by
28 section 4551(c)(1) of the Balanced Budget Act of 1997
29 (111 Stat. 458), to the end of such section and redesign-
30 ating such paragraph as paragraph (19); and

31 (B) by adding at the end the following new para-
32 graph:

33 “(20) IDENTIFICATION OF QUALITY STANDARDS.—

34 “(A) IN GENERAL.—Subject to subparagraph (C),
35 the Secretary shall establish and implement quality
36 standards for suppliers of items and services described
37 in subparagraph (D) to be applied by recognized inde-

1 pendent accreditation organizations (as designated
2 under subparagraph (B)) and with which such sup-
3 pliers shall be required to comply in order to—

4 “(i) furnish any such item or service for which
5 payment is made under this part; and

6 “(ii) receive or retain a provider or supplier
7 number used to submit claims for reimbursement
8 for any such item or service for which payment
9 may be made under this title.

10 “(B) DESIGNATION OF INDEPENDENT ACCREDITA-
11 TION ORGANIZATIONS.—Not later than the date that is
12 1 year after the date on which the Secretary imple-
13 ments the quality standards under subparagraph (A),
14 notwithstanding section 1865(b), the Secretary shall
15 designate and approve one or more independent accred-
16 itation organizations for purposes of such subpara-
17 graph.

18 “(C) QUALITY STANDARDS.—The quality stand-
19 ards described in subparagraph (A) may not be less
20 stringent than the quality standards that would other-
21 wise apply if this paragraph did not apply and shall in-
22 clude consumer services standards.

23 “(D) ITEMS AND SERVICES DESCRIBED.—The
24 items and services described in this subparagraph are
25 the following items and services, as the Secretary deter-
26 mines appropriate:

27 “(i) Covered items (as defined in paragraph
28 (13)) for which payment may otherwise be made
29 under this subsection.

30 “(ii) Prosthetic devices and orthotics and pros-
31 thetics described in section 1834(h)(4).

32 “(iii) Items and services described in section
33 1842(s)(2).

34 “(E) IMPLEMENTATION.—The Secretary may es-
35 tablish by program instruction or otherwise the quality
36 standards under this paragraph, after consultation with
37 representatives of relevant parties. Such standards

1 shall be applied prospectively and shall be published on
 2 the Internet website of the Centers for Medicare &
 3 Medicaid Services.”.

4 (2) ESTABLISHMENT OF CLINICAL CONDITIONS OF
 5 COVERAGE STANDARDS FOR ITEMS OF DURABLE MEDICAL
 6 EQUIPMENT.—Section 1834(a)(1) (42 U.S.C. 1395m(a)(1))
 7 is amended by adding at the end the following new sub-
 8 paragraph:

9 “(E) CLINICAL CONDITIONS FOR COVERAGE.—

10 “(i) IN GENERAL.—The Secretary shall estab-
 11 lish standards for clinical conditions for payment
 12 for covered items under this subsection.

13 “(ii) REQUIREMENTS.—The standards estab-
 14 lished under clause (i) shall include the specifica-
 15 tion of types or classes of covered items that re-
 16 quire, as a condition of payment under this sub-
 17 section, a face-to-face examination of the individual
 18 by a physician (as defined in section 1861(r)(1)),
 19 a physician assistant, nurse practitioner, or a clin-
 20 ical nurse specialist (as those terms are defined in
 21 section 1861(aa)(5)) and a prescription for the
 22 item.

23 “(iii) PRIORITY OF ESTABLISHMENT OF
 24 STANDARDS.—In establishing the standards under
 25 this subparagraph, the Secretary shall first estab-
 26 lish standards for those covered items for which the
 27 Secretary determines there has been a proliferation
 28 of use, consistent findings of charges for covered
 29 items that are not delivered, or consistent findings
 30 of falsification of documentation to provide for pay-
 31 ment of such covered items under this part.

32 “(iv) STANDARDS FOR POWER WHEEL-
 33 CHAIRS.—Effective on the date of the enactment of
 34 this subparagraph, in the case of a covered item
 35 consisting of a motorized or power wheelchair for
 36 an individual, payment may not be made for such
 37 covered item unless a physician (as defined in sec-

1 tion 1861(r)(1)), a physician assistant, nurse prac-
 2 titioner, or a clinical nurse specialist (as those
 3 terms are defined in section 1861(aa)(5)) has con-
 4 ducted a face-to-face examination of the individual
 5 and written a prescription for the item.

6 “(v) LIMITATION ON PAYMENT FOR COVERED
 7 ITEMS.—Payment may not be made for a covered
 8 item under this subsection unless the item meets
 9 any standards established under this subparagraph
 10 for clinical condition of coverage.”.

11 (b) COMPETITIVE ACQUISITION.—

12 (1) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3)

13 is amended to read as follows:

14 “COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

15 “SEC. 1847. (a) ESTABLISHMENT OF COMPETITIVE AC-
 16 QUISITION PROGRAMS.—

17 “(1) IMPLEMENTATION OF PROGRAMS.—

18 “(A) IN GENERAL.—The Secretary shall establish
 19 and implement programs under which competitive ac-
 20 quisition areas are established throughout the United
 21 States for contract award purposes for the furnishing
 22 under this part of competitively priced items and serv-
 23 ices (described in paragraph (2)) for which payment is
 24 made under this part. Such areas may differ for dif-
 25 ferent items and services.

26 “(B) PHASED-IN IMPLEMENTATION.—The
 27 programs—

28 “(i) shall be phased in among competitive ac-
 29 quisition areas in a manner so that the competition
 30 under the programs occurs in—

31 “(I) 10 of the largest metropolitan statis-
 32 tical areas in 2007;

33 “(II) 80 of the largest metropolitan statis-
 34 tical areas in 2009; and

35 “(III) additional areas after 2009; and

36 “(ii) may be phased in first among the highest
 37 cost and highest volume items and services or those

1 items and services that the Secretary determines
2 have the largest savings potential.

3 “(C) WAIVER OF CERTAIN PROVISIONS.—In car-
4 rying out the programs, the Secretary may waive such
5 provisions of the Federal Acquisition Regulation as are
6 necessary for the efficient implementation of this sec-
7 tion, other than provisions relating to confidentiality of
8 information and such other provisions as the Secretary
9 determines appropriate.

10 “(2) ITEMS AND SERVICES DESCRIBED.—The items
11 and services referred to in paragraph (1) are the following:

12 “(A) DURABLE MEDICAL EQUIPMENT AND MED-
13 ICAL SUPPLIES.—Covered items (as defined in section
14 1834(a)(13)) for which payment would otherwise be
15 made under section 1834(a), including items used in
16 infusion and drugs (other than inhalation drugs) and
17 supplies used in conjunction with durable medical
18 equipment, but excluding class III devices under the
19 Federal Food, Drug, and Cosmetic Act.

20 “(B) OTHER EQUIPMENT AND SUPPLIES.—Items
21 and services described in section 1842(s)(2)(D), other
22 than parenteral nutrients, equipment, and supplies.

23 “(C) OFF-THE-SHELF ORTHOTICS.—Orthotics de-
24 scribed in section 1861(s)(9) for which payment would
25 otherwise be made under section 1834(h) which require
26 minimal self-adjustment for appropriate use and do not
27 require expertise in trimming, bending, molding, assem-
28 bling, or customizing to fit to the individual.

29 “(3) EXCEPTION AUTHORITY.—In carrying out the
30 programs under this section, the Secretary may exempt—

31 “(A) rural areas and areas with low population
32 density within urban areas that are not competitive,
33 unless there is a significant national market through
34 mail order for a particular item or service; and

35 “(B) items and services for which the application
36 of competitive acquisition is not likely to result in sig-
37 nificant savings.

1 “(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF
2 DURABLE MEDICAL EQUIPMENT AND OXYGEN.—In the case
3 of a covered item for which payment is made on a rental
4 basis under section 1834(a) and in the case of payment for
5 oxygen under section 1834(a)(5), the Secretary shall estab-
6 lish a process by which rental agreements for the covered
7 items and supply arrangements with oxygen suppliers en-
8 tered into before the application of the competitive acquisi-
9 tion program under this section for the item may be contin-
10 ued notwithstanding this section. In the case of any such
11 continuation, the supplier involved shall provide for appro-
12 priate servicing and replacement, as required under section
13 1834(a).

14 “(5) PHYSICIAN AUTHORIZATION.—

15 “(A) IN GENERAL.—With respect to items or serv-
16 ices included within a particular HCPCS code, the Sec-
17 retary may establish a process for certain items and
18 services under which a physician may prescribe a par-
19 ticular brand or mode of delivery of an item or service
20 within such code if the physician determines that use
21 of the particular item or service would avoid an adverse
22 medical outcome on the individual, as determined by
23 the Secretary.

24 “(B) NO EFFECT ON PAYMENT AMOUNT.—A pre-
25 scription under subparagraph (A) shall not affect the
26 amount of payment otherwise applicable for the item or
27 service under the code involved.

28 “(6) APPLICATION.—For each competitive acquisition
29 area in which the program is implemented under this sub-
30 section with respect to items and services, the payment
31 basis determined under the competition conducted under
32 subsection (b) shall be substituted for the payment basis
33 otherwise applied under section 1834(a), section 1834(h),
34 or section 1842(s), as appropriate.

35 “(b) PROGRAM REQUIREMENTS.—

36 “(1) IN GENERAL.—The Secretary shall conduct a
37 competition among entities supplying items and services de-

1 scribed in subsection (a)(2) for each competitive acquisition
2 area in which the program is implemented under subsection
3 (a) with respect to such items and services.

4 “(2) CONDITIONS FOR AWARDING CONTRACT.—

5 “(A) IN GENERAL.—The Secretary may not award
6 a contract to any entity under the competition con-
7 ducted in an competitive acquisition area pursuant to
8 paragraph (1) to furnish such items or services unless
9 the Secretary finds all of the following:

10 “(i) The entity meets applicable quality stand-
11 ards specified by the Secretary under section
12 1834(a)(20).

13 “(ii) The entity meets applicable financial
14 standards specified by the Secretary, taking into
15 account the needs of small providers.

16 “(iii) The total amounts to be paid to contrac-
17 tors in a competitive acquisition area are expected
18 to be less than the total amounts that would other-
19 wise be paid.

20 “(iv) Access of individuals to a choice of mul-
21 tiple suppliers in the area is maintained.

22 “(B) TIMELY IMPLEMENTATION OF PROGRAM.—
23 Any delay in the implementation of quality standards
24 under section 1834(a)(20) or delay in the receipt of ad-
25 vice from the program oversight committee established
26 under subsection (c) shall not delay the implementation
27 of the competitive acquisition program under this sec-
28 tion.

29 “(3) CONTENTS OF CONTRACT.—

30 “(A) IN GENERAL.—A contract entered into with
31 an entity under the competition conducted pursuant to
32 paragraph (1) is subject to terms and conditions that
33 the Secretary may specify.

34 “(B) TERM OF CONTRACTS.—The Secretary shall
35 recompetete contracts under this section not less often
36 than once every 3 years.

37 “(4) LIMIT ON NUMBER OF CONTRACTORS.—

1 “(A) IN GENERAL.—The Secretary may limit the
2 number of contractors in a competitive acquisition area
3 to the number needed to meet projected demand for
4 items and services covered under the contracts. In
5 awarding contracts, the Secretary shall take into ac-
6 count the ability of bidding entities to furnish items or
7 services in sufficient quantities to meet the anticipated
8 needs of individuals for such items or services in the
9 geographic area covered under the contract on a timely
10 basis.

11 “(B) MULTIPLE WINNERS.—The Secretary shall
12 award contracts to multiple entities submitting bids in
13 each area for an item or service.

14 “(5) PAYMENT.—

15 “(A) IN GENERAL.—Payment under this part for
16 competitively priced items and services described in
17 subsection (a)(2) shall be based on bids submitted and
18 accepted under this section for such items and services.
19 Based on such bids the Secretary shall determine a sin-
20 gle payment amount for each item or service in each
21 competitive acquisition area.

22 “(B) REDUCED BENEFICIARY COST-SHARING.—

23 “(i) APPLICATION OF COINSURANCE.—Pay-
24 ment under this section for items and services shall
25 be in an amount equal to 80 percent of the pay-
26 ment basis described in subparagraph (A).

27 “(ii) APPLICATION OF DEDUCTIBLE.—Before
28 applying clause (i), the individual shall be required
29 to meet the deductible described in section 1833(b).

30 “(C) PAYMENT ON ASSIGNMENT-RELATED
31 BASIS.—Payment for any item or service furnished by
32 the entity may only be made under this section on an
33 assignment-related basis.

34 “(D) CONSTRUCTION.—Nothing in this section
35 shall be construed as precluding the use of an advanced
36 beneficiary notice with respect to a competitively priced
37 item and service.

1 “(6) PARTICIPATING CONTRACTORS.—

2 “(A) IN GENERAL.—Except as provided in sub-
3 section (a)(4), payment shall not be made for items
4 and services described in subsection (a)(2) furnished by
5 a contractor and for which competition is conducted
6 under this section unless—

7 “(i) the contractor has submitted a bid for
8 such items and services under this section; and

9 “(ii) the Secretary has awarded a contract to
10 the contractor for such items and services under
11 this section.

12 “(B) BID DEFINED.—In this section, the term
13 ‘bid’ means an offer to furnish an item or service for
14 a particular price and time period that includes, where
15 appropriate, any services that are attendant to the fur-
16 nishing of the item or service.

17 “(C) RULES FOR MERGERS AND ACQUISITIONS.—
18 In applying subparagraph (A) to a contractor, the con-
19 tractor shall include a successor entity in the case of
20 a merger or acquisition, if the successor entity assumes
21 such contract along with any liabilities that may have
22 occurred thereunder.

23 “(D) PROTECTION OF SMALL SUPPLIERS.—In de-
24 veloping procedures relating to bids and the awarding
25 of contracts under this section, the Secretary shall take
26 appropriate steps to ensure that small suppliers of
27 items and services have an opportunity to be considered
28 for participation in the program under this section.

29 “(7) CONSIDERATION IN DETERMINING CATEGORIES
30 FOR BIDS.—The Secretary may consider the clinical effi-
31 ciency and value of specific items within codes, including
32 whether some items have a greater therapeutic advantage
33 to individuals.

34 “(8) AUTHORITY TO CONTRACT FOR EDUCATION, MON-
35 ITORING, OUTREACH, AND COMPLAINT SERVICES.—The
36 Secretary may enter into contracts with appropriate enti-
37 ties to address complaints from individuals who receive

1 items and services from an entity with a contract under
 2 this section and to conduct appropriate education of and
 3 outreach to such individuals and monitoring quality of serv-
 4 ices with respect to the program.

5 “(9) AUTHORITY TO CONTRACT FOR IMPLEMENTA-
 6 TION.—The Secretary may contract with appropriate enti-
 7 ties to implement the competitive bidding program under
 8 this section.

9 “(10) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—
 10 There shall be no administrative or judicial review under
 11 section 1869, section 1878, or otherwise, of—

12 “(A) the establishment of payment amounts under
 13 paragraph (5);

14 “(B) the awarding of contracts under this section;

15 “(C) the designation of competitive acquisition
 16 areas under subsection (a)(1)(A);

17 “(D) the phased-in implementation under sub-
 18 section (a)(1)(B);

19 “(E) the selection of items and services for com-
 20 petitive acquisition under subsection (a)(2); or

21 “(F) the bidding structure and number of contrac-
 22 tors selected under this section.

23 “(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

24 “(1) ESTABLISHMENT.—The Secretary shall establish
 25 a Program Advisory and Oversight Committee (hereinafter
 26 in this section referred to as the ‘Committee’).

27 “(2) MEMBERSHIP; TERMS.—The Committee shall
 28 consist of such members as the Secretary may appoint who
 29 shall serve for such term as the Secretary may specify.

30 “(3) DUTIES.—

31 “(A) ADVICE.—The Committee shall provide ad-
 32 vice to the Secretary with respect to the following func-
 33 tions:

34 “(i) The implementation of the program under
 35 this section.

36 “(ii) The establishment of financial standards
 37 for purposes of subsection (b)(2)(A)(ii).

1 “(iii) The establishment of requirements for
2 collection of data for the efficient management of
3 the program.

4 “(iv) The development of proposals for effi-
5 cient interaction among manufacturers, providers
6 of services, suppliers (as defined in section
7 1861(d)), and individuals.

8 “(v) The establishment of quality standards
9 under section 1834(a)(20).

10 “(B) ADDITIONAL DUTIES.—The Committee shall
11 perform such additional functions to assist the Sec-
12 retary in carrying out this section as the Secretary may
13 specify.

14 “(4) INAPPLICABILITY OF FACA.—The provisions of
15 the Federal Advisory Committee Act (5 U.S.C. App.) shall
16 not apply.

17 “(5) TERMINATION.—The Committee shall terminate
18 on December 31, 2009.

19 “(d) REPORT.—Not later than July 1, 2009, the Secretary
20 shall submit to Congress a report on the programs under this
21 section. The report shall include information on savings, reduc-
22 tions in cost-sharing, access to and quality of items and serv-
23 ices, and satisfaction of individuals.

24 “(e) DEMONSTRATION PROJECT FOR CLINICAL LABORA-
25 TORY SERVICES.—

26 “(1) IN GENERAL.—The Secretary shall conduct a
27 demonstration project on the application of competitive ac-
28 quisition under this section to clinical diagnostic laboratory
29 tests—

30 “(A) for which payment would otherwise be made
31 under section 1833(h) (other than for pap smear lab-
32 oratory tests under paragraph (7) of such section) or
33 section 1834(d)(1) (relating to colorectal cancer screen-
34 ing tests); and

35 “(B) which are furnished by entities that did not
36 have a face-to-face encounter with the individual.

37 “(2) TERMS AND CONDITIONS.—

1 “(A) IN GENERAL.—Except as provided in sub-
 2 paragraph (B), such project shall be under the same
 3 conditions as are applicable to items and services de-
 4 scribed in subsection (a)(2), excluding subsection
 5 (b)(5)(B) and other conditions as the Secretary deter-
 6 mines to be appropriate.

7 “(B) APPLICATION OF CLIA QUALITY STAND-
 8 ARDS.—The quality standards established by the Sec-
 9 retary under section 353 of the Public Health Service
 10 Act for clinical diagnostic laboratory tests shall apply
 11 to such tests under the demonstration project under
 12 this section in lieu of quality standards described in
 13 subsection (b)(2)(A)(i).

14 “(3) REPORT.—The Secretary shall submit to
 15 Congress—

16 “(A) an initial report on the project not later than
 17 December 31, 2005; and

18 “(B) such progress and final reports on the
 19 project after such date as the Secretary determines ap-
 20 propriate.”.

21 (2) CONFORMING AMENDMENTS.—Section 1833(a)(1)
 22 (42 U.S.C. 13951(a)(1)) is amended—

23 (A) by striking “and (U)” and inserting “(U)”;

24 (B) by inserting before the semicolon at the end
 25 the following: “, and (V) notwithstanding subpara-
 26 graphs (I) (relating to durable medical equipment), (M)
 27 (relating to prosthetic devices and orthotics and pros-
 28 thetics), and (Q) (relating to 1842(s) items), with re-
 29 spect to competitively priced items and services (de-
 30 scribed in section 1847(a)(2)) that are furnished in a
 31 competitive area, the amounts paid shall be the
 32 amounts described in section 1847(b)(5)”;

33 (C) in clause (D)—

34 (i) by striking “or (ii)” and inserting “(ii)”;

35 and

36 (ii) by adding at the end the following: “or
 37 (iii) on the basis of a rate established under a dem-

1 onstration project under section 1847(e), the
2 amount paid shall be equal to 100 percent of such
3 rate.”.

4 (3) GAO REPORT ON IMPACT OF COMPETITIVE ACQUI-
5 SITION ON SUPPLIERS.—

6 (A) STUDY.—The Comptroller General of the
7 United States shall conduct a study on the impact of
8 competitive acquisition of durable medical equipment
9 under section 1847 of the Social Security Act, as
10 amended by paragraph (1), on suppliers and manufac-
11 turers of such equipment and on patients. Such study
12 shall specifically examine the impact of such competi-
13 tive acquisition on access to, and quality of, such equip-
14 ment and service related to such equipment.

15 (B) REPORT.—Not later than January 1, 2009,
16 the Comptroller General shall submit to Congress a re-
17 port on the study conducted under subparagraph (A)
18 and shall include in the report such recommendations
19 as the Comptroller General determines appropriate.

20 (c) TRANSITIONAL FREEZE.—

21 (1) DME.—

22 (A) IN GENERAL.—Section 1834(a)(14) (42
23 U.S.C. 1395m(a)(14)) is amended—

24 (i) in subparagraph (E), by striking “and” at
25 the end;

26 (ii) in subparagraph (F)—

27 (I) by striking “a subsequent year” and
28 inserting “2003”; and

29 (II) by striking “the previous year.” and
30 inserting “2002;” and

31 (iii) by adding at the end the following new
32 subparagraphs:

33 “(G) for 2004 through 2006—

34 “(i) subject to clause (ii), in the case of class
35 III medical devices described in section
36 513(a)(1)(C) of the Federal Food, Drug, and Cos-
37 metic Act (21 U.S.C. 360(c)(1)(C)), the percentage

1 increase described in subparagraph (B) for the year
2 involved; and

3 “(ii) in the case of covered items not described
4 in clause (i), 0 percentage points;

5 “(H) for 2007—

6 “(i) subject to clause (ii), in the case of class
7 III medical devices described in section
8 513(a)(1)(C) of the Federal Food, Drug, and Cos-
9 metic Act (21 U.S.C. 360(c)(1)(C)), the percentage
10 change determined by the Secretary to be appro-
11 priate taking into account recommendations con-
12 tained in the report of the Comptroller General of
13 the United States under section 302(c)(1)(B) of
14 the Medicare Prescription Drug, Improvement, and
15 Modernization Act of 2003; and

16 “(ii) in the case of covered items not described
17 in clause (i), 0 percentage points; and

18 “(I) for 2008—

19 “(i) subject to clause (ii), in the case of class
20 III medical devices described in section
21 513(a)(1)(C) of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360(c)(1)(C)), the percentage
23 increase described in subparagraph (B) (as applied
24 to the payment amount for 2007 determined after
25 the application of the percentage change under sub-
26 paragraph (H)(i)); and

27 “(ii) in the case of covered items not described
28 in clause (i), 0 percentage points; and

29 “(J) for a subsequent year, the percentage in-
30 crease in the consumer price index for all urban con-
31 sumers (U.S. urban average) for the 12-month period
32 ending with June of the previous year.”.

33 (B) GAO REPORT ON CLASS III MEDICAL DE-
34 VICES.—Not later than March 1, 2006, the Comptroller
35 General of the United States shall submit to Congress,
36 and transmit to the Secretary, a report containing rec-
37 ommendations on the appropriate update percentage

1 under section 1834(a)(14) of the Social Security Act
 2 (42 U.S.C. 1395m(a)(14)) for class III medical devices
 3 described in section 513(a)(1)(C) of the Federal Food,
 4 Drug, and Cosmetic Act (21 U.S.C. 360(a)(1)(C)) fur-
 5 nished to medicare beneficiaries during 2007 and 2008.

6 (2) PAYMENT RULE FOR SPECIFIED ITEMS.—Section
 7 1834(a) (42 U.S.C. 1395m(a)), as amended by subsection
 8 (a), is further amended by adding at the end the following
 9 new paragraph:

10 “(21) SPECIAL PAYMENT RULE FOR SPECIFIED ITEMS
 11 AND SUPPLIES.—

12 “(A) IN GENERAL.—Notwithstanding the pre-
 13 ceding provisions of this subsection, for specified items
 14 and supplies (described in subparagraph (B)) furnished
 15 during 2005, the payment amount otherwise deter-
 16 mined under this subsection for such specified items
 17 and supplies shall be reduced by the percentage dif-
 18 ference between—

19 “(i) the amount of payment otherwise deter-
 20 mined for the specified item or supply under this
 21 subsection for 2002, and

22 “(ii) the amount of payment for the specified
 23 item or supply under chapter 89 of title 5, United
 24 States Code, as identified in the column entitled
 25 ‘Median FEHP Price’ in the table entitled ‘SUM-
 26 MARY OF MEDICARE PRICES COMPARED
 27 TO VA, MEDICAID, RETAIL, AND FEHP
 28 PRICES FOR 16 ITEMS’ included in the Testi-
 29 mony of the Inspector General before the Senate
 30 Committee on Appropriations, June 12, 2002, or
 31 any subsequent report by the Inspector General.

32 “(B) SPECIFIED ITEM OR SUPPLY DESCRIBED.—
 33 For purposes of subparagraph (A), a specified item or
 34 supply means oxygen and oxygen equipment, standard
 35 wheelchairs (including standard power wheelchairs),
 36 nebulizers, diabetic supplies consisting of lancets and
 37 testing strips, hospital beds, and air mattresses, but

1 only if the HCPCS code for the item or supply is iden-
2 tified in a table referred to in subparagraph (A)(ii).

3 “(C) APPLICATION OF UPDATE TO SPECIAL PAY-
4 MENT AMOUNT.—The covered item update under para-
5 graph (14) for specified items and supplies for 2006
6 and each subsequent year shall be applied to the pay-
7 ment amount under subparagraph (A) unless payment
8 is made for such items and supplies under section
9 1847.”.

10 (3) PROSTHETIC DEVICES AND ORTHOTICS AND PROS-
11 THETICS.—Section 1834(h)(4)(A) (42 U.S.C.
12 1395m(h)(4)(A)) is amended—

13 (A) in clause (vii), by striking “and” at the end;

14 (B) in clause (viii), by striking “a subsequent
15 year” and inserting “2003”; and

16 (C) by adding at the end the following new
17 clauses:

18 “(ix) for 2004, 2005, and 2006, 0 percent;

19 and

20 “(x) for a subsequent year, the percentage in-
21 crease in the consumer price index for all urban
22 consumers (United States city average) for the 12-
23 month period ending with June of the previous
24 year;”.

25 (d) CONFORMING AMENDMENTS.—

26 (1) DURABLE MEDICAL EQUIPMENT; LIMITATION OF
27 INHERENT REASONABLENESS AUTHORITY.—Section
28 1834(a) (42 U.S.C. 1395m(a)) is amended—

29 (A) in paragraph (1)(B), by striking “The pay-
30 ment basis” and inserting “Subject to subparagraph
31 (F)(i), the payment basis”;

32 (B) in paragraph (1)(C), by striking “This sub-
33 section” and inserting “Subject to subparagraph
34 (F)(ii), this subsection”;

35 (C) by adding at the end of paragraph (1) the fol-
36 lowing new subparagraph:

1 “(F) APPLICATION OF COMPETITIVE ACQUISITION;
 2 LIMITATION OF INHERENT REASONABLENESS AUTHOR-
 3 ITY.—In the case of covered items furnished on or after
 4 January 1, 2009, that are included in a competitive ac-
 5 quisition program in a competitive acquisition area
 6 under section 1847(a)—

7 “(i) the payment basis under this subsection
 8 for such items and services furnished in such area
 9 shall be the payment basis determined under such
 10 competitive acquisition program; and

11 “(ii) the Secretary may use information on the
 12 payment determined under such competitive acqui-
 13 sition programs to adjust the payment amount oth-
 14 erwise recognized under subparagraph (B)(ii) for
 15 an area that is not a competitive acquisition area
 16 under section 1847 and in the case of such adjust-
 17 ment, paragraph (10)(B) shall not be applied.”;
 18 and

19 (D) in paragraph (10)(B), by inserting “in an
 20 area and with respect to covered items and services for
 21 which the Secretary does not make a payment amount
 22 adjustment under paragraph (1)(F)” after “under this
 23 subsection”.

24 (2) OFF-THE-SHELF ORTHOTICS; LIMITATION OF IN-
 25 HERENT REASONABLENESS AUTHORITY.—Section 1834(h)
 26 (42 U.S.C. 1395m(h)) is amended—

27 (A) in paragraph (1)(B), by striking “and (E)”
 28 and inserting “, (E), and (H)(i)”;

29 (B) in paragraph (1)(D), by striking “This sub-
 30 section” and inserting “Subject to subparagraph
 31 (H)(ii), this subsection”; and

32 (C) by adding at the end of paragraph (1) the fol-
 33 lowing new subparagraph:

34 “(H) APPLICATION OF COMPETITIVE ACQUISITION
 35 TO ORTHOTICS; LIMITATION OF INHERENT REASON-
 36 ABLENESS AUTHORITY.—In the case of orthotics de-
 37 scribed in paragraph (2)(C) of section 1847(a) fur-

1 nished on or after January 1, 2009, that are included
2 in a competitive acquisition program in a competitive
3 acquisition area under such section—

4 “(i) the payment basis under this subsection
5 for such orthotics furnished in such area shall be
6 the payment basis determined under such competi-
7 tive acquisition program; and

8 “(ii) the Secretary may use information on the
9 payment determined under such competitive acqui-
10 sition programs to adjust the payment amount oth-
11 erwise recognized under subparagraph (B)(ii) for
12 an area that is not a competitive acquisition area
13 under section 1847, and in the case of such adjust-
14 ment, paragraphs (8) and (9) of section 1842(b)
15 shall not be applied.”.

16 (3) OTHER ITEMS AND SERVICES; LIMITATION OF IN-
17 HERENT REASONABLENESS AUTHORITY.—Section 1842(s)
18 (42 U.S.C. 1395u(s)) is amended—

19 (A) in the first sentence of paragraph (1), by
20 striking “The Secretary” and inserting “Subject to
21 paragraph (3), the Secretary”; and

22 (B) by adding at the end the following new para-
23 graph:

24 “(3) In the case of items and services described in para-
25 graph (2)(D) that are included in a competitive acquisition pro-
26 gram in a competitive acquisition area under section 1847(a)—

27 “(A) the payment basis under this subsection for such
28 items and services furnished in such area shall be the pay-
29 ment basis determined under such competitive acquisition
30 program; and

31 “(B) the Secretary may use information on the pay-
32 ment determined under such competitive acquisition pro-
33 grams to adjust the payment amount otherwise applicable
34 under paragraph (1) for an area that is not a competitive
35 acquisition area under section 1847, and in the case of
36 such adjustment, paragraphs (8) and (9) of section
37 1842(b) shall not be applied.”.

1 (e) REPORT ON ACTIVITIES OF SUPPLIERS.—The Inspec-
 2 tor General of the Department of Health and Human Services
 3 shall conduct a study to determine the extent to which (if any)
 4 suppliers of covered items of durable medical equipment that
 5 are subject to the competitive acquisition program under sec-
 6 tion 1847 of the Social Security Act, as amended by subsection
 7 (a), are soliciting physicians to prescribe certain brands or
 8 modes of delivery of covered items based on profitability. Not
 9 later than July 1, 2009, the Inspector General shall submit to
 10 Congress a report on such study.

11 **SEC. 303. PAYMENT REFORM FOR COVERED OUT-**
 12 **PATIENT DRUGS AND BIOLOGICALS.**

13 (a) ADJUSTMENT TO PHYSICIAN FEE SCHEDULE.—

14 (1) ADJUSTMENT IN PRACTICE EXPENSE RELATIVE
 15 VALUE UNITS.—Section 1848(c)(2) (42 U.S.C. 1395w-
 16 4(c)(2)) is amended—

17 (A) in subparagraph (B)—

18 (i) in clause (ii)(II), by striking “The adjust-
 19 ments” and inserting “Subject to clause (iv), the
 20 adjustments”; and

21 (ii) by adding at the end of subparagraph (B),
 22 the following new clause:

23 “(iv) EXEMPTION FROM BUDGET NEU-
 24 TRALITY.—The additional expenditures attributable
 25 to—

26 “(I) subparagraph (H) shall not be taken
 27 into account in applying clause (ii)(II) for
 28 2004;

29 “(II) subparagraph (I) insofar as it relates
 30 to a physician fee schedule for 2005 or 2006
 31 shall not be taken into account in applying
 32 clause (ii)(II) for drug administration services
 33 under the fee schedule for such year for a spe-
 34 cialty described in subparagraph (I)(ii)(II); and

35 “(III) subparagraph (J) insofar as it re-
 36 lates to a physician fee schedule for 2005 or
 37 2006 shall not be taken into account in apply-

1 ing clause (ii)(II) for drug administration serv-
 2 ices under the fee schedule for such year.”; and
 3 (B) by adding at the end the following new sub-
 4 paragraphs:

5 “(H) ADJUSTMENTS IN PRACTICE EXPENSE REL-
 6 ATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRA-
 7 TION SERVICES BEGINNING IN 2004.—

8 “(i) USE OF SURVEY DATA.—In establishing
 9 the physician fee schedule under subsection (b)
 10 with respect to payments for services furnished on
 11 or after January 1, 2004, the Secretary shall, in
 12 determining practice expense relative value units
 13 under this subsection, utilize a survey submitted to
 14 the Secretary as of January 1, 2003, by a physi-
 15 cian specialty organization pursuant to section 212
 16 of the Medicare, Medicaid, and SCHIP Balanced
 17 Budget Refinement Act of 1999 if the survey—

18 “(I) covers practice expenses for oncology
 19 drug administration services; and

20 “(II) meets criteria established by the Sec-
 21 retary for acceptance of such surveys.

22 “(ii) PRICING OF CLINICAL ONCOLOGY NURSES
 23 IN PRACTICE EXPENSE METHODOLOGY.—If the
 24 survey described in clause (i) includes data on
 25 wages, salaries, and compensation of clinical oncol-
 26 ogy nurses, the Secretary shall utilize such data in
 27 the methodology for determining practice expense
 28 relative value units under subsection (c).

29 “(iii) WORK RELATIVE VALUE UNITS FOR CER-
 30 TAIN DRUG ADMINISTRATION SERVICES.—In estab-
 31 lishing the relative value units under this para-
 32 graph for drug administration services described in
 33 clause (iv) furnished on or after January 1, 2004,
 34 the Secretary shall establish work relative value
 35 units equal to the work relative value units for a
 36 level 1 office medical visit for an established pa-
 37 tient.

1 “(iv) DRUG ADMINISTRATION SERVICES DE-
2 SCRIBED.—The drug administration services de-
3 scribed in this clause are physicians’ services—

4 “(I) which are classified as of October 1,
5 2003, within any of the following groups of
6 procedures: therapeutic or diagnostic infusions
7 (excluding chemotherapy); chemotherapy ad-
8 ministration services; and therapeutic, prophylactic,
9 or diagnostic injections;

10 “(II) for which there are no work relative
11 value units assigned under this subsection as of
12 such date; and

13 “(III) for which national relative value
14 units have been assigned under this subsection
15 as of such date.

16 “(I) ADJUSTMENTS IN PRACTICE EXPENSE REL-
17 ATIVE VALUE UNITS FOR CERTAIN DRUG ADMINISTRA-
18 TION SERVICES BEGINNING WITH 2005.—

19 “(i) IN GENERAL.—In establishing the physi-
20 cian fee schedule under subsection (b) with respect
21 to payments for services furnished on or after Jan-
22 uary 1, 2005 or 2006, the Secretary shall adjust
23 the practice expense relative value units for such
24 year consistent with clause (ii).

25 “(ii) USE OF SUPPLEMENTAL SURVEY DATA.—

26 “(I) IN GENERAL.—Subject to subclause
27 (II), if a specialty submits to the Secretary by
28 not later than March 1, 2004, for 2005, or
29 March 1, 2005, for 2006, data that includes
30 expenses for the administration of drugs and
31 biologicals for which the payment amount is de-
32 termined pursuant to section 1842(o), the Sec-
33 retary shall use such supplemental survey data
34 in carrying out this subparagraph for the years
35 involved insofar as they are collected and pro-
36 vided by entities and organizations consistent
37 with the criteria established by the Secretary

1 pursuant to section 212(a) of the Medicare,
2 Medicaid, and SCHIP Balanced Budget Re-
3 finement Act of 1999.

4 “(II) LIMITATION ON SPECIALTY.—Sub-
5 clause (I) shall apply to a specialty only insofar
6 as not less than 40 percent of payments for the
7 specialty under this title in 2002 are attrib-
8 utable to the administration of drugs and
9 biologicals, as determined by the Secretary.

10 “(III) APPLICATION.—This clause shall
11 not apply with respect to a survey to which
12 subparagraph (H)(i) applies.

13 “(J) PROVISIONS FOR APPROPRIATE REPORTING
14 AND BILLING FOR PHYSICIANS’ SERVICES ASSOCIATED
15 WITH THE ADMINISTRATION OF COVERED OUTPATIENT
16 DRUGS AND BIOLOGICALS.—

17 “(i) EVALUATION OF CODES.—The Secretary
18 shall promptly evaluate existing drug administra-
19 tion codes for physicians’ services to ensure accu-
20 rate reporting and billing for such services, taking
21 into account levels of complexity of the administra-
22 tion and resource consumption.

23 “(ii) USE OF EXISTING PROCESSES.—In car-
24 rying out clause (i), the Secretary shall use existing
25 processes for the consideration of coding changes
26 and, to the extent coding changes are made, shall
27 use such processes in establishing relative values
28 for such services.

29 “(iii) IMPLEMENTATION.—In carrying out
30 clause (i), the Secretary shall consult with rep-
31 resentatives of physician specialties affected by the
32 implementation of section 1847A or section 1847B,
33 and shall take such steps within the Secretary’s au-
34 thority to expedite such considerations under clause
35 (ii).

36 “(iv) SUBSEQUENT, BUDGET NEUTRAL AD-
37 JUSTMENTS PERMITTED.—Nothing in subpara-

1 graph (H) or (I) or this subparagraph shall be con-
2 strued as preventing the Secretary from providing
3 for adjustments in practice expense relative value
4 units under (and consistent with) subparagraph
5 (B) for years after 2004, 2005, or 2006, respec-
6 tively.”.

7 (2) TREATMENT OF OTHER SERVICES CURRENTLY IN
8 THE NONPHYSICIAN WORK POOL.—The Secretary shall
9 make adjustments to the nonphysician work pool method-
10 ology (as such term is used in the final rule promulgated
11 by the Secretary in the Federal Register on December 31,
12 2002 (67 Fed. Reg. 251)), for the determination of prac-
13 tice expense relative value units under the physician fee
14 schedule under section 1848(c)(2)(C)(ii) of the Social Secu-
15 rity Act (42 U.S.C. 1395w-4(c)(2)(C)(ii)), so that the
16 practice expense relative value units for services determined
17 under such methodology are not affected relative to the
18 practice expense relative value units of services not deter-
19 mined under such methodology, as a result of the amend-
20 ments made by paragraph (1).

21 (3) PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS
22 FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECH-
23 NIQUE.—

24 (A) REVIEW OF POLICY.—The Secretary shall re-
25 view the policy, as in effect on October 1, 2003, with
26 respect to payment under section 1848 of the Social
27 Security Act (42 U.S.C. 1395w-4) for the administra-
28 tion of more than 1 drug or biological to an individual
29 on a single day through the push technique.

30 (B) MODIFICATION OF POLICY.—After conducting
31 the review under subparagraph (A), the Secretary shall
32 modify such payment policy as the Secretary deter-
33 mines to be appropriate.

34 (C) EXEMPTION FROM BUDGET NEUTRALITY
35 UNDER PHYSICIAN FEE SCHEDULE.—If the Secretary
36 modifies such payment policy pursuant to subpara-
37 graph (B), any increased expenditures under title

1 XVIII of the Social Security Act resulting from such
 2 modification shall be treated as additional expenditures
 3 attributable to subparagraph (H) of section 1848(c)(2)
 4 of the Social Security Act (42 U.S.C. 1395w-4(c)(2)),
 5 as added by paragraph (1)(B), for purposes of applying
 6 the exemption to budget neutrality under subparagraph
 7 (B)(iv) of such section, as added by paragraph (1)(A).

8 (4) TRANSITIONAL ADJUSTMENT.—

9 (A) IN GENERAL.—In order to provide for a tran-
 10 sition during 2004 and 2005 to the payment system es-
 11 tablished under the amendments made by this section,
 12 in the case of physicians' services consisting of drug
 13 administration services described in subparagraph
 14 (H)(iv) of section 1848(c)(2) of the Social Security Act
 15 (42 U.S.C. 1395w-4(c)(2)), as added by paragraph
 16 (1)(B), furnished on or after January 1, 2004, and be-
 17 fore January 1, 2006, in addition to the amount deter-
 18 mined under the fee schedule under section 1848(b) of
 19 such Act (42 U.S.C. 1395w-4(b)) there also shall be
 20 paid to the physician from the Federal Supplementary
 21 Medical Insurance Trust Fund an amount equal to the
 22 applicable percentage specified in subparagraph (B) of
 23 such fee schedule amount for the services so deter-
 24 mined.

25 (B) APPLICABLE PERCENTAGE.—The applicable
 26 percentage specified in this subparagraph for services
 27 furnished—

28 (i) during 2004, is 32 percent; and

29 (ii) during 2005, is 3 percent.

30 (5) MEDPAC REVIEW AND REPORTS; SECRETARIAL RE-
 31 SPONSE.—

32 (A) REVIEW.—The Medicare Payment Advisory
 33 Commission shall review the payment changes made
 34 under this section insofar as they affect payment under
 35 part B of title XVIII of the Social Security Act—

36 (i) for items and services furnished by
 37 oncologists; and

1 (ii) for drug administration services furnished
2 by other specialists.

3 (B) OTHER MATTERS STUDIED.—In conducting
4 the review under subparagraph (A), the Commission
5 shall also review such changes as they affect—

6 (i) the quality of care furnished to individuals
7 enrolled under part B and the satisfaction of such
8 individuals with that care;

9 (ii) the adequacy of reimbursement as applied
10 in, and the availability in, different geographic
11 areas and to different physician practice sizes; and

12 (iii) the impact on physician practices.

13 (C) REPORTS.—The Commission shall submit to
14 the Secretary and Congress—

15 (i) not later than January 1, 2006, a report
16 on the review conducted under subparagraph
17 (A)(i); and

18 (ii) not later than January 1, 2007, a report
19 on the review conducted under subparagraph
20 (A)(ii).

21 Each such report may include such recommendations
22 regarding further adjustments in such payments as the
23 Commission deems appropriate.

24 (D) SECRETARIAL RESPONSE.—As part of the
25 rulemaking with respect to payment for physicians
26 services under section 1848 of the Social Security Act
27 (42 U.S.C. 1395w-4) for 2007, the Secretary may
28 make appropriate adjustments to payment for items
29 and services described in subparagraph (A)(i), taking
30 into account the report submitted under such subpara-
31 graph (C)(i).

32 (b) APPLICATION OF MARKET-BASED PAYMENT SYS-
33 TEMS.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

34 (1) in paragraph (1), by striking “equal to 95 percent
35 of the average wholesale price.” and inserting “equal to the
36 following:

1 “(A) In the case of any of the following drugs or
2 biologicals, 95 percent of the average wholesale price:

3 “(i) A drug or biological furnished before January
4 1, 2004.

5 “(ii) Blood clotting factors furnished during 2004.

6 “(iii) A drug or biological furnished during 2004
7 that was not available for payment under this part as
8 of April 1, 2003.

9 “(iv) A vaccine described in subparagraph (A) or
10 (B) of section 1861(s)(10) furnished on or after Janu-
11 ary 1, 2004.

12 “(v) A drug or biological furnished during 2004 in
13 connection with the furnishing of renal dialysis services
14 if separately billed by renal dialysis facilities.

15 “(B) In the case of a drug or biological furnished dur-
16 ing 2004 that is not described in—

17 “(i) clause (ii), (iii), (iv), or (v) of subparagraph
18 (A),

19 “(ii) subparagraph (D)(i), or

20 “(iii) subparagraph (F),

21 the amount determined under paragraph (4).

22 “(C) In the case of a drug or biological that is not de-
23 scribed in subparagraph (A)(iv), (D)(i), or (F) furnished on
24 or after January 1, 2005, the amount provided under sec-
25 tion 1847, section 1847A, section 1847B, or section
26 1881(b)(13), as the case may be for the drug or biological.

27 “(D)(i) Except as provided in clause (ii), in the case
28 of infusion drugs furnished through an item of durable
29 medical equipment covered under section 1861(n) on or
30 after January 1, 2004, 95 percent of the average wholesale
31 price for such drug in effect on October 1, 2003.

32 “(ii) In the case of such infusion drugs furnished in
33 a competitive acquisition area under section 1847 on or
34 after January 1, 2007, the amount provided under section
35 1847.

36 “(E) In the case of a drug or biological, consisting of
37 intravenous immune globulin, furnished—

1 “(i) in 2004, the amount of payment provided
2 under paragraph (4); and

3 “(ii) in 2005 and subsequent years, the amount of
4 payment provided under section 1847A.

5 “(F) In the case of blood and blood products (other
6 than blood clotting factors), the amount of payment shall
7 be determined in the same manner as such amount of pay-
8 ment was determined on October 1, 2003.

9 “(G) The provisions of subparagraphs (A) through (F)
10 of this paragraph shall not apply to an inhalation drug or
11 biological furnished through durable medical equipment
12 covered under section 1861(n).”; and

13 (2) by adding at the end the following new paragraph:

14 “(4)(A) Subject to the succeeding provisions of this para-
15 graph, the amount of payment for a drug or biological under
16 this paragraph furnished in 2004 is equal to 85 percent of the
17 average wholesale price (determined as of April 1, 2003) for
18 the drug or biological.

19 “(B) The Secretary shall substitute for the percentage
20 under subparagraph (A) for a drug or biological the percentage
21 that would apply to the drug or biological under the column en-
22 titled ‘Average of GAO and OIG data (percent)’ in the table
23 entitled ‘Table 3.—Medicare Part B Drugs in the Most Recent
24 GAO and OIG Studies’ published on August 20, 2003, in the
25 Federal Register (68 Fed. Reg. 50445).

26 “(C)(i) The Secretary may substitute for the percentage
27 under subparagraph (A) a percentage that is based on data
28 and information submitted by the manufacturer of the drug or
29 biological by October 15, 2003.

30 “(ii) The Secretary may substitute for the percentage
31 under subparagraph (A) with respect to drugs and biologicals
32 furnished during 2004 on or after April 1, 2004, a percentage
33 that is based on data and information submitted by the manu-
34 facturer of the drug or biological after October 15, 2003, and
35 before January 1, 2004.

36 “(D) In no case may the percentage substituted under
37 subparagraph (B) or (C) be less than 80 percent.”.

1 (c) APPLICATION OF AVERAGE SALES PRICE METHODS
 2 BEGINNING IN 2005.—

3 (1) IN GENERAL.—Title XVIII is amended by insert-
 4 ing after section 1847 (42 U.S.C. 1395w-3), as amended
 5 by section 302(b), the following new section:

6 “USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

7 “SEC. 1847A. (a) APPLICATION.—

8 “(1) IN GENERAL.—Except as provided in paragraph
 9 (2), this section shall apply to payment for drugs and
 10 biologicals that are described in section 1842(o)(1)(C) and
 11 that are furnished on or after January 1, 2005.

12 “(2) ELECTION.—This section shall not apply in the
 13 case of a physician who elects under subsection
 14 (a)(1)(A)(ii) of section 1847B for that section to apply in-
 15 stead of this section for the payment for drugs and
 16 biologicals.

17 “(b) PAYMENT AMOUNT.—

18 “(1) IN GENERAL.—Subject to subsections (d)(3)(C)
 19 and (e), the amount of payment determined under this sec-
 20 tion for the billing and payment code for a drug or biologi-
 21 cal (based on a minimum dosage unit) is, subject to appli-
 22 cable deductible and coinsurance—

23 “(A) in the case of a multiple source drug (as de-
 24 fined in subsection (c)(6)(C)), 106 percent of the
 25 amount determined under paragraph (3); or

26 “(B) in the case of a single source drug or biologi-
 27 cal (as defined in subsection (c)(6)(D)), 106 percent of
 28 the amount determined under paragraph (4).

29 “(2) SPECIFICATION OF UNIT.—

30 “(A) SPECIFICATION BY MANUFACTURER.—The
 31 manufacturer of a drug or biological shall specify the
 32 unit associated with each National Drug Code (includ-
 33 ing package size) as part of the submission of data
 34 under section 1927(b)(3)(A)(iii).

35 “(B) UNIT DEFINED.—In this section, the term
 36 ‘unit’ means, with respect to each National Drug Code
 37 (including package size) associated with a drug or bio-

1 logical, the lowest identifiable quantity (such as a cap-
2 sule or tablet, milligram of molecules, or grams) of the
3 drug or biological that is dispensed, exclusive of any
4 diluent without reference to volume measures per-
5 taining to liquids. For years after 2004, the Secretary
6 may establish the unit for a manufacturer to report
7 and methods for counting units as the Secretary deter-
8 mines appropriate to implement this section.

9 “(3) MULTIPLE SOURCE DRUG.—For all drug prod-
10 ucts included within the same multiple source drug billing
11 and payment code, the amount specified in this paragraph
12 is the volume-weighted average of the average sales prices
13 reported under section 1927(b)(3)(A)(iii) determined by—

14 “(A) computing the sum of the products (for each
15 National Drug Code assigned to such drug products)
16 of—

17 “(i) the manufacturer’s average sales price (as
18 defined in subsection (c)); and

19 “(ii) the total number of units specified under
20 paragraph (2) sold; and

21 “(B) dividing the sum determined under subpara-
22 graph (A) by the sum of the total number of units
23 under subparagraph (A)(ii) for all National Drug
24 Codes assigned to such drug products.

25 “(4) SINGLE SOURCE DRUG OR BIOLOGICAL.—The
26 amount specified in this paragraph for a single source drug
27 or biological is the lesser of the following:

28 “(A) AVERAGE SALES PRICE.—The average sales
29 price as determined using the methodology applied
30 under paragraph (3) for all National Drug Codes as-
31 signed to such drug or biological product.

32 “(B) WHOLESAL ACQUISITION COST (WAC).—The
33 wholesale acquisition cost (as defined in subsection
34 (c)(6)(B)) using the methodology applied under para-
35 graph (3) for all National Drug Codes assigned to such
36 drug or biological product.

1 “(5) BASIS FOR PAYMENT AMOUNT.—The payment
2 amount shall be determined under this subsection based on
3 information reported under subsection (f) and without re-
4 gard to any special packaging, labeling, or identifiers on
5 the dosage form or product or package.

6 “(c) MANUFACTURER’S AVERAGE SALES PRICE.—

7 “(1) IN GENERAL.—For purposes of this section, sub-
8 ject to paragraphs (2) and (3), the manufacturer’s ‘average
9 sales price’ means, of a drug or biological for a National
10 Drug Code for a calendar quarter for a manufacturer for
11 a unit—

12 “(A) the manufacturer’s sales to all purchasers
13 (excluding sales exempted in paragraph (2)) in the
14 United States for such drug or biological in the cal-
15 endar quarter; divided by

16 “(B) the total number of such units of such drug
17 or biological sold by the manufacturer in such quarter.

18 “(2) CERTAIN SALES EXEMPTED FROM COMPUTA-
19 TION.—In calculating the manufacturer’s average sales
20 price under this subsection, the following sales shall be ex-
21 cluded:

22 “(A) SALES EXEMPT FROM BEST PRICE.—Sales
23 exempt from the inclusion in the determination of ‘best
24 price’ under section 1927(c)(1)(C)(i).

25 “(B) SALES AT NOMINAL CHARGE.—Such other
26 sales as the Secretary identifies as sales to an entity
27 that are merely nominal in amount (as applied for pur-
28 poses of section 1927(c)(1)(C)(ii)(III), except as the
29 Secretary may otherwise provide).

30 “(3) SALE PRICE NET OF DISCOUNTS.—In calculating
31 the manufacturer’s average sales price under this sub-
32 section, such price shall include volume discounts, prompt
33 pay discounts, cash discounts, free goods that are contin-
34 gent on any purchase requirement, chargebacks, and re-
35 bates (other than rebates under section 1927). For years
36 after 2004, the Secretary may include in such price other
37 price concessions, which may be based on recommendations

1 of the Inspector General, that would result in a reduction
2 of the cost to the purchaser.

3 “(4) PAYMENT METHODOLOGY IN CASES WHERE AV-
4 ERAGE SALES PRICE DURING FIRST QUARTER OF SALES IS
5 UNAVAILABLE.—In the case of a drug or biological during
6 an initial period (not to exceed a full calendar quarter) in
7 which data on the prices for sales for the drug or biological
8 is not sufficiently available from the manufacturer to com-
9 pute an average sales price for the drug or biological, the
10 Secretary may determine the amount payable under this
11 section for the drug or biological based on—

12 “(A) the wholesale acquisition cost; or

13 “(B) the methodologies in effect under this part
14 on November 1, 2003, to determine payment amounts
15 for drugs or biologicals.

16 “(5) FREQUENCY OF DETERMINATIONS.—

17 “(A) IN GENERAL ON A QUARTERLY BASIS.—The
18 manufacturer’s average sales price, for a drug or bio-
19 logical of a manufacturer, shall be calculated by such
20 manufacturer under this subsection on a quarterly
21 basis. In making such calculation insofar as there is a
22 lag in the reporting of the information on rebates and
23 chargebacks under paragraph (3) so that adequate data
24 are not available on a timely basis, the manufacturer
25 shall apply a methodology based on a 12-month rolling
26 average for the manufacturer to estimate costs attrib-
27 utable to rebates and chargebacks. For years after
28 2004, the Secretary may establish a uniform method-
29 ology under this subparagraph to estimate and apply
30 such costs.

31 “(B) UPDATES IN PAYMENT AMOUNTS.—The pay-
32 ment amounts under subsection (b) shall be updated by
33 the Secretary on a quarterly basis and shall be applied
34 based upon the manufacturer’s average sales price cal-
35 culated for the most recent calendar quarter for which
36 data is available.

1 “(C) USE OF CONTRACTORS; IMPLEMENTATION.—
2 The Secretary may contract with appropriate entities to
3 calculate the payment amount under subsection (b).
4 Notwithstanding any other provision of law, the Sec-
5 retary may implement, by program instruction or oth-
6 erwise, any of the provisions of this section.

7 “(6) DEFINITIONS AND OTHER RULES.—In this sec-
8 tion:

9 “(A) MANUFACTURER.—The term ‘manufacturer’
10 means, with respect to a drug or biological, the manu-
11 facturer (as defined in section 1927(k)(5)).

12 “(B) WHOLESALE ACQUISITION COST.—The term
13 ‘wholesale acquisition cost’ means, with respect to a
14 drug or biological, the manufacturer’s list price for the
15 drug or biological to wholesalers or direct purchasers in
16 the United States, not including prompt pay or other
17 discounts, rebates or reductions in price, for the most
18 recent month for which the information is available, as
19 reported in wholesale price guides or other publications
20 of drug or biological pricing data.

21 “(C) MULTIPLE SOURCE DRUG.—

22 “(i) IN GENERAL.—The term ‘multiple source
23 drug’ means, for a calendar quarter, a drug for
24 which there are 2 or more drug products which—

25 “(I) are rated as therapeutically equivalent
26 (under the Food and Drug Administration’s
27 most recent publication of ‘Approved Drug
28 Products with Therapeutic Equivalence Evalua-
29 tions’),

30 “(II) except as provided in subparagraph
31 (E), are pharmaceutically equivalent and bio-
32 equivalent, as determined under subparagraph
33 (F) and as determined by the Food and Drug
34 Administration, and

35 “(III) are sold or marketed in the United
36 States during the quarter.

1 “(ii) EXCEPTION.—With respect to single
2 source drugs or biologicals that are within the same
3 billing and payment code as of October 1, 2003,
4 the Secretary shall treat such single source drugs
5 or biologicals as if the single source drugs or
6 biologicals were multiple source drugs.

7 “(D) SINGLE SOURCE DRUG OR BIOLOGICAL.—
8 The term ‘single source drug or biological’ means—

9 “(i) a biological; or

10 “(ii) a drug which is not a multiple source
11 drug and which is produced or distributed under a
12 new drug application approved by the Food and
13 Drug Administration, including a drug product
14 marketed by any cross-licensed producers or dis-
15 tributors operating under the new drug application.

16 “(E) EXCEPTION FROM PHARMACEUTICAL
17 EQUIVALENCE AND BIOEQUIVALENCE REQUIREMENT.—
18 Subparagraph (C)(ii) shall not apply if the Food and
19 Drug Administration changes by regulation the require-
20 ment that, for purposes of the publication described in
21 subparagraph (C)(i), in order for drug products to be
22 rated as therapeutically equivalent, they must be phar-
23 maceutically equivalent and bioequivalent, as defined in
24 subparagraph (F).

25 “(F) DETERMINATION OF PHARMACEUTICAL
26 EQUIVALENCE AND BIOEQUIVALENCE.—For purposes
27 of this paragraph—

28 “(i) drug products are pharmaceutically equiv-
29 alent if the products contain identical amounts of
30 the same active drug ingredient in the same dosage
31 form and meet compendial or other applicable
32 standards of strength, quality, purity, and identity;
33 and

34 “(ii) drugs are bioequivalent if they do not
35 present a known or potential bioequivalence prob-
36 lem, or, if they do present such a problem, they are

1 shown to meet an appropriate standard of bio-
2 equivalence.

3 “(G) INCLUSION OF VACCINES.—In applying pro-
4 visions of section 1927 under this section, ‘other than
5 a vaccine’ is deemed deleted from section
6 1927(k)(2)(B).

7 “(d) MONITORING OF MARKET PRICES.—

8 “(1) IN GENERAL.—The Inspector General of the De-
9 partment of Health and Human Services shall conduct
10 studies, which may include surveys, to determine the widely
11 available market prices of drugs and biologicals to which
12 this section applies, as the Inspector General, in consulta-
13 tion with the Secretary, determines to be appropriate.

14 “(2) COMPARISON OF PRICES.—Based upon such stud-
15 ies and other data for drugs and biologicals, the Inspector
16 General shall compare the average sales price under this
17 section for drugs and biologicals with—

18 “(A) the widely available market price for such
19 drugs and biologicals (if any); and

20 “(B) the average manufacturer price (as deter-
21 mined under section 1927(k)(1)) for such drugs and
22 biologicals.

23 “(3) LIMITATION ON AVERAGE SALES PRICE.—

24 “(A) IN GENERAL.—The Secretary may disregard
25 the average sales price for a drug or biological that ex-
26 ceeds the widely available market price or the average
27 manufacturer price for such drug or biological by the
28 applicable threshold percentage (as defined in subpara-
29 graph (B)).

30 “(B) APPLICABLE THRESHOLD PERCENTAGE DE-
31 FINED.—In this paragraph, the term ‘applicable
32 threshold percentage’ means—

33 “(i) in 2005, in the case of an average sales
34 price for a drug or biological that exceeds widely
35 available market price or the average manufacturer
36 price, 5 percent; and

1 “(ii) in 2006 and subsequent years, the per-
 2 centage applied under this subparagraph subject to
 3 such adjustment as the Secretary may specify for
 4 the widely available market price or the average
 5 manufacturer price, or both.

6 “(C) AUTHORITY TO ADJUST AVERAGE SALES
 7 PRICE.—If the Inspector General finds that the average
 8 sales price for a drug or biological exceeds such widely
 9 available market price or average manufacturer price
 10 for such drug or biological by the applicable threshold
 11 percentage, the Inspector General shall inform the Sec-
 12 retary (at such times as the Secretary may specify to
 13 carry out this subparagraph) and the Secretary shall,
 14 effective as of the next quarter, substitute for the
 15 amount of payment otherwise determined under this
 16 section for such drug or biological the lesser of—

17 “(i) the widely available market price for the
 18 drug or biological (if any); or

19 “(ii) 103 percent of the average manufacturer
 20 price (as determined under section 1927(k)(1)) for
 21 the drug or biological.

22 “(4) CIVIL MONEY PENALTY.—

23 “(A) IN GENERAL.—If the Secretary determines
 24 that a manufacturer has made a misrepresentation in
 25 the reporting of the manufacturer’s average sales price
 26 for a drug or biological, the Secretary may apply a civil
 27 money penalty in an amount of up to \$10,000 for each
 28 such price misrepresentation and for each day in which
 29 such price misrepresentation was applied.

30 “(B) PROCEDURES.—The provisions of section
 31 1128A (other than subsections (a) and (b)) shall apply
 32 to civil money penalties under subparagraph (B) in the
 33 same manner as they apply to a penalty or proceeding
 34 under section 1128A(a).

35 “(5) WIDELY AVAILABLE MARKET PRICE.—

36 “(A) IN GENERAL.—In this subsection, the term
 37 ‘widely available market price’ means the price that a

1 prudent physician or supplier would pay for the drug
 2 or biological. In determining such price, the Inspector
 3 General shall take into account the discounts, rebates,
 4 and other price concessions routinely made available to
 5 such prudent physicians or suppliers for such drugs or
 6 biologicals.

7 “(B) CONSIDERATIONS.—In determining the price
 8 under subparagraph (A), the Inspector General shall
 9 consider information from one or more of the following
 10 sources:

11 “(i) Manufacturers.

12 “(ii) Wholesalers.

13 “(iii) Distributors.

14 “(iv) Physician supply houses.

15 “(v) Specialty pharmacies.

16 “(vi) Group purchasing arrangements.

17 “(vii) Surveys of physicians.

18 “(viii) Surveys of suppliers.

19 “(ix) Information on such market prices from
 20 insurers.

21 “(x) Information on such market prices from
 22 private health plans.

23 “(e) AUTHORITY TO USE ALTERNATIVE PAYMENT IN RE-
 24 SPONSE TO PUBLIC HEALTH EMERGENCY.—In the case of a
 25 public health emergency under section 319 of the Public Health
 26 Service Act in which there is a documented inability to access
 27 drugs and biologicals, and a concomitant increase in the price,
 28 of a drug or biological which is not reflected in the manufactur-
 29 er’s average sales price for one or more quarters, the Secretary
 30 may use the wholesale acquisition cost (or other reasonable
 31 measure of drug or biological price) instead of the manufactur-
 32 er’s average sales price for such quarters and for subsequent
 33 quarters until the price and availability of the drug or biologi-
 34 cal has stabilized and is substantially reflected in the applicable
 35 manufacturer’s average sales price.

36 “(f) QUARTERLY REPORT ON AVERAGE SALES PRICE.—
 37 For requirements for reporting the manufacturer’s average

1 sales price (and, if required to make payment, the manufactur-
2 er's wholesale acquisition cost) for the drug or biological under
3 this section, see section 1927(b)(3).

4 “(g) JUDICIAL REVIEW.—There shall be no administrative
5 or judicial review under section 1869, section 1878, or other-
6 wise, of—

7 “(1) determinations of payment amounts under this
8 section, including the assignment of National Drug Codes
9 to billing and payment codes;

10 “(2) the identification of units (and package size)
11 under subsection (b)(2);

12 “(3) the method to allocate rebates, chargebacks, and
13 other price concessions to a quarter if specified by the Sec-
14 retary;

15 “(4) the manufacturer's average sales price when it is
16 used for the determination of a payment amount under this
17 section; and

18 “(5) the disclosure of the average manufacturer price
19 by reason of an adjustment under subsection (d)(3)(C) or
20 (e).”.

21 (2) REPORT ON SALES TO PHARMACY BENEFIT MAN-
22 AGERS.—

23 (A) STUDY.—The Secretary shall conduct a study
24 on sales of drugs and biologicals to large volume pur-
25 chasers, such as pharmacy benefit managers and health
26 maintenance organizations, for purposes of determining
27 whether the price at which such drugs and biologicals
28 are sold to such purchasers does not represent the price
29 such drugs and biologicals are made available for pur-
30 chase to prudent physicians.

31 (B) REPORT.—Not later than January 1, 2006,
32 the Secretary shall submit to Congress a report on the
33 study conducted under paragraph (1), and shall include
34 recommendations on whether such sales to large volume
35 purchasers should be excluded from the computation of
36 a manufacturer's average sales price under section

1 “(i) competitive acquisition areas are estab-
2 lished for contract award purposes for acquisition
3 of and payment for categories of competitively bid-
4 dable drugs and biologicals (as defined in para-
5 graph (2)) under this part;

6 “(ii) each physician is given the opportunity
7 annually to elect to obtain drugs and biologicals
8 under the program, rather than under section
9 1847A; and

10 “(iii) each physician who elects to obtain drugs
11 and biologicals under the program makes an an-
12 nual selection under paragraph (5) of the con-
13 tractor through which drugs and biologicals within
14 a category of drugs and biologicals will be acquired
15 and delivered to the physician under this part.

16 This section shall not apply in the case of a physician
17 who elects section 1847A to apply.

18 “(B) IMPLEMENTATION.—For purposes of imple-
19 menting the program, the Secretary shall establish cat-
20 egories of competitively biddable drugs and biologicals.
21 The Secretary shall phase in the program with respect
22 to those categories beginning in 2006 in such manner
23 as the Secretary determines to be appropriate.

24 “(C) WAIVER OF CERTAIN PROVISIONS.—In order
25 to promote competition, in carrying out the program
26 the Secretary may waive such provisions of the Federal
27 Acquisition Regulation as are necessary for the efficient
28 implementation of this section, other than provisions
29 relating to confidentiality of information and such other
30 provisions as the Secretary determines appropriate.

31 “(D) EXCLUSION AUTHORITY.—The Secretary
32 may exclude competitively biddable drugs and
33 biologicals (including a class of such drugs and
34 biologicals) from the competitive bidding system under
35 this section if the application of competitive bidding to
36 such drugs or biologicals—

1 “(i) is not likely to result in significant sav-
2 ings; or

3 “(ii) is likely to have an adverse impact on ac-
4 cess to such drugs or biologicals.

5 “(2) COMPETITIVELY BIDDABLE DRUGS AND
6 BIOLOGICALS AND PROGRAM DEFINED.—For purposes of
7 this section—

8 “(A) COMPETITIVELY BIDDABLE DRUGS AND
9 BIOLOGICALS DEFINED.—The term ‘competitively bid-
10 dable drugs and biologicals’ means a drug or biological
11 described in section 1842(o)(1)(C) and furnished on or
12 after January 1, 2006.

13 “(B) PROGRAM.—The term ‘program’ means the
14 competitive acquisition program under this section.

15 “(C) COMPETITIVE ACQUISITION AREA; AREA.—
16 The terms ‘competitive acquisition area’ and ‘area’
17 mean an appropriate geographic region established by
18 the Secretary under the program.

19 “(D) CONTRACTOR.—The term ‘contractor’ means
20 an entity that has entered into a contract with the Sec-
21 retary under this section.

22 “(3) APPLICATION OF PROGRAM PAYMENT METHOD-
23 OLOGY.—

24 “(A) IN GENERAL.—With respect to competitively
25 biddable drugs and biologicals which are supplied under
26 the program in an area and which are prescribed by a
27 physician who has elected this section to apply—

28 “(i) the claim for such drugs and biologicals
29 shall be submitted by the contractor that supplied
30 the drugs and biologicals;

31 “(ii) collection of amounts of any deductible
32 and coinsurance applicable with respect to such
33 drugs and biologicals shall be the responsibility of
34 such contractor and shall not be collected unless
35 the drug or biological is administered to the indi-
36 vidual involved; and

1 “(iii) the payment under this section (and re-
 2 lated amounts of any applicable deductible and co-
 3 insurance) for such drugs and biologicals—

4 “(I) shall be made only to such contractor;

5 and

6 “(II) shall be conditioned upon the admin-
 7 istration of such drugs and biologicals.

8 “(B) PROCESS FOR ADJUSTMENTS.—The Sec-
 9 retary shall provide a process for adjustments to pay-
 10 ments in the case in which payment is made for drugs
 11 and biologicals which were billed at the time of dis-
 12 pensing but which were not actually administered.

13 “(C) INFORMATION FOR PURPOSES OF COST-SHAR-
 14 ING.—The Secretary shall provide a process by which
 15 physicians submit information to contractors for pur-
 16 poses of the collection of any applicable deductible or
 17 coinsurance amounts under subparagraph (A)(ii).

18 “(4) CONTRACT REQUIRED.—Payment may not be
 19 made under this part for competitively biddable drugs and
 20 biologicals prescribed by a physician who has elected this
 21 section to apply within a category and a competitive acqui-
 22 sition area with respect to which the program applies
 23 unless—

24 “(A) the drugs or biologicals are supplied by a
 25 contractor with a contract under this section for such
 26 category of drugs and biologicals and area; and

27 “(B) the physician has elected such contractor
 28 under paragraph (5) for such category and area.

29 “(5) CONTRACTOR SELECTION PROCESS.—

30 “(A) ANNUAL SELECTION.—

31 “(i) IN GENERAL.—The Secretary shall pro-
 32 vide a process for the selection of a contractor, on
 33 an annual basis and in such exigent circumstances
 34 as the Secretary may provide and with respect to
 35 each category of competitively biddable drugs and
 36 biologicals for an area by selecting physicians.

1 “(ii) TIMING OF SELECTION.—The selection of
2 a contractor under clause (i) shall be made at the
3 time of the election described in section 1847A(a)
4 for this section to apply and shall be coordinated
5 with agreements entered into under section
6 1842(h).

7 “(B) INFORMATION ON CONTRACTORS.—The Sec-
8 retary shall make available to physicians on an ongoing
9 basis, through a directory posted on the Internet
10 website of the Centers for Medicare & Medicaid Serv-
11 ices or otherwise and upon request, a list of the con-
12 tractors under this section in the different competitive
13 acquisition areas.

14 “(C) SELECTING PHYSICIAN DEFINED.—For pur-
15 poses of this section, the term ‘selecting physician’
16 means, with respect to a contractor and category and
17 competitive acquisition area, a physician who has elect-
18 ed this section to apply and has selected to apply under
19 this section such contractor for such category and area.

20 “(b) PROGRAM REQUIREMENTS.—

21 “(1) CONTRACT FOR COMPETITIVELY BIDDABLE
22 DRUGS AND BIOLOGICALS.—The Secretary shall conduct a
23 competition among entities for the acquisition of competi-
24 tively biddable drugs and biologicals. Notwithstanding any
25 other provision of this title, in the case of a multiple source
26 drug, the Secretary shall conduct such competition among
27 entities for the acquisition of at least one competitively bid-
28 dable drug and biological within each billing and payment
29 code within each category for each competitive acquisition
30 area.

31 “(2) CONDITIONS FOR AWARDING CONTRACT.—

32 “(A) IN GENERAL.—The Secretary may not award
33 a contract to any entity under the competition con-
34 ducted in a competitive acquisition area pursuant to
35 paragraph (1) with respect to the acquisition of com-
36 petitively biddable drugs and biologicals within a cat-
37 egory unless the Secretary finds that the entity meets

1 all of the following with respect to the contract period
2 involved:

3 “(i) CAPACITY TO SUPPLY COMPETITIVELY
4 BIDDABLE DRUG OR BIOLOGICAL WITHIN CAT-
5 EGORY.—

6 “(I) IN GENERAL.—The entity has suffi-
7 cient arrangements to acquire and to deliver
8 competitively biddable drugs and biologicals
9 within such category in the area specified in
10 the contract.

11 “(II) SHIPMENT METHODOLOGY.—The en-
12 tity has arrangements in effect for the ship-
13 ment at least 5 days each week of competitively
14 biddable drugs and biologicals under the con-
15 tract and for the timely delivery (including for
16 emergency situations) of such drugs and
17 biologicals in the area under the contract.

18 “(ii) QUALITY, SERVICE, FINANCIAL PERFORM-
19 ANCE AND SOLVENCY STANDARDS.—The entity
20 meets quality, service, financial performance, and
21 solvency standards specified by the Secretary,
22 including—

23 “(I) the establishment of procedures for
24 the prompt response and resolution of com-
25 plaints of physicians and individuals and of in-
26 quiries regarding the shipment of competitively
27 biddable drugs and biologicals; and

28 “(II) a grievance and appeals process for
29 the resolution of disputes.

30 “(B) ADDITIONAL CONSIDERATIONS.—The Sec-
31 retary may refuse to award a contract under this sec-
32 tion, and may terminate such a contract, with an entity
33 based upon—

34 “(i) the suspension or revocation, by the Fed-
35 eral Government or a State government, of the en-
36 tity’s license for the distribution of drugs or
37 biologicals (including controlled substances); or

1 “(ii) the exclusion of the entity under section
2 1128 from participation under this title.

3 “(C) APPLICATION OF MEDICARE PROVIDER OM-
4 BUDSMAN.—For provision providing for a program-
5 wide Medicare Provider Ombudsman to review com-
6 plaints, see section 1868(b), as added by section 923
7 of the Medicare Prescription Drug, Improvement, and
8 Modernization Act of 2003.

9 “(3) AWARDING MULTIPLE CONTRACTS FOR A CAT-
10 EGORY AND AREA.—The Secretary may limit (but not
11 below 2) the number of qualified entities that are awarded
12 such contracts for any category and area. The Secretary
13 shall select among qualified entities based on the following:

14 “(A) The bid prices for competitively biddable
15 drugs and biologicals within the category and area.

16 “(B) Bid price for distribution of such drugs and
17 biologicals.

18 “(C) Ability to ensure product integrity.

19 “(D) Customer service.

20 “(E) Past experience in the distribution of drugs
21 and biologicals, including controlled substances.

22 “(F) Such other factors as the Secretary may
23 specify.

24 “(4) TERMS OF CONTRACTS.—

25 “(A) IN GENERAL.—A contract entered into with
26 an entity under the competition conducted pursuant to
27 paragraph (1) is subject to terms and conditions that
28 the Secretary may specify consistent with this section.

29 “(B) PERIOD OF CONTRACTS.—A contract under
30 this section shall be for a term of 3 years, but may be
31 terminated by the Secretary or the entity with appro-
32 priate, advance notice.

33 “(C) INTEGRITY OF DRUG AND BIOLOGICAL DIS-
34 TRIBUTION SYSTEM.—A contractor (as defined in sub-
35 section (a)(2)(D)) shall—

36 “(i) acquire all drug and biological products it
37 distributes directly from the manufacturer or from

1 a distributor that has acquired the products di-
2 rectly from the manufacturer; and

3 “(ii) comply with any product integrity safe-
4 guards as may be determined to be appropriate by
5 the Secretary.

6 Nothing in this subparagraph shall be construed to re-
7 lieve or exempt any contractor from the provisions of
8 the Federal Food, Drug, and Cosmetic Act that relate
9 to the wholesale distribution of prescription drugs or
10 biologicals.

11 “(D) COMPLIANCE WITH CODE OF CONDUCT AND
12 FRAUD AND ABUSE RULES.—Under the contract—

13 “(i) the contractor shall comply with a code of
14 conduct, specified or recognized by the Secretary,
15 that includes standards relating to conflicts of in-
16 terest; and

17 “(ii) the contractor shall comply with all appli-
18 cable provisions relating to prevention of fraud and
19 abuse, including compliance with applicable guide-
20 lines of the Department of Justice and the Inspec-
21 tor General of the Department of Health and
22 Human Services.

23 “(E) DIRECT DELIVERY OF DRUGS AND
24 BIOLOGICALS TO PHYSICIANS.—Under the contract the
25 contractor shall only supply competitively biddable
26 drugs and biologicals directly to the selecting physi-
27 cians and not directly to individuals, except under cir-
28 cumstances and settings where an individual currently
29 receives a drug or biological in the individual’s home or
30 other non-physician office setting as the Secretary may
31 provide. The contractor shall not deliver drugs and
32 biologicals to a selecting physician except upon receipt
33 of a prescription for such drugs and biologicals, and
34 such necessary data as may be required by the Sec-
35 retary to carry out this section. This section does not—

36 “(i) require a physician to submit a prescrip-
37 tion for each individual treatment; or

1 “(ii) change a physician’s flexibility in terms
2 of writing a prescription for drugs or biologicals for
3 a single treatment or a course of treatment.

4 “(5) PERMITTING ACCESS TO DRUGS AND
5 BIOLOGICALS.—The Secretary shall establish rules under
6 this section under which drugs and biologicals which are
7 acquired through a contractor under this section may be
8 used to resupply inventories of such drugs and biologicals
9 which are administered consistent with safe drug practices
10 and with adequate safeguards against fraud and abuse.
11 The previous sentence shall apply if the physicians can
12 demonstrate to the Secretary all of the following:

13 “(A) The drugs or biologicals are required imme-
14 diately.

15 “(B) The physician could not have reasonably an-
16 ticipated the immediate requirement for the drugs or
17 biologicals.

18 “(C) The contractor could not deliver to the physi-
19 cian the drugs or biologicals in a timely manner.

20 “(D) The drugs or biologicals were administered
21 in an emergency situation.

22 “(6) CONSTRUCTION.—Nothing in this section shall be
23 construed as waiving applicable State requirements relating
24 to licensing of pharmacies.

25 “(c) BIDDING PROCESS.—

26 “(1) IN GENERAL.—In awarding a contract for a cat-
27 egory of drugs and biologicals in an area under the pro-
28 gram, the Secretary shall consider with respect to each en-
29 tity seeking to be awarded a contract the bid price and the
30 other factors referred to in subsection (b)(3).

31 “(2) BID DEFINED.—In this section, the term ‘bid’
32 means an offer to furnish a competitively biddable drug or
33 biological for a particular price and time period.

34 “(3) BIDDING ON A NATIONAL OR REGIONAL BASIS.—
35 Nothing in this section shall be construed as precluding a
36 bidder from bidding for contracts in all areas of the United

1 States or as requiring a bidder to submit a bid for all areas
2 of the United States.

3 “(4) UNIFORMITY OF BIDS WITHIN AREA.—The
4 amount of the bid submitted under a contract offer for any
5 competitively biddable drug or biological for an area shall
6 be the same for that drug or biological for all portions of
7 that area.

8 “(5) CONFIDENTIALITY OF BIDS.—The provisions of
9 subparagraph (D) of section 1927(b)(3) shall apply to peri-
10 ods during which a bid is submitted with respect to a com-
11 petitively biddable drug or biological under this section in
12 the same manner as it applies to information disclosed
13 under such section, except that any reference—

14 “(A) in that subparagraph to a ‘manufacturer or
15 wholesaler’ is deemed a reference to a ‘bidder’ under
16 this section;

17 “(B) in that section to ‘prices charged for drugs’
18 is deemed a reference to a ‘bid’ submitted under this
19 section; and

20 “(C) in clause (i) of that section to ‘this section’,
21 is deemed a reference to ‘part B of title XVIII’.

22 “(6) INCLUSION OF COSTS.—The bid price submitted
23 in a contract offer for a competitively biddable drug or bio-
24 logical shall—

25 “(A) include all costs related to the delivery of the
26 drug or biological to the selecting physician (or other
27 point of delivery); and

28 “(B) include the costs of dispensing (including
29 shipping) of such drug or biological and management
30 fees, but shall not include any costs related to the ad-
31 ministration of the drug or biological, or wastage, spill-
32 age, or spoilage.

33 “(7) PRICE ADJUSTMENTS DURING CONTRACT PERIOD;
34 DISCLOSURE OF COSTS.—Each contract awarded shall pro-
35 vide for—

36 “(A) disclosure to the Secretary the contractor’s
37 reasonable, net acquisition costs for periods specified by

1 the Secretary, not more often than quarterly, of the
2 contract; and

3 “(B) appropriate price adjustments over the pe-
4 riod of the contract to reflect significant increases or
5 decreases in a contractor’s reasonable, net acquisition
6 costs, as so disclosed.

7 “(d) COMPUTATION OF PAYMENT AMOUNTS.—

8 “(1) IN GENERAL.—Payment under this section for
9 competitively biddable drugs or biologicals shall be based on
10 bids submitted and accepted under this section for such
11 drugs or biologicals in an area. Based on such bids the Sec-
12 retary shall determine a single payment amount for each
13 competitively biddable drug or biological in the area.

14 “(2) SPECIAL RULES.—The Secretary shall establish
15 rules regarding the use under this section of the alternative
16 payment amount provided under section 1847A to the use
17 of a price for specific competitively biddable drugs and
18 biologicals in the following cases:

19 “(A) NEW DRUGS AND BIOLOGICALS.—A competi-
20 tively biddable drug or biological for which a payment
21 and billing code has not been established.

22 “(B) OTHER CASES.—Such other exceptional cases
23 as the Secretary may specify in regulations.

24 “(e) COST-SHARING.—

25 “(1) APPLICATION OF COINSURANCE.—Payment under
26 this section for competitively biddable drugs and biologicals
27 shall be in an amount equal to 80 percent of the payment
28 basis described in subsection (d)(1).

29 “(2) DEDUCTIBLE.—Before applying paragraph (1),
30 the individual shall be required to meet the deductible de-
31 scribed in section 1833(b).

32 “(3) COLLECTION.—Such coinsurance and deductible
33 shall be collected by the contractor that supplies the drug
34 or biological involved. Subject to subsection (a)(3)(B), such
35 coinsurance and deductible may be collected in a manner
36 similar to the manner in which the coinsurance and deduct-

1 ible are collected for durable medical equipment under this
2 part.

3 “(f) SPECIAL PAYMENT RULES.—

4 “(1) USE IN EXCLUSION CASES.—If the Secretary ex-
5 cludes a drug or biological (or class of drugs or biologicals)
6 under subsection (a)(1)(D), the Secretary may provide for
7 payment to be made under this part for such drugs and
8 biologicals (or class) using the payment methodology under
9 section 1847A.

10 “(2) APPLICATION OF REQUIREMENT FOR ASSIGN-
11 MENT.—For provision requiring assignment of claims for
12 competitively biddable drugs and biologicals, see section
13 1842(o)(3).

14 “(3) PROTECTION FOR BENEFICIARY IN CASE OF MED-
15 ICAL NECESSITY DENIAL.—For protection of individuals
16 against liability in the case of medical necessity determina-
17 tions, see section 1842(b)(3)(B)(ii)(III).

18 “(g) JUDICIAL REVIEW.—There shall be no administrative
19 or judicial review under section 1869, section 1878, or other-
20 wise, of—

21 “(1) the establishment of payment amounts under
22 subsection (d)(1);

23 “(2) the awarding of contracts under this section;

24 “(3) the establishment of competitive acquisition areas
25 under subsection (a)(2)(C);

26 “(4) the phased-in implementation under subsection
27 (a)(1)(B);

28 “(5) the selection of categories of competitively bid-
29 dable drugs and biologicals for competitive acquisition
30 under such subsection or the selection of a drug in the case
31 of multiple source drugs; or

32 “(6) the bidding structure and number of contractors
33 selected under this section.”.

34 (2) REPORT.—Not later than July 1, 2008, the Sec-
35 retary shall submit to Congress a report on the program
36 conducted under section 1847B of the Social Security Act,
37 as added by paragraph (1). Such report shall include infor-

1 mation on savings, reductions in cost-sharing, access to
 2 competitively biddable drugs and biologicals, the range of
 3 choices of contractors available to physicians, the satisfac-
 4 tion of physicians and of individuals enrolled under this
 5 part, and information comparing prices for drugs and
 6 biologicals under such section and section 1847A of such
 7 Act, as added by subsection (c).

8 (e) ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINIS-
 9 TRATION OF DRUGS AND BIOLOGICALS.—

10 (1) ITEMS AND SERVICES RELATING TO FURNISHING
 11 OF BLOOD CLOTTING FACTORS.—Section 1842(o) (42
 12 U.S.C. 1395u(o)), as amended by subsection (b)(2), is
 13 amended by adding at the end the following new para-
 14 graph:

15 “(5)(A) Subject to subparagraph (B), in the case of clot-
 16 ting factors furnished on or after January 1, 2005, the Sec-
 17 retary shall, after reviewing the January 2003 report to Con-
 18 gress by the Comptroller General of the United States entitled
 19 ‘Payment for Blood Clotting Factor Exceeds Providers Acquisi-
 20 tion Cost’, provide for a separate payment, to the entity which
 21 furnishes to the patient blood clotting factors, for items and
 22 services related to the furnishing of such factors in an amount
 23 that the Secretary determines to be appropriate. Such payment
 24 amount may take into account any or all of the following:

25 “(i) The mixing (if appropriate) and delivery of factors
 26 to an individual, including special inventory management
 27 and storage requirements.

28 “(ii) Ancillary supplies and patient training necessary
 29 for the self-administration of such factors.

30 “(B) In determining the separate payment amount under
 31 subparagraph (A) for blood clotting factors furnished in 2005,
 32 the Secretary shall ensure that the total amount of payments
 33 under this part (as estimated by the Secretary) for such factors
 34 under paragraph (1)(C) and such separate payments for such
 35 factors does not exceed the total amount of payments that
 36 would have been made for such factors under this part (as esti-
 37 mated by the Secretary) if the amendments made by section

1 303 of the Medicare Prescription Drug, Improvement, and
2 Modernization Act of 2003 had not been enacted.

3 “(C) The separate payment amount under this subpara-
4 graph for blood clotting factors furnished in 2006 or a subse-
5 quent year shall be equal to the separate payment amount de-
6 termined under this paragraph for the previous year increased
7 by the percentage increase in the consumer price index for
8 medical care for the 12-month period ending with June of the
9 previous year.”.

10 (2) PHARMACY SUPPLYING FEE FOR CERTAIN DRUGS
11 AND BIOLOGICALS.—Section 1842(o) (42 U.S.C. 1395u(o)),
12 as previously amended, is amended by adding at the end
13 the following new paragraph:

14 “(6) In the case of an immunosuppressive drug described
15 in subparagraph (J) of section 1861(s)(2) and an oral drug de-
16 scribed in subparagraph (Q) or (T) of such section, the Sec-
17 retary shall pay to the pharmacy a supplying fee for such a
18 drug determined appropriate by the Secretary (less the applica-
19 ble deductible and coinsurance amounts).”.

20 (f) LINKAGE OF REVISED DRUG PAYMENTS AND IN-
21 CREASES FOR DRUG ADMINISTRATION.—The Secretary shall
22 not implement the revisions in payment amounts for drugs and
23 biologicals administered by physicians as a result of the amend-
24 ments made by subsection (b) with respect to 2004 unless the
25 Secretary concurrently makes adjustments to the practice ex-
26 pense payment adjustment under the amendments made by
27 subsection (a).

28 (g) PROHIBITION OF ADMINISTRATIVE AND JUDICIAL RE-
29 VIEW.—

30 (1) DRUGS.—Section 1842(o) (42 U.S.C. 1395u(o)),
31 as previously amended, is amended by adding at the end
32 the following new paragraph:

33 “(7) There shall be no administrative or judicial review
34 under section 1869, section 1878, or otherwise, of determina-
35 tions of payment amounts, methods, or adjustments under
36 paragraphs (4) through (6).”.

1 (2) PHYSICIAN FEE SCHEDULE.—Section
2 1848(i)(1)(B) (42 U.S.C. 1395w-4(i)(1)(B)) is amended by
3 striking “subsection (c)(2)(F)” and inserting “subsections
4 (c)(2)(F), (c)(2)(H), and (c)(2)(I)”.

5 (3) MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERV-
6 ICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL,
7 AND TRANSITIONAL ADJUSTMENT.—There shall be no ad-
8 ministrative or judicial review under section 1869, section
9 1878, or otherwise, of determinations of payment amounts,
10 methods, or adjustments under paragraphs (2) through (4)
11 of subsection (a).

12 (h) CONTINUATION OF PAYMENT METHODOLOGY FOR
13 RADIOPHARMACEUTICALS.—Nothing in the amendments made
14 by this section shall be construed as changing the payment
15 methodology under part B of title XVIII of the Social Security
16 Act for radiopharmaceuticals, including the use by carriers of
17 invoice pricing methodology.

18 (i) CONFORMING AMENDMENTS.—

19 (1) APPLICATION OF ASP AND COMPETITIVE BID-
20 DING.—Section 1842(o)(2) (42 U.S.C. 1395u(o)(2)) is
21 amended by adding at the end the following: “This para-
22 graph shall not apply in the case of payment under para-
23 graph (1)(C).”.

24 (2) NO CHANGE IN COVERAGE BASIS.—Section
25 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by
26 inserting “(or would have been so included but for the ap-
27 plication of section 1847B)” after “included in the physi-
28 cians’ bills”.

29 (3) PAYMENT.—(A) Section 1833(a)(1)(S) (42 U.S.C.
30 1395l(a)(1)(S)) is amended by inserting “(or, if applicable,
31 under section 1847, 1847A, or 1847B)” after “1842(o)”.

32 (B) Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)) is
33 amended—

34 (i) by striking “and” at the end of subparagraph
35 (H);

36 (ii) by striking the semicolon at the end of sub-
37 paragraph (I) and inserting “, and”; and

1 (iii) by adding at the end the following new sub-
2 paragraph:

3 “(J) in the case of a drug or biological specified in
4 section 1847A(c)(6)(C) for which payment is made under
5 part B that is furnished in a competitive area under section
6 1847B, that is not furnished by an entity under a contract
7 under such section;”.

8 (4) CONSOLIDATED REPORTING OF PRICING INFORMA-
9 TION.—Section 1927 (42 U.S.C. 1396r–8) is amended—

10 (A) in subsection (a)(1), by inserting “or under
11 part B of title XVIII” after “section 1903(a)”;

12 (B) in subsection (b)(3)(A)—

13 (i) in clause (i), by striking “and” at the end
14 and inserting a semicolon;

15 (ii) in clause (ii), by striking the period and
16 inserting “; and”; and

17 (iii) by adding at the end the following:

18 “(iii) for calendar quarters beginning on or
19 after January 1, 2004, in conjunction with report-
20 ing required under clause (i) and by National Drug
21 Code (including package size)—

22 “(I) the manufacturer’s average sales
23 price (as defined in section 1847A(c)) and the
24 total number of units specified under section
25 1847A(b)(2)(A);

26 “(II) if required to make payment under
27 section 1847A, the manufacturer’s wholesale
28 acquisition cost, as defined in subsection (c)(6)
29 of such section; and

30 “(III) information on those sales that were
31 made at a nominal price or otherwise described
32 in section 1847A(c)(2)(B);

33 for a drug or biological described in subparagraph
34 (C), (D), (E), or (G) of section 1842(o)(1) or sec-
35 tion 1881(b)(13)(A)(ii).

1 Information reported under this subparagraph is sub-
 2 ject to audit by the Inspector General of the Depart-
 3 ment of Health and Human Services.”;

4 (C) in subsection (b)(3)(B)—

5 (i) in the heading, by inserting “AND MANU-
 6 FACTURER’S AVERAGE SALES PRICE” after
 7 “PRICE”; and

8 (ii) by inserting “and manufacturer’s average
 9 sales prices (including wholesale acquisition cost) if
 10 required to make payment” after “manufacturer
 11 prices”; and

12 (D) in subsection (b)(3)(D)—

13 (i) in the matter preceding clause (i), by in-
 14 sserting “(other than the wholesale acquisition cost
 15 for purposes of carrying out section 1847A)” after
 16 “subsection (a)(6)(A)(ii)”; and

17 (ii) in clause (i), by inserting “, to carry out
 18 section 1847A (including the determination and im-
 19 plementation of the payment amount), or to carry
 20 out section 1847B” after “this section”.

21 (5) IMPLEMENTATION.—The provisions of chapter 8 of
 22 title 5, United States Code, shall not apply with respect to
 23 regulations implementing the amendments made by sub-
 24 sections (a), (b), and (e)(3), to regulations implementing
 25 section 304, and to regulations implementing the amend-
 26 ment made by section 305(a), insofar as such regulations
 27 apply in 2004.

28 (6) REPEAL OF STUDY.—Section 4556 of the Bal-
 29 anced Budget Act of 1997 (42 U.S.C. 1395u note) is
 30 amended by striking subsection (c).

31 (j) APPLICATION TO CERTAIN PHYSICIAN SPECIALTIES.—
 32 Insofar as the amendments made by this section apply to pay-
 33 ments for drugs or biologicals and drug administration services
 34 furnished by physicians, such amendments shall only apply to
 35 physicians in the specialties of hematology, hematology/oncol-
 36 ogy, and medical oncology under title XVIII of the Social Secu-
 37 rity Act.

1 **SEC. 304. EXTENSION OF APPLICATION OF PAYMENT RE-**
 2 **FORM FOR COVERED OUTPATIENT DRUGS**
 3 **AND BIOLOGICALS TO OTHER PHYSICIAN**
 4 **SPECIALTIES.**

5 Notwithstanding section 303(j), the amendments made by
 6 section 303 shall also apply to payments for drugs or
 7 biologicals and drug administration services furnished by physi-
 8 cians in specialties other than the specialties of hematology, he-
 9 matology/oncology, and medical oncology.

10 **SEC. 305. PAYMENT FOR INHALATION DRUGS.**

11 (a) IN GENERAL.—Section 1842(o)(1)(G) (42 U.S.C.
 12 1395u(o)(1)(G)), as added by section 303(b), is amended to
 13 read as follows:

14 “(G) In the case of inhalation drugs or biologicals fur-
 15 nished through durable medical equipment covered under
 16 section 1861(n) that are furnished—

17 “(i) in 2004, the amount provided under para-
 18 graph (4) for the drug or biological; and

19 “(ii) in 2005 and subsequent years, the amount
 20 provided under section 1847A for the drug or biologi-
 21 cal.”.

22 (b) GAO STUDY OF MEDICARE PAYMENT FOR INHALA-
 23 TION THERAPY.—

24 (1) STUDY.—The Comptroller General of the United
 25 States shall conduct a study to examine the adequacy of
 26 current reimbursements for inhalation therapy under the
 27 medicare program.

28 (2) REPORT.—Not later than 1 year after the date of
 29 the enactment of this Act, the Comptroller General shall
 30 submit to Congress a report on the study conducted under
 31 paragraph (1).

32 **SEC. 306. DEMONSTRATION PROJECT FOR USE OF RE-**
 33 **COVERY AUDIT CONTRACTORS.**

34 (a) IN GENERAL.—The Secretary shall conduct a dem-
 35 onstration project under this section (in this section referred to
 36 as the “project”) to demonstrate the use of recovery audit con-
 37 tractors under the Medicare Integrity Program in identifying
 38 underpayments and overpayments and recouping overpayments

1 under the medicare program for services for which payment is
2 made under part A or B of title XVIII of the Social Security
3 Act. Under the project—

4 (1) payment may be made to such a contractor on a
5 contingent basis;

6 (2) such percentage as the Secretary may specify of
7 the amount recovered shall be retained by the Secretary
8 and shall be available to the program management account
9 of the Centers for Medicare & Medicaid Services; and

10 (3) the Secretary shall examine the efficacy of such
11 use with respect to duplicative payments, accuracy of cod-
12 ing, and other payment policies in which inaccurate pay-
13 ments arise.

14 (b) SCOPE AND DURATION.—

15 (1) SCOPE.—The project shall cover at least 2 States
16 that are among the States with—

17 (A) the highest per capita utilization rates of
18 medicare services, and

19 (B) at least 3 contractors.

20 (2) DURATION.—The project shall last for not longer
21 than 3 years.

22 (c) WAIVER.—The Secretary shall waive such provisions of
23 title XVIII of the Social Security Act as may be necessary to
24 provide for payment for services under the project in accord-
25 ance with subsection (a).

26 (d) QUALIFICATIONS OF CONTRACTORS.—

27 (1) IN GENERAL.—The Secretary shall enter into a re-
28 covery audit contract under this section with an entity only
29 if the entity has staff that has the appropriate clinical
30 knowledge of and experience with the payment rules and
31 regulations under the medicare program or the entity has
32 or will contract with another entity that has such knowl-
33 edgeable and experienced staff.

34 (2) INELIGIBILITY OF CERTAIN CONTRACTORS.—The
35 Secretary may not enter into a recovery audit contract
36 under this section with an entity to the extent that the en-
37 tity is a fiscal intermediary under section 1816 of the So-

1 cial Security Act (42 U.S.C. 1395h), a carrier under sec-
 2 tion 1842 of such Act (42 U.S.C. 1395u), or a Medicare
 3 Administrative Contractor under section 1874A of such
 4 Act.

5 (3) PREFERENCE FOR ENTITIES WITH DEM-
 6 ONSTRATED PROFICIENCY.—In awarding contracts to re-
 7 covery audit contractors under this section, the Secretary
 8 shall give preference to those risk entities that the Sec-
 9 retary determines have demonstrated more than 3 years di-
 10 rect management experience and a proficiency for cost con-
 11 trol or recovery audits with private insurers, health care
 12 providers, health plans, or under the medicaid program
 13 under title XIX of the Social Security Act.

14 (e) CONSTRUCTION RELATING TO CONDUCT OF INVES-
 15 TIGATION OF FRAUD.—A recovery of an overpayment to a pro-
 16 vider by a recovery audit contractor shall not be construed to
 17 prohibit the Secretary or the Attorney General from inves-
 18 tigating and prosecuting, if appropriate, allegations of fraud or
 19 abuse arising from such overpayment.

20 (f) REPORT.—The Secretary shall submit to Congress a
 21 report on the project not later than 6 months after the date
 22 of its completion. Such reports shall include information on the
 23 impact of the project on savings to the medicare program and
 24 recommendations on the cost-effectiveness of extending or ex-
 25 panding the project.information’ means information about a
 26 conviction for a relevant crime or a finding of patient or resi-
 27 dent abuse.

28 **SEC. 307. PILOT PROGRAM FOR NATIONAL AND STATE**
 29 **BACKGROUND CHECKS ON DIRECT PATIENT**
 30 **ACCESS EMPLOYEES OF LONG-TERM CARE**
 31 **FACILITIES OR PROVIDERS.**

32 (a) AUTHORITY TO CONDUCT PROGRAM.—The Secretary,
 33 in consultation with the Attorney General, shall establish a
 34 pilot program to identify efficient, effective, and economical
 35 procedures for long term care facilities or providers to conduct
 36 background checks on prospective direct patient access employ-
 37 ees.

1 (b) REQUIREMENTS.—

2 (1) IN GENERAL.—Under the pilot program, a long-
3 term care facility or provider in a participating State, prior
4 to employing a direct patient access employee that is first
5 hired on or after the commencement date of the pilot pro-
6 gram in the State, shall conduct a background check on the
7 employee in accordance with such procedures as the partici-
8 pating State shall establish.

9 (2) PROCEDURES.—

10 (A) IN GENERAL.—The procedures established by
11 a participating State under paragraph (1) should be
12 designed to—

13 (i) give a prospective direct access patient em-
14 ployee notice that the long-term care facility or pro-
15 vider is required to perform background checks
16 with respect to new employees;

17 (ii) require, as a condition of employment, that
18 the employee—

19 (I) provide a written statement disclosing
20 any disqualifying information;

21 (II) provide a statement signed by the em-
22 ployee authorizing the facility to request na-
23 tional and State criminal history background
24 checks;

25 (III) provide the facility with a rolled set
26 of the employee's fingerprints; and

27 (IV) provide any other identification infor-
28 mation the participating State may require;

29 (iii) require the facility or provider to check
30 any available registries that would be likely to con-
31 tain disqualifying information about a prospective
32 employee of a long-term care facility or provider;
33 and

34 (iv) permit the facility or provider to obtain
35 State and national criminal history background
36 checks on the prospective employee through a 10-
37 fingerprint check that utilizes State criminal

1 records and the Integrated Automated Fingerprint
 2 Identification System of the Federal Bureau of In-
 3 vestigation.

4 (B) ELIMINATION OF UNNECESSARY CHECKS.—
 5 The procedures established by a participating State
 6 under paragraph (1) shall permit a long-term care fa-
 7 cility or provider to terminate the background check at
 8 any stage at which the facility or provider obtains dis-
 9 qualifying information regarding a prospective direct
 10 patient access employee.

11 (3) PROHIBITION ON HIRING OF ABUSIVE WORKERS.—

12 (A) IN GENERAL.—A long-term care facility or
 13 provider may not knowingly employ any direct patient
 14 access employee who has any disqualifying information.

15 (B) PROVISIONAL EMPLOYMENT.—

16 (i) IN GENERAL.—Under the pilot program, a
 17 participating State may permit a long-term care fa-
 18 cility or provider to provide for a provisional period
 19 of employment for a direct patient access employee
 20 pending completion of a background check, subject
 21 to such supervision during the employee's provi-
 22 sional period of employment as the participating
 23 State determines appropriate.

24 (ii) SPECIAL CONSIDERATION FOR CERTAIN
 25 FACILITIES AND PROVIDERS.—In determining what
 26 constitutes appropriate supervision of a provisional
 27 employee, a participating State shall take into ac-
 28 count cost or other burdens that would be imposed
 29 on small rural long-term care facilities or providers,
 30 as well as the nature of care delivered by such fa-
 31 cilities or providers that are home health agencies
 32 or providers of hospice care.

33 (4) USE OF INFORMATION; IMMUNITY FROM LIABIL-
 34 ITY.—

35 (A) USE OF INFORMATION.—A participating State
 36 shall ensure that a long-term care facility or provider
 37 that obtains information about a direct patient access

1 employee pursuant to a background check uses such in-
2 formation only for the purpose of determining the suit-
3 ability of the employee for employment.

4 (B) IMMUNITY FROM LIABILITY.—A participating
5 State shall ensure that a long-term care facility or pro-
6 vider that, in denying employment for an individual se-
7 lected for hire as a direct patient access employee (in-
8 cluding during any period of provisional employment),
9 reasonably relies upon information obtained through a
10 background check of the individual, shall not be liable
11 in any action brought by the individual based on the
12 employment determination resulting from the informa-
13 tion.

14 (5) AGREEMENTS WITH EMPLOYMENT AGENCIES.—A
15 participating State may establish procedures for facilitating
16 the conduct of background checks on prospective direct pa-
17 tient access employees that are hired by a long-term care
18 facility or provider through an employment agency (includ-
19 ing a temporary employment agency).

20 (6) PENALTIES.—A participating State may impose
21 such penalties as the State determines appropriate to en-
22 force the requirements of the pilot program conducted in
23 that State.

24 (c) PARTICIPATING STATES.—

25 (1) IN GENERAL.—The Secretary shall enter into
26 agreements with not more than 10 States to conduct the
27 pilot program under this section in such States.

28 (2) REQUIREMENTS FOR STATES.—An agreement en-
29 tered into under paragraph (1) shall require that a partici-
30 pating State—

31 (A) be responsible for monitoring compliance with
32 the requirements of the pilot program;

33 (B) have procedures by which a provisional em-
34 ployee or an employee may appeal or dispute the accu-
35 racy of the information obtained in a background check
36 performed under the pilot program; and

37 (C) agree to—

1 (i) review the results of any State or national
 2 criminal history background checks conducted re-
 3 garding a prospective direct patient access em-
 4 ployee to determine whether the employee has any
 5 conviction for a relevant crime;

6 (ii) immediately report to the entity that re-
 7 quested the criminal history background checks the
 8 results of such review; and

9 (iii) in the case of an employee with a convic-
 10 tion for a relevant crime that is subject to report-
 11 ing under section 1128E of the Social Security Act
 12 (42 U.S.C. 1320a-7e), report the existence of such
 13 conviction to the database established under that
 14 section.

15 (3) APPLICATION AND SELECTION CRITERIA.—

16 (A) APPLICATION.—A State seeking to participate
 17 in the pilot program established under this section,
 18 shall submit an application to the Secretary containing
 19 such information and at such time as the Secretary
 20 may specify.

21 (B) SELECTION CRITERIA.—

22 (i) IN GENERAL.—In selecting States to par-
 23 ticipate in the pilot program, the Secretary shall
 24 establish criteria to ensure—

25 (I) geographic diversity;

26 (II) the inclusion of a variety of long-term
 27 care facilities or providers;

28 (III) the evaluation of a variety of pay-
 29 ment mechanisms for covering the costs of con-
 30 ducting the background checks required under
 31 the pilot program; and

32 (IV) the evaluation of a variety of pen-
 33 alties (monetary and otherwise) used by partici-
 34 pating States to enforce the requirements of
 35 the pilot program in such States.

36 (ii) ADDITIONAL CRITERIA.—The Secretary
 37 shall, to the greatest extent practicable, select

1 States to participate in the pilot program in ac-
2 cordance with the following:

3 (I) At least one participating State should
4 permit long-term care facilities or providers to
5 provide for a provisional period of employment
6 pending completion of a background check and
7 at least one such State should not permit such
8 a period of employment.

9 (II) At least one participating State
10 should establish procedures under which em-
11 ployment agencies (including temporary em-
12 ployment agencies) may contact the State di-
13 rectly to conduct background checks on pro-
14 spective direct patient access employees.

15 (III) At least one participating State
16 should include patient abuse prevention train-
17 ing (including behavior training and interven-
18 tions) for managers and employees of long-term
19 care facilities and providers as part of the pilot
20 program conducted in that State.

21 (iii) INCLUSION OF STATES WITH EXISTING
22 PROGRAMS.—Nothing in this section shall be con-
23 strued as prohibiting any State which, as of the
24 date of the enactment of this Act, has procedures
25 for conducting background checks on behalf of any
26 entity described in subsection (g)(5) from being se-
27 lected to participate in the pilot program conducted
28 under this section.

29 (d) PAYMENTS.—Of the amounts made available under
30 subsection (f) to conduct the pilot program under this section,
31 the Secretary shall—

32 (1) make payments to participating States for the
33 costs of conducting the pilot program in such States; and

34 (2) reserve up to 4 percent of such amounts to con-
35 duct the evaluation required under subsection (e).

36 (e) EVALUATION.—The Secretary, in consultation with the
37 Attorney General, shall conduct by grant, contract, or inter-

1 agency agreement an evaluation of the pilot program conducted
2 under this section. Such evaluation shall—

3 (1) review the various procedures implemented by par-
4 ticipating States for long-term care facilities or providers to
5 conduct background checks of direct patient access employ-
6 ees and identify the most efficient, effective, and economi-
7 cal procedures for conducting such background checks;

8 (2) assess the costs of conducting such background
9 checks (including start-up and administrative costs);

10 (3) consider the benefits and problems associated with
11 requiring employees or facilities or providers to pay the
12 costs of conducting such background checks;

13 (4) consider whether the costs of conducting such
14 background checks should be allocated between the medi-
15 care and medicaid programs and if so, identify an equitable
16 methodology for doing so;

17 (5) determine the extent to which conducting such
18 background checks leads to any unintended consequences,
19 including a reduction in the available workforce for such fa-
20 cilities or providers;

21 (6) review forms used by participating States in order
22 to develop, in consultation with the Attorney General, a
23 model form for such background checks;

24 (7) determine the effectiveness of background checks
25 conducted by employment agencies; and

26 (8) recommend appropriate procedures and payment
27 mechanisms for implementing a national criminal back-
28 ground check program for such facilities and providers.

29 (f) FUNDING.—Out of any funds in the Treasury not oth-
30 erwise appropriated, there are appropriated to the Secretary to
31 carry out the pilot program under this section for the period
32 of fiscal years 2004 through 2007, \$25,000,000.

33 (g) DEFINITIONS.—In this section:

34 (1) CONVICTION FOR A RELEVANT CRIME.—The term
35 “conviction for a relevant crime” means any Federal or
36 State criminal conviction for—

1 (A) any offense described in section 1128(a) of the
2 Social Security Act (42 U.S.C. 1320a-7); and

3 (B) such other types of offenses as a participating
4 State may specify for purposes of conducting the pilot
5 program in such State.

6 (2) DISQUALIFYING INFORMATION.—The term “dis-
7 qualifying information” means a conviction for a relevant
8 crime or a finding of patient or resident abuse.

9 (3) FINDING OF PATIENT OR RESIDENT ABUSE.—The
10 term “finding of patient or resident abuse” means any sub-
11 stantiated finding by a State agency under section
12 1819(g)(1)(C) or 1919(g)(1)(C) of the Social Security Act
13 (42 U.S.C. 1395i-3(g)(1)(C), 1396r(g)(1)(C)) or a Federal
14 agency that a direct patient access employee has
15 committed—

16 (A) an act of patient or resident abuse or neglect
17 or a misappropriation of patient or resident property;
18 or

19 (B) such other types of acts as a participating
20 State may specify for purposes of conducting the pilot
21 program in such State.

22 (4) DIRECT PATIENT ACCESS EMPLOYEE.—The term
23 “direct patient access employee” means any individual
24 (other than a volunteer) that has access to a patient or
25 resident of a long-term care facility or provider through
26 employment or through a contract with such facility or pro-
27 vider, as determined by a participating State for purposes
28 of conducting the pilot program in such State.

29 (5) LONG-TERM CARE FACILITY OR PROVIDER.—

30 (A) IN GENERAL.—The term “long-term care fa-
31 cility or provider” means the following facilities or pro-
32 viders which receive payment for services under title
33 XVIII or XIX of the Social Security Act:

34 (i) A skilled nursing facility (as defined in sec-
35 tion 1819(a) of the Social Security Act) (42 U.S.C.
36 1395i-3(a)).

1 (ii) A nursing facility (as defined in section
2 1919(a) in such Act) (42 U.S.C. 1396r(a)).

3 (iii) A home health agency.

4 (iv) A provider of hospice care (as defined in
5 section 1861(dd)(1) of such Act) (42 U.S.C.
6 1395x(dd)(1)).

7 (v) A long-term care hospital (as described in
8 section 1886(d)(1)(B)(iv) of such Act) (42 U.S.C.
9 1395ww(d)(1)(B)(iv)).

10 (vi) A provider of personal care services.

11 (vii) A residential care provider that arranges
12 for, or directly provides, long-term care services.

13 (viii) An intermediate care facility for the
14 mentally retarded (as defined in section 1905(d) of
15 such Act) 42 U.S.C. 1396d(d)).

16 (B) ADDITIONAL FACILITIES OR PROVIDERS.—
17 During the first year in which a pilot program under
18 this section is conducted in a participating State, the
19 State may expand the list of facilities or providers
20 under subparagraph (A) (on a phased-in basis or other-
21 wise) to include such other facilities or providers of
22 long-term care services under such titles as the partici-
23 pating State determines appropriate.

24 (C) EXCEPTIONS.—Such term does not include—

25 (i) any facility or entity that provides, or is a
26 provider of, services described in subparagraph (A)
27 that are exclusively provided to an individual pur-
28 suant to a self-directed arrangement that meets
29 such requirements as the participating State may
30 establish in accordance with guidance from the Sec-
31 retary; or

32 (ii) any such arrangement that is obtained by
33 a patient or resident functioning as an employer.

34 (6) PARTICIPATING STATE.—The term “participating
35 State” means a State with an agreement under subsection
36 (c)(1).

1 **TITLE IV—RURAL PROVISIONS**
 2 **Subtitle A—Provisions Relating to**
 3 **Part A Only**

4 **SEC. 401. EQUALIZING URBAN AND RURAL STANDARD-**
 5 **IZED PAYMENT AMOUNTS UNDER THE MEDI-**
 6 **CARE INPATIENT HOSPITAL PROSPECTIVE**
 7 **PAYMENT SYSTEM.**

8 (a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42 U.S.C.
 9 1395ww(d)(3)(A)(iv)) is amended—

10 (1) by striking “(iv) For discharges” and inserting
 11 “(iv)(I) Subject to subclause (II), for discharges”; and

12 (2) by adding at the end the following new subclause:

13 “(II) For discharges occurring in a fiscal year (begin-
 14 ning with fiscal year 2004), the Secretary shall compute a
 15 standardized amount for hospitals located in any area with-
 16 in the United States and within each region equal to the
 17 standardized amount computed for the previous fiscal year
 18 under this subparagraph for hospitals located in a large
 19 urban area (or, beginning with fiscal year 2005, for all hos-
 20 pitals in the previous fiscal year) increased by the applica-
 21 ble percentage increase under subsection (b)(3)(B)(i) for
 22 the fiscal year involved.”.

23 (b) CONFORMING AMENDMENTS.—

24 (1) COMPUTING DRG-SPECIFIC RATES.—Section
 25 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended—

26 (A) in the heading, by striking “IN DIFFERENT
 27 AREAS”;

28 (B) in the matter preceding clause (i), by striking
 29 “, each of”;

30 (C) in clause (i)—

31 (i) in the matter preceding subclause (I), by
 32 inserting “for fiscal years before fiscal year 2004,”
 33 before “for hospitals”; and

34 (ii) in subclause (II), by striking “and” after
 35 the semicolon at the end;

36 (D) in clause (ii)—

1 (i) in the matter preceding subclause (I), by
 2 inserting “for fiscal years before fiscal year 2004,”
 3 before “for hospitals”; and

4 (ii) in subclause (II), by striking the period at
 5 the end and inserting “; and”; and

6 (E) by adding at the end the following new clause:

7 “(iii) for a fiscal year beginning after fiscal year
 8 2003, for hospitals located in all areas, to the product
 9 of—

10 “(I) the applicable standardized amount (com-
 11 puted under subparagraph (A)), reduced under
 12 subparagraph (B), and adjusted or reduced under
 13 subparagraph (C) for the fiscal year; and

14 “(II) the weighting factor (determined under
 15 paragraph (4)(B)) for that diagnosis-related
 16 group.”.

17 (2) TECHNICAL CONFORMING SUNSET.—Section
 18 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

19 (A) in the matter preceding subparagraph (A), by
 20 inserting “, for fiscal years before fiscal year 1997,”
 21 before “a regional adjusted DRG prospective payment
 22 rate”; and

23 (B) in subparagraph (D), in the matter preceding
 24 clause (i), by inserting “, for fiscal years before fiscal
 25 year 1997,” before “a regional DRG prospective pay-
 26 ment rate for each region,”.

27 (3) ADDITIONAL TECHNICAL AMENDMENT.—Section
 28 1886(d)(3)(A)(iii) (42 U.S.C. 1395ww(d)(3)(A)(iii)) is
 29 amended by striking “in an other urban area” and insert-
 30 ing “in an urban area”.

31 (c) EQUALIZING URBAN AND RURAL STANDARDIZED PAY-
 32 MENT AMOUNTS UNDER THE MEDICARE INPATIENT HOSPITAL
 33 PROSPECTIVE PAYMENT SYSTEM FOR HOSPITALS IN PUERTO
 34 RICO.—

35 (1) IN GENERAL.—Section 1886(d)(9)(A) (42 U.S.C.
 36 1395ww(d)(9)(A)), as amended by section 504, is
 37 amended—

1 (A) in clause (i), by striking “and” after the
2 comma at the end; and

3 (B) by striking clause (ii) and inserting the fol-
4 lowing new clause:

5 “(ii) the applicable Federal percentage (specified in
6 subparagraph (E)) of—

7 “(I) for discharges beginning in a fiscal year be-
8 ginning on or after October 1, 1997, and before Octo-
9 ber 1, 2003, the discharge-weighted average of—

10 “(aa) the national adjusted DRG prospective
11 payment rate (determined under paragraph (3)(D))
12 for hospitals located in a large urban area,

13 “(bb) such rate for hospitals located in other
14 urban areas, and

15 “(cc) such rate for hospitals located in a rural
16 area,

17 for such discharges, adjusted in the manner provided in
18 paragraph (3)(E) for different area wage levels; and

19 “(II) for discharges in a fiscal year beginning on
20 or after October 1, 2003, the national DRG prospective
21 payment rate determined under paragraph (3)(D)(iii)
22 for hospitals located in any area for such discharges,
23 adjusted in the manner provided in paragraph (3)(E)
24 for different area wage levels.

25 As used in this section, the term ‘subsection (d) Puerto Rico
26 hospital’ means a hospital that is located in Puerto Rico and
27 that would be a subsection (d) hospital (as defined in para-
28 graph (1)(B)) if it were located in one of the 50 States.”.

29 (2) APPLICATION OF PUERTO RICO STANDARDIZED
30 AMOUNT BASED ON LARGE URBAN AREAS.—Section
31 1886(d)(9)(C) (42 U.S.C. 1395ww(d)(9)(C)) is amended—

32 (A) in clause (i)—

33 (i) by striking “(i) The Secretary” and insert-
34 ing “(i)(I) For discharges in a fiscal year after fis-
35 cal year 1988 and before fiscal year 2004, the Sec-
36 retary”; and

1 (ii) by adding at the end the following new
2 subclause:

3 “(II) For discharges occurring in a fiscal year (begin-
4 ning with fiscal year 2004), the Secretary shall compute an
5 average standardized amount for hospitals located in any
6 area of Puerto Rico that is equal to the average standard-
7 ized amount computed under subclause (I) for fiscal year
8 2003 for hospitals in a large urban area (or, beginning
9 with fiscal year 2005, for all hospitals in the previous fiscal
10 year) increased by the applicable percentage increase under
11 subsection (b)(3)(B) for the fiscal year involved.”;

12 (B) in clause (ii), by inserting “(or for fiscal year
13 2004 and thereafter, the average standardized
14 amount)” after “each of the average standardized
15 amounts”; and

16 (C) in clause (iii)(I), by striking “for hospitals lo-
17 cated in an urban or rural area, respectively”.

18 (d) IMPLEMENTATION.—

19 (1) IN GENERAL.—The amendments made by sub-
20 sections (a), (b), and (c)(1) of this section shall have no ef-
21 fect on the authority of the Secretary, under subsection
22 (b)(2) of section 402 of Public Law 108–89, to delay imple-
23 mentation of the extension of provisions equalizing urban
24 and rural standardized inpatient hospital payments under
25 subsection (a) of such section 402.

26 (2) APPLICATION OF PUERTO RICO STANDARDIZED
27 AMOUNT BASED ON LARGE URBAN AREAS.—The authority
28 of the Secretary referred to in paragraph (1) shall apply
29 with respect to the amendments made by subsection (c)(2)
30 of this section in the same manner as that authority applies
31 with respect to the extension of provisions equalizing urban
32 and rural standardized inpatient hospital payments under
33 subsection (a) of such section 402, except that any ref-
34 erence in subsection (b)(2)(A) of such section 402 is
35 deemed to be a reference to April 1, 2004.

1 **SEC. 402. ENHANCED DISPROPORTIONATE SHARE HOS-**
 2 **PITAL (DSH) TREATMENT FOR RURAL HOS-**
 3 **PITALS AND URBAN HOSPITALS WITH**
 4 **FEWER THAN 100 BEDS.**

5 (a) DOUBLING THE CAP.—Section 1886(d)(5)(F) (42
 6 U.S.C. 1395ww(d)(5)(F)) is amended by adding at the end the
 7 following new clause:

8 “(xiv)(I) In the case of discharges occurring on or after
 9 April 1, 2004, subject to subclause (II), there shall be sub-
 10 stituted for the disproportionate share adjustment percentage
 11 otherwise determined under clause (iv) (other than subclause
 12 (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the dis-
 13 proportionate share adjustment percentage determined under
 14 clause (vii) (relating to large, urban hospitals).

15 “(II) Under subclause (I), the disproportionate share ad-
 16 justment percentage shall not exceed 12 percent for a hospital
 17 that is not classified as a rural referral center under subpara-
 18 graph (C).”.

19 (b) CONFORMING AMENDMENTS.—Section 1886(d) (42
 20 U.S.C. 1395ww(d)) is amended—

21 (1) in paragraph (5)(F)—

22 (A) in each of subclauses (II), (III), (IV), (V), and
 23 (VI) of clause (iv), by inserting “subject to clause (xiv)
 24 and” before “for discharges occurring”;

25 (B) in clause (viii), by striking “The formula” and
 26 inserting “Subject to clause (xiv), the formula”; and

27 (C) in each of clauses (x), (xi), (xii), and (xiii), by
 28 striking “For purposes” and inserting “Subject to
 29 clause (xiv), for purposes”; and

30 (2) in paragraph (2)(C)(iv)—

31 (A) by striking “or” before “the enactment of sec-
 32 tion 303”; and

33 (B) by inserting before the period at the end the
 34 following: “, or the enactment of section 402(a)(1) of
 35 the Medicare Prescription Drug, Improvement, and
 36 Modernization Act of 2003”.

1 **SEC. 403. ADJUSTMENT TO THE MEDICARE INPATIENT**
 2 **HOSPITAL PROSPECTIVE PAYMENT SYSTEM**
 3 **WAGE INDEX TO REVISE THE LABOR-RE-**
 4 **LATED SHARE OF SUCH INDEX.**

5 (a) ADJUSTMENT.—

6 (1) IN GENERAL.—Section 1886(d)(3)(E) (42 U.S.C.
 7 1395ww(d)(3)(E)) is amended—

8 (A) by striking “WAGE LEVELS.—The Secretary”
 9 and inserting “WAGE LEVELS.—

10 “(i) IN GENERAL.—Except as provided in clause
 11 (ii), the Secretary”; and

12 (B) by adding at the end the following new clause:

13 “(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED
 14 BEGINNING IN FISCAL YEAR 2005.—For discharges oc-
 15 curring on or after October 1, 2004, the Secretary shall
 16 substitute ‘62 percent’ for the proportion described in
 17 the first sentence of clause (i), unless the application
 18 of this clause would result in lower payments to a hos-
 19 pital than would otherwise be made.”.

20 (2) WAIVING BUDGET NEUTRALITY.—Section
 21 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended
 22 by subsection (a), is amended by adding at the end of
 23 clause (i) the following new sentence: “The Secretary shall
 24 apply the previous sentence for any period as if the amend-
 25 ments made by section 403(a)(1) of the Medicare Prescrip-
 26 tion Drug, Improvement, and Modernization Act of 2003
 27 had not been enacted.”.

28 (b) APPLICATION TO PUERTO RICO HOSPITALS.—Section
 29 1886(d)(9)(C)(iv) (42 U.S.C. 1395ww(d)(9)(C)(iv)) is
 30 amended—

31 (1) by inserting “(I)” after “(iv)”;

32 (2) by striking “paragraph (3)(E)” and inserting
 33 “paragraph (3)(E)(i)”; and

34 (3) by adding at the end the following new subclause:

35 “(II) For discharges occurring on or after October 1,
 36 2004, the Secretary shall substitute ‘62 percent’ for the
 37 proportion described in the first sentence of clause (i), un-

1 less the application of this subclause would result in lower
2 payments to a hospital than would otherwise be made.”.

3 **SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED**
4 **IN HOSPITAL MARKET BASKET.**

5 (a) MORE FREQUENT UPDATES IN WEIGHTS.—After re-
6 vising the weights used in the hospital market basket under
7 section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C.
8 1395ww(b)(3)(B)(iii)) to reflect the most current data avail-
9 able, the Secretary shall establish a frequency for revising such
10 weights, including the labor share, in such market basket to re-
11 flect the most current data available more frequently than once
12 every 5 years.

13 (b) INCORPORATION OF EXPLANATION IN RULEMAKING.—
14 The Secretary shall include in the publication of the final rule
15 for payment for inpatient hospital services under section
16 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for
17 fiscal year 2006, an explanation of the reasons for, and options
18 considered, in determining frequency established under sub-
19 section (a).

20 **SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOS-**
21 **PITAL PROGRAM.**

22 (a) INCREASE IN PAYMENT AMOUNTS.—

23 (1) IN GENERAL.—Sections 1814(l), 1834(g)(1), and
24 1883(a)(3) (42 U.S.C. 1395f(l), 1395m(g)(1), and
25 1395tt(a)(3)) are each amended by inserting “equal to 101
26 percent of” before “the reasonable costs”.

27 (2) EFFECTIVE DATE.—The amendments made by
28 paragraph (1) shall apply to payments for services fur-
29 nished during cost reporting periods beginning on or after
30 January 1, 2004.

31 (b) COVERAGE OF COSTS FOR CERTAIN EMERGENCY
32 ROOM ON-CALL PROVIDERS.—

33 (1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C.
34 1395m(g)(5)) is amended—

35 (A) in the heading—

36 (i) by inserting “CERTAIN” before “EMER-
37 GENCY”; and

1 (ii) by striking “PHYSICIANS” and inserting
2 “PROVIDERS”;

3 (B) by striking “emergency room physicians who
4 are on-call (as defined by the Secretary)” and inserting
5 “physicians, physician assistants, nurse practitioners,
6 and clinical nurse specialists who are on-call (as de-
7 fined by the Secretary) to provide emergency services”;
8 and

9 (C) by striking “physicians’ services” and insert-
10 ing “services covered under this title”.

11 (2) EFFECTIVE DATE.—The amendments made by
12 paragraph (1) shall apply with respect to costs incurred for
13 services furnished on or after January 1, 2005.

14 (c) AUTHORIZATION OF PERIODIC INTERIM PAYMENT
15 (PIP).—

16 (1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C.
17 1395g(e)(2)) is amended—

18 (A) in the matter before subparagraph (A), by in-
19 serting “, in the cases described in subparagraphs (A)
20 through (D)” after “1986”;

21 (B) by striking “and” at the end of subparagraph
22 (C);

23 (C) by adding “and” at the end of subparagraph
24 (D); and

25 (D) by inserting after subparagraph (D) the fol-
26 lowing new subparagraph:

27 “(E) inpatient critical access hospital services;”.

28 (2) DEVELOPMENT OF ALTERNATIVE TIMING METH-
29 ODS OF PERIODIC INTERIM PAYMENTS.—With respect to
30 periodic interim payments to critical access hospitals for in-
31 patient critical access hospital services under section
32 1815(e)(2)(E) of the Social Security Act, as added by para-
33 graph (1), the Secretary shall develop alternative methods
34 for the timing of such payments.

35 (3) AUTHORIZATION OF PIP.—The amendments made
36 by paragraph (1) shall apply to payments made on or after
37 July 1, 2004.

1 (d) CONDITION FOR APPLICATION OF SPECIAL PROFES-
2 SIONAL SERVICE PAYMENT ADJUSTMENT.—

3 (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C.
4 1395m(g)(2)) is amended by adding after and below sub-
5 paragraph (B) the following:

6 “The Secretary may not require, as a condition for apply-
7 ing subparagraph (B) with respect to a critical access hos-
8 pital, that each physician or other practitioner providing
9 professional services in the hospital must assign billing
10 rights with respect to such services, except that such sub-
11 paragraph shall not apply to those physicians and practi-
12 tioners who have not assigned such billing rights.”.

13 (2) EFFECTIVE DATE.—

14 (A) IN GENERAL.—Except as provided in subpara-
15 graph (B), the amendment made by paragraph (1)
16 shall apply to cost reporting periods beginning on or
17 after July 1, 2004.

18 (B) RULE OF APPLICATION.—In the case of a crit-
19 ical access hospital that made an election under section
20 1834(g)(2) of the Social Security Act (42 U.S.C.
21 1395m(g)(2)) before November 1, 2003, the amend-
22 ment made by paragraph (1) shall apply to cost report-
23 ing periods beginning on or after July 1, 2001.

24 (e) REVISION OF BED LIMITATION FOR HOSPITALS.—

25 (1) IN GENERAL.—Section 1820(c)(2)(B)(iii) (42
26 U.S.C. 1395i-4(c)(2)(B)(iii)) is amended by striking “15
27 (or, in the case of a facility under an agreement described
28 in subsection (f), 25)” and inserting “25”.

29 (2) CONFORMING AMENDMENT.—Section 1820(f) (42
30 U.S.C. 1395i-4(f)) is amended by striking “and the num-
31 ber of beds used at any time for acute care inpatient serv-
32 ices does not exceed 15 beds”.

33 (3) EFFECTIVE DATE.—The amendments made by
34 this subsection shall apply to designations made before, on,
35 or after January 1, 2004, but any election made pursuant
36 to regulations promulgated to carry out such amendments
37 shall only apply prospectively.

1 (f) PROVISIONS RELATING TO FLEX GRANTS.—

2 (1) ADDITIONAL 4-YEAR PERIOD OF FUNDING.—Sec-
 3 tion 1820(j) (42 U.S.C. 1395i-4(j)) is amended by insert-
 4 ing before the period at the end the following: “, and for
 5 making grants to all States under paragraphs (1) and (2)
 6 of subsection (g), \$35,000,000 in each of fiscal years 2005
 7 through 2008”.

8 (2) ADDITIONAL REQUIREMENTS AND ADMINISTRA-
 9 TION.—Section 1820(g) (42 U.S.C. 1395i-4(g)) is amend-
 10 ed by adding at the end the following new paragraphs:

11 “(4) ADDITIONAL REQUIREMENTS WITH RESPECT TO
 12 FLEX GRANTS.—With respect to grants awarded under
 13 paragraph (1) or (2) from funds appropriated for fiscal
 14 year 2005 and subsequent fiscal years—

15 “(A) CONSULTATION WITH THE STATE HOSPITAL
 16 ASSOCIATION AND RURAL HOSPITALS ON THE MOST AP-
 17 PROPRIATE WAYS TO USE GRANTS.—A State shall con-
 18 sult with the hospital association of such State and
 19 rural hospitals located in such State on the most ap-
 20 propriate ways to use the funds under such grant.

21 “(B) LIMITATION ON USE OF GRANT FUNDS FOR
 22 ADMINISTRATIVE EXPENSES.—A State may not expend
 23 more than the lesser of—

24 “(i) 15 percent of the amount of the grant for
 25 administrative expenses; or

26 “(ii) the State’s federally negotiated indirect
 27 rate for administering the grant.

28 “(5) USE OF FUNDS FOR FEDERAL ADMINISTRATIVE
 29 EXPENSES.—Of the total amount appropriated for grants
 30 under paragraphs (1) and (2) for a fiscal year (beginning
 31 with fiscal year 2005), up to 5 percent of such amount
 32 shall be available to the Health Resources and Services Ad-
 33 ministration for purposes of administering such grants.”.

34 (g) AUTHORITY TO ESTABLISH PSYCHIATRIC AND REHA-
 35 BILITATION DISTINCT PART UNITS.—

1 (1) IN GENERAL.—Section 1820(c)(2) (42 U.S.C.
2 1395i-4(c)(2)) is amended by adding at the end the fol-
3 lowing:

4 “(E) AUTHORITY TO ESTABLISH PSYCHIATRIC
5 AND REHABILITATION DISTINCT PART UNITS.—

6 “(i) IN GENERAL.—Subject to the succeeding
7 provisions of this subparagraph, a critical access
8 hospital may establish—

9 “(I) a psychiatric unit of the hospital that
10 is a distinct part of the hospital; and

11 “(II) a rehabilitation unit of the hospital
12 that is a distinct part of the hospital,
13 if the distinct part meets the requirements (includ-
14 ing conditions of participation) that would other-
15 wise apply to the distinct part if the distinct part
16 were established by a subsection (d) hospital in ac-
17 cordance with the matter following clause (v) of
18 section 1886(d)(1)(B), including any regulations
19 adopted by the Secretary under such section.

20 “(ii) LIMITATION ON NUMBER OF BEDS.—The
21 total number of beds that may be established under
22 clause (i) for a distinct part unit may not exceed
23 10.

24 “(iii) EXCLUSION OF BEDS FROM BED
25 COUNT.—In determining the number of beds of a
26 critical access hospital for purposes of applying the
27 bed limitations referred to in subparagraph (B)(iii)
28 and subsection (f), the Secretary shall not take into
29 account any bed established under clause (i).

30 “(iv) EFFECT OF FAILURE TO MEET REQUIRE-
31 MENTS.—If a psychiatric or rehabilitation unit es-
32 tablished under clause (i) does not meet the re-
33 quirements described in such clause with respect to
34 a cost reporting period, no payment may be made
35 under this title to the hospital for services fur-
36 nished in such unit during such period. Payment to
37 the hospital for services furnished in the unit may

1 resume only after the hospital has demonstrated to
 2 the Secretary that the unit meets such require-
 3 ments.”.

4 (2) PAYMENT ON A PROSPECTIVE PAYMENT BASIS.—
 5 Section 1814(l) (42 U.S.C. 1395f(l)) is amended—

6 (A) by striking “(l) The amount” and inserting
 7 “(l)(1) Except as provided in paragraph (2), the
 8 amount”; and

9 (B) by adding at the end the following new para-
 10 graph:

11 “(2) In the case of a distinct part psychiatric or rehabilita-
 12 tion unit of a critical access hospital described in section
 13 1820(c)(2)(E), the amount of payment for inpatient critical ac-
 14 cess hospital services of such unit shall be equal to the amount
 15 of the payment that would otherwise be made if such services
 16 were inpatient hospital services of a distinct part psychiatric or
 17 rehabilitation unit, respectively, described in the matter fol-
 18 lowing clause (v) of section 1886(d)(1)(B).”.

19 (3) EFFECTIVE DATE.—The amendments made by
 20 this subsection shall apply to cost reporting periods begin-
 21 ning on or after October 1, 2004.

22 (h) WAIVER AUTHORITY.—

23 (1) IN GENERAL.—Section 1820(c)(2)(B)(i)(II) (42
 24 U.S.C. 1395i-4(c)(2)(B)(i)(II)) is amended by inserting
 25 “before January 1, 2006,” after “is certified”.

26 (2) GRANDFATHERING WAIVER AUTHORITY FOR CER-
 27 TAIN FACILITIES.—Section 1820(h) (42 U.S.C. 1395i-
 28 4(h)) is amended—

29 (A) in the heading preceding paragraph (1), by
 30 striking “OF CERTAIN FACILITIES” and inserting
 31 “PROVISIONS”; and

32 (B) by adding at the end the following new para-
 33 graph:

34 “(3) STATE AUTHORITY TO WAIVE 35-MILE RULE.—In
 35 the case of a facility that was designated as a critical ac-
 36 cess hospital before January 1, 2006, and was certified by
 37 the State as being a necessary provider of health care serv-

1 ices to residents in the area under subsection
 2 (c)(2)(B)(i)(II), as in effect before such date, the authority
 3 under such subsection with respect to any redesignation of
 4 such facility shall continue to apply notwithstanding the
 5 amendment made by section 405(h)(1) of the Medicare
 6 Prescription Drug, Improvement, and Modernization Act of
 7 2003.”.

8 **SEC. 406. MEDICARE INPATIENT HOSPITAL PAYMENT**
 9 **ADJUSTMENT FOR LOW-VOLUME HOSPITALS.**

10 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
 11 1395ww(d)) is amended by adding at the end the following new
 12 paragraph:

13 “(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOS-
 14 PITALS.—

15 “(A) IN GENERAL.—In addition to any payments
 16 calculated under this section for a subsection (d) hos-
 17 pital, for discharges occurring during a fiscal year (be-
 18 ginning with fiscal year 2005), the Secretary shall pro-
 19 vide for an additional payment amount to each low-vol-
 20 ume hospital (as defined in subparagraph (C)(i)) for
 21 discharges occurring during that fiscal year that is
 22 equal to the applicable percentage increase (determined
 23 under subparagraph (B) for the hospital involved) in
 24 the amount paid to such hospital under this section for
 25 such discharges (determined without regard to this
 26 paragraph).

27 “(B) APPLICABLE PERCENTAGE INCREASE.—The
 28 Secretary shall determine an applicable percentage in-
 29 crease for purposes of subparagraph (A) as follows:

30 “(i) The Secretary shall determine the empir-
 31 ical relationship for subsection (d) hospitals be-
 32 tween the standardized cost-per-case for such hos-
 33 pitals and the total number of discharges of such
 34 hospitals and the amount of the additional incre-
 35 mental costs (if any) that are associated with such
 36 number of discharges.

1 “(ii) The applicable percentage increase shall
2 be determined based upon such relationship in a
3 manner that reflects, based upon the number of
4 such discharges for a subsection (d) hospital, such
5 additional incremental costs.

6 “(iii) In no case shall the applicable percent-
7 age increase exceed 25 percent.

8 “(C) DEFINITIONS.—

9 “(i) LOW-VOLUME HOSPITAL.—For purposes
10 of this paragraph, the term ‘low-volume hospital’
11 means, for a fiscal year, a subsection (d) hospital
12 (as defined in paragraph (1)(B)) that the Secretary
13 determines is located more than 25 road miles from
14 another subsection (d) hospital and has less than
15 800 discharges during the fiscal year.

16 “(ii) DISCHARGE.—For purposes of subpara-
17 graph (B) and clause (i), the term ‘discharge’
18 means an inpatient acute care discharge of an indi-
19 vidual regardless of whether the individual is enti-
20 tled to benefits under part A.”.

21 (b) JUDICIAL REVIEW.—Section 1886(d)(7)(A) (42 U.S.C.
22 1395ww(d)(7)(A)) is amended by inserting after “to subsection
23 (e)(1)” the following: “or the determination of the applicable
24 percentage increase under paragraph (12)(A)(ii)”.

25 **SEC. 407. TREATMENT OF MISSING COST REPORTING**
26 **PERIODS FOR SOLE COMMUNITY HOS-**
27 **PITALS.**

28 (a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C.
29 1395ww(b)(3)(I)) is amended by adding at the end the fol-
30 lowing new clause:

31 “(iii) In no case shall a hospital be denied treatment as
32 a sole community hospital or payment (on the basis of a target
33 rate as such as a hospital) because data are unavailable for any
34 cost reporting period due to changes in ownership, changes in
35 fiscal intermediaries, or other extraordinary circumstances, so
36 long as data for at least one applicable base cost reporting pe-
37 riod is available.”.

1 (b) EFFECTIVE DATE.—The amendment made by sub-
 2 section (a) shall apply to cost reporting periods beginning on
 3 or after January 1, 2004.

4 **SEC. 408. RECOGNITION OF ATTENDING NURSE PRACTI-**
 5 **TIONERS AS ATTENDING PHYSICIANS TO**
 6 **SERVE HOSPICE PATIENTS.**

7 (a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C.
 8 1395x(dd)(3)(B)) is amended by inserting “or nurse practi-
 9 tioner (as defined in subsection (aa)(5))” after “the physician
 10 (as defined in subsection (r)(1))”.

11 (b) CLARIFICATION OF HOSPICE ROLE OF NURSE PRACTI-
 12 TIONERS.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C.
 13 1395f(a)(7)(A)(i)(I)) is amended by inserting “(which for pur-
 14 poses of this subparagraph does not include a nurse practi-
 15 tioner)” after “attending physician (as defined in section
 16 1861(dd)(3)(B))”.

17 **SEC. 409. RURAL HOSPICE DEMONSTRATION PROJECT.**

18 (a) IN GENERAL.—The Secretary shall conduct a dem-
 19 onstration project for the delivery of hospice care to medicare
 20 beneficiaries in rural areas. Under the project medicare bene-
 21 ficiaries who are unable to receive hospice care in the facility
 22 for lack of an appropriate caregiver are provided such care in
 23 a facility of 20 or fewer beds which offers, within its walls, the
 24 full range of services provided by hospice programs under sec-
 25 tion 1861(dd) of the Social Security Act (42 U.S.C.
 26 1395x(dd)).

27 (b) SCOPE OF PROJECT.—The Secretary shall conduct the
 28 project under this section with respect to no more than 3 hos-
 29 pice programs over a period of not longer than 5 years each.

30 (c) COMPLIANCE WITH CONDITIONS.—Under the dem-
 31 onstration project—

32 (1) the hospice program shall comply with otherwise
 33 applicable requirements, except that it shall not be required
 34 to offer services outside of the home or to meet the require-
 35 ments of section 1861(dd)(2)(A)(iii) of the Social Security
 36 Act; and

1 (2) payments for hospice care shall be made at the
2 rates otherwise applicable to such care under title XVIII of
3 such Act.

4 The Secretary may require the program to comply with such
5 additional quality assurance standards for its provision of serv-
6 ices in its facility as the Secretary deems appropriate.

7 (d) REPORT.—Upon completion of the project, the Sec-
8 retary shall submit a report to Congress on the project and
9 shall include in the report recommendations regarding exten-
10 sion of such project to hospice programs serving rural areas.

11 **SEC. 410. EXCLUSION OF CERTAIN RURAL HEALTH CLIN-**
12 **IC AND FEDERALLY QUALIFIED HEALTH**
13 **CENTER SERVICES FROM THE PROSPECTIVE**
14 **PAYMENT SYSTEM FOR SKILLED NURSING**
15 **FACILITIES.**

16 (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C.
17 1395yy(e)(2)(A)) is amended—

18 (1) in clause (i)(II), by striking “clauses (ii) and (iii)”
19 and inserting “clauses (ii), (iii), and (iv)”;

20 (2) by adding at the end the following new clause:

21 “(iv) EXCLUSION OF CERTAIN RURAL HEALTH
22 CLINIC AND FEDERALLY QUALIFIED HEALTH CEN-
23 TER SERVICES.—Services described in this clause
24 are—

25 “(I) rural health clinic services (as defined
26 in paragraph (1) of section 1861(aa)); and

27 “(II) Federally qualified health center
28 services (as defined in paragraph (3) of such
29 section);

30 that would be described in clause (ii) if such serv-
31 ices were furnished by an individual not affiliated
32 with a rural health clinic or a Federally qualified
33 health center.”.

34 (b) EFFECTIVE DATE.—The amendments made by sub-
35 section (a) shall apply to services furnished on or after January
36 1, 2005.

1 **SEC. 410A. RURAL COMMUNITY HOSPITAL DEMONSTRATION PROGRAM.**
2

3 (a) ESTABLISHMENT OF RURAL COMMUNITY HOSPITAL
4 (RCH) DEMONSTRATION PROGRAM.—

5 (1) IN GENERAL.—The Secretary shall establish a
6 demonstration program to test the feasibility and advis-
7 ability of the establishment of rural community hospitals
8 (as defined in subsection (f)(1)) to furnish covered inpa-
9 tient hospital services (as defined in subsection (f)(2)) to
10 medicare beneficiaries.

11 (2) DEMONSTRATION AREAS.—The program shall be
12 conducted in rural areas selected by the Secretary in States
13 with low population densities, as determined by the Sec-
14 retary.

15 (3) APPLICATION.—Each rural community hospital
16 that is located in a demonstration area selected under para-
17 graph (2) that desires to participate in the demonstration
18 program under this section shall submit an application to
19 the Secretary at such time, in such manner, and containing
20 such information as the Secretary may require.

21 (4) SELECTION OF HOSPITALS.—The Secretary shall
22 select from among rural community hospitals submitting
23 applications under paragraph (3) not more than 15 of such
24 hospitals to participate in the demonstration program
25 under this section.

26 (5) DURATION.—The Secretary shall conduct the dem-
27 onstration program under this section for a 5-year period.

28 (6) IMPLEMENTATION.—The Secretary shall imple-
29 ment the demonstration program not later than January 1,
30 2005, but may not implement the program before October
31 1, 2004.

32 (b) PAYMENT.—

33 (1) IN GENERAL.—The amount of payment under the
34 demonstration program for covered inpatient hospital serv-
35 ices furnished in a rural community hospital, other than
36 such services furnished in a psychiatric or rehabilitation
37 unit of the hospital which is a distinct part, is—

1 (A) for discharges occurring in the first cost re-
2 porting period beginning on or after the implementa-
3 tion of the demonstration program, the reasonable
4 costs of providing such services; and

5 (B) for discharges occurring in a subsequent cost
6 reporting period under the demonstration program, the
7 lesser of—

8 (i) the reasonable costs of providing such serv-
9 ices in the cost reporting period involved; or

10 (ii) the target amount (as defined in para-
11 graph (2)), applicable to the cost reporting period
12 involved.

13 (2) TARGET AMOUNT.—For purposes of paragraph
14 (1)(B)(ii), the term “target amount” means, with respect
15 to a rural community hospital for a particular 12-month
16 cost reporting period—

17 (A) in the case of the second such reporting period
18 for which this subsection is in effect, the reasonable
19 costs of providing such covered inpatient hospital serv-
20 ices as determined under paragraph (1)(A), and

21 (B) in the case of a later reporting period, the tar-
22 get amount for the preceding 12-month cost reporting
23 period,

24 increased by the applicable percentage increase (under
25 clause (i) of section 1886(b)(3)(B) of the Social Security
26 Act (42 U.S.C. 1395ww(b)(3)(B))) in the market basket
27 percentage increase (as defined in clause (iii) of such sec-
28 tion) for that particular cost reporting period.

29 (c) FUNDING.—

30 (1) IN GENERAL.—The Secretary shall provide for the
31 transfer from the Federal Hospital Insurance Trust Fund
32 under section 1817 of the Social Security Act (42 U.S.C.
33 1395i) of such funds as are necessary for the costs of car-
34 rying out the demonstration program under this section.

35 (2) BUDGET NEUTRALITY.—In conducting the dem-
36 onstration program under this section, the Secretary shall
37 ensure that the aggregate payments made by the Secretary

1 do not exceed the amount which the Secretary would have
 2 paid if the demonstration program under this section was
 3 not implemented.

4 (d) WAIVER AUTHORITY.—The Secretary may waive such
 5 requirements of title XVIII of the Social Security Act (42
 6 U.S.C. 1395 et seq.) as may be necessary for the purpose of
 7 carrying out the demonstration program under this section.

8 (e) REPORT.—Not later than 6 months after the comple-
 9 tion of the demonstration program under this section, the Sec-
 10 retary shall submit to Congress a report on such program, to-
 11 gether with recommendations for such legislation and adminis-
 12 trative action as the Secretary determines to be appropriate.

13 (f) DEFINITIONS.—In this section:

14 (1) RURAL COMMUNITY HOSPITAL DEFINED.—

15 (A) IN GENERAL.—The term “rural community
 16 hospital” means a hospital (as defined in section
 17 1861(e) of the Social Security Act (42 U.S.C.
 18 1395x(e))) that—

19 (i) is located in a rural area (as defined in sec-
 20 tion 1886(d)(2)(D) of such Act (42 U.S.C.
 21 1395ww(d)(2)(D))) or treated as being so located
 22 pursuant to section 1886(d)(8)(E) of such Act (42
 23 U.S.C. 1395ww(d)(8)(E));

24 (ii) subject to paragraph (2), has fewer than
 25 51 acute care inpatient beds, as reported in its
 26 most recent cost report;

27 (iii) makes available 24-hour emergency care
 28 services; and

29 (iv) is not eligible for designation, or has not
 30 been designated, as a critical access hospital under
 31 section 1820.

32 (B) TREATMENT OF PSYCHIATRIC AND REHABILI-
 33 TATION UNITS.—For purposes of paragraph (1)(B),
 34 beds in a psychiatric or rehabilitation unit of the hos-
 35 pital which is a distinct part of the hospital shall not
 36 be counted.

1 (2) COVERED INPATIENT HOSPITAL SERVICES.—The
 2 term “covered inpatient hospital services” means inpatient
 3 hospital services, and includes extended care services fur-
 4 nished under an agreement under section 1883 of the So-
 5 cial Security Act (42 U.S.C. 1395tt).

6 **Subtitle B—Provisions Relating to**
 7 **Part B Only**

8 **SEC. 411. 2-YEAR EXTENSION OF HOLD HARMLESS PRO-**
 9 **VISIONS FOR SMALL RURAL HOSPITALS AND**
 10 **SOLE COMMUNITY HOSPITALS UNDER THE**
 11 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
 12 **PITAL OUTPATIENT DEPARTMENT SERV-**
 13 **ICES.**

14 (a) HOLD HARMLESS PROVISIONS.—

15 (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42
 16 U.S.C. 1395l(t)(7)(D)(i)) is amended—

17 (A) in the heading, by striking “SMALL” and in-
 18 sserting “CERTAIN”;

19 (B) by inserting “or a sole community hospital (as
 20 defined in section 1886(d)(5)(D)(iii)) located in a rural
 21 area” after “100 beds”; and

22 (C) by striking “2004” and inserting “2006”.

23 (2) EFFECTIVE DATE.—The amendment made by
 24 paragraph (1)(B) shall apply with respect to cost reporting
 25 periods beginning on and after January 1, 2004.

26 (b) STUDY; AUTHORIZATION OF ADJUSTMENT.—Section
 27 1833(t) (42 U.S.C. 1395l(t)) is amended—

28 (1) by redesignating paragraph (13) as paragraph
 29 (16); and

30 (2) by inserting after paragraph (12) the following
 31 new paragraph:

32 “(13) AUTHORIZATION OF ADJUSTMENT FOR RURAL
 33 HOSPITALS.—

34 “(A) STUDY.—The Secretary shall conduct a
 35 study to determine if, under the system under this sub-
 36 section, costs incurred by hospitals located in rural
 37 areas by ambulatory payment classification groups

1 (APCs) exceed those costs incurred by hospitals located
2 in urban areas.

3 “(B) AUTHORIZATION OF ADJUSTMENT.—Insofar
4 as the Secretary determines under subparagraph (A)
5 that costs incurred by hospitals located in rural areas
6 exceed those costs incurred by hospitals located in
7 urban areas, the Secretary shall provide for an appro-
8 priate adjustment under paragraph (2)(E) to reflect
9 those higher costs by January 1, 2006.”.

10 **SEC. 412. ESTABLISHMENT OF FLOOR ON WORK GEO-**
11 **GRAPHIC ADJUSTMENT.**

12 Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)) is
13 amended—

14 (1) in subparagraph (A), by striking “subparagraphs
15 (B) and (C)” and inserting “subparagraphs (B), (C), and
16 (E)”; and

17 (2) by adding at the end the following new subpara-
18 graph:

19 “(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC
20 INDEX.—After calculating the work geographic index in
21 subparagraph (A)(iii), for purposes of payment for
22 services furnished on or after January 1, 2004, and be-
23 fore January 1, 2007, the Secretary shall increase the
24 work geographic index to 1.00 for any locality for
25 which such work geographic index is less than 1.00.”.

26 **SEC. 413. MEDICARE INCENTIVE PAYMENT PROGRAM**
27 **IMPROVEMENTS FOR PHYSICIAN SCARCITY.**

28 (a) ADDITIONAL INCENTIVE PAYMENT FOR CERTAIN PHY-
29 SICIAN SCARCITY AREAS.—Section 1833 (42 U.S.C. 1395l) is
30 amended by adding at the end the following new subsection:

31 “(u) INCENTIVE PAYMENTS FOR PHYSICIAN SCARCITY
32 AREAS.—

33 “(1) IN GENERAL.—In the case of physicians’ services
34 furnished on or after January 1, 2005, and before January
35 1, 2008—

1 “(A) by a primary care physician in a primary
2 care scarcity county (identified under paragraph (4));
3 or

4 “(B) by a physician who is not a primary care
5 physician in a specialist care scarcity county (as so
6 identified),

7 in addition to the amount of payment that would otherwise
8 be made for such services under this part, there also shall
9 be paid an amount equal to 5 percent of the payment
10 amount for the service under this part.

11 “(2) DETERMINATION OF RATIOS OF PHYSICIANS TO
12 MEDICARE BENEFICIARIES IN AREA.—Based upon available
13 data, the Secretary shall establish for each county or equiv-
14 alent area in the United States, the following:

15 “(A) NUMBER OF PHYSICIANS PRACTICING IN THE
16 AREA.—The number of physicians who furnish physi-
17 cians’ services in the active practice of medicine or os-
18 teopathy in that county or area, other than physicians
19 whose practice is exclusively for the Federal Govern-
20 ment, physicians who are retired, or physicians who
21 only provide administrative services. Of such number,
22 the number of such physicians who are—

23 “(i) primary care physicians; or

24 “(ii) physicians who are not primary care phy-
25 sicians.

26 “(B) NUMBER OF MEDICARE BENEFICIARIES RE-
27 SIDING IN THE AREA.—The number of individuals who
28 are residing in the county and are entitled to benefits
29 under part A or enrolled under this part, or both (in
30 this subsection referred to as ‘individuals’).

31 “(C) DETERMINATION OF RATIOS.—

32 “(i) PRIMARY CARE RATIO.—The ratio (in this
33 paragraph referred to as the ‘primary care ratio’)
34 of the number of primary care physicians (deter-
35 mined under subparagraph (A)(i)), to the number
36 of individuals determined under subparagraph (B).

1 “(ii) SPECIALIST CARE RATIO.—The ratio (in
2 this paragraph referred to as the ‘specialist care
3 ratio’) of the number of other physicians (deter-
4 mined under subparagraph (A)(ii)), to the number
5 of individuals determined under subparagraph (B).

6 “(3) RANKING OF COUNTIES.—The Secretary shall
7 rank each such county or area based separately on its pri-
8 mary care ratio and its specialist care ratio.

9 “(4) IDENTIFICATION OF COUNTIES.—

10 “(A) IN GENERAL.—The Secretary shall identify—

11 “(i) those counties and areas (in this para-
12 graph referred to as ‘primary care scarcity coun-
13 ties’) with the lowest primary care ratios that rep-
14 resent, if each such county or area were weighted
15 by the number of individuals determined under
16 paragraph (2)(B), an aggregate total of 20 percent
17 of the total of the individuals determined under
18 such paragraph; and

19 “(ii) those counties and areas (in this sub-
20 section referred to as ‘specialist care scarcity coun-
21 ties’) with the lowest specialist care ratios that rep-
22 resent, if each such county or area were weighted
23 by the number of individuals determined under
24 paragraph (2)(B), an aggregate total of 20 percent
25 of the total of the individuals determined under
26 such paragraph.

27 “(B) PERIODIC REVISIONS.—The Secretary shall
28 periodically revise the counties or areas identified in
29 subparagraph (A) (but not less often than once every
30 three years) unless the Secretary determines that there
31 is no new data available on the number of physicians
32 practicing in the county or area or the number of indi-
33 viduals residing in the county or area, as identified in
34 paragraph (2).

35 “(C) IDENTIFICATION OF COUNTIES WHERE SERV-
36 ICE IS FURNISHED.—For purposes of paying the addi-
37 tional amount specified in paragraph (1), if the Sec-

1 retary uses the 5-digit postal ZIP Code where the serv-
 2 ice is furnished, the dominant county of the postal ZIP
 3 Code (as determined by the United States Postal Serv-
 4 ice, or otherwise) shall be used to determine whether
 5 the postal ZIP Code is in a scarcity county identified
 6 in subparagraph (A) or revised in subparagraph (B).

7 “(D) JUDICIAL REVIEW.—There shall be no ad-
 8 ministrative or judicial review under section 1869,
 9 1878, or otherwise, respecting—

10 “(i) the identification of a county or area;

11 “(ii) the assignment of a specialty of any phy-
 12 sician under this paragraph;

13 “(iii) the assignment of a physician to a coun-
 14 ty under paragraph (2); or

15 “(iv) the assignment of a postal ZIP Code to
 16 a county or other area under this subsection.

17 “(5) RURAL CENSUS TRACTS.—To the extent feasible,
 18 the Secretary shall treat a rural census tract of a metro-
 19 politan statistical area (as determined under the most re-
 20 cent modification of the Goldsmith Modification, originally
 21 published in the Federal Register on February 27, 1992
 22 (57 Fed. Reg. 6725)), as an equivalent area for purposes
 23 of qualifying as a primary care scarcity county or specialist
 24 care scarcity county under this subsection.

25 “(6) PHYSICIAN DEFINED.—For purposes of this
 26 paragraph, the term ‘physician’ means a physician de-
 27 scribed in section 1861(r)(1) and the term ‘primary care
 28 physician’ means a physician who is identified in the avail-
 29 able data as a general practitioner, family practice practi-
 30 tioner, general internist, or obstetrician or gynecologist.

31 “(7) PUBLICATION OF LIST OF COUNTIES; POSTING ON
 32 WEBSITE.—With respect to a year for which a county or
 33 area is identified or revised under paragraph (4), the Sec-
 34 retary shall identify such counties or areas as part of the
 35 proposed and final rule to implement the physician fee
 36 schedule under section 1848 for the applicable year. The
 37 Secretary shall post the list of counties identified or revised

1 under paragraph (4) on the Internet website of the Centers
2 for Medicare & Medicaid Services.”.

3 (b) IMPROVEMENT TO MEDICARE INCENTIVE PAYMENT
4 PROGRAM.—

5 (1) IN GENERAL.—Section 1833(m) (42 U.S.C.
6 1395l(m)) is amended—

7 (A) by inserting “(1)” after “(m)”;

8 (B) in paragraph (1), as designated by subpara-
9 graph (A)—

10 (i) by inserting “in a year” after “In the case
11 of physicians’ services furnished”; and

12 (ii) by inserting “as identified by the Secretary
13 prior to the beginning of such year” after “as a
14 health professional shortage area”; and

15 (C) by adding at the end the following new para-
16 graphs:

17 “(2) For each health professional shortage area identified
18 in paragraph (1) that consists of an entire county, the Sec-
19 retary shall provide for the additional payment under para-
20 graph (1) without any requirement on the physician to identify
21 the health professional shortage area involved. The Secretary
22 may implement the previous sentence using the method speci-
23 fied in subsection (u)(4)(C).

24 “(3) The Secretary shall post on the Internet website of
25 the Centers for Medicare & Medicaid Services a list of the
26 health professional shortage areas identified in paragraph (1)
27 that consist of a partial county to facilitate the additional pay-
28 ment under paragraph (1) in such areas.

29 “(4) There shall be no administrative or judicial review
30 under section 1869, section 1878, or otherwise, respecting—

31 “(A) the identification of a county or area;

32 “(B) the assignment of a specialty of any physician
33 under this paragraph;

34 “(C) the assignment of a physician to a county under
35 this subsection; or

36 “(D) the assignment of a postal zip code to a county
37 or other area under this subsection.”.

1 (2) EFFECTIVE DATE.—The amendments made by
2 paragraph (1) shall apply to physicians' services furnished
3 on or after January 1, 2005.

4 (c) GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAY-
5 MENTS FOR PHYSICIANS' SERVICES.—

6 (1) STUDY.—The Comptroller General of the United
7 States shall conduct a study of differences in payment
8 amounts under the physician fee schedule under section
9 1848 of the Social Security Act (42 U.S.C. 1395w-4) for
10 physicians' services in different geographic areas. Such
11 study shall include—

12 (A) an assessment of the validity of the geographic
13 adjustment factors used for each component of the fee
14 schedule;

15 (B) an evaluation of the measures used for such
16 adjustment, including the frequency of revisions;

17 (C) an evaluation of the methods used to deter-
18 mine professional liability insurance costs used in com-
19 puting the malpractice component, including a review
20 of increases in professional liability insurance premiums
21 and variation in such increases by State and physician
22 specialty and methods used to update the geographic
23 cost of practice index and relative weights for the mal-
24 practice component; and

25 (D) an evaluation of the effect of the adjustment
26 to the physician work geographic index under section
27 1848(e)(1)(E) of the Social Security Act, as added by
28 section 412, on physician location and retention in
29 areas affected by such adjustment, taking into
30 account—

31 (i) differences in recruitment costs and reten-
32 tion rates for physicians, including specialists, be-
33 tween large urban areas and other areas; and

34 (ii) the mobility of physicians, including spe-
35 cialists, over the last decade.

36 (2) REPORT.—Not later than 1 year after the date of
37 the enactment of this Act, the Comptroller General shall

1 submit to Congress a report on the study conducted under
 2 paragraph (1). The report shall include recommendations
 3 regarding the use of more current data in computing geo-
 4 graphic cost of practice indices as well as the use of data
 5 directly representative of physicians' costs (rather than
 6 proxy measures of such costs).

7 **SEC. 414. PAYMENT FOR RURAL AND URBAN AMBU-**
 8 **LANCE SERVICES.**

9 (a) PHASE-IN PROVIDING FLOOR USING BLEND OF FEE
 10 SCHEDULE AND REGIONAL FEE SCHEDULES.—Section 1834(l)
 11 (42 U.S.C. 1395m(l)) is amended—

12 (1) in paragraph (2)(E), by inserting “consistent with
 13 paragraph (11)” after “in an efficient and fair manner”;
 14 and

15 (2) by redesignating paragraph (8), as added by sec-
 16 tion 221(a) of BIPA (114 Stat. 2763A–486), as paragraph
 17 (9); and

18 (3) by adding at the end the following new paragraph:

19 “(10) PHASE-IN PROVIDING FLOOR USING BLEND OF
 20 FEE SCHEDULE AND REGIONAL FEE SCHEDULES.—In car-
 21 rying out the phase-in under paragraph (2)(E) for each
 22 level of ground service furnished in a year, the portion of
 23 the payment amount that is based on the fee schedule shall
 24 be the greater of the amount determined under such fee
 25 schedule (without regard to this paragraph) or the fol-
 26 lowing blended rate of the fee schedule under paragraph
 27 (1) and of a regional fee schedule for the region involved:

28 “(A) For 2004 (for services furnished on or after
 29 July 1, 2004), the blended rate shall be based 20 per-
 30 cent on the fee schedule under paragraph (1) and 80
 31 percent on the regional fee schedule.

32 “(B) For 2005, the blended rate shall be based 40
 33 percent on the fee schedule under paragraph (1) and
 34 60 percent on the regional fee schedule.

35 “(C) For 2006, the blended rate shall be based 60
 36 percent on the fee schedule under paragraph (1) and
 37 40 percent on the regional fee schedule.

1 “(D) For 2007, 2008, and 2009, the blended rate
2 shall be based 80 percent on the fee schedule under
3 paragraph (1) and 20 percent on the regional fee
4 schedule.

5 “(E) For 2010 and each succeeding year, the
6 blended rate shall be based 100 percent on the fee
7 schedule under paragraph (1).

8 For purposes of this paragraph, the Secretary shall estab-
9 lish a regional fee schedule for each of the nine census divi-
10 sions (referred to in section 1886(d)(2)) using the method-
11 ology (used in establishing the fee schedule under para-
12 graph (1)) to calculate a regional conversion factor and a
13 regional mileage payment rate and using the same payment
14 adjustments and the same relative value units as used in
15 the fee schedule under such paragraph.”.

16 (b) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
17 TRIPS.—Section 1834(l), as amended by subsection (a), is
18 amended by adding at the end the following new paragraph:

19 “(11) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG
20 TRIPS.—In the case of ground ambulance services fur-
21 nished on or after July 1, 2004, and before January 1,
22 2009, regardless of where the transportation originates, the
23 fee schedule established under this subsection shall provide
24 that, with respect to the payment rate for mileage for a
25 trip above 50 miles the per mile rate otherwise established
26 shall be increased by $\frac{1}{4}$ of the payment per mile otherwise
27 applicable to miles in excess of 50 miles in such trip.”.

28 (c) IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY
29 CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.—

30 (1) IN GENERAL.—Section 1834(l) (42 U.S.C.
31 1395m(l)), as amended by subsections (a) and (b), is
32 amended by adding at the end the following new para-
33 graph:

34 “(12) ASSISTANCE FOR RURAL PROVIDERS FUR-
35 NISHING SERVICES IN LOW POPULATION DENSITY AREAS.—

36 “(A) IN GENERAL.—In the case of ground ambu-
37 lance services furnished on or after July 1, 2004, and

1 before January 1, 2010, for which the transportation
2 originates in a qualified rural area (identified under
3 subparagraph (B)(iii)), the Secretary shall provide for
4 a percent increase in the base rate of the fee schedule
5 for a trip established under this subsection. In estab-
6 lishing such percent increase, the Secretary shall esti-
7 mate the average cost per trip for such services (not
8 taking into account mileage) in the lowest quartile as
9 compared to the average cost per trip for such services
10 (not taking into account mileage) in the highest quar-
11 tile of all rural county populations.

12 “(B) IDENTIFICATION OF QUALIFIED RURAL
13 AREAS.—

14 “(i) DETERMINATION OF POPULATION DEN-
15 SITY IN AREA.—Based upon data from the United
16 States decennial census for the year 2000, the Sec-
17 retary shall determine, for each rural area, the pop-
18 ulation density for that area.

19 “(ii) RANKING OF AREAS.—The Secretary
20 shall rank each such area based on such population
21 density.

22 “(iii) IDENTIFICATION OF QUALIFIED RURAL
23 AREAS.—The Secretary shall identify those areas
24 (in subparagraph (A) referred to as ‘qualified rural
25 areas’) with the lowest population densities that
26 represent, if each such area were weighted by the
27 population of such area (as used in computing such
28 population densities), an aggregate total of 25 per-
29 cent of the total of the population of all such areas.

30 “(iv) RURAL AREA.—For purposes of this
31 paragraph, the term ‘rural area’ has the meaning
32 given such term in section 1886(d)(2)(D). If fea-
33 sible, the Secretary shall treat a rural census tract
34 of a metropolitan statistical area (as determined
35 under the most recent modification of the Gold-
36 smith Modification, originally published in the Fed-
37 eral Register on February 27, 1992 (57 Fed. Reg.

1 6725) as a rural area for purposes of this para-
2 graph.

3 “(v) JUDICIAL REVIEW.—There shall be no
4 administrative or judicial review under section
5 1869, 1878, or otherwise, respecting the identifica-
6 tion of an area under this subparagraph.”.

7 (2) USE OF DATA.—In order to promptly implement
8 section 1834(l)(12) of the Social Security Act, as added by
9 paragraph (1), the Secretary may use data furnished by the
10 Comptroller General of the United States.

11 (d) TEMPORARY INCREASE FOR GROUND AMBULANCE
12 SERVICES.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended
13 by subsections (a), (b), and (c), is amended by adding at the
14 end the following new paragraph:

15 “(13) TEMPORARY INCREASE FOR GROUND AMBU-
16 LANCE SERVICES.—

17 “(A) IN GENERAL.—After computing the rates
18 with respect to ground ambulance services under the
19 other applicable provisions of this subsection, in the
20 case of such services furnished on or after July 1,
21 2004, and before January 1, 2007, for which the trans-
22 portation originates in—

23 “(i) a rural area described in paragraph (9) or
24 in a rural census tract described in such para-
25 graph, the fee schedule established under this sec-
26 tion shall provide that the rate for the service oth-
27 erwise established, after the application of any in-
28 crease under paragraphs (11) and (12), shall be in-
29 creased by 2 percent; and

30 “(ii) an area not described in clause (i), the
31 fee schedule established under this subsection shall
32 provide that the rate for the service otherwise es-
33 tablished, after the application of any increase
34 under paragraph (11), shall be increased by 1 per-
35 cent.

36 “(B) APPLICATION OF INCREASED PAYMENTS
37 AFTER 2006.—The increased payments under subpara-

1 graph (A) shall not be taken into account in calculating
 2 payments for services furnished after the period speci-
 3 fied in such subparagraph.”.

4 (e) IMPLEMENTATION.—The Secretary may implement the
 5 amendments made by this section, and revise the conversion
 6 factor applicable under section 1834(l) of the Social Security
 7 Act (42 U.S.C. 1395m(l)) for purposes of implementing such
 8 amendments, on an interim final basis, or by program instruc-
 9 tion.

10 (f) GAO REPORT ON COSTS AND ACCESS.—Not later than
 11 December 31, 2005, the Comptroller General of the United
 12 States shall submit to Congress an initial report on how costs
 13 differ among the types of ambulance providers and on access,
 14 supply, and quality of ambulance services in those regions and
 15 States that have a reduction in payment under the medicare
 16 ambulance fee schedule (under section 1834(l) of the Social Se-
 17 curity Act, as amended by this Act). Not later than December
 18 31, 2007, the Comptroller General shall submit to Congress a
 19 final report on such access and supply.

20 (g) TECHNICAL AMENDMENTS.—(1) Section 221(c) of
 21 BIPA (114 Stat. 2763A–487) is amended by striking “sub-
 22 section (b)(2)” and inserting “subsection (b)(3)”.

23 (2) Section 1861(v)(1) (42 U.S.C. 1395x(v)(1)) is amend-
 24 ed by moving subparagraph (U) 4 ems to the left.

25 **SEC. 415. PROVIDING APPROPRIATE COVERAGE OF**
 26 **RURAL AIR AMBULANCE SERVICES.**

27 (a) COVERAGE.—Section 1834(l) (42 U.S.C. 1395m(l)), as
 28 amended by subsections (a), (b), (c), and (d) of section 414,
 29 is amended by adding at the end the following new paragraph:

30 “(14) PROVIDING APPROPRIATE COVERAGE OF RURAL
 31 AIR AMBULANCE SERVICES.—

32 “(A) IN GENERAL.—The regulations described in
 33 section 1861(s)(7) shall provide, to the extent that any
 34 ambulance services (whether ground or air) may be
 35 covered under such section, that a rural air ambulance
 36 service (as defined in subparagraph (C)) is reimbursed

1 under this subsection at the air ambulance rate if the
2 air ambulance service—

3 “(i) is reasonable and necessary based on the
4 health condition of the individual being transported
5 at or immediately prior to the time of the trans-
6 port; and

7 “(ii) complies with equipment and crew re-
8 quirements established by the Secretary.

9 “(B) SATISFACTION OF REQUIREMENT OF MEDI-
10 CALLY NECESSARY.—The requirement of subparagraph
11 (A)(i) is deemed to be met for a rural air ambulance
12 service if—

13 “(i) subject to subparagraph (D), such service
14 is requested by a physician or other qualified med-
15 ical personnel (as specified by the Secretary) who
16 reasonably determines or certifies that the individ-
17 ual’s condition is such that the time needed to
18 transport the individual by land or the instability
19 of transportation by land poses a threat to the indi-
20 vidual’s survival or seriously endangers the individ-
21 ual’s health; or

22 “(ii) such service is furnished pursuant to a
23 protocol that is established by a State or regional
24 emergency medical service (EMS) agency and rec-
25 ognized or approved by the Secretary under which
26 the use of an air ambulance is recommended, if
27 such agency does not have an ownership interest in
28 the entity furnishing such service.

29 “(C) RURAL AIR AMBULANCE SERVICE DE-
30 FINED.—For purposes of this paragraph, the term
31 ‘rural air ambulance service’ means fixed wing and ro-
32 tary wing air ambulance service in which the point of
33 pick up of the individual occurs in a rural area (as de-
34 fined in section 1886(d)(2)(D)) or in a rural census
35 tract of a metropolitan statistical area (as determined
36 under the most recent modification of the Goldsmith

1 Modification, originally published in the Federal Reg-
2 ister on February 27, 1992 (57 Fed. Reg. 6725)).

3 “(D) LIMITATION.—

4 “(i) IN GENERAL.—Subparagraph (B)(i) shall
5 not apply if there is a financial or employment rela-
6 tionship between the person requesting the rural
7 air ambulance service and the entity furnishing the
8 ambulance service, or an entity under common
9 ownership with the entity furnishing the air ambu-
10 lance service, or a financial relationship between an
11 immediate family member of such requester and
12 such an entity.

13 “(ii) EXCEPTION.—Where a hospital and the
14 entity furnishing rural air ambulance services are
15 under common ownership, clause (i) shall not apply
16 to remuneration (through employment or other re-
17 lationship) by the hospital of the requester or im-
18 mediate family member if the remuneration is for
19 provider-based physician services furnished in a
20 hospital (as described in section 1887) which are
21 reimbursed under part A and the amount of the re-
22 muneration is unrelated directly or indirectly to the
23 provision of rural air ambulance services.”

24 (b) CONFORMING AMENDMENT.—Section 1861(s)(7) (42
25 U.S.C. 1395x(s)(7)) is amended by inserting “, subject to sec-
26 tion 1834(l)(14),” after “but”.

27 (c) EFFECTIVE DATE.—The amendments made by this
28 subsection shall apply to services furnished on or after January
29 1, 2005.

30 **SEC. 416. TREATMENT OF CERTAIN CLINICAL DIAG-**
31 **NOSTIC LABORATORY TESTS FURNISHED TO**
32 **HOSPITAL OUTPATIENTS IN CERTAIN RURAL**
33 **AREAS.**

34 (a) IN GENERAL.—Notwithstanding subsections (a), (b),
35 and (h) of section 1833 of the Social Security Act (42 U.S.C.
36 1395l) and section 1834(d)(1) of such Act (42 U.S.C.
37 1395m(d)(1)), in the case of a clinical diagnostic laboratory

1 test covered under part B of title XVIII of such Act that is
 2 furnished during a cost reporting period described in subsection
 3 (b) by a hospital with fewer than 50 beds that is located in a
 4 qualified rural area (identified under paragraph (12)(B)(iii) of
 5 section 1834(l) of the Social Security Act (42 U.S.C.
 6 1395m(l)), as added by section 414(c) as part of outpatient
 7 services of the hospital, the amount of payment for such test
 8 shall be 100 percent of the reasonable costs of the hospital in
 9 furnishing such test.

10 (b) APPLICATION.—A cost reporting period described in
 11 this subsection is a cost reporting period beginning during the
 12 2-year period beginning on July 1, 2004.

13 (c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERV-
 14 ICES.—For purposes of subsection (a), in determining whether
 15 clinical diagnostic laboratory services are furnished as part of
 16 outpatient services of a hospital, the Secretary shall apply the
 17 same rules that are used to determine whether clinical diag-
 18 nostic laboratory services are furnished as an outpatient critical
 19 access hospital service under section 1834(g)(4) of the Social
 20 Security Act (42 U.S.C. 1395m(g)(4)).

21 **SEC. 417. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.**
 22

23 Section 4207 of the Balanced Budget Act of 1997 (Public
 24 Law 105–33) is amended—

25 (1) in subsection (a)(4), by striking “4-year” and in-
 26 serting “8-year”; and

27 (2) in subsection (d)(3), by striking “\$30,000,000”
 28 and inserting “\$60,000,000”.

29 **SEC. 418. REPORT ON DEMONSTRATION PROJECT PER-**
 30 **MITTING SKILLED NURSING FACILITIES TO**
 31 **BE ORIGINATING TELEHEALTH SITES; AU-**
 32 **THORITY TO IMPLEMENT.**

33 (a) EVALUATION.—The Secretary, acting through the Ad-
 34 ministrator of the Health Resources and Services Administra-
 35 tion in consultation with the Administrator of the Centers for
 36 Medicare & Medicaid Services, shall evaluate demonstration
 37 projects conducted by the Secretary under which skilled nurs-
 38 ing facilities (as defined in section 1819(a) of the Social Secu-

1 rity Act (42 U.S.C. 1395i–3(a)) are treated as originating sites
2 for telehealth services.

3 (b) REPORT.—Not later than January 1, 2005, the Sec-
4 retary shall submit to Congress a report on the evaluation con-
5 ducted under subsection (a). Such report shall include rec-
6 ommendations on mechanisms to ensure that permitting a
7 skilled nursing facility to serve as an originating site for the
8 use of telehealth services or any other service delivered via a
9 telecommunications system does not serve as a substitute for
10 in-person visits furnished by a physician, or for in-person visits
11 furnished by a physician assistant, nurse practitioner or clinical
12 nurse specialist, as is otherwise required by the Secretary.

13 (c) AUTHORITY TO EXPAND ORIGINATING TELEHEALTH
14 SITES TO INCLUDE SKILLED NURSING FACILITIES.—Insofar
15 as the Secretary concludes in the report required under sub-
16 section (b) that it is advisable to permit a skilled nursing facil-
17 ity to be an originating site for telehealth services under section
18 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)), and
19 that the Secretary can establish the mechanisms to ensure such
20 permission does not serve as a substitute for in-person visits
21 furnished by a physician, or for in-person visits furnished by
22 a physician assistant, nurse practitioner or clinical nurse spe-
23 cialist, the Secretary may deem a skilled nursing facility to be
24 an originating site under paragraph (4)(C)(ii) of such section
25 beginning on January 1, 2006.

26 **Subtitle C—Provisions Relating to** 27 **Parts A and B**

28 **SEC. 421. 1-YEAR INCREASE FOR HOME HEALTH SERV-** 29 **ICES FURNISHED IN A RURAL AREA.**

30 (a) IN GENERAL.—With respect to episodes and visits
31 ending on or after April 1, 2004, and before April 1, 2005, in
32 the case of home health services furnished in a rural area (as
33 defined in section 1886(d)(2)(D) of the Social Security Act (42
34 U.S.C. 1395ww(d)(2)(D))), the Secretary shall increase the
35 payment amount otherwise made under section 1895 of such
36 Act (42 U.S.C. 1395fff) for such services by 5 percent.

1 (b) WAIVING BUDGET NEUTRALITY.—The Secretary shall
 2 not reduce the standard prospective payment amount (or
 3 amounts) under section 1895 of the Social Security Act (42
 4 U.S.C. 1395fff) applicable to home health services furnished
 5 during a period to offset the increase in payments resulting
 6 from the application of subsection (a).

7 (c) NO EFFECT ON SUBSEQUENT PERIODS.—The pay-
 8 ment increase provided under subsection (a) for a period under
 9 such subsection—

10 (1) shall not apply to episodes and visits ending after
 11 such period; and

12 (2) shall not be taken into account in calculating the
 13 payment amounts applicable for episodes and visits occur-
 14 ring after such period.

15 **SEC. 422. REDISTRIBUTION OF UNUSED RESIDENT POSI-**
 16 **TIONS.**

17 (a) IN GENERAL.—Section 1886(h) (42 U.S.C.
 18 1395ww(h)(4)) is amended—

19 (1) in paragraph (4)(F)(i), by inserting “subject to
 20 paragraph (7),” after “October 1, 1997,”;

21 (2) in paragraph (4)(H)(i), by inserting “and subject
 22 to paragraph (7)” after “subparagraphs (F) and (G)”; and

23 (3) by adding at the end the following new paragraph:

24 “(7) REDISTRIBUTION OF UNUSED RESIDENT POSI-
 25 TIONS.—

26 “(A) REDUCTION IN LIMIT BASED ON UNUSED PO-
 27 SITIONS.—

28 “(i) PROGRAMS SUBJECT TO REDUCTION.—

29 “(I) IN GENERAL.—Except as provided in
 30 subclause (II), if a hospital’s reference resident
 31 level (specified in clause (ii)) is less than the
 32 otherwise applicable resident limit (as defined
 33 in subparagraph (C)(ii)), effective for portions
 34 of cost reporting periods occurring on or after
 35 July 1, 2005, the otherwise applicable resident
 36 limit shall be reduced by 75 percent of the dif-

1 ference between such otherwise applicable resi-
2 dent limit and such reference resident level.

3 “(II) EXCEPTION FOR SMALL RURAL HOS-
4 PITALS.—This subparagraph shall not apply to
5 a hospital located in a rural area (as defined in
6 subsection (d)(2)(D)(ii)) with fewer than 250
7 acute care inpatient beds.

8 “(ii) REFERENCE RESIDENT LEVEL.—

9 “(I) IN GENERAL.—Except as otherwise
10 provided in subclauses (II) and (III), the ref-
11 erence resident level specified in this clause for
12 a hospital is the resident level for the most re-
13 cent cost reporting period of the hospital end-
14 ing on or before September 30, 2002, for which
15 a cost report has been settled (or, if not, sub-
16 mitted (subject to audit)), as determined by the
17 Secretary.

18 “(II) USE OF MOST RECENT ACCOUNTING
19 PERIOD TO RECOGNIZE EXPANSION OF EXIST-
20 ING PROGRAMS.—If a hospital submits a timely
21 request to increase its resident level due to an
22 expansion of an existing residency training pro-
23 gram that is not reflected on the most recent
24 settled cost report, after audit and subject to
25 the discretion of the Secretary, the reference
26 resident level for such hospital is the resident
27 level for the cost reporting period that includes
28 July 1, 2003, as determined by the Secretary.

29 “(III) EXPANSIONS UNDER NEWLY AP-
30 PROVED PROGRAMS.—Upon the timely request
31 of a hospital, the Secretary shall adjust the ref-
32 erence resident level specified under subclause
33 (I) or (II) to include the number of medical
34 residents that were approved in an application
35 for a medical residency training program that
36 was approved by an appropriate accrediting or-
37 ganization (as determined by the Secretary) be-

1 fore January 1, 2002, but which was not in op-
2 eration during the cost reporting period used
3 under subclause (I) or (II), as the case may be,
4 as determined by the Secretary.

5 “(iii) AFFILIATION.—The provisions of clause
6 (i) shall be applied to hospitals which are members
7 of the same affiliated group (as defined by the Sec-
8 retary under paragraph (4)(H)(ii)) as of July 1,
9 2003.

10 “(B) REDISTRIBUTION.—

11 “(i) IN GENERAL.—The Secretary is author-
12 ized to increase the otherwise applicable resident
13 limit for each qualifying hospital that submits a
14 timely application under this subparagraph by such
15 number as the Secretary may approve for portions
16 of cost reporting periods occurring on or after July
17 1, 2005. The aggregate number of increases in the
18 otherwise applicable resident limits under this sub-
19 paragraph may not exceed the Secretary’s estimate
20 of the aggregate reduction in such limits attrib-
21 utable to subparagraph (A).

22 “(ii) CONSIDERATIONS IN REDISTRIBUTION.—
23 In determining for which hospitals the increase in
24 the otherwise applicable resident limit is provided
25 under clause (i), the Secretary shall take into ac-
26 count the demonstrated likelihood of the hospital
27 filling the positions within the first 3 cost reporting
28 periods beginning on or after July 1, 2005, made
29 available under this subparagraph, as determined
30 by the Secretary.

31 “(iii) PRIORITY FOR RURAL AND SMALL
32 URBAN AREAS.—In determining for which hospitals
33 and residency training programs an increase in the
34 otherwise applicable resident limit is provided
35 under clause (i), the Secretary shall distribute the
36 increase to programs of hospitals located in the fol-
37 lowing priority order:

1 “(I) First, to hospitals located in rural
2 areas (as defined in subsection (d)(2)(D)(ii)).

3 “(II) Second, to hospitals located in urban
4 areas that are not large urban areas (as de-
5 fined for purposes of subsection (d)).

6 “(III) Third, to other hospitals in a State
7 if the residency training program involved is in
8 a specialty for which there are not other resi-
9 dency training programs in the State.

10 Increases of residency limits within the same pri-
11 ority category under this clause shall be determined
12 by the Secretary.

13 “(iv) LIMITATION.—In no case shall more
14 than 25 full-time equivalent additional residency
15 positions be made available under this subpara-
16 graph with respect to any hospital.

17 “(v) APPLICATION OF LOCALITY ADJUSTED
18 NATIONAL AVERAGE PER RESIDENT AMOUNT.—
19 With respect to additional residency positions in a
20 hospital attributable to the increase provided under
21 this subparagraph, notwithstanding any other pro-
22 vision of this subsection, the approved FTE resi-
23 dent amount is deemed to be equal to the locality
24 adjusted national average per resident amount
25 computed under paragraph (4)(E) for that hos-
26 pital.

27 “(vi) CONSTRUCTION.—Nothing in this sub-
28 paragraph shall be construed as permitting the re-
29 distribution of reductions in residency positions at-
30 tributable to voluntary reduction programs under
31 paragraph (6), under a demonstration project ap-
32 proved as of October 31, 2003, under the authority
33 of section 402 of Public Law 90–248, or as affect-
34 ing the ability of a hospital to establish new med-
35 ical residency training programs under paragraph
36 (4)(H).

1 “(C) RESIDENT LEVEL AND LIMIT DEFINED.—In
2 this paragraph:

3 “(i) RESIDENT LEVEL.—The term ‘resident
4 level’ means, with respect to a hospital, the total
5 number of full-time equivalent residents, before the
6 application of weighting factors (as determined
7 under paragraph (4)), in the fields of allopathic
8 and osteopathic medicine for the hospital.

9 “(ii) OTHERWISE APPLICABLE RESIDENT
10 LIMIT.—The term ‘otherwise applicable resident
11 limit’ means, with respect to a hospital, the limit
12 otherwise applicable under subparagraphs (F)(i)
13 and (H) of paragraph (4) on the resident level for
14 the hospital determined without regard to this
15 paragraph.

16 “(D) JUDICIAL REVIEW.—There shall be no ad-
17 ministrative or judicial review under section 1869,
18 1878, or otherwise, with respect to determinations
19 made under this paragraph.”.

20 (b) CONFORMING PROVISIONS.—(1) Section
21 1886(d)(5)(B) (42 U.S.C. 1395ww(d)(5)(B)) is amended—

22 (A) in the second sentence of clause (ii), by striking
23 “For discharges” and inserting “Subject to clause (ix), for
24 discharges”;

25 (B) in clause (v), by adding at the end the following:
26 “The provisions of subsection (h)(7) shall apply with re-
27 spect to the first sentence of this clause in the same man-
28 ner as it applies with respect to subsection (h)(4)(F)(i).”;
29 and

30 (C) by adding at the end the following new clause:

31 “(ix) For discharges occurring on or after July 1,
32 2005, insofar as an additional payment amount under this
33 subparagraph is attributable to resident positions redistrib-
34 uted to a hospital under subsection (h)(7)(B), in computing
35 the indirect teaching adjustment factor under clause (ii)
36 the adjustment shall be computed in a manner as if ‘c’

1 were equal to 0.66 with respect to such resident posi-
2 tions.”.

3 (2) Chapter 35 of title 44, United States Code, shall not
4 apply with respect to applications under section 1886(h)(7) of
5 the Social Security Act, as added by subsection (a)(3).

6 (c) REPORT ON EXTENSION OF APPLICATIONS UNDER
7 REDISTRIBUTION PROGRAM.—Not later than July 1, 2005, the
8 Secretary shall submit to Congress a report containing rec-
9 ommendations regarding whether to extend the deadline for ap-
10 plications for an increase in resident limits under section
11 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by
12 subsection (a)).

13 **Subtitle D—Other Provisions**

14 **SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COL-** 15 **LABORATIVE EFFORTS THAT BENEFIT MEDI-** 16 **CALLY UNDERSERVED POPULATIONS.**

17 (a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C.
18 1320a–7(b)(3)), as amended by section 101(e)(2), is
19 amended—

20 (1) in subparagraph (F), by striking “and” after the
21 semicolon at the end;

22 (2) in subparagraph (G), by striking the period at the
23 end and inserting “; and”; and

24 (3) by adding at the end the following new subpara-
25 graph:

26 “(H) any remuneration between a health center
27 entity described under clause (i) or (ii) of section
28 1905(l)(2)(B) and any individual or entity providing
29 goods, items, services, donations, loans, or a combina-
30 tion thereof, to such health center entity pursuant to
31 a contract, lease, grant, loan, or other agreement, if
32 such agreement contributes to the ability of the health
33 center entity to maintain or increase the availability, or
34 enhance the quality, of services provided to a medically
35 underserved population served by the health center en-
36 tity.”.

1 (b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER
2 ENTITY ARRANGEMENTS.—

3 (1) ESTABLISHMENT.—

4 (A) IN GENERAL.—The Secretary shall establish,
5 on an expedited basis, standards relating to the excep-
6 tion described in section 1128B(b)(3)(H) of the Social
7 Security Act, as added by subsection (a), for health
8 center entity arrangements to the antikickback pen-
9 alties.

10 (B) FACTORS TO CONSIDER.—The Secretary shall
11 consider the following factors, among others, in estab-
12 lishing standards relating to the exception for health
13 center entity arrangements under subparagraph (A):

14 (i) Whether the arrangement between the
15 health center entity and the other party results in
16 savings of Federal grant funds or increased reve-
17 nues to the health center entity.

18 (ii) Whether the arrangement between the
19 health center entity and the other party restricts or
20 limits an individual's freedom of choice.

21 (iii) Whether the arrangement between the
22 health center entity and the other party protects a
23 health care professional's independent medical
24 judgment regarding medically appropriate treat-
25 ment.

26 The Secretary may also include other standards and
27 criteria that are consistent with the intent of Congress
28 in enacting the exception established under this section.

29 (2) DEADLINE.—Not later than 1 year after the date
30 of the enactment of this Act the Secretary shall publish
31 final regulations establishing the standards described in
32 paragraph (1).

33 **SEC. 432. OFFICE OF RURAL HEALTH POLICY IMPROVE-**
34 **MENTS.**

35 Section 711(b) (42 U.S.C. 912(b)) is amended—

36 (1) in paragraph (3), by striking “and” after the
37 comma at the end;

1 (2) in paragraph (4), by striking the period at the end
2 and inserting “, and”; and

3 (3) by inserting after paragraph (4) the following new
4 paragraph:

5 “(5) administer grants, cooperative agreements, and
6 contracts to provide technical assistance and other activities
7 as necessary to support activities related to improving
8 health care in rural areas.”.

9 **SEC. 433. MEDPAC STUDY ON RURAL HOSPITAL PAY-**
10 **MENT ADJUSTMENTS.**

11 (a) IN GENERAL.—The Medicare Payment Advisory Com-
12 mission shall conduct a study of the impact of sections 401
13 through 406, 411, 416, and 505. The Commission shall analyze
14 the effect on total payments, growth in costs, capital spending,
15 and such other payment effects under those sections.

16 (b) REPORTS.—

17 (1) INTERIM REPORT.—Not later than 18 months
18 after the date of the enactment of this Act, the Commission
19 shall submit to Congress an interim report on the matters
20 studied under subsection (a) with respect only to changes
21 to the critical access hospital provisions under section 405.

22 (2) FINAL REPORT.—Not later than 3 years after the
23 date of the enactment of this Act, the Commission shall
24 submit to Congress a final report on all matters studied
25 under subsection (a).

26 **SEC. 434. FRONTIER EXTENDED STAY CLINIC DEM-**
27 **ONSTRATION PROJECT.**

28 (a) AUTHORITY TO CONDUCT DEMONSTRATION
29 PROJECT.—The Secretary shall waive such provisions of the
30 medicare program established under title XVIII of the Social
31 Security Act (42 U.S.C. 1395 et seq.) as are necessary to con-
32 duct a demonstration project under which frontier extended
33 stay clinics described in subsection (b) in isolated rural areas
34 are treated as providers of items and services under the medi-
35 care program.

36 (b) CLINICS DESCRIBED.—A frontier extended stay clinic
37 is described in this subsection if the clinic—

1 (1) is located in a community where the closest short-
2 term acute care hospital or critical access hospital is at
3 least 75 miles away from the community or is inaccessible
4 by public road; and

5 (2) is designed to address the needs of—

6 (A) seriously or critically ill or injured patients
7 who, due to adverse weather conditions or other rea-
8 sons, cannot be transferred quickly to acute care refer-
9 ral centers; or

10 (B) patients who need monitoring and observation
11 for a limited period of time.

12 (c) SPECIFICATION OF CODES.—The Secretary shall deter-
13 mine the appropriate life-safety codes for such clinics that treat
14 patients for needs referred to in subsection (b)(2).

15 (d) FUNDING.—

16 (1) IN GENERAL.—Subject to paragraph (2), there are
17 authorized to be appropriated, in appropriate part from the
18 Federal Hospital Insurance Trust Fund and the Federal
19 Supplementary Medical Insurance Trust Fund, such sums
20 as are necessary to conduct the demonstration project
21 under this section.

22 (2) BUDGET NEUTRAL IMPLEMENTATION.—In con-
23 ducting the demonstration project under this section, the
24 Secretary shall ensure that the aggregate payments made
25 by the Secretary under the medicare program do not exceed
26 the amount which the Secretary would have paid under the
27 medicare program if the demonstration project under this
28 section was not implemented.

29 (e) 3-YEAR PERIOD.—The Secretary shall conduct the
30 demonstration under this section for a 3-year period.

31 (f) REPORT.—Not later than the date that is 1 year after
32 the date on which the demonstration project concludes, the Sec-
33 retary shall submit to Congress a report on the demonstration
34 project, together with such recommendations for legislation or
35 administrative action as the Secretary determines appropriate.

36 (g) DEFINITIONS.—In this section, the terms “hospital”
37 and “critical access hospital” have the meanings given such

1 terms in subsections (e) and (mm), respectively, of section
2 1861 of the Social Security Act (42 U.S.C. 1395x).

3 **TITLE V—PROVISIONS RELATING**
4 **TO PART A**
5 **Subtitle A—Inpatient Hospital**
6 **Services**

7 **SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAY-**
8 **MENT UPDATES.**

9 (a) IN GENERAL.—Section 1886(b)(3)(B)(i) (42 U.S.C.
10 1395ww(b)(3)(B)(i)) is amended—

- 11 (1) by striking “and” at the end of subclause (XVIII);
12 (2) by striking subclause (XIX); and
13 (3) by inserting after subclause (XVIII) the following
14 new subclauses:

15 “(XIX) for each of fiscal years 2004 through 2007,
16 subject to clause (vii), the market basket percentage in-
17 crease for hospitals in all areas; and

18 “(XX) for fiscal year 2008 and each subsequent fiscal
19 year, the market basket percentage increase for hospitals in
20 all areas.”.

21 (b) SUBMISSION OF HOSPITAL QUALITY DATA.—Section
22 1886(b)(3)(B) (42 U.S.C. 1395ww(b)(3)(B)) is amended by
23 adding at the end the following new clause:

24 “(vii)(I) For purposes of clause (i)(XIX) for each of fiscal
25 years 2005 through 2007, in a case of a subsection (d) hospital
26 that does not submit data to the Secretary in accordance with
27 subclause (II) with respect to such a fiscal year, the applicable
28 percentage increase under such clause for such fiscal year shall
29 be reduced by 0.4 percentage points. Such reduction shall apply
30 only with respect to the fiscal year involved, and the Secretary
31 shall not take into account such reduction in computing the ap-
32 plicable percentage increase under clause (i)(XIX) for a subse-
33 quent fiscal year.

34 “(II) Each subsection (d) hospital shall submit to the Sec-
35 retary quality data (for a set of 10 indicators established by
36 the Secretary as of November 1, 2003) that relate to the qual-

1 ity of care furnished by the hospital in inpatient settings in a
 2 form and manner, and at a time, specified by the Secretary for
 3 purposes of this clause, but with respect to fiscal year 2005,
 4 the Secretary shall provide for a 30-day grace period for the
 5 submission of data by a hospital.”.

6 (c) GAO STUDY AND REPORT ON APPROPRIATENESS OF
 7 PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR
 8 INPATIENT HOSPITAL SERVICES.—

9 (1) STUDY.—The Comptroller General of the United
 10 States, using the most current data available, shall conduct
 11 a study to determine—

12 (A) the appropriate level and distribution of pay-
 13 ments in relation to costs under the prospective pay-
 14 ment system under section 1886 of the Social Security
 15 Act (42 U.S.C. 1395ww) for inpatient hospital services
 16 furnished by subsection (d) hospitals (as defined in
 17 subsection (d)(1)(B) of such section); and

18 (B) whether there is a need to adjust such pay-
 19 ments under such system to reflect legitimate dif-
 20 ferences in costs across different geographic areas,
 21 kinds of hospitals, and types of cases.

22 (2) REPORT.—Not later than 24 months after the
 23 date of the enactment of this Act, the Comptroller General
 24 of the United States shall submit to Congress a report on
 25 the study conducted under paragraph (1) together with
 26 such recommendations for legislative and administrative ac-
 27 tion as the Comptroller General determines appropriate.

28 **SEC. 502. REVISION OF THE INDIRECT MEDICAL EDU-**
 29 **CATION (IME) ADJUSTMENT PERCENTAGE.**

30 (a) IN GENERAL.—Section 1886(d)(5)(B)(ii) (42 U.S.C.
 31 1395ww(d)(5)(B)(ii)) is amended—

32 (1) in subclause (VI), by striking “and” after the
 33 semicolon at the end;

34 (2) in subclause (VII)—

35 (A) by inserting “and before April 1, 2004,” after
 36 “on or after October 1, 2002,”; and

1 (B) by striking the period at the end and inserting
2 a semicolon; and

3 (3) by adding at the end the following new subclauses:

4 “(VIII) on or after April 1, 2004, and before Oc-
5 tober 1, 2004, ‘c’ is equal to 1.47;

6 “(IX) during fiscal year 2005, ‘c’ is equal to 1.42;

7 “(X) during fiscal year 2006, ‘c’ is equal to 1.37;

8 “(XI) during fiscal year 2007, ‘c’ is equal to 1.32;

9 and

10 “(XII) on or after October 1, 2007, ‘c’ is equal to
11 1.35.”.

12 (b) CONFORMING AMENDMENT RELATING TO DETER-
13 MINATION OF STANDARDIZED AMOUNT.—Section
14 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is amended—

15 (1) by striking “1999 or” and inserting “1999,”; and

16 (2) by inserting “, or the Medicare Prescription Drug,
17 Improvement, and Modernization Act of 2003” after
18 “2000”.

19 (c) EFFECTIVE DATE.—The amendments made by this
20 section shall apply to discharges occurring on or after April 1,
21 2004.

22 **SEC. 503. RECOGNITION OF NEW MEDICAL TECH-**
23 **NOLOGIES UNDER INPATIENT HOSPITAL**
24 **PROSPECTIVE PAYMENT SYSTEM.**

25 (a) IMPROVING TIMELINESS OF DATA COLLECTION.—Sec-
26 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended
27 by adding at the end the following new clause:

28 “(vii) Under the mechanism under this subparagraph, the
29 Secretary shall provide for the addition of new diagnosis and
30 procedure codes in April 1 of each year, but the addition of
31 such codes shall not require the Secretary to adjust the pay-
32 ment (or diagnosis-related group classification) under this sub-
33 section until the fiscal year that begins after such date.”.

34 (b) ELIGIBILITY STANDARD FOR TECHNOLOGY
35 OUTLIERS.—

36 (1) ADJUSTMENT OF THRESHOLD.—Section
37 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is

1 amended by inserting “(applying a threshold specified by
2 the Secretary that is the lesser of 75 percent of the stand-
3 arized amount (increased to reflect the difference between
4 cost and charges) or 75 percent of one standard deviation
5 for the diagnosis-related group involved)” after “is inad-
6 equate”.

7 (2) PROCESS FOR PUBLIC INPUT.—Section
8 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended
9 by subsection (a), is amended—

10 (A) in clause (i), by adding at the end the fol-
11 lowing: “Such mechanism shall be modified to meet the
12 requirements of clause (viii).”; and

13 (B) by adding at the end the following new clause:
14 “(viii) The mechanism established pursuant to clause (i)
15 shall be adjusted to provide, before publication of a proposed
16 rule, for public input regarding whether a new service or tech-
17 nology represents an advance in medical technology that sub-
18 stantially improves the diagnosis or treatment of individuals en-
19 titled to benefits under part A as follows:

20 “(I) The Secretary shall make public and periodically
21 update a list of all the services and technologies for which
22 an application for additional payment under this subpara-
23 graph is pending.

24 “(II) The Secretary shall accept comments, rec-
25 ommendations, and data from the public regarding whether
26 the service or technology represents a substantial improve-
27 ment.

28 “(III) The Secretary shall provide for a meeting at
29 which organizations representing hospitals, physicians, such
30 individuals, manufacturers, and any other interested party
31 may present comments, recommendations, and data to the
32 clinical staff of the Centers for Medicare & Medicaid Serv-
33 ices before publication of a notice of proposed rulemaking
34 regarding whether service or technology represents a sub-
35 stantial improvement.”.

36 (c) PREFERENCE FOR USE OF DRG ADJUSTMENT.—Sec-
37 tion 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)), as amended

1 by subsections (a) and (b), is amended by adding at the end
2 the following new clause:

3 “(ix) Before establishing any add-on payment under this
4 subparagraph with respect to a new technology, the Secretary
5 shall seek to identify one or more diagnosis-related groups as-
6 sociated with such technology, based on similar clinical or ana-
7 tomical characteristics and the cost of the technology. Within
8 such groups the Secretary shall assign an eligible new tech-
9 nology into a diagnosis-related group where the average costs
10 of care most closely approximate the costs of care of using the
11 new technology. No add-on payment under this subparagraph
12 shall be made with respect to such new technology and this
13 clause shall not affect the application of paragraph
14 (4)(C)(iii).”.

15 (d) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL
16 INPATIENT TECHNOLOGY.—

17 (1) IN GENERAL.—Section 1886(d)(5)(K)(ii)(III) (42
18 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking
19 “subject to paragraph (4)(C)(iii),”.

20 (2) NOT BUDGET NEUTRAL.—There shall be no reduc-
21 tion or other adjustment in payments under section 1886
22 of the Social Security Act because an additional payment
23 is provided under subsection (d)(5)(K)(ii)(III) of such sec-
24 tion.

25 (e) EFFECTIVE DATE.—

26 (1) IN GENERAL.—The Secretary shall implement the
27 amendments made by this section so that they apply to
28 classification for fiscal years beginning with fiscal year
29 2005.

30 (2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL
31 YEAR 2004 THAT ARE DENIED.—In the case of an applica-
32 tion for a classification of a medical service or technology
33 as a new medical service or technology under section
34 1886(d)(5)(K) of the Social Security Act (42 U.S.C.
35 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and
36 that is denied—

1 (A) the Secretary shall automatically reconsider
 2 the application as an application for fiscal year 2005
 3 under the amendments made by this section; and

4 (B) the maximum time period otherwise permitted
 5 for such classification of the service or technology shall
 6 be extended by 12 months.

7 **SEC. 504. INCREASE IN FEDERAL RATE FOR HOSPITALS**
 8 **IN PUERTO RICO.**

9 Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is
 10 amended—

11 (1) in subparagraph (A)—

12 (A) in clause (i), by striking “for discharges begin-
 13 ning on or after October 1, 1997, 50 percent (and for
 14 discharges between October 1, 1987, and September
 15 30, 1997, 75 percent)” and inserting “the applicable
 16 Puerto Rico percentage (specified in subparagraph
 17 (E))”; and

18 (B) in clause (ii), by striking “for discharges be-
 19 ginning in a fiscal year beginning on or after October
 20 1, 1997, 50 percent (and for discharges between Octo-
 21 ber 1, 1987, and September 30, 1997, 25 percent)”
 22 and inserting “the applicable Federal percentage (spec-
 23 ified in subparagraph (E))”; and

24 (2) by adding at the end the following new subpara-
 25 graph:

26 “(E) For purposes of subparagraph (A), for discharges
 27 occurring—

28 “(i) on or after October 1, 1987, and before October
 29 1, 1997, the applicable Puerto Rico percentage is 75 per-
 30 cent and the applicable Federal percentage is 25 percent;

31 “(ii) on or after October 1, 1997, and before April 1,
 32 2004, the applicable Puerto Rico percentage is 50 percent
 33 and the applicable Federal percentage is 50 percent;

34 “(iii) on or after April 1, 2004, and before October 1,
 35 2004, the applicable Puerto Rico percentage is 37.5 percent
 36 and the applicable Federal percentage is 62.5 percent; and

1 “(iv) on or after October 1, 2004, the applicable Puer-
2 to Rico percentage is 25 percent and the applicable Federal
3 percentage is 75 percent.”.

4 **SEC. 505. WAGE INDEX ADJUSTMENT RECLASSIFICA-**
5 **TION REFORM.**

6 (a) IN GENERAL.—Section 1886(d) (42 U.S.C.
7 1395ww(d)), as amended by section 406, is amended by adding
8 at the end the following new paragraph:

9 “(13)(A) In order to recognize commuting patterns among
10 geographic areas, the Secretary shall establish a process
11 through application or otherwise for an increase of the wage
12 index applied under paragraph (3)(E) for subsection (d) hos-
13 pitals located in a qualifying county described in subparagraph
14 (B) in the amount computed under subparagraph (D) based on
15 out-migration of hospital employees who reside in that county
16 to any higher wage index area.

17 “(B) The Secretary shall establish criteria for a qualifying
18 county under this subparagraph based on the out-migration re-
19 ferred to in subparagraph (A) and differences in the area wage
20 indices. Under such criteria the Secretary shall, utilizing such
21 data as the Secretary determines to be appropriate, establish—

22 “(i) a threshold percentage, established by the Sec-
23 retary, of the weighted average of the area wage index or
24 indices for the higher wage index areas involved;

25 “(ii) a threshold (of not less than 10 percent) for min-
26 imum out-migration to a higher wage index area or areas;
27 and

28 “(iii) a requirement that the average hourly wage of
29 the hospitals in the qualifying county equals or exceeds the
30 average hourly wage of all the hospitals in the area in
31 which the qualifying county is located.

32 “(C) For purposes of this paragraph, the term ‘higher
33 wage index area’ means, with respect to a county, an area with
34 a wage index that exceeds that of the county.

35 “(D) The increase in the wage index under subparagraph
36 (A) for a qualifying county shall be equal to the percentage of
37 the hospital employees residing in the qualifying county who

1 are employed in any higher wage index area multiplied by the
2 sum of the products, for each higher wage index area of—

3 “(i) the difference between—

4 “(I) the wage index for such higher wage index
5 area, and

6 “(II) the wage index of the qualifying county; and

7 “(ii) the number of hospital employees residing in the
8 qualifying county who are employed in such higher wage
9 index area divided by the total number of hospital employ-
10 ees residing in the qualifying county who are employed in
11 any higher wage index area.

12 “(E) The process under this paragraph may be based
13 upon the process used by the Medicare Geographic Classifica-
14 tion Review Board under paragraph (10). As the Secretary de-
15 termines to be appropriate to carry out such process, the Sec-
16 retary may require hospitals (including subsection (d) hospitals
17 and other hospitals) and critical access hospitals, as required
18 under section 1866(a)(1)(T), to submit data regarding the lo-
19 cation of residence, or the Secretary may use data from other
20 sources.

21 “(F) A wage index increase under this paragraph shall be
22 effective for a period of 3 fiscal years, except that the Secretary
23 shall establish procedures under which a subsection (d) hospital
24 may elect to waive the application of such wage index increase.

25 “(G) A hospital in a county that has a wage index increase
26 under this paragraph for a period and that has not waived the
27 application of such an increase under subparagraph (F) is not
28 eligible for reclassification under paragraph (8) or (10) during
29 that period.

30 “(H) Any increase in a wage index under this paragraph
31 for a county shall not be taken into account for purposes of—

32 “(i) computing the wage index for portions of the wage
33 index area (not including the county) in which the county
34 is located; or

35 “(ii) applying any budget neutrality adjustment with
36 respect to such index under paragraph (8)(D).

1 “(I) The thresholds described in subparagraph (B), data
2 on hospital employees used under this paragraph, and any de-
3 termination of the Secretary under the process described in
4 subparagraph (E) shall be final and shall not be subject to ju-
5 dicial review.”.

6 (b) CONFORMING AMENDMENTS.—Section 1866(a)(1) (42
7 U.S.C. 1395cc(a)(1)) is amended—

8 (1) in subparagraph (R), by striking “and” at the end;

9 (2) in subparagraph (S), by striking the period at the
10 end and inserting “, and”; and

11 (3) by inserting after subparagraph (S) the following
12 new subparagraph:

13 “(T) in the case of hospitals and critical access hos-
14 pitals, to furnish to the Secretary such data as the Sec-
15 retary determines appropriate pursuant to subparagraph
16 (E) of section 1886(d)(12) to carry out such section.”.

17 (c) EFFECTIVE DATE.—The amendments made by this
18 section shall first apply to the wage index for discharges occur-
19 ring on or after October 1, 2004. In initially implementing such
20 amendments, the Secretary may modify the deadlines otherwise
21 applicable under clauses (ii) and (iii)(I) of section
22 1886(d)(10)(C) of the Social Security Act (42 U.S.C.
23 1395ww(d)(10)(C)), for submission of, and actions on, applica-
24 tions relating to changes in hospital geographic reclassification.

25 **SEC. 506. LIMITATION ON CHARGES FOR INPATIENT**
26 **HOSPITAL CONTRACT HEALTH SERVICES**
27 **PROVIDED TO INDIANS BY MEDICARE PAR-**
28 **TICIPATING HOSPITALS.**

29 (a) IN GENERAL.—Section 1866(a)(1) (42 U.S.C.
30 1395cc(a)(1)), as amended by section 505(b), is amended—

31 (1) in subparagraph (S), by striking “and” at the end;

32 (2) in subparagraph (T), by striking the period and in-
33 serting “, and”; and

34 (3) by inserting after subparagraph (T) the following
35 new subparagraph:

36 “(U) in the case of hospitals which furnish inpatient
37 hospital services for which payment may be made under

1 this title, to be a participating provider of medical care
2 both—

3 “(i) under the contract health services program
4 funded by the Indian Health Service and operated by
5 the Indian Health Service, an Indian tribe, or tribal or-
6 ganization (as those terms are defined in section 4 of
7 the Indian Health Care Improvement Act), with respect
8 to items and services that are covered under such pro-
9 gram and furnished to an individual eligible for such
10 items and services under such program; and

11 “(ii) under any program funded by the Indian
12 Health Service and operated by an urban Indian orga-
13 nization with respect to the purchase of items and serv-
14 ices for an eligible urban Indian (as those terms are de-
15 fined in such section 4),

16 in accordance with regulations promulgated by the Sec-
17 retary regarding admission practices, payment method-
18 ology, and rates of payment (including the acceptance of no
19 more than such payment rate as payment in full for such
20 items and services.”.

21 (b) EFFECTIVE DATE.—The amendments made by this
22 section shall apply as of a date specified by the Secretary of
23 Health and Human Services (but in no case later than 1 year
24 after the date of enactment of this Act) to medicare partici-
25 pation agreements in effect (or entered into) on or after such
26 date.

27 (c) PROMULGATION OF REGULATIONS.—The Secretary
28 shall promulgate regulations to carry out the amendments
29 made by subsection (a).

30 **SEC. 507. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**
31 **MEDICARE LIMITS ON PHYSICIAN REFER-**
32 **RELS.**

33 (a) LIMITS ON PHYSICIAN REFERRALS.—

34 (1) OWNERSHIP AND INVESTMENT INTERESTS IN
35 WHOLE HOSPITALS.—

36 (A) IN GENERAL.—Section 1877(d)(3) (42 U.S.C.
37 1395nn(d)(3)) is amended—

1 (i) by striking “, and” at the end of subpara-
 2 graph (A) and inserting a semicolon; and

3 (ii) by redesignating subparagraph (B) as sub-
 4 paragraph (C) and inserting after subparagraph
 5 (A) the following new subparagraph:

6 “(B) effective for the 18-month period beginning
 7 on the date of the enactment of the Medicare Prescrip-
 8 tion Drug, Improvement, and Modernization Act of
 9 2003, the hospital is not a specialty hospital (as de-
 10 fined in subsection (h)(7)); and”.

11 (B) DEFINITION.—Section 1877(h) (42 U.S.C.
 12 1395nn(h)) is amended by adding at the end the fol-
 13 lowing:

14 “(7) SPECIALTY HOSPITAL.—

15 “(A) IN GENERAL.—For purposes of this section,
 16 except as provided in subparagraph (B), the term ‘spe-
 17 cialty hospital’ means a subsection (d) hospital (as de-
 18 fined in section 1886(d)(1)(B)) that is primarily or ex-
 19 clusively engaged in the care and treatment of one of
 20 the following categories:

21 “(i) Patients with a cardiac condition.

22 “(ii) Patients with an orthopedic condition.

23 “(iii) Patients receiving a surgical procedure.

24 “(iv) Any other specialized category of services
 25 that the Secretary designates as inconsistent with
 26 the purpose of permitting physician ownership and
 27 investment interests in a hospital under this sec-
 28 tion.

29 “(B) EXCEPTION.—For purposes of this section,
 30 the term ‘specialty hospital’ does not include any
 31 hospital—

32 “(i) determined by the Secretary—

33 “(I) to be in operation before November
 34 18, 2003; or

35 “(II) under development as of such date;

1 “(ii) for which the number of physician inves-
2 tors at any time on or after such date is no greater
3 than the number of such investors as of such date;

4 “(iii) for which the type of categories de-
5 scribed in subparagraph (A) at any time on or
6 after such date is no different than the type of
7 such categories as of such date;

8 “(iv) for which any increase in the number of
9 beds occurs only in the facilities on the main cam-
10 pus of the hospital and does not exceed 50 percent
11 of the number of beds in the hospital as of Novem-
12 ber 18, 2003, or 5 beds, whichever is greater; and

13 “(v) that meets such other requirements as
14 the Secretary may specify.”.

15 (2) OWNERSHIP AND INVESTMENT INTERESTS IN A
16 RURAL PROVIDER.—Section 1877(d)(2) (42 U.S.C.
17 1395m(d)(2)) is amended to read as follows:

18 “(2) RURAL PROVIDERS.—In the case of designated
19 health services furnished in a rural area (as defined in sec-
20 tion 1886(d)(2)(D)) by an entity, if—

21 “(A) substantially all of the designated health
22 services furnished by the entity are furnished to indi-
23 viduals residing in such a rural area; and

24 “(B) effective for the 18-month period beginning
25 on the date of the enactment of the Medicare Prescrip-
26 tion Drug, Improvement, and Modernization Act of
27 2003, the entity is not a specialty hospital (as defined
28 in subsection (h)(7)).”.

29 (b) APPLICATION OF EXCEPTION FOR HOSPITALS UNDER
30 DEVELOPMENT.—For purposes of section 1877(h)(7)(B)(i)(II)
31 of the Social Security Act, as added by subsection (a)(1)(B),
32 in determining whether a hospital is under development as of
33 November 18, 2003, the Secretary shall consider—

34 (1) whether architectural plans have been completed,
35 funding has been received, zoning requirements have been
36 met, and necessary approvals from appropriate State agen-
37 cies have been received; and

1 (2) any other evidence the Secretary determines would
2 indicate whether a hospital is under development as of such
3 date.

4 (c) STUDIES.—

5 (1) MEDPAC STUDY.—The Medicare Payment Advi-
6 sory Commission, in consultation with the Comptroller
7 General of the United States, shall conduct a study to
8 determine—

9 (A) any differences in the costs of health care
10 services furnished to patients by physician-owned spe-
11 cialty hospitals and the costs of such services furnished
12 by local full-service community hospitals within specific
13 diagnosis-related groups;

14 (B) the extent to which specialty hospitals, relative
15 to local full-service community hospitals, treat patients
16 in certain diagnosis-related groups within a category,
17 such as cardiology, and an analysis of the selection;

18 (C) the financial impact of physician-owned spe-
19 cialty hospitals on local full-service community hos-
20 pitals;

21 (D) how the current diagnosis-related group sys-
22 tem should be updated to better reflect the cost of de-
23 livering care in a hospital setting; and

24 (E) the proportions of payments received, by type
25 of payer, between the specialty hospitals and local full-
26 service community hospitals.

27 (2) HHS STUDY.—The Secretary shall conduct a
28 study of a representative sample of specialty hospitals—

29 (A) to determine the percentage of patients admit-
30 ted to physician-owned specialty hospitals who are re-
31 ferred by physicians with an ownership interest;

32 (B) to determine the referral patterns of physician
33 owners, including the percentage of patients they re-
34 ferred to physician-owned specialty hospitals and the
35 percentage of patients they referred to local full-service
36 community hospitals for the same condition;

1 (C) to compare the quality of care furnished in
 2 physician-owned specialty hospitals and in local full-
 3 service community hospitals for similar conditions and
 4 patient satisfaction with such care; and

5 (D) to assess the differences in uncompensated
 6 care, as defined by the Secretary, between the specialty
 7 hospital and local full-service community hospitals, and
 8 the relative value of any tax exemption available to
 9 such hospitals.

10 (3) REPORTS.—Not later than 15 months after the
 11 date of the enactment of this Act, the Commission and the
 12 Secretary, respectively, shall each submit to Congress a re-
 13 port on the studies conducted under paragraphs (1) and
 14 (2), respectively, and shall include any recommendations
 15 for legislation or administrative changes.

16 **SEC. 508. 1-TIME APPEALS PROCESS FOR HOSPITAL**
 17 **WAGE INDEX CLASSIFICATION.**

18 (a) ESTABLISHMENT OF PROCESS.—

19 (1) IN GENERAL.—The Secretary shall establish not
 20 later than January 1, 2004, by instruction or otherwise a
 21 process under which a hospital may appeal the wage index
 22 classification otherwise applicable to the hospital and select
 23 another area within the State (or, at the discretion of the
 24 Secretary, within a contiguous State) to which to be reclas-
 25 sified.

26 (2) PROCESS REQUIREMENTS.—The process estab-
 27 lished under paragraph (1) shall be consistent with the fol-
 28 lowing:

29 (A) Such an appeal may be filed as soon as pos-
 30 sible after the date of the enactment of this Act but
 31 shall be filed by not later than February 15, 2004.

32 (B) Such an appeal shall be heard by the Medicare
 33 Geographic Reclassification Review Board.

34 (C) There shall be no further administrative or ju-
 35 dicial review of a decision of such Board.

36 (3) RECLASSIFICATION UPON SUCCESSFUL APPEAL.—
 37 If the Medicare Geographic Reclassification Review Board

1 determines that the hospital is a qualifying hospital (as de-
 2 fined in subsection (c)), the hospital shall be reclassified to
 3 the area selected under paragraph (1). Such reclassification
 4 shall apply with respect to discharges occurring during the
 5 3-year period beginning with April 1, 2004.

6 (4) INAPPLICABILITY OF CERTAIN PROVISIONS.—Ex-
 7 cept as the Secretary may provide, the provisions of para-
 8 graphs (8) and (10) of section 1886(d) of the Social Secu-
 9 rity Act (42 U.S.C. 1395ww(d)) shall not apply to an ap-
 10 peal under this section.

11 (b) APPLICATION OF RECLASSIFICATION.—In the case of
 12 an appeal decided in favor of a qualifying hospital under sub-
 13 section (a), the wage index reclassification shall not affect the
 14 wage index computation for any area or for any other hospital
 15 and shall not be effected in a budget neutral manner. The pro-
 16 visions of this section shall not affect payment for discharges
 17 occurring after the end of the 3-year-period referred to in sub-
 18 section (a).

19 (c) QUALIFYING HOSPITAL DEFINED.—For purposes of
 20 this section, the term “qualifying hospital” means a subsection
 21 (d) hospital (as defined in section 1886(d)(1)(B) of the Social
 22 Security Act, 42 U.S.C. 1395ww(d)(1)(B)) that—

23 (1) does not qualify for a change in wage index classi-
 24 fication under paragraph (8) or (10) of section 1886(d) of
 25 the Social Security Act (42 U.S.C. 1395ww(d)) on the
 26 basis of requirements relating to distance or commuting;
 27 and

28 (2) meets such other criteria, such as quality, as the
 29 Secretary may specify by instruction or otherwise.

30 The Secretary may modify the wage comparison guidelines pro-
 31 mulgated under section 1886(d)(10)(D) of such Act (42 U.S.C.
 32 1395ww(d)(10)(D)) in carrying out this section.

33 (d) WAGE INDEX CLASSIFICATION.—For purposes of this
 34 section, the term “wage index classification” means the geo-
 35 graphic area in which it is classified for purposes of deter-
 36 mining for a fiscal year the factor used to adjust the DRG pro-
 37 spective payment rate under section 1886(d) of the Social Se-

1 security Act (42 U.S.C. 1395ww(d)) for area differences in hos-
 2 pital wage levels that applies to such hospital under paragraph
 3 (3)(E) of such section.

4 (e) LIMITATION ON EXPENDITURES.—The aggregate
 5 amount of additional expenditures resulting from the applica-
 6 tion of this section shall not exceed \$900,000,000.

7 (f) TRANSITIONAL EXTENSION.—Any reclassification of a
 8 county or other area made by Act of Congress for purposes of
 9 making payments under section 1886(d) of the Social Security
 10 Act (42 U.S.C. 1395ww(d)) that expired on September 30,
 11 2003, shall be deemed to be in effect during the period begin-
 12 ning on January 1, 2004, and ending on September 30, 2004.

13 **Subtitle B—Other Provisions**

14 **SEC. 511. PAYMENT FOR COVERED SKILLED NURSING** 15 **FACILITY SERVICES.**

16 (a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—
 17 Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is
 18 amended to read as follows:

19 “(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

20 “(A) IN GENERAL.—Subject to subparagraph (B),
 21 in the case of a resident of a skilled nursing facility
 22 who is afflicted with acquired immune deficiency syn-
 23 drome (AIDS), the per diem amount of payment other-
 24 wise applicable (determined without regard to any in-
 25 crease under section 101 of the Medicare, Medicaid,
 26 and SCHIP Balanced Budget Refinement Act of 1999,
 27 or under section 314(a) of Medicare, Medicaid, and
 28 SCHIP Benefits Improvement and Protection Act of
 29 2000), shall be increased by 128 percent to reflect in-
 30 creased costs associated with such residents.

31 “(B) SUNSET.—Subparagraph (A) shall not apply
 32 on and after such date as the Secretary certifies that
 33 there is an appropriate adjustment in the case mix
 34 under paragraph (4)(G)(i) to compensate for the in-
 35 creased costs associated with residents described in
 36 such subparagraph.”.

1 (b) EFFECTIVE DATE.—The amendment made by para-
 2 graph (1) shall apply to services furnished on or after October
 3 1, 2004.

4 **SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERV-**
 5 **ICES.**

6 (a) COVERAGE OF HOSPICE CONSULTATION SERVICES.—
 7 Section 1812(a) (42 U.S.C. 1395d(a)) is amended—

8 (1) by striking “and” at the end of paragraph (3);

9 (2) by striking the period at the end of paragraph (4)
 10 and inserting “; and”; and

11 (3) by inserting after paragraph (4) the following new
 12 paragraph:

13 “(5) for individuals who are terminally ill, have not
 14 made an election under subsection (d)(1), and have not
 15 previously received services under this paragraph, services
 16 that are furnished by a physician (as defined in section
 17 1861(r)(1)) who is either the medical director or an em-
 18 ployee of a hospice program and that—

19 “(A) consist of—

20 “(i) an evaluation of the individual’s need for
 21 pain and symptom management, including the indi-
 22 vidual’s need for hospice care; and

23 “(ii) counseling the individual with respect to
 24 hospice care and other care options; and

25 “(B) may include advising the individual regarding
 26 advanced care planning.”.

27 (b) PAYMENT.—Section 1814(i) (42 U.S.C. 1395f(i)) is
 28 amended by adding at the end the following new paragraph:

29 “(4) The amount paid to a hospice program with respect
 30 to the services under section 1812(a)(5) for which payment
 31 may be made under this part shall be equal to an amount es-
 32 tablished for an office or other outpatient visit for evaluation
 33 and management associated with presenting problems of mod-
 34 erate severity and requiring medical decisionmaking of low
 35 complexity under the fee schedule established under section
 36 1848(b), other than the portion of such amount attributable to
 37 the practice expense component.”.

1 (c) CONFORMING AMENDMENT.—Section
 2 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended
 3 by inserting before the comma at the end the following: “and
 4 services described in section 1812(a)(5)”.

5 (d) EFFECTIVE DATE.—The amendments made by this
 6 section shall apply to services provided by a hospice program
 7 on or after January 1, 2005.

8 **SEC. 513. STUDY ON PORTABLE DIAGNOSTIC**
 9 **ULTRASOUND SERVICES FOR BENE-**
 10 **FICIARIES IN SKILLED NURSING FACILITIES.**

11 (a) STUDY.—The Comptroller General of the United
 12 States shall conduct a study of portable diagnostic ultrasound
 13 services furnished to medicare beneficiaries in skilled nursing
 14 facilities. Such study shall consider the following:

15 (1) TYPES OF EQUIPMENT; TRAINING.—The types of
 16 portable diagnostic ultrasound services furnished to such
 17 beneficiaries, the types of portable ultrasound equipment
 18 used to furnish such services, and the technical skills, or
 19 training, or both, required for technicians to furnish such
 20 services.

21 (2) CLINICAL APPROPRIATENESS.—The clinical appro-
 22 priateness of transporting portable diagnostic ultrasound
 23 diagnostic and technicians to patients in skilled nursing fa-
 24 cilities as opposed to transporting such patients to a hos-
 25 pital or other facility that furnishes diagnostic ultrasound
 26 services.

27 (3) FINANCIAL IMPACT.—The financial impact if
 28 Medicare were make a separate payment for portable
 29 ultrasound diagnostic services, including the impact of sep-
 30 arate payments—

31 (A) for transportation and technician services for
 32 residents during a resident in a part A stay, that would
 33 otherwise be paid for under the prospective payment
 34 system for covered skilled nursing facility services
 35 (under section 1888(e) of the Social Security Act (42
 36 U.S.C. 1395yy(e)); and

1 (B) for such services for residents in a skilled
2 nursing facility after a part A stay.

3 (4) CREDENTIALING REQUIREMENTS.—Whether the
4 Secretary should establish credentialing or other require-
5 ments for technicians that furnish diagnostic ultrasound
6 services to medicare beneficiaries.

7 (b) REPORT.—Not later than 2 years after the date of the
8 enactment of this Act, the Comptroller General shall submit to
9 Congress a report on the study conducted under subsection (a),
10 and shall include any recommendations for legislation or ad-
11 ministrative change as the Comptroller General determines ap-
12 propriate.

13 **TITLE VI—PROVISIONS RELATING**
14 **TO PART B**
15 **Subtitle A—Provisions Relating to**
16 **Physicians’ Services**

17 **SEC. 601. REVISION OF UPDATES FOR PHYSICIANS’**
18 **SERVICES.**

19 (a) UPDATE FOR 2004 AND 2005.—

20 (1) IN GENERAL.—Section 1848(d) (42 U.S.C.
21 1395w-4(d)) is amended by adding at the end the following
22 new paragraph:

23 “(5) UPDATE FOR 2004 AND 2005.—The update to the
24 single conversion factor established in paragraph (1)(C) for
25 each of 2004 and 2005 shall be not less than 1.5 percent.”.

26 (2) CONFORMING AMENDMENT.—Paragraph (4)(B) of
27 such section is amended, in the matter before clause (i), by
28 inserting “and paragraph (5)” after “subparagraph (D)”.

29 (3) NOT TREATED AS CHANGE IN LAW AND REGULA-
30 TION IN SUSTAINABLE GROWTH RATE DETERMINATION.—
31 The amendments made by this subsection shall not be
32 treated as a change in law for purposes of applying section
33 1848(f)(2)(D) of the Social Security Act (42 U.S.C.
34 1395w-4(f)(2)(D)).

35 (b) USE OF 10-YEAR ROLLING AVERAGE IN COMPUTING
36 GROSS DOMESTIC PRODUCT.—

1 (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C.
2 1395w-4(f)(2)(C)) is amended—

3 (A) by striking “projected” and inserting “annual
4 average”; and

5 (B) by striking “from the previous applicable pe-
6 riod to the applicable period involved” and inserting
7 “during the 10-year period ending with the applicable
8 period involved”.

9 (2) EFFECTIVE DATE.—The amendments made by
10 paragraph (1) shall apply to computations of the sustain-
11 able growth rate for years beginning with 2003.

12 **SEC. 602. TREATMENT OF PHYSICIANS’ SERVICES FUR-**
13 **NISHED IN ALASKA.**

14 Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)), as amend-
15 ed by section 421, is amended—

16 (1) in subparagraph (A), by striking “subparagraphs
17 (B), (C), (E), and (F)” and inserting “subparagraphs (B),
18 (C), (E), (F) and (G)”; and

19 (2) by adding at the end the following new subpara-
20 graph:

21 “(G) FLOOR FOR PRACTICE EXPENSE, MAL-
22 PRACTICE, AND WORK GEOGRAPHIC INDICES FOR SERV-
23 ICES FURNISHED IN ALASKA.—For purposes of pay-
24 ment for services furnished in Alaska on or after Janu-
25 ary 1, 2004, and before January 1, 2006, after calcu-
26 lating the practice expense, malpractice, and work geo-
27 graphic indices in clauses (i), (ii), and (iii) of subpara-
28 graph (A) and in subparagraph (B), the Secretary shall
29 increase any such index to 1.67 if such index would
30 otherwise be less than 1.67.”.

31 **SEC. 603. INCLUSION OF PODIATRISTS, DENTISTS, AND**
32 **OPTOMETRISTS UNDER PRIVATE CON-**
33 **TRACTING AUTHORITY.**

34 Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is
35 amended by striking “section 1861(r)(1)” and inserting “para-
36 graphs (1), (2), (3), and (4) of section 1861(r)”.

1 **SEC. 604. GAO STUDY ON ACCESS TO PHYSICIANS' SERV-**
 2 **ICES.**

3 (a) STUDY.—The Comptroller General of the United
 4 States shall conduct a study on access of medicare beneficiaries
 5 to physicians' services under the medicare program. The study
 6 shall include—

7 (1) an assessment of the use by beneficiaries of such
 8 services through an analysis of claims submitted by physi-
 9 cians for such services under part B of the medicare pro-
 10 gram;

11 (2) an examination of changes in the use by bene-
 12 ficiaries of physicians' services over time; and

13 (3) an examination of the extent to which physicians
 14 are not accepting new medicare beneficiaries as patients.

15 (b) REPORT.—Not later than 18 months after the date of
 16 the enactment of this Act, the Comptroller General shall submit
 17 to Congress a report on the study conducted under subsection
 18 (a). The report shall include a determination whether—

19 (1) data from claims submitted by physicians under
 20 part B of the medicare program indicate potential access
 21 problems for medicare beneficiaries in certain geographic
 22 areas; and

23 (2) access by medicare beneficiaries to physicians'
 24 services may have improved, remained constant, or deterio-
 25 rated over time.

26 **SEC. 605. COLLABORATIVE DEMONSTRATION-BASED RE-**
 27 **VIEW OF PHYSICIAN PRACTICE EXPENSE GE-**
 28 **OGRAPHIC ADJUSTMENT DATA.**

29 (a) IN GENERAL.—Not later than January 1, 2005, the
 30 Secretary shall, in collaboration with State and other appro-
 31 priate organizations representing physicians, and other appro-
 32 priate persons, review and consider alternative data sources
 33 than those currently used in establishing the geographic index
 34 for the practice expense component under the medicare physi-
 35 cian fee schedule under section 1848(e)(1)(A)(i) of the Social
 36 Security Act (42 U.S.C. 1395w-4(e)(1)(A)(i)).

1 (b) SITES.—The Secretary shall select two physician pay-
2 ment localities in which to carry out subsection (a). One local-
3 ity shall include rural areas and at least one locality shall be
4 a statewide locality that includes both urban and rural areas.

5 (c) REPORT AND RECOMMENDATIONS.—

6 (1) REPORT.—Not later than January 1, 2006, the
7 Secretary shall submit to Congress a report on the review
8 and consideration conducted under subsection (a). Such re-
9 port shall include information on the alternative developed
10 data sources considered by the Secretary under subsection
11 (a), including the accuracy and validity of the data as
12 measures of the elements of the geographic index for prac-
13 tice expenses under the medicare physician fee schedule as
14 well as the feasibility of using such alternative data nation-
15 wide in lieu of current proxy data used in such index, and
16 the estimated impacts of using such alternative data.

17 (2) RECOMMENDATIONS.—The report submitted under
18 paragraph (1) shall contain recommendations on which
19 data sources reviewed and considered under subsection (a)
20 are appropriate for use in calculating the geographic index
21 for practice expenses under the medicare physician fee
22 schedule.

23 **SEC. 606. MEDPAC REPORT ON PAYMENT FOR PHYSI-**
24 **CIAANS' SERVICES.**

25 (a) PRACTICE EXPENSE COMPONENT.—Not later than 1
26 year after the date of the enactment of this Act, the Medicare
27 Payment Advisory Commission shall submit to Congress a re-
28 port on the effect of refinements to the practice expense compo-
29 nent of payments for physicians' services, after the transition
30 to a full resource-based payment system in 2002, under section
31 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such re-
32 port shall examine the following matters by physician specialty:

33 (1) The effect of such refinements on payment for
34 physicians' services.

35 (2) The interaction of the practice expense component
36 with other components of and adjustments to payment for
37 physicians' services under such section.

1 (3) The appropriateness of the amount of compensa-
2 tion by reason of such refinements.

3 (4) The effect of such refinements on access to care
4 by medicare beneficiaries to physicians' services.

5 (5) The effect of such refinements on physician par-
6 ticipation under the medicare program.

7 (b) VOLUME OF PHYSICIANS' SERVICES.—Not later than
8 1 year after the date of the enactment of this Act, the Medicare
9 Payment Advisory Commission shall submit to Congress a re-
10 port on the extent to which increases in the volume of physi-
11 cians' services under part B of the medicare program are a re-
12 sult of care that improves the health and well-being of medicare
13 beneficiaries. The study shall include the following:

14 (1) An analysis of recent and historic growth in the
15 components that the Secretary includes under the sustain-
16 able growth rate (under section 1848(f) of the Social Secu-
17 rity Act (42 U.S.C. 1395w-4(f))).

18 (2) An examination of the relative growth of volume
19 in physicians' services between medicare beneficiaries and
20 other populations.

21 (3) An analysis of the degree to which new technology,
22 including coverage determinations of the Centers for Medi-
23 care & Medicaid Services, has affected the volume of physi-
24 cians' services.

25 (4) An examination of the impact on volume of demo-
26 graphic changes.

27 (5) An examination of shifts in the site of service or
28 services that influence the number and intensity of services
29 furnished in physicians' offices and the extent to which
30 changes in reimbursement rates to other providers have ef-
31 fected these changes.

32 (6) An evaluation of the extent to which the Centers
33 for Medicare & Medicaid Services takes into account the
34 impact of law and regulations on the sustainable growth
35 rate.

1 **Subtitle B—Preventive Services**

2 **SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYS-** 3 **ICAL EXAMINATION.**

4 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
 5 1395x(s)(2)) is amended—

6 (1) in subparagraph (U), by striking “and” at the
 7 end;

8 (2) in subparagraph (V)(iii), by inserting “and” at the
 9 end; and

10 (3) by adding at the end the following new subpara-
 11 graph:

12 “(W) an initial preventive physical examination (as de-
 13 fined in subsection (ww));”.

14 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
 15 1395x) is amended by adding at the end the following new sub-
 16 section:

17 “Initial Preventive Physical Examination

18 “(ww)(1) The term ‘initial preventive physical examina-
 19 tion’ means physicians’ services consisting of a physical exam-
 20 ination (including measurement of height, weight, and blood
 21 pressure, and an electrocardiogram) with the goal of health
 22 promotion and disease detection and includes education, coun-
 23 seling, and referral with respect to screening and other preven-
 24 tive services described in paragraph (2), but does not include
 25 clinical laboratory tests.

26 “(2) The screening and other preventive services described
 27 in this paragraph include the following:

28 “(A) Pneumococcal, influenza, and hepatitis B vaccine
 29 and administration under subsection (s)(10).

30 “(B) Screening mammography as defined in sub-
 31 section (jj).

32 “(C) Screening pap smear and screening pelvic exam
 33 as defined in subsection (nn).

34 “(D) Prostate cancer screening tests as defined in
 35 subsection (oo).

36 “(E) Colorectal cancer screening tests as defined in
 37 subsection (pp).

1 “(F) Diabetes outpatient self-management training
2 services as defined in subsection (qq)(1).

3 “(G) Bone mass measurement as defined in subsection
4 (rr).

5 “(H) Screening for glaucoma as defined in subsection
6 (uu).

7 “(I) Medical nutrition therapy services as defined in
8 subsection (vv).

9 “(J) Cardiovascular screening blood tests as defined in
10 subsection (xx)(1).

11 “(K) Diabetes screening tests as defined in subsection
12 (yy).”.

13 (c) PAYMENT AS PHYSICIANS’ SERVICES.—Section
14 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by inserting
15 “(2)(W),” after “(2)(S),”.

16 (d) OTHER CONFORMING AMENDMENTS.—(1) Section
17 1862(a) (42 U.S.C. 1395y(a)), as amended by section
18 303(i)(3)(B), is amended—

19 (A) in paragraph (1)—

20 (i) by striking “and” at the end of subparagraph
21 (I);

22 (ii) by striking the semicolon at the end of sub-
23 paragraph (J) and inserting “, and”; and

24 (iii) by adding at the end the following new sub-
25 paragraph:

26 “(K) in the case of an initial preventive physical exam-
27 ination, which is performed not later than 6 months after
28 the date the individual’s first coverage period begins under
29 part B;”;

30 (B) in paragraph (7), by striking “or (H)” and insert-
31 ing “(H), or (K)”.

32 (2) Clauses (i) and (ii) of section 1861(s)(2)(K) (42
33 U.S.C. 1395x(s)(2)(K)) are each amended by inserting “and
34 services described in subsection (ww)(1)” after “services which
35 would be physicians’ services”.

36 (e) EFFECTIVE DATE.—The amendments made by this
37 section shall apply to services furnished on or after January 1,

1 2005, but only for individuals whose coverage period under part
2 B begins on or after such date.

3 **SEC. 612. COVERAGE OF CARDIOVASCULAR SCREENING**
4 **BLOOD TESTS.**

5 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
6 1395x(s)(2)), as amended by section 611(a), is amended—

7 (1) in subparagraph (V)(iii), by striking “and” at the
8 end;

9 (2) in subparagraph (W), by inserting “and” at the
10 end; and

11 (3) by adding at the end the following new subpara-
12 graph:

13 “(X) cardiovascular screening blood tests (as defined
14 in subsection (xx)(1));”.

15 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
16 1395x) is amended by adding at the end the following new sub-
17 section:

18 “Cardiovascular Screening Blood Test

19 “(xx)(1) The term ‘cardiovascular screening blood test’
20 means a blood test for the early detection of cardiovascular dis-
21 ease (or abnormalities associated with an elevated risk of car-
22 diovascular disease) that tests for the following:

23 “(A) Cholesterol levels and other lipid or triglyceride
24 levels.

25 “(B) Such other indications associated with the pres-
26 ence of, or an elevated risk for, cardiovascular disease as
27 the Secretary may approve for all individuals (or for some
28 individuals determined by the Secretary to be at risk for
29 cardiovascular disease), including indications measured by
30 noninvasive testing.

31 The Secretary may not approve an indication under subpara-
32 graph (B) for any individual unless a blood test for such is rec-
33 ommended by the United States Preventive Services Task
34 Force.

35 “(2) The Secretary shall establish standards, in consulta-
36 tion with appropriate organizations, regarding the frequency
37 for each type of cardiovascular screening blood tests, except

1 that such frequency may not be more often than once every 2
2 years.”.

3 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
4 1395y(a)(1)), as amended by section 611(d), is amended—

5 (1) by striking “and” at the end of subparagraph (J);

6 (2) by striking the semicolon at the end of subpara-
7 graph (K) and inserting “, and”; and

8 (3) by adding at the end the following new subpara-
9 graph:

10 “(L) in the case of cardiovascular screening blood
11 tests (as defined in section 1861(xx)(1)), which are per-
12 formed more frequently than is covered under section
13 1861(xx)(2);”.

14 (d) EFFECTIVE DATE.—The amendments made by this
15 section shall apply to tests furnished on or after January 1,
16 2005.

17 **SEC. 613. COVERAGE OF DIABETES SCREENING TESTS.**

18 (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C.
19 1395x(s)(2)), as amended by section 612(a), is amended—

20 (1) in subparagraph (W), by striking “and” at the
21 end;

22 (2) in subparagraph (X), by adding “and” at the end;
23 and

24 (3) by adding at the end the following new subpara-
25 graph:

26 “(Y) diabetes screening tests (as defined in subsection
27 (yy));”.

28 (b) SERVICES DESCRIBED.—Section 1861 (42 U.S.C.
29 1395x), as amended by section 612(b), is amended by adding
30 at the end the following new subsection:

31 “Diabetes Screening Tests

32 “(yy)(1) The term ‘diabetes screening tests’ means testing
33 furnished to an individual at risk for diabetes (as defined in
34 paragraph (2)) for the purpose of early detection of diabetes,
35 including—

36 “(A) a fasting plasma glucose test; and

1 “(B) such other tests, and modifications to tests, as
2 the Secretary determines appropriate, in consultation with
3 appropriate organizations.

4 “(2) For purposes of paragraph (1), the term ‘individual
5 at risk for diabetes’ means an individual who has any of the
6 following risk factors for diabetes:

7 “(A) Hypertension.

8 “(B) Dyslipidemia.

9 “(C) Obesity, defined as a body mass index greater
10 than or equal to 30 kg/m².

11 “(D) Previous identification of an elevated impaired
12 fasting glucose.

13 “(E) Previous identification of impaired glucose toler-
14 ance.

15 “(F) A risk factor consisting of at least 2 of the fol-
16 lowing characteristics:

17 “(i) Overweight, defined as a body mass index
18 greater than 25, but less than 30, kg/m².

19 “(ii) A family history of diabetes.

20 “(iii) A history of gestational diabetes mellitus or
21 delivery of a baby weighing greater than 9 pounds.

22 “(iv) 65 years of age or older.

23 “(3) The Secretary shall establish standards, in consulta-
24 tion with appropriate organizations, regarding the frequency of
25 diabetes screening tests, except that such frequency may not be
26 more often than twice within the 12-month period following the
27 date of the most recent diabetes screening test of that indi-
28 vidual.”.

29 (c) FREQUENCY.—Section 1862(a)(1) (42 U.S.C.
30 1395y(a)(1)), as amended by section 612(c), is amended—

31 (1) by striking “and” at the end of subparagraph (K);

32 (2) by striking the semicolon at the end of subpara-
33 graph (L) and inserting “, and”; and

34 (3) by adding at the end the following new subpara-
35 graph:

1 “(M) in the case of a diabetes screening test (as de-
 2 fined in section 1861(yy)(1)), which is performed more fre-
 3 quently than is covered under section 1861(yy)(3);”.

4 (d) EFFECTIVE DATE.—The amendments made by this
 5 section shall apply to tests furnished on or after January 1,
 6 2005.

7 **SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
 8 **RAPHY SERVICES.**

9 (a) EXCLUSION FROM OPD FEE SCHEDULE.—Section
 10 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by
 11 inserting before the period at the end the following: “and does
 12 not include screening mammography (as defined in section
 13 1861(jj)) and diagnostic mammography”.

14 (b) CONFORMING AMENDMENT.—Section 1833(a)(2)(E)(i)
 15 (42 U.S.C. 1395l(a)(2)(E)(i)) is amended by inserting “and,
 16 for services furnished on or after January 1, 2005, diagnostic
 17 mammography” after “screening mammography”.

18 (c) EFFECTIVE DATE.—The amendments made by this
 19 section shall apply—

20 (1) in the case of screening mammography, to services
 21 furnished on or after the date of the enactment of this Act;
 22 and

23 (2) in the case of diagnostic mammography, to serv-
 24 ices furnished on or after January 1, 2005.

25 **Subtitle C—Other Provisions**

26 **SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD)**
 27 **PAYMENT REFORM.**

28 (a) PAYMENT FOR DRUGS.—

29 (1) SPECIAL RULES FOR CERTAIN DRUGS AND
 30 BIOLOGICALS.—Section 1833(t) (42 U.S.C. 1395l(t)), as
 31 amended by section 411(b), is amended by inserting after
 32 paragraph (13) the following new paragraphs:

33 “(14) DRUG APC PAYMENT RATES.—

34 “(A) IN GENERAL.—The amount of payment
 35 under this subsection for a specified covered outpatient
 36 drug (defined in subparagraph (B)) that is furnished

1 as part of a covered OPD service (or group of serv-
 2 ices)—

3 “(i) in 2004, in the case of—

4 “(I) a sole source drug shall in no case be
 5 less than 88 percent, or exceed 95 percent, of
 6 the reference average wholesale price for the
 7 drug;

8 “(II) an innovator multiple source drug
 9 shall in no case exceed 68 percent of the ref-
 10 erence average wholesale price for the drug; or

11 “(III) a noninnovator multiple source drug
 12 shall in no case exceed 46 percent of the ref-
 13 erence average wholesale price for the drug;

14 “(ii) in 2005, in the case of—

15 “(I) a sole source drug shall in no case be
 16 less than 83 percent, or exceed 95 percent, of
 17 the reference average wholesale price for the
 18 drug;

19 “(II) an innovator multiple source drug
 20 shall in no case exceed 68 percent of the ref-
 21 erence average wholesale price for the drug; or

22 “(III) a noninnovator multiple source drug
 23 shall in no case exceed 46 percent of the ref-
 24 erence average wholesale price for the drug; or

25 “(iii) in a subsequent year, shall be equal, sub-
 26 ject to subparagraph (E)—

27 “(I) to the average acquisition cost for the
 28 drug for that year (which, at the option of the
 29 Secretary, may vary by hospital group (as de-
 30 fined by the Secretary based on volume of cov-
 31 ered OPD services or other relevant character-
 32 istics)), as determined by the Secretary taking
 33 into account the hospital acquisition cost sur-
 34 vey data under subparagraph (D); or

35 “(II) if hospital acquisition cost data are
 36 not available, the average price for the drug in
 37 the year established under section 1842(o), sec-

1 tion 1847A, or section 1847B, as the case may
2 be, as calculated and adjusted by the Secretary
3 as necessary for purposes of this paragraph.

4 “(B) SPECIFIED COVERED OUTPATIENT DRUG DE-
5 FINED.—

6 “(i) IN GENERAL.—In this paragraph, the
7 term ‘specified covered outpatient drug’ means,
8 subject to clause (ii), a covered outpatient drug (as
9 defined in section 1927(k)(2)) for which a separate
10 ambulatory payment classification group (APC) has
11 been established and that is—

12 “(I) a radiopharmaceutical; or

13 “(II) a drug or biological for which pay-
14 ment was made under paragraph (6) (relating
15 to pass-through payments) on or before Decem-
16 ber 31, 2002.

17 “(ii) EXCEPTION.—Such term does not
18 include—

19 “(I) a drug or biological for which pay-
20 ment is first made on or after January 1,
21 2003, under paragraph (6);

22 “(II) a drug or biological for which a tem-
23 porary HCPCS code has not been assigned; or

24 “(III) during 2004 and 2005, an orphan
25 drug (as designated by the Secretary).

26 “(C) PAYMENT FOR DESIGNATED ORPHAN DRUGS
27 DURING 2004 AND 2005.—The amount of payment under
28 this subsection for an orphan drug designated by the
29 Secretary under subparagraph (B)(ii)(III) that is fur-
30 nished as part of a covered OPD service (or group of
31 services) during 2004 and 2005 shall equal such
32 amount as the Secretary may specify.

33 “(D) ACQUISITION COST SURVEY FOR HOSPITAL
34 OUTPATIENT DRUGS.—

35 “(i) ANNUAL GAO SURVEYS IN 2004 AND
36 2005.—

1 “(I) IN GENERAL.—The Comptroller Gen-
2 eral of the United States shall conduct a survey
3 in each of 2004 and 2005 to determine the
4 hospital acquisition cost for each specified cov-
5 ered outpatient drug. Not later than April 1,
6 2005, the Comptroller General shall furnish
7 data from such surveys to the Secretary for use
8 in setting the payment rates under subpara-
9 graph (A) for 2006.

10 “(II) RECOMMENDATIONS.—Upon the
11 completion of such surveys, the Comptroller
12 General shall recommend to the Secretary the
13 frequency and methodology of subsequent sur-
14 veys to be conducted by the Secretary under
15 clause (ii).

16 “(ii) SUBSEQUENT SECRETARIAL SURVEYS.—
17 The Secretary, taking into account such rec-
18 ommendations, shall conduct periodic subsequent
19 surveys to determine the hospital acquisition cost
20 for each specified covered outpatient drug for use
21 in setting the payment rates under subparagraph
22 (A).

23 “(iii) SURVEY REQUIREMENTS.—The surveys
24 conducted under clauses (i) and (ii) shall have a
25 large sample of hospitals that is sufficient to gen-
26 erate a statistically significant estimate of the aver-
27 age hospital acquisition cost for each specified cov-
28 ered outpatient drug. With respect to the surveys
29 conducted under clause (i), the Comptroller Gen-
30 eral shall report to Congress on the justification for
31 the size of the sample used in order to assure the
32 validity of such estimates.

33 “(iv) DIFFERENTIATION IN COST.—In con-
34 ducting surveys under clause (i), the Comptroller
35 General shall determine and report to Congress if
36 there is (and the extent of any) variation in hos-
37 pital acquisition costs for drugs among hospitals

1 based on the volume of covered OPD services per-
 2 formed by such hospitals or other relevant charac-
 3 teristics of such hospitals (as defined by the Comp-
 4 troller General).

5 “(v) COMMENT ON PROPOSED RATES.—Not
 6 later than 30 days after the date the Secretary pro-
 7 mulgated proposed rules setting forth the payment
 8 rates under subparagraph (A) for 2006, the Comp-
 9 troller General shall evaluate such proposed rates
 10 and submit to Congress a report regarding the ap-
 11 propriateness of such rates based on the surveys
 12 the Comptroller General has conducted under
 13 clause (i).

14 “(E) ADJUSTMENT IN PAYMENT RATES FOR OVER-
 15 HEAD COSTS.—

16 “(i) MEDPAC REPORT ON DRUG APC DE-
 17 SIGN.—The Medicare Payment Advisory Commis-
 18 sion shall submit to the Secretary, not later than
 19 July 1, 2005, a report on adjustment of payment
 20 for ambulatory payment classifications for specified
 21 covered outpatient drugs to take into account over-
 22 head and related expenses, such as pharmacy serv-
 23 ices and handling costs. Such report shall include—

24 “(I) a description and analysis of the data
 25 available with regard to such expenses;

26 “(II) a recommendation as to whether
 27 such a payment adjustment should be made;
 28 and

29 “(III) if such adjustment should be made,
 30 a recommendation regarding the methodology
 31 for making such an adjustment.

32 “(ii) ADJUSTMENT AUTHORIZED.—The Sec-
 33 retary may adjust the weights for ambulatory pay-
 34 ment classifications for specified covered outpatient
 35 drugs to take into account the recommendations
 36 contained in the report submitted under clause (i).

1 “(F) CLASSES OF DRUGS.—For purposes of this
2 paragraph:

3 “(i) SOLE SOURCE DRUGS.—The term ‘sole
4 source drug’ means—

5 “(I) a biological product (as defined under
6 section 1861(t)(1)); or

7 “(II) a single source drug (as defined in
8 section 1927(k)(7)(A)(iv)).

9 “(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—
10 The term ‘innovator multiple source drug’ has the
11 meaning given such term in section
12 1927(k)(7)(A)(ii).

13 “(iii) NONINNOVATOR MULTIPLE SOURCE
14 DRUGS.—The term ‘noninnovator multiple source
15 drug’ has the meaning given such term in section
16 1927(k)(7)(A)(iii).

17 “(G) REFERENCE AVERAGE WHOLESALE PRICE.—
18 The term ‘reference average wholesale price’ means,
19 with respect to a specified covered outpatient drug, the
20 average wholesale price for the drug as determined
21 under section 1842(o) as of May 1, 2003.

22 “(H) INAPPLICABILITY OF EXPENDITURES IN DE-
23 TERMINING CONVERSION, WEIGHTING, AND OTHER AD-
24 JUSTMENT FACTORS.—Additional expenditures result-
25 ing from this paragraph shall not be taken into account
26 in establishing the conversion, weighting, and other ad-
27 justment factors for 2004 and 2005 under paragraph
28 (9), but shall be taken into account for subsequent
29 years.

30 “(15) PAYMENT FOR NEW DRUGS AND BIOLOGICALS
31 UNTIL HCPCS CODE ASSIGNED.—With respect to payment
32 under this part for an outpatient drug or biological that is
33 covered under this part and is furnished as part of covered
34 OPD services for which a HCPCS code has not been as-
35 signed, the amount provided for payment for such drug or
36 biological under this part shall be equal to 95 percent of
37 the average wholesale price for the drug or biological.”.

1 (2) REDUCTION IN THRESHOLD FOR SEPARATE APCS
2 FOR DRUGS.—Section 1833(t)(16), as redesignated section
3 411(b), is amended by adding at the end the following new
4 subparagraph:

5 “(B) THRESHOLD FOR ESTABLISHMENT OF SEPA-
6 RATE APCS FOR DRUGS.—The Secretary shall reduce
7 the threshold for the establishment of separate ambula-
8 tory payment classification groups (APCs) with respect
9 to drugs or biologicals to \$50 per administration for
10 drugs and biologicals furnished in 2005 and 2006.”.

11 (3) EXCLUSION OF SEPARATE DRUG APCS FROM
12 OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by
13 adding at the end the following new subparagraph:

14 “(E) EXCLUSION OF SEPARATE DRUG AND BIO-
15 LOGICAL APCS FROM OUTLIER PAYMENTS.—No addi-
16 tional payment shall be made under subparagraph (A)
17 in the case of ambulatory payment classification groups
18 established separately for drugs or biologicals.”.

19 (4) PAYMENT FOR PASS THROUGH DRUGS.—Section
20 1833(t)(6)(D)(i) (42 U.S.C. 13951(t)(6)(D)(i)) is amended
21 by inserting after “under section 1842(o)” the following:
22 “(or if the drug or biological is covered under a competitive
23 acquisition contract under section 1847B, an amount deter-
24 mined by the Secretary equal to the average price for the
25 drug or biological for all competitive acquisition areas and
26 year established under such section as calculated and ad-
27 justed by the Secretary for purposes of this paragraph)”.

28 (5) CONFORMING AMENDMENT TO BUDGET NEU-
29 TRALITY REQUIREMENT.—Section 1833(t)(9)(B) (42
30 U.S.C. 13951(t)(9)(B)) is amended by adding at the end
31 the following: “In determining adjustments under the pre-
32 ceding sentence for 2004 and 2005, the Secretary shall not
33 take into account under this subparagraph or paragraph
34 (2)(E) any expenditures that would not have been made
35 but for the application of paragraph (14).”.

1 (6) EFFECTIVE DATE.—The amendments made by
2 this subsection shall apply to items and services furnished
3 on or after January 1, 2004.

4 (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.—

5 (1) IN GENERAL.—Section 1833(t)(16), as redesignated
6 by section 411(b) and as amended by subsection
7 (a)(2), is amended by adding at the end the following new
8 subparagraph:

9 “(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY
10 AT CHARGES ADJUSTED TO COST.—Notwithstanding
11 the preceding provisions of this subsection, for a device
12 of brachytherapy consisting of a seed or seeds (or ra-
13 dioactive source) furnished on or after January 1,
14 2004, and before January 1, 2007, the payment basis
15 for the device under this subsection shall be equal to
16 the hospital’s charges for each device furnished, ad-
17 justed to cost. Charges for such devices shall not be in-
18 cluded in determining any outlier payment under this
19 subsection.”.

20 (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY
21 DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2)) is
22 amended—

23 (A) in subparagraph (F), by striking “and” at the
24 end;

25 (B) in subparagraph (G), by striking the period at
26 the end and inserting “; and”; and

27 (C) by adding at the end the following new sub-
28 paragraph:

29 “(H) with respect to devices of brachytherapy con-
30 sisting of a seed or seeds (or radioactive source), the
31 Secretary shall create additional groups of covered
32 OPD services that classify such devices separately from
33 the other services (or group of services) paid for under
34 this subsection in a manner reflecting the number, iso-
35 tope, and radioactive intensity of such devices fur-
36 nished, including separate groups for palladium-103
37 and iodine-125 devices.”.

1 (3) GAO REPORT.—The Comptroller General of the
 2 United States shall conduct a study to determine appro-
 3 priate payment amounts under section 1833(t)(16)(C) of
 4 the Social Security Act, as added by paragraph (1), for de-
 5 vices of brachytherapy. Not later than January 1, 2005,
 6 the Comptroller General shall submit to Congress and the
 7 Secretary a report on the study conducted under this para-
 8 graph, and shall include specific recommendations for ap-
 9 propriate payments for such devices.

10 **SEC. 622. LIMITATION OF APPLICATION OF FUNCTIONAL**
 11 **EQUIVALENCE STANDARD.**

12 Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by
 13 adding at the end the following new subparagraph:

14 “(F) LIMITATION OF APPLICATION OF FUNC-
 15 TIONAL EQUIVALENCE STANDARD.—

16 “(i) IN GENERAL.—The Secretary may not
 17 publish regulations that apply a functional equiva-
 18 lence standard to a drug or biological under this
 19 paragraph.

20 “(ii) APPLICATION.—Clause (i) shall apply to
 21 the application of a functional equivalence standard
 22 to a drug or biological on or after the date of en-
 23 actment of the Medicare Prescription Drug, Im-
 24 provement, and Modernization Act of 2003
 25 unless—

26 “(I) such application was being made to
 27 such drug or biological prior to such date of en-
 28 actment; and

29 “(II) the Secretary applies such standard
 30 to such drug or biological only for the purpose
 31 of determining eligibility of such drug or bio-
 32 logical for additional payments under this para-
 33 graph and not for the purpose of any other
 34 payments under this title.

35 “(iii) RULE OF CONSTRUCTION.—Nothing in
 36 this subparagraph shall be construed to effect the
 37 Secretary’s authority to deem a particular drug to

1 be identical to another drug if the 2 products are
2 pharmaceutically equivalent and bioequivalent, as
3 determined by the Commissioner of Food and
4 Drugs.”.

5 **SEC. 623. PAYMENT FOR RENAL DIALYSIS SERVICES.**

6 (a) INCREASE IN RENAL DIALYSIS COMPOSITE RATE FOR
7 SERVICES FURNISHED.—The last sentence of section
8 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended—

9 (1) by striking “and” before “for such services” the
10 second place it appears;

11 (2) by inserting “and before January 1, 2005,” after
12 “January 1, 2001,”; and

13 (3) by inserting before the period at the end the fol-
14 lowing: “, and for such services furnished on or after Janu-
15 ary 1, 2005, by 1.6 percent above such composite rate pay-
16 ment amounts for such services furnished on December 31,
17 2004”.

18 (b) RESTORING COMPOSITE RATE EXCEPTIONS FOR PEDI-
19 ATRIC FACILITIES.—

20 (1) IN GENERAL.—Section 422(a)(2) of BIPA is
21 amended—

22 (A) in subparagraph (A), by striking “and (C)”
23 and inserting “, (C), and (D)”;

24 (B) in subparagraph (B), by striking “In the
25 case” and inserting “Subject to subparagraph (D), in
26 the case”; and

27 (C) by adding at the end the following new sub-
28 paragraph:

29 “(D) INAPPLICABILITY TO PEDIATRIC FACILI-
30 TIES.—Subparagraphs (A) and (B) shall not apply, as
31 of October 1, 2002, to pediatric facilities that do not
32 have an exception rate described in subparagraph (C)
33 in effect on such date. For purposes of this subpara-
34 graph, the term ‘pediatric facility’ means a renal facil-
35 ity at least 50 percent of whose patients are individuals
36 under 18 years of age.”.

1 (2) CONFORMING AMENDMENT.—The fourth sentence
 2 of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)) is amended
 3 by striking “The Secretary” and inserting “Subject to sec-
 4 tion 422(a)(2) of the Medicare, Medicaid, and SCHIP Ben-
 5 efits Improvement and Protection Act of 2000, the Sec-
 6 retary”.

7 (c) INSPECTOR GENERAL STUDIES ON ESRD DRUGS.—

8 (1) IN GENERAL.—The Inspector General of the De-
 9 partment of Health and Human Services shall conduct two
 10 studies with respect to drugs and biologicals (including
 11 erythropoietin) furnished to end-stage renal disease pa-
 12 tients under the medicare program which are separately
 13 billed by end stage renal disease facilities.

14 (2) STUDIES ON ESRD DRUGS.—

15 (A) EXISTING DRUGS.—The first study under
 16 paragraph (1) shall be conducted with respect to such
 17 drugs and biologicals for which a billing code exists
 18 prior to January 1, 2004.

19 (B) NEW DRUGS.—The second study under para-
 20 graph (1) shall be conducted with respect to such drugs
 21 and biologicals for which a billing code does not exist
 22 prior to January 1, 2004.

23 (3) MATTERS STUDIED.—Under each study conducted
 24 under paragraph (1), the Inspector General shall—

25 (A) determine the difference between the amount
 26 of payment made to end stage renal disease facilities
 27 under title XVIII of the Social Security Act for such
 28 drugs and biologicals and the acquisition costs of such
 29 facilities for such drugs and biologicals and which are
 30 separately billed by end stage renal disease facilities,
 31 and

32 (B) estimate the rates of growth of expenditures
 33 for such drugs and biologicals billed by such facilities.

34 (4) REPORTS.—

35 (A) EXISTING ESRD DRUGS.—Not later than April
 36 1, 2004, the Inspector General shall report to the Sec-
 37 retary on the study described in paragraph (2)(A).

1 (B) NEW ESRD DRUGS.—Not later than April 1,
2 2006, the Inspector General shall report to the Sec-
3 retary on the study described in paragraph (2)(B).

4 (d) BASIC CASE-MIX ADJUSTED COMPOSITE RATE FOR
5 RENAL DIALYSIS FACILITY SERVICES.—(1) Section 1881(b)
6 (42 U.S.C. 1395rr(b)) is amended by adding at the end the fol-
7 lowing new paragraphs:

8 “(12)(A) In lieu of payment under paragraph (7) begin-
9 ning with services furnished on January 1, 2005, the Secretary
10 shall establish a basic case-mix adjusted prospective payment
11 system for dialysis services furnished by providers of services
12 and renal dialysis facilities in a year to individuals in a facility
13 and to such individuals at home. The case-mix under such sys-
14 tem shall be for a limited number of patient characteristics.

15 “(B) The system described in subparagraph (A) shall
16 include—

17 “(i) the services comprising the composite rate estab-
18 lished under paragraph (7); and

19 “(ii) the difference between payment amounts under
20 this title for separately billed drugs and biologicals (includ-
21 ing erythropoietin) and acquisition costs of such drugs and
22 biologicals, as determined by the Inspector General reports
23 to the Secretary as required by section 623(c) of the Medi-
24 care Prescription Drug, Improvement, and Modernization
25 Act of 2003—

26 “(I) beginning with 2005, for such drugs and
27 biologicals for which a billing code exists prior to Janu-
28 ary 1, 2004; and

29 “(II) beginning with 2007, for such drugs and
30 biologicals for which a billing code does not exist prior
31 to January 1, 2004,

32 adjusted to 2005, or 2007, respectively, as determined to
33 be appropriate by the Secretary.

34 “(C)(i) In applying subparagraph (B)(ii) for 2005, such
35 payment amounts under this title shall be determined using the
36 methodology specified in paragraph (13)(A)(i).

1 “(ii) For 2006, the Secretary shall provide for an adjust-
2 ment to the payments under clause (i) to reflect the difference
3 between the payment amounts using the methodology under
4 paragraph (13)(A)(i) and the payment amount determined
5 using the methodology applied by the Secretary under para-
6 graph (13)(A)(iii) of such paragraph, as estimated by the Sec-
7 retary.

8 “(D) The Secretary shall adjust the payment rates under
9 such system by a geographic index as the Secretary determines
10 to be appropriate. If the Secretary applies a geographic index
11 under this paragraph that differs from the index applied under
12 paragraph (7) the Secretary shall phase-in the application of
13 the index under this paragraph over a multiyear period.

14 “(E)(i) Such system shall be designed to result in the
15 same aggregate amount of expenditures for such services, as
16 estimated by the Secretary, as would have been made for 2005
17 if this paragraph did not apply.

18 “(ii) The adjustment made under subparagraph (B)(ii)(II)
19 shall be done in a manner to result in the same aggregate
20 amount of expenditures after such adjustment as would other-
21 wise have been made for such services for 2006 or 2007, re-
22 spectively, as estimated by the Secretary, if this paragraph did
23 not apply.

24 “(F) Beginning with 2006, the Secretary shall annually
25 increase the basic case-mix adjusted payment amounts estab-
26 lished under this paragraph, by an amount determined by—

27 “(i) applying the estimated growth in expenditures for
28 drugs and biologicals (including erythropoietin) that are
29 separately billable to the component of the basic case-mix
30 adjusted system described in subparagraph (B)(ii); and

31 “(ii) converting the amount determined in clause (i) to
32 an increase applicable to the basic case-mix adjusted pay-
33 ment amounts established under subparagraph (B).

34 Nothing in this paragraph shall be construed as providing for
35 an update to the composite rate component of the basic case-
36 mix adjusted system under subparagraph (B).

1 “(G) There shall be no administrative or judicial review
2 under section 1869, section 1878, or otherwise, of the case-mix
3 system, relative weights, payment amounts, the geographic ad-
4 justment factor, or the update for the system established under
5 this paragraph, or the determination of the difference between
6 medicare payment amounts and acquisition costs for separately
7 billed drugs and biologicals (including erythropoietin) under
8 this paragraph and paragraph (13).

9 “(13)(A) The payment amounts under this title for sepa-
10 rately billed drugs and biologicals furnished in a year, begin-
11 ning with 2004, are as follows:

12 “(i) For such drugs and biologicals (other than eryth-
13 ropoietin) furnished in 2004, the amount determined under
14 section 1842(o)(1)(A)(v) for the drug or biological.

15 “(ii) For such drugs and biologicals (including eryth-
16 ropoietin) furnished in 2005, the acquisition cost of the
17 drug or biological, as determined by the Inspector General
18 reports to the Secretary as required by section 623(c) of
19 the Medicare Prescription Drug, Improvement, and Mod-
20 ernization Act of 2003. Insofar as the Inspector General
21 has not determined the acquisition cost with respect to a
22 drug or biological, the Secretary shall determine the pay-
23 ment amount for such drug or biological.

24 “(iii) For such drugs and biologicals (including eryth-
25 ropoietin) furnished in 2006 and subsequent years, such
26 acquisition cost or the amount determined under section
27 1847A for the drug or biological, as the Secretary may
28 specify.

29 “(B)(i) Drugs and biologicals (including erythropoietin)
30 which were separately billed under this subsection on the day
31 before the date of the enactment of the Medicare Prescription
32 Drug, Improvement, and Modernization Act of 2003 shall con-
33 tinue to be separately billed on and after such date.

34 “(ii) Nothing in this paragraph, section 1842(o), section
35 1847A, or section 1847B shall be construed as requiring or au-
36 thORIZING the bundling of payment for drugs and biologicals

1 into the basic case-mix adjusted payment system under this
2 paragraph.”.

3 (2) Paragraph (7) of such section is amended in the first
4 sentence by striking “The Secretary” and inserting “Subject to
5 paragraph (12), the Secretary”.

6 (3) Paragraph (11)(B) of such section is amended by in-
7 serting “subject to paragraphs (12) and (13)” before “payment
8 for such item”.

9 (e) DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED
10 PAYMENT SYSTEM FOR ESRD SERVICES.—

11 (1) IN GENERAL.—The Secretary shall establish a
12 demonstration project of the use of a fully case-mix ad-
13 justed payment system for end stage renal disease services
14 under section 1881 of the Social Security Act (42 U.S.C.
15 1395rr) for patient characteristics identified in the report
16 under subsection (f) that bundles into such payment rates
17 amounts for—

18 (A) drugs and biologicals (including erythro-
19 poietin) furnished to end stage renal disease patients
20 under the medicare program which are separately billed
21 by end stage renal disease facilities (as of the date of
22 the enactment of this Act); and

23 (B) clinical laboratory tests related to such drugs
24 and biologicals.

25 (2) FACILITIES INCLUDED IN THE DEMONSTRATION.—
26 In conducting the demonstration under this subsection, the
27 Secretary shall ensure the participation of a sufficient num-
28 ber of providers of dialysis services and renal dialysis facili-
29 ties, but in no case to exceed 500. In selecting such pro-
30 viders and facilities, the Secretary shall ensure that the fol-
31 lowing types of providers are included in the demonstra-
32 tion:

33 (A) Urban providers and facilities.

34 (B) Rural providers and facilities.

35 (C) Not-for-profit providers and facilities.

36 (D) For-profit providers and facilities.

37 (E) Independent providers and facilities.

1 (F) Specialty providers and facilities, including pe-
2 diatric providers and facilities and small providers and
3 facilities.

4 (3) TEMPORARY ADD-ON PAYMENT FOR DIALYSIS
5 SERVICES FURNISHED UNDER THE DEMONSTRATION.—

6 (A) IN GENERAL.—During the period of the dem-
7 onstration project, the Secretary shall increase payment
8 rates that would otherwise apply under section 1881(b)
9 of such Act (42 U.S.C. 1395rr(b)) by 1.6 percent for
10 dialysis services furnished in facilities in the dem-
11 onstration site.

12 (B) RULES OF CONSTRUCTION.—Nothing in this
13 subsection shall be construed as—

14 (i) as an annual update under section 1881(b)
15 of the Social Security Act (42 U.S.C. 1395rr(b));

16 (ii) as increasing the baseline for payments
17 under such section; or

18 (iii) requiring the budget neutral implementa-
19 tion of the demonstration project under this sub-
20 section.

21 (4) 3-YEAR PERIOD.—The Secretary shall conduct the
22 demonstration under this subsection for the 3-year period
23 beginning on January 1, 2006.

24 (5) USE OF ADVISORY BOARD.—

25 (A) IN GENERAL.—In carrying out the demonstra-
26 tion under this subsection, the Secretary shall establish
27 an advisory board comprised of representatives de-
28 scribed in subparagraph (B) to provide advice and rec-
29 ommendations with respect to the establishment and
30 operation of such demonstration.

31 (B) REPRESENTATIVES.—Representatives referred
32 to in subparagraph (A) include representatives of the
33 following:

34 (i) Patient organizations.

35 (ii) Individuals with expertise in end stage
36 renal dialysis services, such as clinicians, econo-
37 mists, and researchers.

1 (iii) The Medicare Payment Advisory Commis-
 2 sion, established under section 1805 of the Social
 3 Security Act (42 U.S.C. 1395b–6).

4 (iv) The National Institutes of Health.

5 (v) Network organizations under section
 6 1881(c) of the Social Security Act (42 U.S.C.
 7 1395rr(c)).

8 (vi) Medicare contractors to monitor quality of
 9 care.

10 (vii) Providers of services and renal dialysis
 11 facilities furnishing end stage renal disease serv-
 12 ices.

13 (C) TERMINATION OF ADVISORY PANEL.—The ad-
 14 visory panel shall terminate on December 31, 2008.

15 (6) AUTHORIZATION OF APPROPRIATIONS.—There are
 16 authorized to be appropriated, in appropriate part from the
 17 Federal Hospital Insurance Trust Fund and the Federal
 18 Supplementary Medical Insurance Trust Fund, \$5,000,000
 19 in fiscal year 2006 to conduct the demonstration under this
 20 subsection.

21 (f) REPORT ON A BUNDLED PROSPECTIVE PAYMENT SYS-
 22 TEM FOR END STAGE RENAL DISEASE SERVICES.—

23 (1) REPORT.—

24 (A) IN GENERAL.—Not later than October 1,
 25 2005, the Secretary shall submit to Congress a report
 26 detailing the elements and features for the design and
 27 implementation of a bundled prospective payment sys-
 28 tem for services furnished by end stage renal disease
 29 facilities including, to the maximum extent feasible,
 30 bundling of drugs, clinical laboratory tests, and other
 31 items that are separately billed by such facilities. The
 32 report shall include a description of the methodology to
 33 be used for the establishment of payment rates, includ-
 34 ing components of the new system described in para-
 35 graph (2).

36 (B) RECOMMENDATIONS.—The Secretary shall in-
 37 clude in such report recommendations on elements, fea-

1 tures, and methodology for a bundled prospective pay-
 2 ment system or other issues related to such system as
 3 the Secretary determines to be appropriate.

4 (2) ELEMENTS AND FEATURES OF A BUNDLED PRO-
 5 SPECTIVE PAYMENT SYSTEM.—The report required under
 6 paragraph (1) shall include the following elements and fea-
 7 tures of a bundled prospective payment system:

8 (A) BUNDLE OF ITEMS AND SERVICES.—A de-
 9 scription of the bundle of items and services to be in-
 10 cluded under the prospective payment system.

11 (B) CASE MIX.—A description of the case-mix ad-
 12 justment to account for the relative resource use of dif-
 13 ferent types of patients.

14 (C) WAGE INDEX.—A description of an adjust-
 15 ment to account for geographic differences in wages.

16 (D) RURAL AREAS.—The appropriateness of es-
 17 tablishing a specific payment adjustment to account for
 18 additional costs incurred by rural facilities.

19 (E) OTHER ADJUSTMENTS.—Such other adjust-
 20 ments as may be necessary to reflect the variation in
 21 costs incurred by facilities in caring for patients with
 22 end stage renal disease.

23 (F) UPDATE FRAMEWORK.—A methodology for
 24 appropriate updates under the prospective payment
 25 system.

26 (G) ADDITIONAL RECOMMENDATIONS.—Such
 27 other matters as the Secretary determines to be appro-
 28 priate.

29 **SEC. 624. 2-YEAR MORATORIUM ON THERAPY CAPS;**
 30 **PROVISIONS RELATING TO REPORTS.**

31 (a) ADDITIONAL MORATORIUM ON THERAPY CAPS.—

32 (1) 2004 AND 2005.—Section 1833(g)(4) (42 U.S.C.
 33 1395l(g)(4)) is amended by striking “and 2002” and in-
 34 serting “2002, 2004, and 2005”.

35 (2) REMAINDER OF 2003.—For the period beginning
 36 on the date of the enactment of this Act and ending of De-
 37 cember 31, 2003, the Secretary shall not apply the provi-

1 sions of paragraphs (1), (2), and (3) of section 1833(g) to
 2 expenses incurred with respect to services described in such
 3 paragraphs during such period. Nothing in the preceding
 4 sentence shall be construed as affecting the application of
 5 such paragraphs by the Secretary before the date of the en-
 6 actment of this Act.

7 (b) PROMPT SUBMISSION OF OVERDUE REPORTS ON PAY-
 8 MENT AND UTILIZATION OF OUTPATIENT THERAPY SERV-
 9 ICES.—Not later than March 31, 2004, the Secretary shall sub-
 10 mit to Congress the reports required under section 4541(d)(2)
 11 of the Balanced Budget Act of 1997 (Public Law 105–33; 111
 12 Stat. 457) (relating to alternatives to a single annual dollar cap
 13 on outpatient therapy) and under section 221(d) of the Medi-
 14 care, Medicaid, and SCHIP Balanced Budget Refinement Act
 15 of 1999 (Appendix F, 113 Stat. 1501A–352), as enacted into
 16 law by section 1000(a)(6) of Public Law 106–113 (relating to
 17 utilization patterns for outpatient therapy).

18 (c) GAO REPORT IDENTIFYING CONDITIONS AND DIS-
 19 EASES JUSTIFYING WAIVER OF THERAPY CAP.—

20 (1) STUDY.—The Comptroller General of the United
 21 States shall identify conditions or diseases that may justify
 22 waiving the application of the therapy caps under section
 23 1833(g) of the Social Security Act (42 U.S.C. 1395l(g))
 24 with respect to such conditions or diseases.

25 (2) REPORT TO CONGRESS.—Not later than October 1,
 26 2004, the Comptroller General shall submit to Congress a
 27 report on the conditions and diseases identified under para-
 28 graph (1), and shall include a recommendation of criteria,
 29 with respect to such conditions and disease, under which a
 30 waiver of the therapy caps would apply.

31 **SEC. 625. WAIVER OF PART B LATE ENROLLMENT PEN-**
 32 **ALTY FOR CERTAIN MILITARY RETIREES;**
 33 **SPECIAL ENROLLMENT PERIOD.**

34 (a) WAIVER OF PENALTY.—

35 (1) IN GENERAL.—Section 1839(b) (42 U.S.C.
 36 1395r(b)) is amended by adding at the end the following
 37 new sentence: “No increase in the premium shall be ef-

1 fected for a month in the case of an individual who enrolls
2 under this part during 2001, 2002, 2003, or 2004 and who
3 demonstrates to the Secretary before December 31, 2004,
4 that the individual is a covered beneficiary (as defined in
5 section 1072(5) of title 10, United States Code). The Sec-
6 retary of Health and Human Services shall consult with the
7 Secretary of Defense in identifying individuals described in
8 the previous sentence.”.

9 (2) EFFECTIVE DATE.—The amendment made by
10 paragraph (1) shall apply to premiums for months begin-
11 ning with January 2004. The Secretary shall establish a
12 method for providing rebates of premium penalties paid for
13 months on or after January 2004 for which a penalty does
14 not apply under such amendment but for which a penalty
15 was previously collected.

16 (b) MEDICARE PART B SPECIAL ENROLLMENT PERIOD.—

17 (1) IN GENERAL.—In the case of any individual who,
18 as of the date of the enactment of this Act, is eligible to
19 enroll but is not enrolled under part B of title XVIII of the
20 Social Security Act and is a covered beneficiary (as defined
21 in section 1072(5) of title 10, United States Code), the
22 Secretary of Health and Human Services shall provide for
23 a special enrollment period during which the individual may
24 enroll under such part. Such period shall begin as soon as
25 possible after the date of the enactment of this Act and
26 shall end on December 31, 2004.

27 (2) COVERAGE PERIOD.—In the case of an individual
28 who enrolls during the special enrollment period provided
29 under paragraph (1), the coverage period under part B of
30 title XVIII of the Social Security Act shall begin on the
31 first day of the month following the month in which the in-
32 dividual enrolls.

33 **SEC. 626. PAYMENT FOR SERVICES FURNISHED IN AM-**
34 **BULATORY SURGICAL CENTERS.**

35 (a) REDUCTIONS IN PAYMENT UPDATES.—Section
36 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended to read as
37 follows:

1 “(C)(i) Notwithstanding the second sentence of each of
 2 subparagraphs (A) and (B), except as otherwise specified in
 3 clauses (ii), (iii), and (iv), if the Secretary has not updated
 4 amounts established under such subparagraphs or under sub-
 5 paragraph (D), with respect to facility services furnished dur-
 6 ing a fiscal year (beginning with fiscal year 1986 or a calendar
 7 year (beginning with 2006)), such amounts shall be increased
 8 by the percentage increase in the Consumer Price Index for all
 9 urban consumers (U.S. city average) as estimated by the Sec-
 10 retary for the 12-month period ending with the midpoint of the
 11 year involved.

12 “(ii) In each of the fiscal years 1998 through 2002, the
 13 increase under this subparagraph shall be reduced (but not
 14 below zero) by 2.0 percentage points.

15 “(iii) In fiscal year 2004, beginning with April 1, 2004,
 16 the increase under this subparagraph shall be the Consumer
 17 Price Index for all urban consumers (U.S. city average) as esti-
 18 mated by the Secretary for the 12-month period ending with
 19 March 31, 2003, minus 3.0 percentage points.

20 “(iv) In fiscal year 2005, the last quarter of calendar year
 21 2005, and each of calendar years 2006 through 2009, the in-
 22 crease under this subparagraph shall be 0 percent.”.

23 (b) REPEAL OF SURVEY REQUIREMENT AND IMPLEMEN-
 24 TATION OF NEW SYSTEM.—Section 1833(i)(2) (42 U.S.C.
 25 1395l(i)(2)) is amended—

26 (1) in subparagraph (A)—

27 (A) in the matter preceding clause (i), by striking
 28 “The” and inserting “For services furnished prior to
 29 the implementation of the system described in subpara-
 30 graph (D), the”; and

31 (B) in clause (i), by striking “taken not later than
 32 January 1, 1995, and every 5 years thereafter,”; and

33 (2) by adding at the end the following new subpara-
 34 graph:

35 “(D)(i) Taking into account the recommendations in the
 36 report under section 626(d) of Medicare Prescription Drug,
 37 Improvement, and Modernization Act of 2003, the Secretary

1 shall implement a revised payment system for payment of sur-
2 gical services furnished in ambulatory surgical centers.

3 “(ii) In the year the system described in clause (i) is im-
4 plemented, such system shall be designed to result in the same
5 aggregate amount of expenditures for such services as would be
6 made if this subparagraph did not apply, as estimated by the
7 Secretary.

8 “(iii) The Secretary shall implement the system described
9 in clause (i) for periods in a manner so that it is first effective
10 beginning on or after January 1, 2006, and not later than Jan-
11 uary 1, 2008.

12 “(iv) There shall be no administrative or judicial review
13 under section 1869, 1878, or otherwise, of the classification
14 system, the relative weights, payment amounts, and the geo-
15 graphic adjustment factor, if any, under this subparagraph.”.

16 (c) CONFORMING AMENDMENT.—Section 1833(a)(1) (42
17 U.S.C. 1395l(a)(1)) is amended by adding the following new
18 subparagraph:

19 “(G) with respect to facility services furnished in
20 connection with a surgical procedure specified pursuant
21 to subsection (i)(1)(A) and furnished to an individual
22 in an ambulatory surgical center described in such sub-
23 section, for services furnished beginning with the imple-
24 mentation date of a revised payment system for such
25 services in such facilities specified in subsection
26 (i)(2)(D), the amounts paid shall be 80 percent of the
27 lesser of the actual charge for the services or the
28 amount determined by the Secretary under such revised
29 payment system.”.

30 (d) GAO STUDY OF AMBULATORY SURGICAL CENTER
31 PAYMENTS.—

32 (1) STUDY.—

33 (A) IN GENERAL.—The Comptroller General of
34 the United States shall conduct a study that compares
35 the relative costs of procedures furnished in ambulatory
36 surgical centers to the relative costs of procedures fur-
37 nished in hospital outpatient departments under section

1 1833(t) of the Social Security Act (42 U.S.C.
2 1395l(t)). The study shall also examine how accurately
3 ambulatory payment categories reflect procedures fur-
4 nished in ambulatory surgical centers.

5 (B) CONSIDERATION OF ASC DATA.—In con-
6 ducting the study under paragraph (1), the Comptroller
7 General shall consider data submitted by ambulatory
8 surgical centers regarding the matters described in
9 clauses (i) through (iii) of paragraph (2)(B).

10 (2) REPORT AND RECOMMENDATIONS.—

11 (A) REPORT.—Not later than January 1, 2005,
12 the Comptroller General shall submit to Congress a re-
13 port on the study conducted under paragraph (1).

14 (B) RECOMMENDATIONS.—The report submitted
15 under subparagraph (A) shall include recommendations
16 on the following matters:

17 (i) The appropriateness of using the groups of
18 covered services and relative weights established
19 under the outpatient prospective payment system
20 as the basis of payment for ambulatory surgical
21 centers.

22 (ii) If the relative weights under such hospital
23 outpatient prospective payment system are appro-
24 priate for such purpose—

25 (I) whether the payment rates for ambula-
26 tory surgical centers should be based on a uni-
27 form percentage of the payment rates or
28 weights under such outpatient system; or

29 (II) whether the payment rates for ambu-
30 latory surgical centers should vary, or the
31 weights should be revised, based on specific
32 procedures or types of services (such as oph-
33 thalmology and pain management services).

34 (iii) Whether a geographic adjustment should
35 be used for payment of services furnished in ambu-
36 latory surgical centers, and if so, the labor and
37 nonlabor shares of such payment.

1 **SEC. 627. PAYMENT FOR CERTAIN SHOES AND INSERTS**
2 **UNDER THE FEE SCHEDULE FOR ORTHOTICS**
3 **AND PROSTHETICS.**

4 (a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o))
5 is amended—

6 (1) in paragraph (1)(B), by striking “no more than
7 the limits established under paragraph (2)” and inserting
8 “no more than the amount of payment applicable under
9 paragraph (2)”; and

10 (2) in paragraph (2), to read as follows:

11 “(2)(A) Except as provided by the Secretary under sub-
12 paragraphs (B) and (C), the amount of payment under this
13 paragraph for custom molded shoes, extra-depth shoes, and in-
14 serts shall be the amount determined for such items by the
15 Secretary under section 1834(h).

16 “(B) The Secretary may establish payment amounts for
17 shoes and inserts that are lower than the amount established
18 under section 1834(h) if the Secretary finds that shoes and in-
19 serts of an appropriate quality are readily available at or below
20 the amount established under such section.

21 “(C) In accordance with procedures established by the
22 Secretary, an individual entitled to benefits with respect to
23 shoes described in section 1861(s)(12) may substitute modifica-
24 tion of such shoes instead of obtaining one (or more, as speci-
25 fied by the Secretary) pair of inserts (other than the original
26 pair of inserts with respect to such shoes). In such case, the
27 Secretary shall substitute, for the payment amount established
28 under section 1834(h), a payment amount that the Secretary
29 estimates will assure that there is no net increase in expendi-
30 tures under this subsection as a result of this subparagraph.”.

31 (b) CONFORMING AMENDMENTS.—(1) Section
32 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by in-
33 serting “(and includes shoes described in section 1861(s)(12))”
34 after “in section 1861(s)(9)”.

35 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amend-
36 ed by striking subparagraph (C).

1 (c) EFFECTIVE DATE.—The amendments made by this
 2 section shall apply to items furnished on or after January 1,
 3 2005.

4 **SEC. 628. PAYMENT FOR CLINICAL DIAGNOSTIC LAB-**
 5 **ORATORY TESTS.**

6 Section 1833(h)(2)(A)(ii)(IV) (42 U.S.C.
 7 1395l(h)(2)(A)(ii)(IV)) is amended by striking “and 1998
 8 through 2002” and inserting “, 1998 through 2002, and 2004
 9 through 2008”.

10 **SEC. 629. INDEXING PART B DEDUCTIBLE TO INFLA-**
 11 **TION.**

12 The first sentence of section 1833(b) (42 U.S.C. 1395l(b))
 13 is amended by striking “and \$100 for 1991 and subsequent
 14 years” and inserting the following: “, \$100 for 1991 through
 15 2004, \$110 for 2005, and for a subsequent year the amount
 16 of such deductible for the previous year increased by the annual
 17 percentage increase in the monthly actuarial rate under section
 18 1839(a)(1) ending with such subsequent year (rounded to the
 19 nearest \$1)”.

20 **SEC. 630. 5-YEAR AUTHORIZATION OF REIMBURSEMENT**
 21 **FOR ALL MEDICARE PART B SERVICES FUR-**
 22 **NISHED BY CERTAIN INDIAN HOSPITALS**
 23 **AND CLINICS.**

24 Section 1880(e)(1)(A) (42 U.S.C. 1395qq(e)(1)(A)) is
 25 amended by inserting “(and for items and services furnished
 26 during the 5-year period beginning on January 1, 2005, all
 27 items and services for which payment may be made under part
 28 B)” after “for services described in paragraph (2)”.

29 **Subtitle D—Additional Demonstra-**
 30 **tions, Studies, and Other Provi-**
 31 **sions**

32 **SEC. 641. DEMONSTRATION PROJECT FOR COVERAGE**
 33 **OF CERTAIN PRESCRIPTION DRUGS AND**
 34 **BIOLOGICALS.**

35 (a) DEMONSTRATION PROJECT.—The Secretary shall con-
 36 duct a demonstration project under part B of title XVIII of the
 37 Social Security Act under which payment is made for drugs or
 38 biologicals that are prescribed as replacements for drugs and

1 biologicals described in section 1861(s)(2)(A) or 1861(s)(2)(Q)
 2 of such Act (42 U.S.C. 1395x(s)(2)(A), 1395x(s)(2)(Q)), or
 3 both, for which payment is made under such part. Such project
 4 shall provide for cost-sharing applicable with respect to such
 5 drugs or biologicals in the same manner as cost-sharing applies
 6 with respect to part D drugs under standard prescription drug
 7 coverage (as defined in section 1860D-2(b) of the Social Secu-
 8 rity Act, as added by section 101(a)).

9 (b) DEMONSTRATION PROJECT SITES.—The project estab-
 10 lished under this section shall be conducted in sites selected by
 11 the Secretary.

12 (c) DURATION.—The Secretary shall conduct the dem-
 13 onstration project for the 2-year period beginning on the date
 14 that is 90 days after the date of the enactment of this Act, but
 15 in no case may the project extend beyond December 31, 2005.

16 (d) LIMITATION.—Under the demonstration project over
 17 the duration of the project, the Secretary may not provide—

- 18 (1) coverage for more than 50,000 patients; and
- 19 (2) more than \$500,000,000 in funding.

20 (e) REPORT.—Not later than July 1, 2006, the Secretary
 21 shall submit to Congress a report on the project. The report
 22 shall include an evaluation of patient access to care and patient
 23 outcomes under the project, as well as an analysis of the cost
 24 effectiveness of the project, including an evaluation of the costs
 25 savings (if any) to the medicare program attributable to re-
 26 duced physicians' services and hospital outpatient departments
 27 services for administration of the biological.

28 **SEC. 642. EXTENSION OF COVERAGE OF INTRAVENOUS**
 29 **IMMUNE GLOBULIN (IVIG) FOR THE TREAT-**
 30 **MENT OF PRIMARY IMMUNE DEFICIENCY**
 31 **DISEASES IN THE HOME.**

32 (a) IN GENERAL.—Section 1861 (42 U.S.C. 1395x), as
 33 amended by sections 611(a) and 612(a) is amended—

- 34 (1) in subsection (s)(2)—
- 35 (A) by striking “and” at the end of subparagraph
- 36 (X);

1 (B) by adding “and” at the end of subparagraph
2 (Y); and

3 (C) by adding at the end the following new sub-
4 paragraph:

5 “(Z) intravenous immune globulin for the treat-
6 ment of primary immune deficiency diseases in the
7 home (as defined in subsection (zz));”; and

8 (2) by adding at the end the following new subsection:

9 “Intravenous Immune Globulin
10 “(zz) The term ‘intravenous immune globulin’ means an
11 approved pooled plasma derivative for the treatment in the pa-
12 tient’s home of a patient with a diagnosed primary immune de-
13 ficiency disease, but not including items or services related to
14 the administration of the derivative, if a physician determines
15 administration of the derivative in the patient’s home is medi-
16 cally appropriate.”.

17 (b) PAYMENT AS A DRUG OR BIOLOGICAL.—Section
18 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by in-
19 serting “(including intravenous immune globulin (as defined in
20 section 1861(zz)))” after “with respect to drugs and
21 biologicals”.

22 (c) EFFECTIVE DATE.—The amendments made by this
23 section shall apply to items furnished administered on or after
24 January 1, 2004.

25 **SEC. 643. MEDPAC STUDY OF COVERAGE OF SURGICAL**
26 **FIRST ASSISTING SERVICES OF CERTIFIED**
27 **REGISTERED NURSE FIRST ASSISTANTS.**

28 (a) STUDY.—The Medicare Payment Advisory Commission
29 (in this section referred to as the “Commission”) shall conduct
30 a study on the feasibility and advisability of providing for pay-
31 ment under part B of title XVIII of the Social Security Act
32 for surgical first assisting services furnished by a certified reg-
33 istered nurse first assistant to medicare beneficiaries.

34 (b) REPORT.—Not later than January 1, 2005, the Com-
35 mission shall submit to Congress a report on the study con-
36 ducted under subsection (a) together with recommendations for

1 such legislation or administrative action as the Commission de-
2 termines to be appropriate.

3 (c) DEFINITIONS.—In this section:

4 (1) SURGICAL FIRST ASSISTING SERVICES.—The term
5 “surgical first assisting services” means services consisting
6 of first assisting a physician with surgery and related pre-
7 operative, intraoperative, and postoperative care (as deter-
8 mined by the Secretary) furnished by a certified registered
9 nurse first assistant (as defined in paragraph (2)) which
10 the certified registered nurse first assistant is legally au-
11 thorized to perform by the State in which the services are
12 performed.

13 (2) CERTIFIED REGISTERED NURSE FIRST ASSIST-
14 ANT.—The term “certified registered nurse first assistant”
15 means an individual who—

16 (A) is a registered nurse and is licensed to prac-
17 tice nursing in the State in which the surgical first as-
18 sisting services are performed;

19 (B) has completed a minimum of 2,000 hours of
20 first assisting a physician with surgery and related pre-
21 operative, intraoperative, and postoperative care; and

22 (C) is certified as a registered nurse first assistant
23 by an organization recognized by the Secretary.

24 **SEC. 644. MEDPAC STUDY OF PAYMENT FOR CARDIO-**
25 **THORACIC SURGEONS.**

26 (a) STUDY.—The Medicare Payment Advisory Commission
27 (in this section referred to as the “Commission”) shall conduct
28 a study on the practice expense relative values established by
29 the Secretary of Health and Human Services under the medi-
30 care physician fee schedule under section 1848 of the Social
31 Security Act (42 U.S.C. 1395w-4) for physicians in the special-
32 ties of thoracic and cardiac surgery to determine whether such
33 values adequately take into account the attendant costs that
34 such physicians incur in providing clinical staff for patient care
35 in hospitals.

36 (b) REPORT.—Not later than January 1, 2005, the Com-
37 mission shall submit to Congress a report on the study con-

1 ducted under subsection (a) together with recommendations for
 2 such legislation or administrative action as the Commission de-
 3 termines to be appropriate.

4 **SEC. 645. STUDIES RELATING TO VISION IMPAIRMENTS.**

5 (a) COVERAGE OF OUTPATIENT VISION SERVICES FUR-
 6 NISHED BY VISION REHABILITATION PROFESSIONALS UNDER
 7 PART B.—

8 (1) STUDY.—The Secretary shall conduct a study to
 9 determine the feasibility and advisability of providing for
 10 payment for vision rehabilitation services furnished by vi-
 11 sion rehabilitation professionals.

12 (2) REPORT.—Not later than January 1, 2005, the
 13 Secretary shall submit to Congress a report on the study
 14 conducted under paragraph (1) together with recommenda-
 15 tions for such legislation or administrative action as the
 16 Secretary determines to be appropriate.

17 (3) VISION REHABILITATION PROFESSIONAL DE-
 18 FINED.—In this subsection, the term “vision rehabilitation
 19 professional” means an orientation and mobility specialist,
 20 a rehabilitation teacher, or a low vision therapist.

21 (b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION
 22 PROJECT TO TEST FEASIBILITY OF USING PPO NETWORKS
 23 TO REDUCE COSTS OF ACQUIRING EYEGASSES FOR MEDI-
 24 CARE BENEFICIARIES AFTER CATARACT SURGERY.—Not later
 25 than 1 year after the date of the enactment of this Act, the
 26 Secretary shall submit to Congress a report on the feasibility
 27 of establishing a two-year demonstration project under which
 28 the Secretary enters into arrangements with vision care pre-
 29 ferred provider organization networks to furnish and pay for
 30 conventional eyeglasses subsequent to each cataract surgery
 31 with insertion of an intraocular lens on behalf of Medicare
 32 beneficiaries. In such report, the Secretary shall include an es-
 33 timate of potential cost savings to the Medicare program
 34 through the use of such networks, taking into consideration
 35 quality of service and beneficiary access to services offered by
 36 vision care preferred provider organization networks.

1 **SEC. 646. MEDICARE HEALTH CARE QUALITY DEM-**
 2 **ONSTRATION PROGRAMS.**

3 Title XVIII (42 U.S.C. 1395 et seq.) is amended by in-
 4 serting after section 1866B the following new section:

5 “HEALTH CARE QUALITY DEMONSTRATION PROGRAM

6 “SEC. 1866C. (a) DEFINITIONS.—In this section:

7 “(1) BENEFICIARY.—The term ‘beneficiary’ means an
 8 individual who is entitled to benefits under part A and en-
 9 rolled under part B, including any individual who is en-
 10 rolled in a Medicare Advantage plan under part C.

11 “(2) HEALTH CARE GROUP.—

12 “(A) IN GENERAL.—The term ‘health care group’
 13 means—

14 “(i) a group of physicians that is organized at
 15 least in part for the purpose of providing physi-
 16 cian’s services under this title;

17 “(ii) an integrated health care delivery system
 18 that delivers care through coordinated hospitals,
 19 clinics, home health agencies, ambulatory surgery
 20 centers, skilled nursing facilities, rehabilitation fa-
 21 cilities and clinics, and employed, independent, or
 22 contracted physicians; or

23 “(iii) an organization representing regional
 24 coalitions of groups or systems described in clause
 25 (i) or (ii).

26 “(B) INCLUSION.—As the Secretary determines
 27 appropriate, a health care group may include a hospital
 28 or any other individual or entity furnishing items or
 29 services for which payment may be made under this
 30 title that is affiliated with the health care group under
 31 an arrangement structured so that such hospital, indi-
 32 vidual, or entity participates in a demonstration project
 33 under this section.

34 “(3) PHYSICIAN.—Except as otherwise provided for by
 35 the Secretary, the term ‘physician’ means any individual
 36 who furnishes services that may be paid for as physicians’
 37 services under this title.

1 “(b) DEMONSTRATION PROJECTS.—The Secretary shall
2 establish a 5-year demonstration program under which the Sec-
3 retary shall approve demonstration projects that examine
4 health delivery factors that encourage the delivery of improved
5 quality in patient care, including—

6 “(1) the provision of incentives to improve the safety
7 of care provided to beneficiaries;

8 “(2) the appropriate use of best practice guidelines by
9 providers and services by beneficiaries;

10 “(3) reduced scientific uncertainty in the delivery of
11 care through the examination of variations in the utiliza-
12 tion and allocation of services, and outcomes measurement
13 and research;

14 “(4) encourage shared decision making between pro-
15 viders and patients;

16 “(5) the provision of incentives for improving the qual-
17 ity and safety of care and achieving the efficient allocation
18 of resources;

19 “(6) the appropriate use of culturally and ethnically
20 sensitive health care delivery; and

21 “(7) the financial effects on the health care market-
22 place of altering the incentives for care delivery and chang-
23 ing the allocation of resources.

24 “(c) ADMINISTRATION BY CONTRACT.—

25 “(1) IN GENERAL.—Except as otherwise provided in
26 this section, the Secretary may administer the demonstra-
27 tion program established under this section in a manner
28 that is similar to the manner in which the demonstration
29 program established under section 1866A is administered
30 in accordance with section 1866B.

31 “(2) ALTERNATIVE PAYMENT SYSTEMS.—A health
32 care group that receives assistance under this section may,
33 with respect to the demonstration project to be carried out
34 with such assistance, include proposals for the use of alter-
35 native payment systems for items and services provided to
36 beneficiaries by the group that are designed to—

1 “(A) encourage the delivery of high quality care
2 while accomplishing the objectives described in sub-
3 section (b); and

4 “(B) streamline documentation and reporting re-
5 quirements otherwise required under this title.

6 “(3) BENEFITS.—A health care group that receives
7 assistance under this section may, with respect to the dem-
8 onstration project to be carried out with such assistance,
9 include modifications to the package of benefits available
10 under the original medicare fee-for-service program under
11 parts A and B or the package of benefits available through
12 a Medicare Advantage plan under part C. The criteria em-
13 ployed under the demonstration program under this section
14 to evaluate outcomes and determine best practice guidelines
15 and incentives shall not be used as a basis for the denial
16 of medicare benefits under the demonstration program to
17 patients against their wishes (or if the patient is incom-
18 petent, against the wishes of the patient’s surrogate) on the
19 basis of the patient’s age or expected length of life or of
20 the patient’s present or predicted disability, degree of med-
21 ical dependency, or quality of life.

22 “(d) ELIGIBILITY CRITERIA.—To be eligible to receive as-
23 sistance under this section, an entity shall—

24 “(1) be a health care group;

25 “(2) meet quality standards established by the Sec-
26 retary, including—

27 “(A) the implementation of continuous quality im-
28 provement mechanisms that are aimed at integrating
29 community-based support services, primary care, and
30 referral care;

31 “(B) the implementation of activities to increase
32 the delivery of effective care to beneficiaries;

33 “(C) encouraging patient participation in pref-
34 erence-based decisions;

35 “(D) the implementation of activities to encourage
36 the coordination and integration of medical service de-
37 livery; and

1 “(E) the implementation of activities to measure
2 and document the financial impact on the health care
3 marketplace of altering the incentives of health care de-
4 livery and changing the allocation of resources; and

5 “(3) meet such other requirements as the Secretary
6 may establish.

7 “(e) WAIVER AUTHORITY.—The Secretary may waive such
8 requirements of titles XI and XVIII as may be necessary to
9 carry out the purposes of the demonstration program estab-
10 lished under this section.

11 “(f) BUDGET NEUTRALITY.—With respect to the 5-year
12 period of the demonstration program under subsection (b), the
13 aggregate expenditures under this title for such period shall not
14 exceed the aggregate expenditures that would have been ex-
15 pended under this title if the program established under this
16 section had not been implemented.

17 “(g) NOTICE REQUIREMENTS.—In the case of an indi-
18 vidual that receives health care items or services under a dem-
19 onstration program carried out under this section, the Sec-
20 retary shall ensure that such individual is notified of any waiv-
21 ers of coverage or payment rules that are applicable to such in-
22 dividual under this title as a result of the participation of the
23 individual in such program.

24 “(h) PARTICIPATION AND SUPPORT BY FEDERAL AGEN-
25 CIES.—In carrying out the demonstration program under this
26 section, the Secretary may direct—

27 “(1) the Director of the National Institutes of Health
28 to expand the efforts of the Institutes to evaluate current
29 medical technologies and improve the foundation for evi-
30 dence-based practice;

31 “(2) the Administrator of the Agency for Healthcare
32 Research and Quality to, where possible and appropriate,
33 use the program under this section as a laboratory for the
34 study of quality improvement strategies and to evaluate,
35 monitor, and disseminate information relevant to such pro-
36 gram; and

1 “(3) the Administrator of the Centers for Medicare &
 2 Medicaid Services and the Administrator of the Center for
 3 Medicare Choices to support linkages of relevant medicare
 4 data to registry information from participating health care
 5 groups for the beneficiary populations served by the partici-
 6 pating groups, for analysis supporting the purposes of the
 7 demonstration program, consistent with the applicable pro-
 8 visions of the Health Insurance Portability and Account-
 9 ability Act of 1996.”.

10 **SEC. 647. MEDPAC STUDY ON DIRECT ACCESS TO PHYS-**
 11 **ICAL THERAPY SERVICES.**

12 (a) STUDY.—The Medicare Payment Advisory Commission
 13 (in this section referred to as the “Commission”) shall conduct
 14 a study on the feasibility and advisability of allowing medicare
 15 fee-for-service beneficiaries direct access to outpatient physical
 16 therapy services and physical therapy services furnished as
 17 comprehensive rehabilitation facility services.

18 (b) REPORT.—Not later than January 1, 2005, the Com-
 19 mission shall submit to Congress a report on the study con-
 20 ducted under subsection (a) together with recommendations for
 21 such legislation or administrative action as the Commission de-
 22 termines to be appropriate.

23 (c) DIRECT ACCESS DEFINED.—The term “direct access”
 24 means, with respect to outpatient physical therapy services and
 25 physical therapy services furnished as comprehensive outpatient
 26 rehabilitation facility services, coverage of and payment for
 27 such services in accordance with the provisions of title XVIII
 28 of the Social Security Act, except that sections 1835(a)(2),
 29 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2),
 30 1395x(p), and 1395x(cc), respectively) shall be applied—

31 (1) without regard to any requirement that—

32 (A) an individual be under the care of (or referred
 33 by) a physician; or

34 (B) services be provided under the supervision of
 35 a physician; and

36 (2) by allowing a physician or a qualified physical
 37 therapist to satisfy any requirement for—

- 1 (A) certification and recertification; and
 2 (B) establishment and periodic review of a plan of
 3 care.

4 **SEC. 648. DEMONSTRATION PROJECT FOR CONSUMER-**
 5 **DIRECTED CHRONIC OUTPATIENT SERVICES.**

6 (a) ESTABLISHMENT.—

7 (1) IN GENERAL.—Subject to the succeeding provi-
 8 sions of this section, the Secretary shall establish dem-
 9 onstration projects (in this section referred to as “dem-
 10 onstration projects”) under which the Secretary shall evalu-
 11 ate methods that improve the quality of care provided to
 12 individuals with chronic conditions and that reduce expend-
 13 itures that would otherwise be made under the medicare
 14 program on behalf of such individuals for such chronic con-
 15 ditions, such methods to include permitting those bene-
 16 ficiaries to direct their own health care needs and services.

17 (2) INDIVIDUALS WITH CHRONIC CONDITIONS DE-
 18 FINED.—In this section, the term “individuals with chronic
 19 conditions” means an individual entitled to benefits under
 20 part A of title XVIII of the Social Security Act, and en-
 21 rolled under part B of such title, but who is not enrolled
 22 under part C of such title who is diagnosed as having one
 23 or more chronic conditions (as defined by the Secretary),
 24 such as diabetes.

25 (b) DESIGN OF PROJECTS.—

26 (1) EVALUATION BEFORE IMPLEMENTATION OF
 27 PROJECT.—

28 (A) IN GENERAL.—In establishing the demonstra-
 29 tion projects under this section, the Secretary shall
 30 evaluate best practices employed by group health plans
 31 and practices under State plans for medical assistance
 32 under the medicaid program under title XIX of the So-
 33 cial Security Act, as well as best practices in the pri-
 34 vate sector or other areas, of methods that permit pa-
 35 tients to self-direct the provision of personal care serv-
 36 ices. The Secretary shall evaluate such practices for a

1 1-year period and, based on such evaluation, shall de-
2 sign the demonstration project.

3 (B) REQUIREMENT FOR ESTIMATE OF BUDGET
4 NEUTRAL COSTS.—As part of the evaluation under sub-
5 paragraph (A), the Secretary shall evaluate the costs of
6 furnishing care under the projects. The Secretary may
7 not implement the demonstration projects under this
8 section unless the Secretary determines that the costs
9 of providing care to individuals with chronic conditions
10 under the project will not exceed the costs, in the ag-
11 gregate, of furnishing care to such individuals under
12 title XVIII of the Social Security Act, that would other-
13 wise be paid without regard to the demonstration
14 projects for the period of the project.

15 (2) SCOPE OF SERVICES.—The Secretary shall deter-
16 mine the appropriate scope of personal care services that
17 would apply under the demonstration projects.

18 (c) VOLUNTARY PARTICIPATION.—Participation of pro-
19 viders of services and suppliers, and of individuals with chronic
20 conditions, in the demonstration projects shall be voluntary.

21 (d) DEMONSTRATION PROJECTS SITES.—Not later than 2
22 years after the date of the enactment of this Act, the Secretary
23 shall conduct a demonstration project in at least one area that
24 the Secretary determines has a population of individuals enti-
25 tled to benefits under part A of title XVIII of the Social Secu-
26 rity Act, and enrolled under part B of such title, with a rate
27 of incidence of diabetes that significantly exceeds the national
28 average rate of all areas.

29 (e) EVALUATION AND REPORT.—

30 (1) EVALUATIONS.—The Secretary shall conduct eval-
31 uations of the clinical and cost effectiveness of the dem-
32 onstration projects.

33 (2) REPORTS.—Not later than 2 years after the com-
34 mencement of the demonstration projects, and biannually
35 thereafter, the Secretary shall submit to Congress a report
36 on the evaluation, and shall include in the report the fol-
37 lowing:

1 (A) An analysis of the patient outcomes and costs
 2 of furnishing care to the individuals with chronic condi-
 3 tions participating in the projects as compared to such
 4 outcomes and costs to other individuals for the same
 5 health conditions.

6 (B) Evaluation of patient satisfaction under the
 7 demonstration projects.

8 (C) Such recommendations regarding the exten-
 9 sion, expansion, or termination of the projects as the
 10 Secretary determines appropriate.

11 (f) WAIVER AUTHORITY.—The Secretary shall waive com-
 12 pliance with the requirements of title XVIII of the Social Secu-
 13 rity Act (42 U.S.C. 1395 et seq.) to such extent and for such
 14 period as the Secretary determines is necessary to conduct
 15 demonstration projects.

16 (g) AUTHORIZATION OF APPROPRIATIONS.—(1) Payments
 17 for the costs of carrying out the demonstration project under
 18 this section shall be made from the Federal Supplementary
 19 Medical Insurance Trust Fund under section 1841 of such Act
 20 (42 U.S.C. 1395t).

21 (2) There are authorized to be appropriated from such
 22 Trust Fund such sums as may be necessary for the Secretary
 23 to enter into contracts with appropriate organizations for the
 24 design, implementation, and evaluation of the demonstration
 25 project.

26 (3) In no case may expenditures under this section exceed
 27 the aggregate expenditures that would otherwise have been
 28 made for the provision of personal care services.

29 **SEC. 649. MEDICARE CARE MANAGEMENT PERFORM-**
 30 **ANCE DEMONSTRATION.**

31 (a) ESTABLISHMENT.—

32 (1) IN GENERAL.—The Secretary shall establish a
 33 pay-for-performance demonstration program with physi-
 34 cians to meet the needs of eligible beneficiaries through the
 35 adoption and use of health information technology and evi-
 36 dence-based outcomes measures for—

37 (A) promoting continuity of care;

- 1 (B) helping stabilize medical conditions;
2 (C) preventing or minimizing acute exacerbations
3 of chronic conditions; and
4 (D) reducing adverse health outcomes, such as ad-
5 verse drug interactions related to polypharmacy.

6 (2) SITES.—The Secretary shall designate no more
7 than 4 sites at which to conduct the demonstration pro-
8 gram under this section, of which—

- 9 (A) 2 shall be in an urban area;
10 (B) 1 shall be in a rural area; and
11 (C) 1 shall be in a State with a medical school
12 with a Department of Geriatrics that manages rural
13 outreach sites and is capable of managing patients with
14 multiple chronic conditions, one of which is dementia.

15 (3) DURATION.—The Secretary shall conduct the dem-
16 onstration program under this section for a 3-year period.

17 (4) CONSULTATION.—In carrying out the demonstra-
18 tion program under this section, the Secretary shall consult
19 with private sector and non-profit groups that are under-
20 taking similar efforts to improve quality and reduce avoid-
21 able hospitalizations for chronically ill patients.

22 (b) PARTICIPATION.—

23 (1) IN GENERAL.—A physician who provides care for
24 a minimum number of eligible beneficiaries (as specified by
25 the Secretary) may participate in the demonstration pro-
26 gram under this section if such physician agrees, to phase-
27 in over the course of the 3-year demonstration period and
28 with the assistance provided under subsection (d)(2)—

29 (A) the use of health information technology to
30 manage the clinical care of eligible beneficiaries con-
31 sistent with paragraph (3); and

32 (B) the electronic reporting of clinical quality and
33 outcomes measures in accordance with requirements es-
34 tablished by the Secretary under the demonstration
35 program.

36 (2) SPECIAL RULE.—In the case of the sites referred
37 to in subparagraphs (B) and (C) of subsection (a)(2), a

1 physician who provides care for a minimum number of
2 beneficiaries with two or more chronic conditions, including
3 dementia (as specified by the Secretary), may participate in
4 the program under this section if such physician agrees to
5 the requirements in subparagraphs (A) and (B) of para-
6 graph (1).

7 (3) PRACTICE STANDARDS.—Each physician partici-
8 pating in the demonstration program under this section
9 must demonstrate the ability—

10 (A) to assess each eligible beneficiary for condi-
11 tions other than chronic conditions, such as impaired
12 cognitive ability and co-morbidities, for the purposes of
13 developing care management requirements;

14 (B) to serve as the primary contact of eligible
15 beneficiaries in accessing items and services for which
16 payment may be made under the medicare program;

17 (C) to establish and maintain health care informa-
18 tion system for such beneficiaries;

19 (D) to promote continuity of care across providers
20 and settings;

21 (E) to use evidence-based guidelines and meet
22 such clinical quality and outcome measures as the Sec-
23 retary shall require;

24 (F) to promote self-care through the provision of
25 patient education and support for patients or, where
26 appropriate, family caregivers;

27 (G) when appropriate, to refer such beneficiaries
28 to community service organizations; and

29 (H) to meet such other complex care management
30 requirements as the Secretary may specify.

31 The guidelines and measures required under subparagraph
32 (E) shall be designed to take into account beneficiaries with
33 multiple chronic conditions.

34 (c) PAYMENT METHODOLOGY.—Under the demonstration
35 program under this section the Secretary shall pay a per bene-
36 ficiary amount to each participating physician who meets or ex-
37 ceeds specific performance standards established by the Sec-

1 retary with respect to the clinical quality and outcome meas-
2 ures reported under subsection (b)(1)(B). Such amount may
3 vary based on different levels of performance or improvement.

4 (d) ADMINISTRATION.—

5 (1) USE OF QUALITY IMPROVEMENT ORGANIZA-
6 TIONS.—The Secretary shall contract with quality improve-
7 ment organizations or such other entities as the Secretary
8 deems appropriate to enroll physicians and evaluate their
9 performance under the demonstration program under this
10 section.

11 (2) TECHNICAL ASSISTANCE.—The Secretary shall re-
12 quire in such contracts that the contractor be responsible
13 for technical assistance and education as needed to physi-
14 cians enrolled in the demonstration program under this sec-
15 tion for the purpose of aiding their adoption of health in-
16 formation technology, meeting practice standards, and im-
17 plementing required clinical and outcomes measures.

18 (e) FUNDING.—

19 (1) IN GENERAL.—The Secretary shall provide for the
20 transfer from the Federal Supplementary Medical Insur-
21 ance Trust Fund established under section 1841 of the So-
22 cial Security Act (42 U.S.C. 1395t) of such funds as are
23 necessary for the costs of carrying out the demonstration
24 program under this section.

25 (2) BUDGET NEUTRALITY.—In conducting the dem-
26 onstration program under this section, the Secretary shall
27 ensure that the aggregate payments made by the Secretary
28 do not exceed the amount which the Secretary estimates
29 would have been paid if the demonstration program under
30 this section was not implemented.

31 (f) WAIVER AUTHORITY.—The Secretary may waive such
32 requirements of titles XI and XVIII of the Social Security Act
33 (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be necessary for
34 the purpose of carrying out the demonstration program under
35 this section.

36 (g) REPORT.—Not later than 12 months after the date of
37 completion of the demonstration program under this section,

1 the Secretary shall submit to Congress a report on such pro-
 2 gram, together with recommendations for such legislation and
 3 administrative action as the Secretary determines to be appro-
 4 priate.

5 (h) DEFINITIONS.—In this section:

6 (1) ELIGIBLE BENEFICIARY.—The term “eligible bene-
 7 ficiary” means any individual who—

8 (A) is entitled to benefits under part A and en-
 9 rolled for benefits under part B of title XVIII of the
 10 Social Security Act and is not enrolled in a plan under
 11 part C of such title; and

12 (B) has one or more chronic medical conditions
 13 specified by the Secretary (one of which may be cog-
 14 nitive impairment).

15 (2) HEALTH INFORMATION TECHNOLOGY.—The term
 16 “health information technology” means email communica-
 17 tion, clinical alerts and reminders, and other information
 18 technology that meets such functionality, interoperability,
 19 and other standards as prescribed by the Secretary.

20 **SEC. 650. GAO STUDY AND REPORT ON THE PROPAGA-**
 21 **TION OF CONCIERGE CARE.**

22 (a) STUDY.—

23 (1) IN GENERAL.—The Comptroller General of the
 24 United States shall conduct a study on concierge care (as
 25 defined in paragraph (2)) to determine the extent to which
 26 such care—

27 (A) is used by medicare beneficiaries (as defined
 28 in section 1802(b)(5)(A) of the Social Security Act (42
 29 U.S.C. 1395a(b)(5)(A))); and

30 (B) has impacted upon the access of medicare
 31 beneficiaries (as so defined) to items and services for
 32 which reimbursement is provided under the medicare
 33 program under title XVIII of the Social Security Act
 34 (42 U.S.C. 1395 et seq.).

35 (2) CONCIERGE CARE.—In this section, the term “con-
 36 cierge care” means an arrangement under which, as a pre-
 37 requisite for the provision of a health care item or service

1 to an individual, a physician, practitioner (as described in
2 section 1842(b)(18)(C) of the Social Security Act (42
3 U.S.C. 1395u(b)(18)(C))), or other individual—

4 (A) charges a membership fee or another inci-
5 dental fee to an individual desiring to receive the health
6 care item or service from such physician, practitioner,
7 or other individual; or

8 (B) requires the individual desiring to receive the
9 health care item or service from such physician, practi-
10 tioner, or other individual to purchase an item or serv-
11 ice.

12 (b) REPORT.—Not later than the date that is 12 months
13 after the date of enactment of this Act, the Comptroller Gen-
14 eral of the United States shall submit to Congress a report on
15 the study conducted under subsection (a)(1) together with such
16 recommendations for legislative or administrative action as the
17 Comptroller General determines to be appropriate.

18 **SEC. 651. DEMONSTRATION OF COVERAGE OF CHIRO-**
19 **PRACTIC SERVICES UNDER MEDICARE.**

20 (a) DEFINITIONS.—In this section:

21 (1) CHIROPRACTIC SERVICES.—The term “chiropractic
22 services” has the meaning given that term by the Secretary
23 for purposes of the demonstration projects, but shall in-
24 clude, at a minimum—

25 (A) care for neuromusculoskeletal conditions typ-
26 ical among eligible beneficiaries; and

27 (B) diagnostic and other services that a chiro-
28 practor is legally authorized to perform by the State or
29 jurisdiction in which such treatment is provided.

30 (2) DEMONSTRATION PROJECT.—The term “dem-
31 onstration project” means a demonstration project estab-
32 lished by the Secretary under subsection (b)(1).

33 (3) ELIGIBLE BENEFICIARY.—The term “eligible bene-
34 ficiary” means an individual who is enrolled under part B
35 of the medicare program.

1 (4) MEDICARE PROGRAM.—The term “medicare pro-
2 gram” means the health benefits program under title
3 XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

4 (b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC
5 SERVICES UNDER MEDICARE.—

6 (1) ESTABLISHMENT.—The Secretary shall establish
7 demonstration projects in accordance with the provisions of
8 this section for the purpose of evaluating the feasibility and
9 advisability of covering chiropractic services under the
10 medicare program (in addition to the coverage provided for
11 services consisting of treatment by means of manual ma-
12 nipulation of the spine to correct a subluxation described
13 in section 1861(r)(5) of the Social Security Act (42 U.S.C.
14 1395x(r)(5))).

15 (2) NO PHYSICIAN APPROVAL REQUIRED.—In estab-
16 lishing the demonstration projects, the Secretary shall en-
17 sure that an eligible beneficiary who participates in a dem-
18 onstration project, including an eligible beneficiary who is
19 enrolled for coverage under a Medicare+Choice plan (or,
20 on and after January 1, 2006, under a Medicare Advan-
21 tage plan), is not required to receive approval from a physi-
22 cian or other health care provider in order to receive a
23 chiropractic service under a demonstration project.

24 (3) CONSULTATION.—In establishing the demonstra-
25 tion projects, the Secretary shall consult with chiropractors,
26 organizations representing chiropractors, eligible bene-
27 ficiaries, and organizations representing eligible bene-
28 ficiaries.

29 (4) PARTICIPATION.—Any eligible beneficiary may
30 participate in the demonstration projects on a voluntary
31 basis.

32 (c) CONDUCT OF DEMONSTRATION PROJECTS.—

33 (1) DEMONSTRATION SITES.—

34 (A) SELECTION OF DEMONSTRATION SITES.—The
35 Secretary shall conduct demonstration projects at 4
36 demonstration sites.

1 (B) GEOGRAPHIC DIVERSITY.—Of the sites de-
2 scribed in subparagraph (A)—

3 (i) 2 shall be in rural areas; and

4 (ii) 2 shall be in urban areas.

5 (C) SITES LOCATED IN HPSAS.—At least 1 site de-
6 scribed in clause (i) of subparagraph (B) and at least
7 1 site described in clause (ii) of such subparagraph
8 shall be located in an area that is designated under sec-
9 tion 332(a)(1)(A) of the Public Health Service Act (42
10 U.S.C. 254e(a)(1)(A)) as a health professional shortage
11 area.

12 (2) IMPLEMENTATION; DURATION.—

13 (A) IMPLEMENTATION.—The Secretary shall not
14 implement the demonstration projects before October 1,
15 2004.

16 (B) DURATION.—The Secretary shall complete the
17 demonstration projects by the date that is 2 years after
18 the date on which the first demonstration project is im-
19 plemented.

20 (d) EVALUATION AND REPORT.—

21 (1) EVALUATION.—The Secretary shall conduct an
22 evaluation of the demonstration projects—

23 (A) to determine whether eligible beneficiaries who
24 use chiropractic services use a lesser overall amount of
25 items and services for which payment is made under
26 the medicare program than eligible beneficiaries who do
27 not use such services;

28 (B) to determine the cost of providing payment for
29 chiropractic services under the medicare program;

30 (C) to determine the satisfaction of eligible bene-
31 ficiaries participating in the demonstration projects and
32 the quality of care received by such beneficiaries; and

33 (D) to evaluate such other matters as the Sec-
34 retary determines is appropriate.

35 (2) REPORT.—Not later than the date that is 1 year
36 after the date on which the demonstration projects con-
37 clude, the Secretary shall submit to Congress a report on

1 the evaluation conducted under paragraph (1) together
 2 with such recommendations for legislation or administrative
 3 action as the Secretary determines is appropriate.

4 (e) WAIVER OF MEDICARE REQUIREMENTS.—The Sec-
 5 retary shall waive compliance with such requirements of the
 6 medicare program to the extent and for the period the Sec-
 7 retary finds necessary to conduct the demonstration projects.

8 (f) FUNDING.—

9 (1) DEMONSTRATION PROJECTS.—

10 (A) IN GENERAL.—Subject to subparagraph (B)
 11 and paragraph (2), the Secretary shall provide for the
 12 transfer from the Federal Supplementary Insurance
 13 Trust Fund under section 1841 of the Social Security
 14 Act (42 U.S.C. 1395t) of such funds as are necessary
 15 for the costs of carrying out the demonstration projects
 16 under this section.

17 (B) LIMITATION.—In conducting the demonstra-
 18 tion projects under this section, the Secretary shall en-
 19 sure that the aggregate payments made by the Sec-
 20 retary under the medicare program do not exceed the
 21 amount which the Secretary would have paid under the
 22 medicare program if the demonstration projects under
 23 this section were not implemented.

24 (2) EVALUATION AND REPORT.—There are authorized
 25 to be appropriated such sums as are necessary for the pur-
 26 pose of developing and submitting the report to Congress
 27 under subsection (d).

28 **TITLE VII—PROVISIONS RELATING**
 29 **TO PARTS A AND B**
 30 **Subtitle A—Home Health Services**

31 **SEC. 701. UPDATE IN HOME HEALTH SERVICES.**

32 (a) CHANGE TO CALENDAR YEAR UPDATE.—Section
 33 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended—

34 (1) in paragraph (3)(B)(i)—

35 (A) by striking “each fiscal year (beginning with
 36 fiscal year 2002)” and inserting “fiscal year 2002 and

1 for fiscal year 2003 and for each subsequent year (be-
2 ginning with 2004)”; and

3 (B) by inserting “or year” after “the fiscal year”;
4 (2) in paragraph (3)(B)(ii)—

5 (A) in subclause (I), by striking “or” at the end;

6 (B) by redesignating subclause (II) as subclause
7 (III);

8 (C) in subclause (III), as so redesignated, by strik-
9 ing “any subsequent fiscal year” and inserting “2004
10 and any subsequent year”; and

11 (D) by inserting after subclause (I) the following
12 new subclause:

13 “(II) for the last calendar quarter of 2003
14 and the first calendar quarter of 2004, the
15 home health market basket percentage in-
16 crease; or”;

17 (3) in paragraph (3)(B)(iii), by inserting “or year”
18 after “fiscal year” each place it appears; and

19 (4) in paragraph (3)(B)(iv)—

20 (A) by inserting “or year” after “fiscal year” each
21 place it appears; and

22 (B) by inserting “or years” after “fiscal years”;
23 and

24 (5) in paragraph (5), by inserting “or year” after “fis-
25 cal year”.

26 (b) ADJUSTMENT TO UPDATES FOR 2004, 2005, AND
27 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C.
28 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(2), is
29 amended—

30 (1) by striking “or” at the end of subclause (II);

31 (2) by redesignating subclause (III) as subclause (IV);

32 (3) in subclause (IV), as so redesignated, by striking
33 “2004” and inserting “2007”; and

34 (4) by inserting after subclause (II) the following new
35 subclause:

36 “(III) the last 3 calendar quarters of
37 2004, and each of 2005 and 2006 the home

1 health market basket percentage increase
 2 minus 0.8 percentage points; or”.

3 **SEC. 702. DEMONSTRATION PROJECT TO CLARIFY THE**
 4 **DEFINITION OF HOMEBOUND.**

5 (a) DEMONSTRATION PROJECT.—Not later than 180 days
 6 after the date of the enactment of this Act, the Secretary shall
 7 conduct a 2-year demonstration project under part B of title
 8 XVIII of the Social Security Act under which medicare bene-
 9 ficiaries with chronic conditions described in subsection (b) are
 10 deemed to be homebound for purposes of receiving home health
 11 services under the medicare program.

12 (b) MEDICARE BENEFICIARY DESCRIBED.—For purposes
 13 of subsection (a), a medicare beneficiary is eligible to be
 14 deemed to be homebound, without regard to the purpose, fre-
 15 quency, or duration of absences from the home, if—

16 (1) the beneficiary has been certified by one physician
 17 as an individual who has a permanent and severe, disabling
 18 condition that is not expected to improve;

19 (2) the beneficiary is dependent upon assistance from
 20 another individual with at least 3 out of the 5 activities of
 21 daily living for the rest of the beneficiary’s life;

22 (3) the beneficiary requires skilled nursing services for
 23 the rest of the beneficiary’s life and the skilled nursing is
 24 more than medication management;

25 (4) an attendant is required to visit the beneficiary on
 26 a daily basis to monitor and treat the beneficiary’s medical
 27 condition or to assist the beneficiary with activities of daily
 28 living;

29 (5) the beneficiary requires technological assistance or
 30 the assistance of another person to leave the home; and

31 (6) the beneficiary does not regularly work in a paid
 32 position full-time or part-time outside the home.

33 (c) DEMONSTRATION PROJECT SITES.—The demonstra-
 34 tion project established under this section shall be conducted in
 35 3 States selected by the Secretary to represent the Northeast,
 36 Midwest, and Western regions of the United States.

1 (d) LIMITATION ON NUMBER OF PARTICIPANTS.—The ag-
2 gregate number of such beneficiaries that may participate in
3 the project may not exceed 15,000.

4 (e) DATA.—The Secretary shall collect such data on the
5 demonstration project with respect to the provision of home
6 health services to medicare beneficiaries that relates to quality
7 of care, patient outcomes, and additional costs, if any, to the
8 medicare program.

9 (f) REPORT TO CONGRESS.—Not later than 1 year after
10 the date of the completion of the demonstration project under
11 this section, the Secretary shall submit to Congress a report on
12 the project using the data collected under subsection (e). The
13 report shall include the following:

14 (1) An examination of whether the provision of home
15 health services to medicare beneficiaries under the project
16 has had any of the following effects:

17 (A) Has adversely affected the provision of home
18 health services under the medicare program.

19 (B) Has directly caused an increase of expendi-
20 tures under the medicare program for the provision of
21 such services that is directly attributable to such clar-
22 ification.

23 (2) The specific data evidencing the amount of any in-
24 crease in expenditures that is directly attributable to the
25 demonstration project (expressed both in absolute dollar
26 terms and as a percentage) above expenditures that would
27 otherwise have been incurred for home health services
28 under the medicare program.

29 (3) Specific recommendations to exempt permanently
30 and severely disabled homebound beneficiaries from restric-
31 tions on the length, frequency, and purpose of their ab-
32 sences from the home to qualify for home health services
33 without incurring additional costs to the medicare program.

34 (g) WAIVER AUTHORITY.—The Secretary shall waive com-
35 pliance with the requirements of title XVIII of the Social Secu-
36 rity Act (42 U.S.C. 1395 et seq.) to such extent and for such

1 period as the Secretary determines is necessary to conduct
2 demonstration projects.

3 (h) CONSTRUCTION.—Nothing in this section shall be con-
4 strued as waiving any applicable civil monetary penalty, crimi-
5 nal penalty, or other remedy available to the Secretary under
6 title XI or title XVIII of the Social Security Act for acts pro-
7 hibited under such titles, including penalties for false certifi-
8 cations for purposes of receipt of items or services under the
9 medicare program.

10 (i) AUTHORIZATION OF APPROPRIATIONS.—Payments for
11 the costs of carrying out the demonstration project under this
12 section shall be made from the Federal Supplementary Medical
13 Insurance Trust Fund under section 1841 of such Act (42
14 U.S.C. 1395t).

15 (j) DEFINITIONS.—In this section:

16 (1) MEDICARE BENEFICIARY.—The term “medicare
17 beneficiary” means an individual who is enrolled under part
18 B of title XVIII of the Social Security Act.

19 (2) HOME HEALTH SERVICES.—The term “home
20 health services” has the meaning given such term in section
21 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

22 (3) ACTIVITIES OF DAILY LIVING DEFINED.—The
23 term “activities of daily living” means eating, toileting,
24 transferring, bathing, and dressing.

25 **SEC. 703. DEMONSTRATION PROJECT FOR MEDICAL**
26 **ADULT DAY-CARE SERVICES.**

27 (a) ESTABLISHMENT.—Subject to the succeeding provi-
28 sions of this section, the Secretary shall establish a demonstra-
29 tion project (in this section referred to as the “demonstration
30 project”) under which the Secretary shall, as part of a plan of
31 an episode of care for home health services established for a
32 medicare beneficiary, permit a home health agency, directly or
33 under arrangements with a medical adult day-care facility, to
34 provide medical adult day-care services as a substitute for a
35 portion of home health services that would otherwise be pro-
36 vided in the beneficiary’s home.

37 (b) PAYMENT.—

1 (1) IN GENERAL.—Subject to paragraph (2), the
2 amount of payment for an episode of care for home health
3 services, a portion of which consists of substitute medical
4 adult day-care services, under the demonstration project
5 shall be made at a rate equal to 95 percent of the amount
6 that would otherwise apply for such home health services
7 under section 1895 of the Social Security Act (42 U.S.C.
8 1395fff). In no case may a home health agency, or a med-
9 ical adult day-care facility under arrangements with a home
10 health agency, separately charge a beneficiary for medical
11 adult day-care services furnished under the plan of care.

12 (2) ADJUSTMENT IN CASE OF OVERUTILIZATION OF
13 SUBSTITUTE ADULT DAY-CARE SERVICES TO ENSURE
14 BUDGET NEUTRALITY.—The Secretary shall monitor the
15 expenditures under the demonstration project and under
16 title XVIII of the Social Security Act for home health serv-
17 ices. If the Secretary estimates that the total expenditures
18 under the demonstration project and under such title
19 XVIII for home health services for a period determined by
20 the Secretary exceed expenditures that would have been
21 made under such title XVIII for home health services for
22 such period if the demonstration project had not been con-
23 ducted, the Secretary shall adjust the rate of payment to
24 medical adult day-care facilities under paragraph (1) in
25 order to eliminate such excess.

26 (c) DEMONSTRATION PROJECT SITES.—The demonstra-
27 tion project established under this section shall be conducted in
28 not more than 5 sites in States selected by the Secretary that
29 license or certify providers of services that furnish medical
30 adult day-care services.

31 (d) DURATION.—The Secretary shall conduct the dem-
32 onstration project for a period of 3 years.

33 (e) VOLUNTARY PARTICIPATION.—Participation of medi-
34 care beneficiaries in the demonstration project shall be vol-
35 untary. The total number of such beneficiaries that may par-
36 ticipate in the project at any given time may not exceed
37 15,000.

1 (f) PREFERENCE IN SELECTING AGENCIES.—In selecting
 2 home health agencies to participate under the demonstration
 3 project, the Secretary shall give preference to those agencies
 4 that are currently licensed or certified through common owner-
 5 ship and control to furnish medical adult day-care services.

6 (g) WAIVER AUTHORITY.—The Secretary may waive such
 7 requirements of title XVIII of the Social Security Act as may
 8 be necessary for the purposes of carrying out the demonstra-
 9 tion project, other than waiving the requirement that an indi-
 10 vidual be homebound in order to be eligible for benefits for
 11 home health services.

12 (h) EVALUATION AND REPORT.—The Secretary shall con-
 13 duct an evaluation of the clinical and cost-effectiveness of the
 14 demonstration project. Not later than 6 months after the com-
 15 pletion of the project, the Secretary shall submit to Congress
 16 a report on the evaluation, and shall include in the report the
 17 following:

18 (1) An analysis of the patient outcomes and costs of
 19 furnishing care to the medicare beneficiaries participating
 20 in the project as compared to such outcomes and costs to
 21 beneficiaries receiving only home health services for the
 22 same health conditions.

23 (2) Such recommendations regarding the extension,
 24 expansion, or termination of the project as the Secretary
 25 determines appropriate.

26 (i) DEFINITIONS.—In this section:

27 (1) HOME HEALTH AGENCY.—The term “home health
 28 agency” has the meaning given such term in section
 29 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

30 (2) MEDICAL ADULT DAY-CARE FACILITY.—The term
 31 “medical adult day-care facility” means a facility that—

32 (A) has been licensed or certified by a State to
 33 furnish medical adult day-care services in the State for
 34 a continuous 2-year period;

35 (B) is engaged in providing skilled nursing serv-
 36 ices and other therapeutic services directly or under ar-
 37 rangement with a home health agency;

1 (C) is licensed and certified by the State in which
 2 it operates or meets such standards established by the
 3 Secretary to assure quality of care and such other re-
 4 quirements as the Secretary finds necessary in the in-
 5 terest of the health and safety of individuals who are
 6 furnished services in the facility; and

7 (D) provides medical adult day-care services.

8 (3) MEDICAL ADULT DAY-CARE SERVICES.—The term
 9 “medical adult day-care services” means—

10 (A) home health service items and services de-
 11 scribed in paragraphs (1) through (7) of section
 12 1861(m) furnished in a medical adult day-care facility;

13 (B) a program of supervised activities furnished in
 14 a group setting in the facility that—

15 (i) meet such criteria as the Secretary deter-
 16 mines appropriate; and

17 (ii) is designed to promote physical and mental
 18 health of the individuals; and

19 (C) such other services as the Secretary may
 20 specify.

21 (4) MEDICARE BENEFICIARY.—The term “medicare
 22 beneficiary” means an individual entitled to benefits under
 23 part A of this title, enrolled under part B of this title, or
 24 both.

25 **SEC. 704. TEMPORARY SUSPENSION OF OASIS REQUIRE-**
 26 **MENT FOR COLLECTION OF DATA ON NON-**
 27 **MEDICARE AND NON-MEDICAID PATIENTS.**

28 (a) IN GENERAL.—During the period described in sub-
 29 section (b), the Secretary may not require, under section
 30 4602(e) of the Balanced Budget Act of 1997 (Public Law 105-
 31 33; 111 Stat. 467) or otherwise under OASIS, a home health
 32 agency to gather or submit information that relates to an indi-
 33 vidual who is not eligible for benefits under either title XVIII
 34 or title XIX of the Social Security Act (such information in
 35 this section referred to as “non-medicare/medicaid OASIS in-
 36 formation”).

1 (b) PERIOD OF SUSPENSION.—The period described in
2 this subsection—

3 (1) begins on the date of the enactment of this Act;
4 and

5 (2) ends on the last day of the second month begin-
6 ning after the date as of which the Secretary has published
7 final regulations regarding the collection and use by the
8 Centers for Medicare & Medicaid Services of non-medicare/
9 medicaid OASIS information following the submission of
10 the report required under subsection (c).

11 (c) REPORT.—

12 (1) STUDY.—The Secretary shall conduct a study on
13 how non-medicare/medicaid OASIS information is and can
14 be used by large home health agencies. Such study shall
15 examine—

16 (A) whether there are unique benefits from the
17 analysis of such information that cannot be derived
18 from other information available to, or collected by,
19 such agencies; and

20 (B) the value of collecting such information by
21 small home health agencies compared to the adminis-
22 trative burden related to such collection.

23 In conducting the study the Secretary shall obtain rec-
24 ommendations from quality assessment experts in the use
25 of such information and the necessity of small, as well as
26 large, home health agencies collecting such information.

27 (2) REPORT.—The Secretary shall submit to Congress
28 a report on the study conducted under paragraph (1) by
29 not later than 18 months after the date of the enactment
30 of this Act.

31 (d) CONSTRUCTION.—Nothing in this section shall be con-
32 strued as preventing home health agencies from collecting non-
33 medicare/medicaid OASIS information for their own use.

34 **SEC. 705. MEDPAC STUDY ON MEDICARE MARGINS OF**
35 **HOME HEALTH AGENCIES.**

36 (a) STUDY.—The Medicare Payment Advisory Commission
37 shall conduct a study of payment margins of home health agen-

1 “(2)(A) Subject to subparagraphs (B), payment may be
 2 made with respect to services provided by such an institution
 3 only to such extent and under such conditions, limitations, and
 4 requirements (in addition to or in lieu of the conditions, limita-
 5 tions, and requirements otherwise applicable) as may be pro-
 6 vided in regulations consistent with section 1821.

7 “(B) Notwithstanding any other provision of this title,
 8 payment may not be made under subparagraph (A)—

9 “(i) in a year insofar as such payments exceed
 10 \$700,000; and

11 “(ii) after December 31, 2006.”.

12 **Subtitle B—Graduate Medical** 13 **Education**

14 **SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH** 15 **COST PROGRAMS.**

16 Section 1886(h)(2)(D)(iv) (42 U.S.C.
 17 1395ww(h)(2)(D)(iv)) is amended—

18 (1) in subclause (I)—

19 (A) by inserting “AND 2004 THROUGH 2013” after
 20 “AND 2002”; and

21 (B) by inserting “or during the period beginning
 22 with fiscal year 2004 and ending with fiscal year 2013”
 23 after “during fiscal year 2001 or fiscal year 2002”;
 24 and

25 (2) in subclause (II)—

26 (A) by striking “fiscal year 2004, or fiscal year
 27 2005,” and

28 (B) by striking “For a” and inserting “For the”.

29 **SEC. 712. EXCEPTION TO INITIAL RESIDENCY PERIOD** 30 **FOR GERIATRIC RESIDENCY OR FELLOW-** 31 **SHIP PROGRAMS.**

32 (a) CLARIFICATION OF CONGRESSIONAL INTENT.—Con-
 33 gress intended section 1886(h)(5)(F)(ii) of the Social Security
 34 Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added by section 9202
 35 of the Consolidated Omnibus Budget Reconciliation Act of
 36 1985 (Public Law 99–272), to provide an exception to the ini-
 37 tial residency period for geriatric residency or fellowship pro-

1 grams such that, where a particular approved geriatric training
2 program requires a resident to complete 2 years of training to
3 initially become board eligible in the geriatric specialty, the 2
4 years spent in the geriatric training program are treated as
5 part of the resident's initial residency period, but are not
6 counted against any limitation on the initial residency period.

7 (b) INTERIM FINAL REGULATORY AUTHORITY AND EF-
8 FECTIVE DATE.—The Secretary shall promulgate interim final
9 regulations consistent with the congressional intent expressed
10 in this section after notice and pending opportunity for public
11 comment to be effective for cost reporting periods beginning on
12 or after October 1, 2003.

13 **SEC. 713. TREATMENT OF VOLUNTEER SUPERVISION.**

14 (a) MORATORIUM ON CHANGES IN TREATMENT.—During
15 the 1-year period beginning on January 1, 2004, for purposes
16 of applying subsections (d)(5)(B) and (h) of section 1886 of
17 the Social Security Act (42 U.S.C. 1395ww), the Secretary
18 shall allow all hospitals to count residents in osteopathic and
19 allopathic family practice programs in existence as of January
20 1, 2002, who are training at non-hospital sites, without regard
21 to the financial arrangement between the hospital and the
22 teaching physician practicing in the non-hospital site to which
23 the resident has been assigned.

24 (b) STUDY AND REPORT.—

25 (1) STUDY.—The Inspector General of the Depart-
26 ment of Health and Human Services shall conduct a study
27 of the appropriateness of alternative payment methodolo-
28 gies under such sections for the costs of training residents
29 in non-hospital settings.

30 (2) REPORT.—Not later than 1 year after the date of
31 the enactment of this Act, the Inspector General shall sub-
32 mit to Congress a report on the study conducted under
33 paragraph (1), together with such recommendations as the
34 Inspector General determines appropriate.

**Subtitle C—Chronic Care
Improvement**

**SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT
UNDER TRADITIONAL FEE-FOR-SERVICE.**

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new section:

“CHRONIC CARE IMPROVEMENT

“SEC. 1807. (a) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS.—

“(1) IN GENERAL.—The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this title for targeted beneficiaries with one or more threshold conditions.

“(2) DEFINITIONS.—For purposes of this section:

“(A) CHRONIC CARE IMPROVEMENT PROGRAM.—The term ‘chronic care improvement program’ means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c).

“(B) CHRONIC CARE IMPROVEMENT ORGANIZATION.—The term ‘chronic care improvement organization’ means an entity that has entered into an agreement under subsection (b) or (c) to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

“(C) CARE MANAGEMENT PLAN.—The term ‘care management plan’ means a plan established under sub-

1 section (d) for a participant in a chronic care improve-
2 ment program.

3 “(D) THRESHOLD CONDITION.—The term ‘thresh-
4 old condition’ means a chronic condition, such as con-
5 gestive heart failure, diabetes, chronic obstructive pul-
6 monary disease (COPD), or other diseases or condi-
7 tions, as selected by the Secretary as appropriate for
8 the establishment of a chronic care improvement pro-
9 gram.

10 “(E) TARGETED BENEFICIARY.—The term ‘tar-
11 geted beneficiary’ means, with respect to a chronic care
12 improvement program, an individual who—

13 “(i) is entitled to benefits under part A and
14 enrolled under part B, but not enrolled in a plan
15 under part C;

16 “(ii) has one or more threshold conditions cov-
17 ered under such program; and

18 “(iii) has been identified under subsection
19 (d)(1) as a potential participant in such program.

20 “(3) CONSTRUCTION.—Nothing in this section shall be
21 construed as—

22 “(A) expanding the amount, duration, or scope of
23 benefits under this title;

24 “(B) providing an entitlement to participate in a
25 chronic care improvement program under this section;

26 “(C) providing for any hearing or appeal rights
27 under section 1869, 1878, or otherwise, with respect to
28 a chronic care improvement program under this sec-
29 tion; or

30 “(D) providing benefits under a chronic care im-
31 provement program for which a claim may be sub-
32 mitted to the Secretary by any provider of services or
33 supplier (as defined in section 1861(d)).

34 “(b) DEVELOPMENTAL PHASE (PHASE I).—

35 “(1) IN GENERAL.—In carrying out this section, the
36 Secretary shall enter into agreements consistent with sub-
37 section (f) with chronic care improvement organizations for

1 the development, testing, and evaluation of chronic care im-
2 provement programs using randomized controlled trials.
3 The first such agreement shall be entered into not later
4 than 12 months after the date of the enactment of this sec-
5 tion.

6 “(2) AGREEMENT PERIOD.—The period of an agree-
7 ment under this subsection shall be for 3 years.

8 “(3) MINIMUM PARTICIPATION.—

9 “(A) IN GENERAL.—The Secretary shall enter into
10 agreements under this subsection in a manner so that
11 chronic care improvement programs offered under this
12 section are offered in geographic areas that, in the ag-
13 gregate, consist of areas in which at least 10 percent
14 of the aggregate number of medicare beneficiaries re-
15 side.

16 “(B) MEDICARE BENEFICIARY DEFINED.—In this
17 paragraph, the term ‘medicare beneficiary’ means an
18 individual who is entitled to benefits under part A, en-
19 rolled under part B, or both, and who resides in the
20 United States.

21 “(4) SITE SELECTION.—In selecting geographic areas
22 in which agreements are entered into under this subsection,
23 the Secretary shall ensure that each chronic care improve-
24 ment program is conducted in a geographic area in which
25 at least 10,000 targeted beneficiaries reside among other
26 individuals entitled to benefits under part A, enrolled under
27 part B, or both to serve as a control population.

28 “(5) INDEPENDENT EVALUATIONS OF PHASE I PRO-
29 GRAMS.—The Secretary shall contract for an independent
30 evaluation of the programs conducted under this sub-
31 section. Such evaluation shall be done by a contractor with
32 knowledge of chronic care management programs and dem-
33 onstrated experience in the evaluation of such programs.
34 Each evaluation shall include an assessment of the fol-
35 lowing factors of the programs:

1 “(A) Quality improvement measures, such as ad-
2 herence to evidence-based guidelines and rehospitaliza-
3 tion rates.

4 “(B) Beneficiary and provider satisfaction.

5 “(C) Health outcomes.

6 “(D) Financial outcomes, including any cost sav-
7 ings to the program under this title.

8 “(c) EXPANDED IMPLEMENTATION PHASE (PHASE II).—

9 “(1) IN GENERAL.—With respect to chronic care im-
10 provement programs conducted under subsection (b), if the
11 Secretary finds that the results of the independent evalua-
12 tion conducted under subsection (b)(6) indicate that the
13 conditions specified in paragraph (2) have been met by a
14 program (or components of such program), the Secretary
15 shall enter into agreements consistent with subsection (f) to
16 expand the implementation of the program (or components)
17 to additional geographic areas not covered under the pro-
18 gram as conducted under subsection (b), which may include
19 the implementation of the program on a national basis.
20 Such expansion shall begin not earlier than 2 years after
21 the program is implemented under subsection (b) and not
22 later than 6 months after the date of completion of such
23 program.

24 “(2) CONDITIONS FOR EXPANSION OF PROGRAMS.—

25 The conditions specified in this paragraph are, with respect
26 to a chronic care improvement program conducted under
27 subsection (b) for a threshold condition, that the program
28 is expected to—

29 “(A) improve the clinical quality of care;

30 “(B) improve beneficiary satisfaction; and

31 “(C) achieve targets for savings to the program
32 under this title specified by the Secretary in the agree-
33 ment within a range determined to be appropriate by
34 the Secretary, subject to the application of budget neu-
35 trality with respect to the program and not taking into
36 account any payments by the organization under the

1 agreement under the program for risk under subsection
2 (f)(3)(B).

3 “(3) INDEPENDENT EVALUATIONS OF PHASE II PRO-
4 GRAMS.—The Secretary shall carry out evaluations of pro-
5 grams expanded under this subsection as the Secretary de-
6 termines appropriate. Such evaluations shall be carried out
7 in the similar manner as is provided under subsection
8 (b)(5).

9 “(d) IDENTIFICATION AND ENROLLMENT OF PROSPEC-
10 TIVE PROGRAM PARTICIPANTS.—

11 “(1) IDENTIFICATION OF PROSPECTIVE PROGRAM PAR-
12 TICIPANTS.—The Secretary shall establish a method for
13 identifying targeted beneficiaries who may benefit from
14 participation in a chronic care improvement program.

15 “(2) INITIAL CONTACT BY SECRETARY.—The Sec-
16 retary shall communicate with each targeted beneficiary
17 concerning participation in a chronic care improvement
18 program. Such communication may be made by the Sec-
19 retary and shall include information on the following:

20 “(A) A description of the advantages to the bene-
21 ficiary in participating in a program.

22 “(B) Notification that the organization offering a
23 program may contact the beneficiary directly con-
24 cerning such participation.

25 “(C) Notification that participation in a program
26 is voluntary.

27 “(D) A description of the method for the bene-
28 ficiary to participate or for declining to participate and
29 the method for obtaining additional information con-
30 cerning such participation.

31 “(3) VOLUNTARY PARTICIPATION.—A targeted bene-
32 ficiary may participate in a chronic care improvement pro-
33 gram on a voluntary basis and may terminate participation
34 at any time.

35 “(e) CHRONIC CARE IMPROVEMENT PROGRAMS.—

36 “(1) IN GENERAL.—Each chronic care improvement
37 program shall—

1 “(A) have a process to screen each targeted bene-
2 fiary for conditions other than threshold conditions,
3 such as impaired cognitive ability and co-morbidities,
4 for the purposes of developing an individualized, goal-
5 oriented care management plan under paragraph (2);

6 “(B) provide each targeted beneficiary partici-
7 pating in the program with such plan; and

8 “(C) carry out such plan and other chronic care
9 improvement activities in accordance with paragraph
10 (3).

11 “(2) ELEMENTS OF CARE MANAGEMENT PLANS.—A
12 care management plan for a targeted beneficiary shall be
13 developed with the beneficiary and shall, to the extent ap-
14 propriate, include the following:

15 “(A) A designated point of contact responsible for
16 communications with the beneficiary and for facili-
17 tating communications with other health care providers
18 under the plan.

19 “(B) Self-care education for the beneficiary
20 (through approaches such as disease management or
21 medical nutrition therapy) and education for primary
22 caregivers and family members.

23 “(C) Education for physicians and other providers
24 and collaboration to enhance communication of relevant
25 clinical information.

26 “(D) The use of monitoring technologies that en-
27 able patient guidance through the exchange of perti-
28 nent clinical information, such as vital signs, sympto-
29 matic information, and health self-assessment.

30 “(E) The provision of information about hospice
31 care, pain and palliative care, and end-of-life care.

32 “(3) CONDUCT OF PROGRAMS.—In carrying out para-
33 graph (1)(C) with respect to a participant, the chronic care
34 improvement organization shall—

35 “(A) guide the participant in managing the par-
36 ticipant’s health (including all co-morbidities, relevant
37 health care services, and pharmaceutical needs) and in

1 performing activities as specified under the elements of
2 the care management plan of the participant;

3 “(B) use decision-support tools such as evidence-
4 based practice guidelines or other criteria as deter-
5 mined by the Secretary; and

6 “(C) develop a clinical information database to
7 track and monitor each participant across settings and
8 to evaluate outcomes.

9 “(4) ADDITIONAL RESPONSIBILITIES.—

10 “(A) OUTCOMES REPORT.—Each chronic care im-
11 provement organization offering a chronic care im-
12 provement program shall monitor and report to the
13 Secretary, in a manner specified by the Secretary, on
14 health care quality, cost, and outcomes.

15 “(B) ADDITIONAL REQUIREMENTS.—Each such
16 organization and program shall comply with such addi-
17 tional requirements as the Secretary may specify.

18 “(5) ACCREDITATION.—The Secretary may provide
19 that chronic care improvement programs and chronic care
20 improvement organizations that are accredited by qualified
21 organizations (as defined by the Secretary) may be deemed
22 to meet such requirements under this section as the Sec-
23 retary may specify.

24 “(f) TERMS OF AGREEMENTS.—

25 “(1) TERMS AND CONDITIONS.—

26 “(A) IN GENERAL.—An agreement under this sec-
27 tion with a chronic care improvement organization shall
28 contain such terms and conditions as the Secretary
29 may specify consistent with this section.

30 “(B) CLINICAL, QUALITY IMPROVEMENT, AND FI-
31 NANCIAL REQUIREMENTS.—The Secretary may not
32 enter into an agreement with such an organization
33 under this section for the operation of a chronic care
34 improvement program unless—

35 “(i) the program and organization meet the
36 requirements of subsection (e) and such clinical,
37 quality improvement, financial, and other require-

1 ments as the Secretary deems to be appropriate for
2 the targeted beneficiaries to be served; and

3 “(ii) the organization demonstrates to the sat-
4 isfaction of the Secretary that the organization is
5 able to assume financial risk for performance under
6 the agreement (as applied under paragraph (3)(B))
7 with respect to payments made to the organization
8 under such agreement through available reserves,
9 reinsurance, withholds, or such other means as the
10 Secretary determines appropriate.

11 “(2) MANNER OF PAYMENT.—Subject to paragraph
12 (3)(B), the payment under an agreement under—

13 “(A) subsection (b) shall be computed on a per-
14 member per-month basis; or

15 “(B) subsection (c) may be on a per-member per-
16 month basis or such other basis as the Secretary and
17 organization may agree.

18 “(3) APPLICATION OF PERFORMANCE STANDARDS.—

19 “(A) SPECIFICATION OF PERFORMANCE STAND-
20 ARDS.—Each agreement under this section with a
21 chronic care improvement organization shall specify
22 performance standards for each of the factors specified
23 in subsection (c)(2), including clinical quality and
24 spending targets under this title, against which the per-
25 formance of the chronic care improvement organization
26 under the agreement is measured.

27 “(B) ADJUSTMENT OF PAYMENT BASED ON PER-
28 FORMANCE.—

29 “(i) IN GENERAL.—Each such agreement shall
30 provide for adjustments in payment rates to an or-
31 ganization under the agreement insofar as the Sec-
32 retary determines that the organization failed to
33 meet the performance standards specified in the
34 agreement under subparagraph (A).

35 “(ii) FINANCIAL RISK FOR PERFORMANCE.—
36 In the case of an agreement under subsection (b)
37 or (c), the agreement shall provide for a full recov-

1 ery for any amount by which the fees paid to the
2 organization under the agreement exceed the esti-
3 mated savings to the programs under this title at-
4 tributable to implementation of such agreement.

5 “(4) BUDGET NEUTRAL PAYMENT CONDITION.—Under
6 this section, the Secretary shall ensure that the aggregate
7 sum of medicare program benefit expenditures for bene-
8 ficiaries participating in chronic care improvement pro-
9 grams and funds paid to chronic care improvement organi-
10 zations under this section, shall not exceed the medicare
11 program benefit expenditures that the Secretary estimates
12 would have been made for such targeted beneficiaries in the
13 absence of such programs.

14 “(g) FUNDING.—(1) Subject to paragraph (2), there are
15 appropriated to the Secretary, in appropriate part from the
16 Federal Hospital Insurance Trust Fund and the Federal Sup-
17 plementary Medical Insurance Trust Fund, such sums as may
18 be necessary to provide for agreements with chronic care im-
19 provement programs under this section.

20 “(2) In no case shall the funding under this section exceed
21 \$100,000,000 in aggregate increased expenditures under this
22 title (after taking into account any savings attributable to the
23 operation of this section) over the 3-fiscal-year period beginning
24 on October 1, 2003.”.

25 (b) REPORTS.—The Secretary shall submit to Congress re-
26 ports on the operation of section 1807 of the Social Security
27 Act, as added by subsection (a), as follows:

28 (1) Not later than 2 years after the date of the imple-
29 mentation of such section, the Secretary shall submit to
30 Congress an interim report on the scope of implementation
31 of the programs under subsection (b) of such section, the
32 design of the programs, and preliminary cost and quality
33 findings with respect to those programs based on the fol-
34 lowing measures of the programs:

35 (A) Quality improvement measures, such as adher-
36 ence to evidence-based guidelines and rehospitalization
37 rates.

1 (B) Beneficiary and provider satisfaction.

2 (C) Health outcomes.

3 (D) Financial outcomes.

4 (2) Not later than 3 years and 6 months after the
5 date of the implementation of such section the Secretary
6 shall submit to Congress an update to the report required
7 under paragraph (1) on the results of such programs.

8 (3) The Secretary shall submit to Congress 2 addi-
9 tional biennial reports on the chronic care improvement
10 programs conducted under such section. The first such re-
11 port shall be submitted not later than 2 years after the re-
12 port is submitted under paragraph (2). Each such report
13 shall include information on—

14 (A) the scope of implementation (in terms of both
15 regions and chronic conditions) of the chronic care im-
16 provement programs;

17 (B) the design of the programs; and

18 (C) the improvements in health outcomes and fi-
19 nancial efficiencies that result from such implementa-
20 tion.

21 **SEC. 722. MEDICARE ADVANTAGE QUALITY IMPROVE-**
22 **MENT PROGRAMS.**

23 (a) IN GENERAL.—Section 1852(e) (42 U.S.C. 1395w-
24 22(e)) is amended—

25 (1) in the heading, by striking “ASSURANCE” and in-
26 serting “IMPROVEMENT”;

27 (2) by amending paragraphs (1) through (3) to read
28 as follows:

29 “(1) IN GENERAL.—Each MA organization shall have
30 an ongoing quality improvement program for the purpose
31 of improving the quality of care provided to enrollees in
32 each MA plan offered by such organization (other than an
33 MA private fee-for-service plan or an MSA plan).

34 “(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As
35 part of the quality improvement program under paragraph
36 (1), each MA organization shall have a chronic care im-
37 provement program. Each chronic care improvement pro-

1 gram shall have a method for monitoring and identifying
2 enrollees with multiple or sufficiently severe chronic condi-
3 tions that meet criteria established by the organization for
4 participation under the program.

5 “(3) DATA.—

6 “(A) COLLECTION, ANALYSIS, AND REPORTING.—

7 “(i) IN GENERAL.—Except as provided in
8 clauses (ii) and (iii) with respect to plans described
9 in such clauses and subject to subparagraph (B),
10 as part of the quality improvement program under
11 paragraph (1), each MA organization shall provide
12 for the collection, analysis, and reporting of data
13 that permits the measurement of health outcomes
14 and other indices of quality.

15 “(ii) APPLICATION TO MA REGIONAL PLANS.—

16 The Secretary shall establish as appropriate by reg-
17 ulation requirements for the collection, analysis,
18 and reporting of data that permits the measure-
19 ment of health outcomes and other indices of qual-
20 ity for MA organizations with respect to MA re-
21 gional plans. Such requirements may not exceed
22 the requirements under this subparagraph with re-
23 spect to MA local plans that are preferred provider
24 organization plans.

25 “(iii) APPLICATION TO PREFERRED PROVIDER
26 ORGANIZATIONS.—Clause (i) shall apply to MA or-
27 ganizations with respect to MA local plans that are
28 preferred provider organization plans only insofar
29 as services are furnished by providers or services,
30 physicians, and other health care practitioners and
31 suppliers that have contracts with such organiza-
32 tion to furnish services under such plans.

33 “(iv) DEFINITION OF PREFERRED PROVIDER
34 ORGANIZATION PLAN.—In this subparagraph, the
35 term ‘preferred provider organization plan’ means
36 an MA plan that—

1 “(I) has a network of providers that have
2 agreed to a contractually specified reimburse-
3 ment for covered benefits with the organization
4 offering the plan;

5 “(II) provides for reimbursement for all
6 covered benefits regardless of whether such
7 benefits are provided within such network of
8 providers; and

9 “(III) is offered by an organization that is
10 not licensed or organized under State law as a
11 health maintenance organization.

12 “(B) LIMITATIONS.—

13 “(i) TYPES OF DATA.—The Secretary shall not
14 collect under subparagraph (A) data on quality,
15 outcomes, and beneficiary satisfaction to facilitate
16 consumer choice and program administration other
17 than the types of data that were collected by the
18 Secretary as of November 1, 2003.

19 “(ii) CHANGES IN TYPES OF DATA.—Subject
20 to subclause (iii), the Secretary may only change
21 the types of data that are required to be submitted
22 under subparagraph (A) after submitting to Con-
23 gress a report on the reasons for such changes that
24 was prepared in consultation with MA organiza-
25 tions and private accrediting bodies.

26 “(iii) CONSTRUCTION.—Nothing in the sub-
27 section shall be construed as restricting the ability
28 of the Secretary to carry out the duties under sec-
29 tion 1851(d)(4)(D).”;

30 (3) in paragraph (4)(B)—

31 (A) by amending clause (i) to read as follows:

32 “(i) Paragraphs (1) through (3) of this sub-
33 section (relating to quality improvement pro-
34 grams).”; and

35 (B) by adding at the end the following new clause:

1 “(vii) The requirements described in section
2 1860D–4(j), to the extent such requirements apply
3 under section 1860D–21(c).”; and

4 (4) by striking paragraph (5).

5 (b) CONFORMING AMENDMENT.—Section 1852(c)(1)(I)
6 (42 U.S.C. 1395w–22(c)(1)(I)) is amended to read as follows:

7 “(I) QUALITY IMPROVEMENT PROGRAM.—A de-
8 scription of the organization’s quality improvement pro-
9 gram under subsection (e).”.

10 (c) EFFECTIVE DATE.—The amendments made by this
11 section shall apply with respect to contract years beginning on
12 and after January 1, 2006.

13 **SEC. 723. CHRONICALLY ILL MEDICARE BENEFICIARY**
14 **RESEARCH, DATA, DEMONSTRATION STRAT-**
15 **EGY.**

16 (a) DEVELOPMENT OF PLAN.—Not later than 6 months
17 after the date of the enactment of this Act, the Secretary shall
18 develop a plan to improve quality of care and reduce the cost
19 of care for chronically ill medicare beneficiaries.

20 (b) PLAN REQUIREMENTS.—The plan will utilize existing
21 data and identify data gaps, develop research initiatives, and
22 propose intervention demonstration programs to provide better
23 health care for chronically ill medicare beneficiaries. The plan
24 shall—

25 (1) integrate existing data sets including, the Medicare
26 Current Beneficiary Survey (MCBS), Minimum Data Set
27 (MDS), Outcome and Assessment Information Set
28 (OASIS), data from Quality Improvement Organizations
29 (QIO), and claims data;

30 (2) identify any new data needs and a methodology to
31 address new data needs;

32 (3) plan for the collection of such data in a data ware-
33 house; and

34 (4) develop a research agenda using such data.

35 (c) CONSULTATION.—In developing the plan under this
36 section, the Secretary shall consult with experts in the fields of
37 care for the chronically ill (including clinicians).

1 (d) IMPLEMENTATION.—Not later than 2 years after the
 2 date of the enactment of this Act, the Secretary shall imple-
 3 ment the plan developed under this section. The Secretary may
 4 contract with appropriate entities to implement such plan.

5 (e) AUTHORIZATION OF APPROPRIATIONS.—There are au-
 6 thorized to be appropriated to the Secretary such sums as may
 7 be necessary in fiscal years 2004 and 2005 to carry out this
 8 section.

9 **Subtitle D—Other Provisions**

10 **SEC. 731. IMPROVEMENTS IN NATIONAL AND LOCAL** 11 **COVERAGE DETERMINATION PROCESS TO** 12 **RESPOND TO CHANGES IN TECHNOLOGY.**

13 (a) NATIONAL AND LOCAL COVERAGE DETERMINATION
 14 PROCESS.—

15 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y),
 16 as amended by sections 948 and 950, is amended—

17 (A) in the third sentence of subsection (a), by in-
 18 serting “consistent with subsection (l)” after “the Sec-
 19 retary shall ensure”; and

20 (B) by adding at the end the following new sub-
 21 section:

22 “(l) NATIONAL AND LOCAL COVERAGE DETERMINATION
 23 PROCESS.—

24 “(1) FACTORS AND EVIDENCE USED IN MAKING NA-
 25 TIONAL COVERAGE DETERMINATIONS.—The Secretary shall
 26 make available to the public the factors considered in mak-
 27 ing national coverage determinations of whether an item or
 28 service is reasonable and necessary. The Secretary shall de-
 29 velop guidance documents to carry out this paragraph in a
 30 manner similar to the development of guidance documents
 31 under section 701(h) of the Federal Food, Drug, and Cos-
 32 metic Act (21 U.S.C. 371(h)).

33 “(2) TIMEFRAME FOR DECISIONS ON REQUESTS FOR
 34 NATIONAL COVERAGE DETERMINATIONS.—In the case of a
 35 request for a national coverage determination that—

36 “(A) does not require a technology assessment
 37 from an outside entity or deliberation from the Medi-

1 care Coverage Advisory Committee, the decision on the
2 request shall be made not later than 6 months after the
3 date of the request; or

4 “(B) requires such an assessment or deliberation
5 and in which a clinical trial is not requested, the deci-
6 sion on the request shall be made not later than 9
7 months after the date of the request.

8 “(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL
9 COVERAGE DETERMINATIONS.—

10 “(A) PERIOD FOR PROPOSED DECISION.—Not
11 later than the end of the 6-month period (or 9-month
12 period for requests described in paragraph (2)(B)) that
13 begins on the date a request for a national coverage de-
14 termination is made, the Secretary shall make a draft
15 of proposed decision on the request available to the
16 public through the Internet website of the Centers for
17 Medicare & Medicaid Services or other appropriate
18 means.

19 “(B) 30-DAY PERIOD FOR PUBLIC COMMENT.—Be-
20 ginning on the date the Secretary makes a draft of the
21 proposed decision available under subparagraph (A),
22 the Secretary shall provide a 30-day period for public
23 comment on such draft.

24 “(C) 60-DAY PERIOD FOR FINAL DECISION.—Not
25 later than 60 days after the conclusion of the 30-day
26 period referred to under subparagraph (B), the Sec-
27 retary shall—

28 “(i) make a final decision on the request;

29 “(ii) include in such final decision summaries
30 of the public comments received and responses to
31 such comments;

32 “(iii) make available to the public the clinical
33 evidence and other data used in making such a de-
34 cision when the decision differs from the rec-
35 ommendations of the Medicare Coverage Advisory
36 Committee; and

1 “(iv) in the case of a final decision under
2 clause (i) to grant the request for the national cov-
3 erage determination, the Secretary shall assign a
4 temporary or permanent code (whether existing or
5 unclassified) and implement the coding change.

6 “(4) CONSULTATION WITH OUTSIDE EXPERTS IN CER-
7 TAIN NATIONAL COVERAGE DETERMINATIONS.—With re-
8 spect to a request for a national coverage determination for
9 which there is not a review by the Medicare Coverage Advi-
10 sory Committee, the Secretary shall consult with appro-
11 priate outside clinical experts.

12 “(5) LOCAL COVERAGE DETERMINATION PROCESS.—

13 “(A) PLAN TO PROMOTE CONSISTENCY OF COV-
14 ERAGE DETERMINATIONS.—The Secretary shall develop
15 a plan to evaluate new local coverage determinations to
16 determine which determinations should be adopted na-
17 tionally and to what extent greater consistency can be
18 achieved among local coverage determinations.

19 “(B) CONSULTATION.—The Secretary shall re-
20 quire the fiscal intermediaries or carriers providing
21 services within the same area to consult on all new
22 local coverage determinations within the area.

23 “(C) DISSEMINATION OF INFORMATION.—The
24 Secretary should serve as a center to disseminate infor-
25 mation on local coverage determinations among fiscal
26 intermediaries and carriers to reduce duplication of ef-
27 fort.

28 “(6) NATIONAL AND LOCAL COVERAGE DETERMINA-
29 TION DEFINED.—For purposes of this subsection—

30 “(A) NATIONAL COVERAGE DETERMINATION.—
31 The term ‘national coverage determination’ means a
32 determination by the Secretary with respect to whether
33 or not a particular item or service is covered nationally
34 under this title.

35 “(B) LOCAL COVERAGE DETERMINATION.—The
36 term ‘local coverage determination’ has the meaning
37 given that in section 1869(f)(2)(B).”.

1 (2) EFFECTIVE DATE.—The amendments made by
2 paragraph (1) shall apply to national coverage determina-
3 tions as of January 1, 2004, and section 1862(l)(5) of the
4 Social Security Act, as added by such paragraph, shall
5 apply to local coverage determinations made on or after
6 July 1, 2004.

7 (b) MEDICARE COVERAGE OF ROUTINE COSTS ASSOCI-
8 ATED WITH CERTAIN CLINICAL TRIALS OF CATEGORY A DE-
9 VICES.—

10 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y),
11 as amended by subsection (a), is amended by adding at the
12 end the following new subsection:

13 “(m) COVERAGE OF ROUTINE COSTS ASSOCIATED WITH
14 CERTAIN CLINICAL TRIALS OF CATEGORY A DEVICES.—

15 “(1) IN GENERAL.—In the case of an individual enti-
16 tled to benefits under part A, or enrolled under part B, or
17 both who participates in a category A clinical trial, the Sec-
18 retary shall not exclude under subsection (a)(1) payment
19 for coverage of routine costs of care (as defined by the Sec-
20 retary) furnished to such individual in the trial.

21 “(2) CATEGORY A CLINICAL TRIAL.—For purposes of
22 paragraph (1), a ‘category A clinical trial’ means a trial of
23 a medical device if—

24 “(A) the trial is of an experimental/investigational
25 (category A) medical device (as defined in regulations
26 under section 405.201(b) of title 42, Code of Federal
27 Regulations (as in effect as of September 1, 2003));

28 “(B) the trial meets criteria established by the
29 Secretary to ensure that the trial conforms to appro-
30 priate scientific and ethical standards; and

31 “(C) in the case of a trial initiated before January
32 1, 2010, the device involved in the trial has been deter-
33 mined by the Secretary to be intended for use in the
34 diagnosis, monitoring, or treatment of an immediately
35 life-threatening disease or condition.”.

36 (2) EFFECTIVE DATE.—The amendment made by
37 paragraph (1) shall apply to routine costs incurred on and

1 after January 1, 2005, and, as of such date, section
 2 411.15(o) of title 42, Code of Federal Regulations, is su-
 3 perseded to the extent inconsistent with section 1862(m) of
 4 the Social Security Act, as added by such paragraph.

5 (3) RULE OF CONSTRUCTION.—Nothing in the amend-
 6 ment made by paragraph (1) shall be construed as applying
 7 to, or affecting, coverage or payment for a nonexperi-
 8 mental/investigational (category B) device.

9 (c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not
 10 later than July 1, 2004, the Secretary shall implement revised
 11 procedures for the issuance of temporary national HCPCS
 12 codes under part B of title XVIII of the Social Security Act.

13 **SEC. 732. EXTENSION OF TREATMENT OF CERTAIN PHY-**
 14 **SICIAN PATHOLOGY SERVICES UNDER MEDI-**
 15 **CARE.**

16 Section 542(c) of BIPA (114 Stat. 2763A–551) is amend-
 17 ed by inserting “, and for services furnished during 2005 and
 18 2006” before the period at the end.

19 **SEC. 733. PAYMENT FOR PANCREATIC ISLET CELL IN-**
 20 **VESTIGATIONAL TRANSPLANTS FOR MEDI-**
 21 **CARE BENEFICIARIES IN CLINICAL TRIALS.**

22 (a) CLINICAL TRIAL.—

23 (1) IN GENERAL.—The Secretary, acting through the
 24 National Institute of Diabetes and Digestive and Kidney
 25 Disorders, shall conduct a clinical investigation of pan-
 26 creatic islet cell transplantation which includes medicare
 27 beneficiaries.

28 (2) AUTHORIZATION OF APPROPRIATIONS.—There are
 29 authorized to be appropriated to the Secretary such sums
 30 as may be necessary to conduct the clinical investigation
 31 under paragraph (1).

32 (b) MEDICARE PAYMENT.—Not earlier than October 1,
 33 2004, the Secretary shall pay for the routine costs as well as
 34 transplantation and appropriate related items and services (as
 35 described in subsection (c)) in the case of medicare bene-
 36 ficiaries who are participating in a clinical trial described in
 37 subsection (a) as if such transplantation were covered under

1 title XVIII of such Act and as would be paid under part A or
2 part B of such title for such beneficiary.

3 (c) SCOPE OF PAYMENT.—For purposes of subsection (b):

4 (1) The term “routine costs” means reasonable and
5 necessary routine patient care costs (as defined in the Cen-
6 ters for Medicare & Medicaid Services Coverage Issues
7 Manual, section 30–1), including immunosuppressive drugs
8 and other followup care.

9 (2) The term “transplantation and appropriate related
10 items and services” means items and services related to the
11 acquisition and delivery of the pancreatic islet cell trans-
12 plantation, notwithstanding any national noncoverage de-
13 termination contained in the Centers for Medicare & Med-
14 icaid Services Coverage Issues Manual.

15 (3) The term “medicare beneficiary” means an indi-
16 vidual who is entitled to benefits under part A of title
17 XVIII of the Social Security Act, or enrolled under part B
18 of such title, or both.

19 (d) CONSTRUCTION.—The provisions of this section shall
20 not be construed—

21 (1) to permit payment for partial pancreatic tissue or
22 islet cell transplantation under title XVIII of the Social Se-
23 curity Act other than payment as described in subsection
24 (b); or

25 (2) as authorizing or requiring coverage or payment
26 conveying—

27 (A) benefits under part A of such title to a bene-
28 ficiary not entitled to such part A; or

29 (B) benefits under part B of such title to a bene-
30 ficiary not enrolled in such part B.

31 **SEC. 734. RESTORATION OF MEDICARE TRUST FUNDS.**

32 (a) DEFINITIONS.—In this section:

33 (1) CLERICAL ERROR.—The term “clerical error”
34 means a failure that occurs on or after April 15, 2001, to
35 have transferred the correct amount from the general fund
36 of the Treasury to a Trust Fund.

1 (2) TRUST FUND.—The term “Trust Fund” means
2 the Federal Hospital Insurance Trust Fund established
3 under section 1817 of the Social Security Act (42 U.S.C.
4 1395i) and the Federal Supplementary Medical Insurance
5 Trust Fund established under section 1841 of such Act (42
6 U.S.C. 1395t).

7 (b) CORRECTION OF TRUST FUND HOLDINGS.—

8 (1) IN GENERAL.—The Secretary of the Treasury
9 shall take the actions described in paragraph (2) with re-
10 spect to the Trust Fund with the goal being that, after
11 such actions are taken, the holdings of the Trust Fund will
12 replicate, to the extent practicable in the judgment of the
13 Secretary of the Treasury, in consultation with the Sec-
14 retary, the holdings that would have been held by the Trust
15 Fund if the clerical error involved had not occurred.

16 (2) OBLIGATIONS ISSUED AND REDEEMED.—The Sec-
17 retary of the Treasury shall—

18 (A) issue to the Trust Fund obligations under
19 chapter 31 of title 31, United States Code, that bear
20 issue dates, interest rates, and maturity dates that are
21 the same as those for the obligations that—

22 (i) would have been issued to the Trust Fund
23 if the clerical error involved had not occurred; or

24 (ii) were issued to the Trust Fund and were
25 redeemed by reason of the clerical error involved;
26 and

27 (B) redeem from the Trust Fund obligations that
28 would have been redeemed from the Trust Fund if the
29 clerical error involved had not occurred.

30 (c) APPROPRIATION.—There is appropriated to the Trust
31 Fund, out of any money in the Treasury not otherwise appro-
32 priated, an amount determined by the Secretary of the Treas-
33 ury, in consultation with the Secretary, to be equal to the inter-
34 est income lost by the Trust Fund through the date on which
35 the appropriation is being made as a result of the clerical error
36 involved.

1 (d) CONGRESSIONAL NOTICE.—In the case of a clerical
 2 error that occurs after April 15, 2001, the Secretary of the
 3 Treasury, before taking action to correct the error under this
 4 section, shall notify the appropriate committees of Congress
 5 concerning such error and the actions to be taken under this
 6 section in response to such error.

7 (e) DEADLINE.—With respect to the clerical error that oc-
 8 curred on April 15, 2001, not later than 120 days after the
 9 date of the enactment of this Act—

10 (1) the Secretary of the Treasury shall take the ac-
 11 tions under subsection (b)(1); and

12 (2) the appropriation under subsection (c) shall be
 13 made.

14 **SEC. 735. MODIFICATIONS TO MEDICARE PAYMENT AD-**
 15 **VISORY COMMISSION (MEDPAC).**

16 (a) EXAMINATION OF BUDGET CONSEQUENCES.—Section
 17 1805(b) (42 U.S.C. 1395b–6(b)) is amended by adding at the
 18 end the following new paragraph:

19 “(8) EXAMINATION OF BUDGET CONSEQUENCES.—Be-
 20 fore making any recommendations, the Commission shall
 21 examine the budget consequences of such recommendations,
 22 directly or through consultation with appropriate expert en-
 23 tities.”.

24 (b) CONSIDERATION OF EFFICIENT PROVISION OF SERV-
 25 ICES.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–
 26 6(b)(2)(B)(i)) is amended by inserting “the efficient provision
 27 of” after “expenditures for”.

28 (c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

29 (1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C.
 30 1395b–6(c)(2)(D)) is amended by adding at the end the
 31 following: “Members of the Commission shall be treated as
 32 employees of Congress for purposes of applying title I of
 33 the Ethics in Government Act of 1978 (Public Law 95–
 34 521).”.

35 (2) EFFECTIVE DATE.—The amendment made by
 36 paragraph (1) shall take effect on January 1, 2004.

37 (d) ADDITIONAL REPORTS.—

1 (1) DATA NEEDS AND SOURCES.—The Medicare Pay-
 2 ment Advisory Commission shall conduct a study, and sub-
 3 mit a report to Congress by not later than June 1, 2004,
 4 on the need for current data, and sources of current data
 5 available, to determine the solvency and financial cir-
 6 cumstances of hospitals and other medicare providers of
 7 services.

8 (2) USE OF TAX-RELATED RETURNS.—Using return
 9 information provided under Form 990 of the Internal Rev-
 10 enue Service, the Commission shall submit to Congress, by
 11 not later than June 1, 2004, a report on the following:

12 (A) Investments, endowments, and fundraising of
 13 hospitals participating under the medicare program and
 14 related foundations.

15 (B) Access to capital financing for private and for
 16 not-for-profit hospitals.

17 (e) REPRESENTATION OF EXPERTS IN PRESCRIPTION
 18 DRUGS.—

19 (1) IN GENERAL.—Section 1805(c)(2)(B) (42 U.S.C.
 20 1395b–6(c)(2)(B)) is amended by inserting “experts in the
 21 area of pharmaco-economics or prescription drug benefit
 22 programs,” after “other health professionals,”.

23 (2) APPOINTMENT.—The Comptroller General of the
 24 United States shall ensure that the membership of the
 25 Commission complies with the amendment made by para-
 26 graph (1) with respect to appointments made on or after
 27 the date of the enactment of this Act.

28 **SEC. 736. TECHNICAL AMENDMENTS.**

29 (a) PART A.—(1) Section 1814(a) (42 U.S.C. 1395f(a)) is
 30 amended—

31 (A) by striking the seventh sentence, as added by sec-
 32 tion 322(a)(1) of BIPA (114 Stat. 2763A–501); and

33 (B) in paragraph (7)(A)—

34 (i) in clause (i), by inserting before the comma at
 35 the end the following: “based on the physician’s or
 36 medical director’s clinical judgment regarding the nor-
 37 mal course of the individual’s illness”; and

1 (ii) in clause (ii), by inserting before the semicolon
2 at the end the following: “based on such clinical judg-
3 ment”.

4 (2) Section 1814(b) (42 U.S.C. 1395f(b)), in the matter
5 preceding paragraph (1), is amended by inserting a comma
6 after “1813”.

7 (3) Section 1815(e)(1)(B) (42 U.S.C. 1395g(e)(1)(B)), in
8 the matter preceding clause (i), is amended by striking “of hos-
9 pital” and inserting “of a hospital”.

10 (4) Section 1816(c)(2)(B)(ii) (42 U.S.C.
11 1395h(c)(2)(B)(ii)) is amended—

12 (A) by striking “and” at the end of subclause (III);
13 and

14 (B) by striking the period at the end of subclause (IV)
15 and inserting “, and”.

16 (5) Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is
17 amended—

18 (A) in clause (i)(I), by striking the comma at the end
19 and inserting a semicolon; and

20 (B) in clause (ii), by striking “the Medicare and med-
21 icaid programs” and inserting “the programs under this
22 title and title XIX”.

23 (6) Section 1817(k)(6)(B) (42 U.S.C. 1395i(k)(6)(B)) is
24 amended by striking “Medicare program under title XVIII”
25 and inserting “program under this title”.

26 (7) Section 1818 (42 U.S.C. 1395i-2) is amended—

27 (A) in subsection (d)(6)(A) is amended by inserting
28 “of such Code” after “3111(b)”; and

29 (B) in subsection (g)(2)(B) is amended by striking
30 “subsection (b).” and inserting “subsection (b)”.

31 (8) Section 1819 (42 U.S.C. 1395i-3) is amended—

32 (A) in subsection (b)(4)(C)(i), by striking “at least at
33 least” and inserting “at least”;

34 (B) in subsection (d)(1)(A), by striking “physical men-
35 tal” and inserting “physical, mental”; and

36 (C) in subsection (f)(2)(B)(iii), by moving the last sen-
37 tence 2 ems to the left.

1 (9) Section 1886(b)(3)(I)(i)(I) (42 U.S.C.
2 1395ww(b)(3)(I)(i)(I)) is amended by striking “the the” and
3 inserting “the”.

4 (10) The heading of subsection (mm) of section 1861 (42
5 U.S.C. 1395x) is amended to read as follows:

6 “Critical Access Hospital; Critical Access Hospital Services”.

7 (11) Paragraphs (1) and (2) of section 1861(tt) (42
8 U.S.C. 1395x(tt)) are each amended by striking “rural primary
9 care” and inserting “critical access”.

10 (12) Section 1865(b)(3)(B) (42 U.S.C. 1395bb(b)(3)(B))
11 is amended by striking “section 1819 and 1861(j)” and insert-
12 ing “sections 1819 and 1861(j)”.

13 (13) Section 1866(b)(2) (42 U.S.C. 1395cc(b)(2)) is
14 amended by moving subparagraph (D) 2 ems to the left.

15 (14) Section 1867 (42 U.S.C. 1395dd) is amended—

16 (A) in the matter following clause (ii) of subsection
17 (d)(1)(B), by striking “is is” and inserting “is”;

18 (B) in subsection (e)(1)(B), by striking “a pregnant
19 women” and inserting “a pregnant woman”; and

20 (C) in subsection (e)(2), by striking “means hospital”
21 and inserting “means a hospital”.

22 (15) Section 1886(g)(3)(B) (42 U.S.C. 1395ww(g)(3)(B))
23 is amended by striking “(as defined in subsection
24 (d)(5)(D)(iii))” and inserting “(as defined in subsection
25 (d)(5)(D)(iii))”.

26 (b) PART B.—(1) Section 1833(h)(5)(D) (42 U.S.C.
27 1395l(h)(5)(D)) is amended by striking “clinic,,” and inserting
28 “clinic,”.

29 (2) Section 1833(t)(3)(C)(ii) (42 U.S.C.
30 1395l(t)(3)(C)(ii)) is amended by striking “clause (iii)” and in-
31 serting “clause (iv)”.

32 (3) Section 1861(v)(1)(S)(ii)(III) (42 U.S.C.
33 1395x(v)(1)(S)(ii)(III)) is amended by striking “(as defined in
34 section 1886(d)(5)(D)(iii))” and inserting “(as defined in sec-
35 tion 1886(d)(5)(D)(iii))”.

1 (4) Section 1834(b)(4)(D)(iv) (42 U.S.C.
2 1395m(b)(4)(D)(iv)) is amended by striking “clauses (vi)” and
3 inserting “clause (vi)”.

4 (5) Section 1834(m)(4)(C)(ii)(III) (42 U.S.C.
5 1395m(m)(4)(C)(ii)(III)) is amended by striking “1861(aa)(s)”
6 and inserting “1861(aa)(2)”.

7 (6) Section 1838(a)(1) (42 U.S.C. 1395q(a)(1)) is amend-
8 ed by inserting a comma after “1966”.

9 (7) The second sentence of section 1839(a)(4) (42 U.S.C.
10 1395r(a)(4)) is amended by striking “which will” and inserting
11 “will”.

12 (8) Section 1842(c)(2)(B)(ii) (42 U.S.C.
13 1395u(c)(2)(B)(ii)) is amended—

14 (A) by striking “and” at the end of subclause (III);
15 and

16 (B) by striking the period at the end of subclause (IV)
17 and inserting “, and”.

18 (9) Section 1842(i)(2) (42 U.S.C. 1395u(i)(2)) is amended
19 by striking “services, a physician” and inserting “services, to
20 a physician”.

21 (10) Section 1848(i)(3)(A) (42 U.S.C. 1395w-4(i)(3)(A))
22 is amended by striking “a comparable services” and inserting
23 “comparable services”.

24 (11) Section 1861(s)(2)(K)(i) (42 U.S.C.
25 1395x(s)(2)(K)(i)) is amended by striking “; and but” and in-
26 serting “, but”.

27 (12) Section 1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B))
28 is amended by striking “,” and inserting a comma.

29 (13) Section 128(b)(2) of BIPA (114 Stat. 2763A-480) is
30 amended by striking “Not later that” and inserting “Not later
31 than” each place it appears.

32 (c) PARTS A AND B.—(1) Section 1812(a)(3) (42 U.S.C.
33 1395d(a)(3)) is amended—

34 (A) by striking “for individuals not” and inserting “in
35 the case of individuals not”; and

36 (B) by striking “for individuals so” and inserting “in
37 the case of individuals so”.

1 (2)(A) Section 1814(a) (42 U.S.C. 1395f(a)) is amended
2 in the sixth sentence by striking “leave home,” and inserting
3 “leave home and”.

4 (B) Section 1835(a) (42 U.S.C. 1395n(a)) is amended in
5 the seventh sentence by striking “leave home,” and inserting
6 “leave home and”.

7 (3) Section 1891(d)(1) (42 U.S.C. 1395bbb(d)(1)) is
8 amended by striking “subsection (c)(2)(C)(I)” and inserting
9 “subsection (c)(2)(C)(i)(I)”.

10 (4) Section 1861(v) (42 U.S.C. 1395x(v)) is amended by
11 moving paragraph (8) (including clauses (i) through (v) of such
12 paragraph) 2 ems to the left.

13 (5) Section 1866B(b)(7)(D) (42 U.S.C. 1395cc-
14 2(b)(7)(D)) is amended by striking “(c)(2)(A)(ii)” and insert-
15 ing “(c)(2)(B)”.

16 (6) Section 1886(h)(3)(D)(ii)(III) (42 U.S.C.
17 1395ww(h)(3)(D)(ii)(III)) is amended by striking “and” after
18 the comma at the end.

19 (7) Section 1893(a) (42 U.S.C. 1395ddd(a)) is amended
20 by striking “Medicare program” and inserting “medicare pro-
21 gram”.

22 (8) Section 1896(b)(4) (42 U.S.C. 1395ggg(b)(4)) is
23 amended by striking “701(f)” and inserting “712(f)”.

24 (d) PART C.—(1) Section 1853 (42 U.S.C. 1395w-23), as
25 amended by section 607 of BIPA (114 Stat. 2763A-558), is
26 amended—

27 (A) in subsection (a)(3)(C)(ii), by striking “clause
28 (iii)” and inserting “clause (iv)”;

29 (B) in subsection (a)(3)(C), by redesignating the
30 clause (iii) added by such section 607 as clause (iv); and

31 (C) in subsection (c)(5), by striking “(a)(3)(C)(iii)”
32 and inserting “(a)(3)(C)(iv)”.

33 (2) Section 1876 (42 U.S.C. 1395mm) is amended—

34 (A) in subsection (c)(2)(B), by striking “significant”
35 and inserting “significant”; and

36 (B) in subsection (j)(2), by striking “this setion” and
37 inserting “this section”.

1 (e) MEDIGAP.—Section 1882 (42 U.S.C. 1395ss) is
2 amended—

3 (1) in subsection (d)(3)(A)(i)(II), by striking “plan a
4 medicare supplemental policy” and inserting “plan, a medi-
5 care supplemental policy”;

6 (2) in subsection (d)(3)(B)(iii)(II), by striking “to the
7 best of the issuer or seller’s knowledge” and inserting “to
8 the best of the issuer’s or seller’s knowledge”;

9 (3) in subsection (g)(2)(A), by striking “medicare sup-
10 plement policies” and inserting “medicare supplemental
11 policies”;

12 (4) in subsection (p)(2)(B), by striking “, and” and
13 inserting “; and”; and

14 (5) in subsection (s)(3)(A)(iii), by striking “pre-exist-
15 ing” and inserting “preexisting”.

16 **TITLE VIII—COST CONTAINMENT**
17 **Subtitle A—Cost Containment**

18 **SEC. 801. INCLUSION IN ANNUAL REPORT OF MEDICARE**
19 **TRUSTEES OF INFORMATION ON STATUS OF**
20 **MEDICARE TRUST FUNDS.**

21 (a) DETERMINATIONS OF EXCESS GENERAL REVENUE
22 MEDICARE FUNDING.—

23 (1) IN GENERAL.—The Board of Trustees of each
24 medicare trust fund shall include in the annual reports sub-
25 mitted under subsection (b)(2) of sections 1817 and 1841
26 of the Social Security Act (42 U.S.C. 1395i and 1395t)—

27 (A) the information described in subsection (b);

28 and

29 (B) a determination as to whether there is pro-
30 jected to be excess general revenue medicare funding
31 (as defined in subsection (c)) for the fiscal year in
32 which the report is submitted or for any of the suc-
33 ceeding 6 fiscal years.

34 (2) MEDICARE FUNDING WARNING.—For purposes of
35 section 1105(h) of title 31, United States Code, and this
36 subtitle, an affirmative determination under paragraph
37 (1)(B) in 2 consecutive annual reports shall be treated as

1 a medicare funding warning in the year in which the sec-
2 ond such report is made.

3 (3) 7-FISCAL-YEAR REPORTING PERIOD.—For pur-
4 poses of this subtitle, the term “7-fiscal-year reporting pe-
5 riod” means, with respect to a year in which an annual re-
6 port described in paragraph (1) is made, the period of 7
7 consecutive fiscal years beginning with the fiscal year in
8 which the report is submitted.

9 (b) INFORMATION.—The information described in this sub-
10 section for an annual report in a year is as follows:

11 (1) PROJECTIONS OF GROWTH OF GENERAL REVENUE
12 SPENDING.—A statement of the general revenue medicare
13 funding as a percentage of the total medicare outlays for
14 each of the following:

15 (A) Each fiscal year within the 7-fiscal-year re-
16 porting period.

17 (B) Previous fiscal years and as of 10, 50, and 75
18 years after such year.

19 (2) COMPARISON WITH OTHER GROWTH TRENDS.—A
20 comparison of the trend of such percentages with the an-
21 nual growth rate in the following:

22 (A) The gross domestic product.

23 (B) Private health costs.

24 (C) National health expenditures.

25 (D) Other appropriate measures.

26 (3) PART D SPENDING.—Expenditures, including
27 trends in expenditures, under part D of title XVIII of the
28 Social Security Act, as added by section 101.

29 (4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A
30 financial analysis of the combined medicare trust funds if
31 general revenue medicare funding were limited to the per-
32 centage specified in subsection (c)(1)(B) of total medicare
33 outlays.

34 (c) DEFINITIONS.—For purposes of this section:

35 (1) EXCESS GENERAL REVENUE MEDICARE FUND-
36 ING.—The term “excess general revenue medicare funding”
37 means, with respect to a fiscal year, that—

1 (A) general revenue medicare funding (as defined
2 in paragraph (2)), expressed as a percentage of total
3 medicare outlays (as defined in paragraph (4)) for the
4 fiscal year; exceeds

5 (B) 45 percent.

6 (2) GENERAL REVENUE MEDICARE FUNDING.—The
7 term “general revenue medicare funding” means for a
8 year—

9 (A) the total medicare outlays (as defined in para-
10 graph (4)) for the year; minus

11 (B) the dedicated medicare financing sources (as
12 defined in paragraph (3)) for the year.

13 (3) DEDICATED MEDICARE FINANCING SOURCES.—
14 The term “dedicated medicare financing sources” means
15 the following:

16 (A) HOSPITAL INSURANCE TAX.—Amounts appro-
17 priated to the Hospital Insurance Trust Fund under
18 the third sentence of section 1817(a) of the Social Se-
19 curity Act (42 U.S.C. 1395i(a)) and amounts trans-
20 ferred to such Trust Fund under section 7(c)(2) of the
21 Railroad Retirement Act of 1974 (45 U.S.C.
22 231f(c)(2)).

23 (B) TAXATION OF CERTAIN OASDI BENEFITS.—
24 Amounts appropriated to the Hospital Insurance Trust
25 Fund under section 121(e)(1)(B) of the Social Security
26 Amendments of 1983 (Public Law 98–21), as inserted
27 by section 13215(c) of the Omnibus Budget Reconcili-
28 ation Act of 1993 (Public Law 103–66).

29 (C) STATE TRANSFERS.—The State share of
30 amounts paid to the Federal Government by a State
31 under section 1843 of the Social Security Act (42
32 U.S.C. 1395v) or pursuant to section 1935(c) of such
33 Act.

34 (D) PREMIUMS.—The following premiums:

35 (i) PART A.—Premiums paid by non-Federal
36 sources under sections 1818 and section 1818A (42
37 U.S.C. 1395i–2 and 1395i–2a) of such Act.

1 (ii) PART B.—Premiums paid by non-Federal
 2 sources under section 1839 of such Act (42 U.S.C.
 3 1395r), including any adjustments in premiums
 4 under such section.

5 (iii) PART D.—Monthly beneficiary premiums
 6 paid under part D of title XVIII of such Act, as
 7 added by section 101, and MA monthly prescription
 8 drug beneficiary premiums paid under part C of
 9 such title insofar as they are attributable to basic
 10 prescription drug coverage.

11 Premiums under clauses (ii) and (iii) shall be determined
 12 without regard to any reduction in such premiums attrib-
 13 utable to a beneficiary rebate under section 1854(b)(1)(C)
 14 of such title, as amended by section 222(b)(1), and pre-
 15 miums under clause (iii) are deemed to include any
 16 amounts paid under section 1860D–13(b) of such title, as
 17 added by section 101.

18 (E) GIFTS.—Amounts received by the medicare
 19 trust funds under section 201(i) of the Social Security
 20 Act (42 U.S.C. 401(i)).

21 (4) TOTAL MEDICARE OUTLAYS.—The term “total
 22 medicare outlays” means total outlays from the medicare
 23 trust funds and shall—

24 (A) include payments made to plans under part C
 25 of title XVIII of the Social Security Act that are attrib-
 26 utable to any rebates under section 1854(b)(1)(C) of
 27 such Act (42 U.S.C. 1395w–24(b)(1)(C)), as amended
 28 by section 222(b)(1);

29 (B) include administrative expenditures made in
 30 carrying out title XVIII of such Act and Federal out-
 31 lays under section 1935(b) of such Act, as added by
 32 section 103(a)(2); and

33 (C) offset outlays by the amount of fraud and
 34 abuse collections insofar as they are applied or depos-
 35 ited into a medicare trust fund.

36 (5) MEDICARE TRUST FUND.—The term “medicare
 37 trust fund” means—

1 (A) the Federal Hospital Insurance Trust Fund
 2 established under section 1817 of the Social Security
 3 Act (42 U.S.C. 1395i); and

4 (B) the Federal Supplementary Medical Insurance
 5 Trust Fund established under section 1841 of such Act
 6 (42 U.S.C. 1395t), including the Medicare Prescription
 7 Drug Account under such Trust Fund.

8 (d) CONFORMING AMENDMENTS.—

9 (1) FEDERAL HOSPITAL INSURANCE TRUST FUND.—
 10 Section 1817(b)(2) (42 U.S.C. 1395i(b)(2)) is amended by
 11 adding at the end the following: “Each report provided
 12 under paragraph (2) beginning with the report in 2005
 13 shall include the information specified in section 801(a) of
 14 Medicare Prescription Drug, Improvement, and Moderniza-
 15 tion Act of 2003.”.

16 (2) FEDERAL SUPPLEMENTARY MEDICAL INSURANCE
 17 TRUST FUND.—Section 1841(b)(2) (42 U.S.C. 1395t(b)(2))
 18 is amended by adding at the end the following: “Each re-
 19 port provided under paragraph (2) beginning with the re-
 20 port in 2005 shall include the information specified in sec-
 21 tion 801(a) of Medicare Prescription Drug, Improvement,
 22 and Modernization Act of 2003.”.

23 (e) NOTICE OF MEDICARE FUNDING WARNING.—When-
 24 ever any report described in subsection (a) contains a deter-
 25 mination that for any fiscal year within the 7-fiscal-year report-
 26 ing period there will be excess general revenue medicare fund-
 27 ing, Congress and the President should address the matter
 28 under existing rules and procedures.

29 **SEC. 802. PRESIDENTIAL SUBMISSION OF LEGISLATION.**

30 (a) IN GENERAL.—Section 1105 of title 31, United States
 31 Code, is amended by adding at the end the following new sub-
 32 section:

33 “(h)(1) If there is a medicare funding warning under sec-
 34 tion 801(a)(2) of the Medicare Prescription Drug, Improve-
 35 ment, and Modernization Act of 2003 made in a year, the
 36 President shall submit to Congress, within the 15-day period
 37 beginning on the date of the budget submission to Congress

1 under subsection (a) for the succeeding year, proposed legisla-
2 tion to respond to such warning.

3 “(2) Paragraph (1) does not apply if, during the year in
4 which the warning is made, legislation is enacted which elimi-
5 nates excess general revenue medicare funding (as defined in
6 section 801(c) of the Medicare Prescription Drug, Improve-
7 ment, and Modernization Act of 2003) for the 7-fiscal-year re-
8 porting period, as certified by the Board of Trustees of each
9 medicare trust fund (as defined in section 801(c)(5) of such
10 Act) not later than 30 days after the date of the enactment of
11 such legislation.”.

12 (b) SENSE OF CONGRESS.—It is the sense of Congress
13 that legislation submitted pursuant to section 1105(h) of title
14 31, United States Code, in a year should be designed to elimi-
15 nate excess general revenue medicare funding (as defined in
16 section 801(c)) for the 7-fiscal-year period that begins in such
17 year.

18 **SEC. 803. PROCEDURES IN THE HOUSE OF REPRESENTA-**
19 **TIVES.**

20 (a) INTRODUCTION AND REFERRAL OF PRESIDENT’S LEG-
21 ISLATIVE PROPOSAL.—

22 (1) INTRODUCTION.—In the case of a legislative pro-
23 posal submitted by the President pursuant to section
24 1105(h) of title 31, United States Code, within the 15-day
25 period specified in paragraph (1) of such section, the Ma-
26 jority Leader of the House of Representatives (or his des-
27 ignee) and the Minority Leader of the House of Represent-
28 atives (or his designee) shall introduce such proposal (by
29 request), the title of which is as follows: “A bill to respond
30 to a medicare funding warning.” Such bill shall be intro-
31 duced within 3 legislative days after Congress receives such
32 proposal.

33 (2) REFERRAL.—Any legislation introduced pursuant
34 to paragraph (1) shall be referred to the appropriate com-
35 mittees of the House of Representatives.

36 (b) DIRECTION TO THE APPROPRIATE HOUSE COMMIT-
37 TEES.—

1 (1) IN GENERAL.—In the House, in any year during
 2 which the President is required to submit proposed legisla-
 3 tion to Congress under section 1105(h) of title 31, United
 4 States Code, the appropriate committees shall report medi-
 5 care funding legislation by not later than June 30 of such
 6 year.

7 (2) MEDICARE FUNDING LEGISLATION.—For purposes
 8 of this section, the term “medicare funding legislation”
 9 means—

10 (A) legislation introduced pursuant to subsection
 11 (a)(1), but only if the legislative proposal upon which
 12 the legislation is based was submitted within the 15-
 13 day period referred to in such subsection; or

14 (B) any bill the title of which is as follows: “A bill
 15 to respond to a medicare funding warning.”.

16 (3) CERTIFICATION.—With respect to any medicare
 17 funding legislation or any amendment to such legislation to
 18 respond to a medicare funding warning, the chairman of
 19 the Committee on the Budget of the House shall certify—

20 (A) whether or not such legislation eliminates ex-
 21 cess general revenue medicare funding (as defined in
 22 section 801(c)) for each fiscal year in the 7-fiscal-year
 23 reporting period; and

24 (B) with respect to such an amendment, whether
 25 the legislation, as amended, would eliminate excess gen-
 26 eral revenue medicare funding (as defined in section
 27 801(c)) for each fiscal year in such 7-fiscal-year report-
 28 ing period.

29 (c) FALLBACK PROCEDURE FOR FLOOR CONSIDERATION
 30 IF THE HOUSE FAILS TO VOTE ON FINAL PASSAGE BY JULY
 31 30.—

32 (1) After July 30 of any year during which the Presi-
 33 dent is required to submit proposed legislation to Congress
 34 under section 1105(h) of title 31, United States Code, un-
 35 less the House of Representatives has voted on final pas-
 36 sage of any medicare funding legislation for which there is
 37 an affirmative certification under subsection (b)(3)(A),

1 then, after the expiration of not less than 30 calendar days
 2 (and concurrently 5 legislative days), it is in order to move
 3 to discharge any committee to which medicare funding leg-
 4 islation which has such a certification and which has been
 5 referred to such committee for 30 calendar days from fur-
 6 ther consideration of the legislation.

7 (2) A motion to discharge may be made only by an in-
 8 dividual favoring the legislation, may be made only if sup-
 9 ported by one-fifth of the total membership of the House
 10 (a quorum being present), and is highly privileged in the
 11 House. Debate thereon shall be limited to not more than
 12 one hour, the time to be divided in the House equally be-
 13 tween those favoring and those opposing the motion. An
 14 amendment to the motion is not in order, and it is not in
 15 order to move to reconsider the vote by which the motion
 16 is agreed to or disagreed to.

17 (3) Only one motion to discharge a particular com-
 18 mittee may be adopted under this subsection in any session
 19 of a Congress.

20 (4) Notwithstanding paragraph (1), it shall not be in
 21 order to move to discharge a committee from further con-
 22 sideration of medicare funding legislation pursuant to this
 23 subsection during a session of a Congress if, during the
 24 previous session of the Congress, the House passed medi-
 25 care funding legislation for which there is an affirmative
 26 certification under subsection (b)(3)(A).

27 (d) FLOOR CONSIDERATION IN THE HOUSE OF DIS-
 28 CHARGED LEGISLATION.—

29 (1) In the House, not later than 3 legislative days
 30 after any committee has been discharged from further con-
 31 sideration of legislation under subsection (c), the Speaker
 32 shall resolve the House into the Committee of the Whole
 33 for consideration of the legislation.

34 (2) The first reading of the legislation shall be dis-
 35 pensed with. All points of order against consideration of the
 36 legislation are waived. General debate shall be confined to
 37 the legislation and shall not exceed five hours, which shall

1 be divided equally between those favoring and those oppos-
2 ing the legislation. After general debate the legislation shall
3 be considered for amendment under the five-minute rule.
4 During consideration of the legislation, no amendments
5 shall be in order in the House or in the Committee of the
6 Whole except those for which there has been an affirmative
7 certification under subsection (b)(3)(B). All points of order
8 against consideration of any such amendment in the Com-
9 mittee of the Whole are waived. The legislation, together
10 with any amendments which shall be in order, shall be con-
11 sidered as read. During the consideration of the bill for
12 amendment, the Chairman of the Committee of the Whole
13 may accord priority in recognition on the basis of whether
14 the Member offering an amendment has caused it to be
15 printed in the portion of the Congressional Record des-
16 ignated for that purpose in clause 8 of Rule XVIII of the
17 Rules of the House of Representatives. Debate on any
18 amendment shall not exceed one hour, which shall be di-
19 vided equally between those favoring and those opposing
20 the amendment, and no pro forma amendments shall be of-
21 fered during the debate. The total time for debate on all
22 amendments shall not exceed 10 hours. At the conclusion
23 of consideration of the legislation for amendment, the Com-
24 mittee shall rise and report the legislation to the House
25 with such amendments as may have been adopted. The pre-
26 vious question shall be considered as ordered on the legisla-
27 tion and amendments thereto to final passage without in-
28 tervening motion except one motion to recommit with or
29 without instructions. If the Committee of the Whole rises
30 and reports that it has come to no resolution on the bill,
31 then on the next legislative day the House shall, imme-
32 diately after the third daily order of business under clause
33 1 of Rule XIV of the Rules of the House of Representa-
34 tives, resolve into the Committee of the Whole for further
35 consideration of the bill.

36 (3) All appeals from the decisions of the Chair relating
37 to the application of the Rules of the House of Representa-

1 tives to the procedure relating to any such legislation shall
2 be decided without debate.

3 (4) Except to the extent specifically provided in the
4 preceding provisions of this subsection, consideration of any
5 such legislation and amendments thereto (or any con-
6 ference report thereon) shall be governed by the Rules of
7 the House of Representatives applicable to other bills and
8 resolutions, amendments, and conference reports in similar
9 circumstances.

10 (e) LEGISLATIVE DAY DEFINED.—As used in this section,
11 the term “legislative day” means a day on which the House of
12 Representatives is in session.

13 (f) RESTRICTION ON WAIVER.—In the House, the provi-
14 sions of this section may be waived only by a rule or order pro-
15 posing only to waive such provisions.

16 (g) RULEMAKING POWER.—The provisions of this section
17 are enacted by the Congress—

18 (1) as an exercise of the rulemaking power of the
19 House of Representatives and, as such, shall be considered
20 as part of the rules of that House and shall supersede
21 other rules only to the extent that they are inconsistent
22 therewith; and

23 (2) with full recognition of the constitutional right of
24 that House to change the rules (so far as they relate to the
25 procedures of that House) at any time, in the same man-
26 ner, and to the same extent as in the case of any other rule
27 of that House.

28 **SEC. 804. PROCEDURES IN THE SENATE.**

29 (a) INTRODUCTION AND REFERRAL OF PRESIDENT’S LEG-
30 ISLATIVE PROPOSAL.—

31 (1) INTRODUCTION.—In the case of a legislative pro-
32 posal submitted by the President pursuant to section
33 1105(h) of title 31, United States Code, within the 15-day
34 period specified in paragraph (1) of such section, the Ma-
35 jority Leader and Minority Leader of the Senate (or their
36 designees) shall introduce such proposal (by request), the
37 title of which is as follows: “A bill to respond to a medicare

1 funding warning.” Such bill shall be introduced within 3
2 days of session after Congress receives such proposal.

3 (2) REFERRAL.—Any legislation introduced pursuant
4 to paragraph (1) shall be referred to the Committee on Fi-
5 nance.

6 (b) MEDICARE FUNDING LEGISLATION.—For purposes of
7 this section, the term “medicare funding legislation” means—

8 (1) legislation introduced pursuant to subsection
9 (a)(1), but only if the legislative proposal upon which the
10 legislation is based was submitted within the 15-day period
11 referred to in such subsection; or

12 (2) any bill the title of which is as follows: “A bill to
13 respond to a medicare funding warning.”.

14 (c) QUALIFICATION FOR SPECIAL PROCEDURES.—

15 (1) IN GENERAL.—The special procedures set forth in
16 subsections (d) and (e) shall apply to medicare funding leg-
17 islation, as described in subsection (b), only if the
18 legislation—

19 (A) is medicare funding legislation that is passed
20 by the House of Representatives; or

21 (B) contains matter within the jurisdiction of the
22 Committee on Finance in the Senate.

23 (2) FAILURE TO QUALIFY FOR SPECIAL PROCE-
24 DURES.—If the medicare funding legislation does not sat-
25 isfy paragraph (1), then the legislation shall be considered
26 under the ordinary procedures of the Standing Rules of the
27 Senate.

28 (d) DISCHARGE.—

29 (1) IN GENERAL.—If the Committee on Finance has
30 not reported medicare funding legislation described in sub-
31 section (c)(1) by June 30 of a year in which the President
32 is required to submit medicare funding legislation to Con-
33 gress under section 1105(h) of title 31, United States
34 Code, then any Senator may move to discharge the Com-
35 mittee of any single medicare funding legislation measure.
36 Only one such motion shall be in order in any session of
37 Congress.

1 (2) DEBATE LIMITS.—Debate in the Senate on any
2 such motion to discharge, and all appeals in connection
3 therewith, shall be limited to not more than 2 hours. The
4 time shall be equally divided between, and controlled by,
5 the maker of the motion and the Majority Leader, or their
6 designees, except that in the event the Majority Leader is
7 in favor of such motion, the time in opposition thereto shall
8 be controlled by the Minority Leader or the Minority Leader’s
9 designee. A point of order under this subsection may
10 be made at any time. It is not in order to move to proceed
11 to another measure or matter while such motion (or the
12 motion to reconsider such motion) is pending.

13 (3) AMENDMENTS.—No amendment to the motion to
14 discharge shall be in order.

15 (4) EXCEPTION IF CERTIFIED LEGISLATION EN-
16 ACTED.—Notwithstanding paragraph (1), it shall not be in
17 order to discharge the Committee from further consider-
18 ation of medicare funding legislation pursuant to this sub-
19 section during a session of a Congress if the chairman of
20 the Committee on the Budget of the Senate certifies that
21 medicare funding legislation has been enacted that elimi-
22 nates excess general revenue medicare funding (as defined
23 in section 801(c)) for each fiscal year in the 7-fiscal-year
24 reporting period.

25 (e) CONSIDERATION.—After the date on which the Com-
26 mittee on Finance has reported medicare funding legislation
27 described in subsection (c)(1), or has been discharged (under
28 subsection (d)) from further consideration of, such legislation,
29 it is in order (even though a previous motion to the same effect
30 has been disagreed to) for any Member of the Senate to move
31 to proceed to the consideration of such legislation.

32 (f) RULES OF THE SENATE.—This section is enacted by
33 the Senate—

34 (1) as an exercise of the rulemaking power of the Sen-
35 ate and as such it is deemed a part of the rules of the Sen-
36 ate, but applicable only with respect to the procedure to be
37 followed in the Senate in the case of a bill described in this

1 paragraph, and it supersedes other rules only to the extent
2 that it is inconsistent with such rules; and

3 (2) with full recognition of the constitutional right of
4 the Senate to change the rules (so far as relating to the
5 procedure of the Senate) at any time, in the same manner,
6 and to the same extent as in the case of any other rule of
7 the Senate.

8 **Subtitle B—Income-Related Reduc-**
9 **tion in Part B Premium Subsidy**

10 **SEC. 811. INCOME-RELATED REDUCTION IN PART B PRE-**
11 **MIUM SUBSIDY.**

12 (a) IN GENERAL.—Section 1839 (42 U.S.C. 1395r), as
13 amended by section 241(c), is amended by adding at the end
14 the following:

15 “(i) REDUCTION IN PREMIUM SUBSIDY BASED ON IN-
16 COME.—

17 “(1) IN GENERAL.—In the case of an individual whose
18 modified adjusted gross income exceeds the threshold
19 amount under paragraph (2), the monthly amount of the
20 premium subsidy applicable to the premium under this sec-
21 tion for a month after December 2006 shall be reduced
22 (and the monthly premium shall be increased) by the
23 monthly adjustment amount specified in paragraph (3).

24 “(2) THRESHOLD AMOUNT.—For purposes of this sub-
25 section, the threshold amount is—

26 “(A) except as provided in subparagraph (B),
27 \$80,000, and

28 “(B) in the case of a joint return, twice the
29 amount applicable under subparagraph (A) for the cal-
30 endar year.

31 “(3) MONTHLY ADJUSTMENT AMOUNT.—

32 “(A) IN GENERAL.—Subject to subparagraph (B),
33 the monthly adjustment amount specified in this para-
34 graph for an individual for a month in a year is equal
35 to the product of the following:

36 “(i) SLIDING SCALE PERCENTAGE.—The ap-
37 plicable percentage specified in the table in sub-

1 paragraph (C) for the individual minus 25 percent-
2 age points.

3 “(ii) UNSUBSIDIZED PART B PREMIUM
4 AMOUNT.—200 percent of the monthly actuarial
5 rate for enrollees age 65 and over (as determined
6 under subsection (a)(1) for the year).

7 “(B) 5-YEAR PHASE IN.—The monthly adjustment
8 amount specified in this paragraph for an individual for
9 a month in a year before 2011 is equal to the following
10 percentage of the monthly adjustment amount specified
11 in subparagraph (A):

12 “(i) For 2007, 20 percent.

13 “(ii) For 2008, 40 percent.

14 “(iii) For 2009, 60 percent.

15 “(iv) for 2010, 80 percent.

16 “(C) APPLICABLE PERCENTAGE.—

17 “(i) IN GENERAL.—

“If the modified adjusted gross income is:	The applicable percentage is:
More than \$80,000 but not more than \$100,000	35 percent
More than \$100,000 but not more than \$150,000	50 percent
More than \$150,000 but not more than \$200,000	65 percent
More than \$200,000	80 percent.

18 “(ii) JOINT RETURNS.—In the case of a joint
19 return, clause (i) shall be applied by substituting
20 dollar amounts which are twice the dollar amounts
21 otherwise applicable under clause (i) for the cal-
22 endar year.

23 “(iii) MARRIED INDIVIDUALS FILING SEPA-
24 RATE RETURNS.—In the case of an individual
25 who—

26 “(I) is married as of the close of the tax-
27 able year (within the meaning of section 7703
28 of the Internal Revenue Code of 1986) but does
29 not file a joint return for such year, and

1 “(II) does not live apart from such indi-
 2 vidual’s spouse at all times during the taxable
 3 year,
 4 clause (i) shall be applied by reducing each of the
 5 dollar amounts otherwise applicable under such
 6 clause for the calendar year by the threshold
 7 amount for such year applicable to an unmarried
 8 individual.

9 “(4) MODIFIED ADJUSTED GROSS INCOME.—

10 “(A) IN GENERAL.—For purposes of this sub-
 11 section, the term ‘modified adjusted gross income’
 12 means adjusted gross income (as defined in section 62
 13 of the Internal Revenue Code of 1986)—

14 “(i) determined without regard to sections
 15 135, 911, 931, and 933 of such Code; and

16 “(ii) increased by the amount of interest re-
 17 ceived or accrued during the taxable year which is
 18 exempt from tax under such Code.

19 In the case of an individual filing a joint return, any
 20 reference in this subsection to the modified adjusted
 21 gross income of such individual shall be to such re-
 22 turn’s modified adjusted gross income.

23 “(B) TAXABLE YEAR TO BE USED IN DETER-
 24 MINING MODIFIED ADJUSTED GROSS INCOME.—

25 “(i) IN GENERAL.—In applying this subsection
 26 for an individual’s premiums in a month in a year,
 27 subject to clause (ii) and subparagraph (C), the in-
 28 dividual’s modified adjusted gross income shall be
 29 such income determined for the individual’s last
 30 taxable year beginning in the second calendar year
 31 preceding the year involved.

32 “(ii) TEMPORARY USE OF OTHER DATA.—If,
 33 as of October 15 before a calendar year, the Sec-
 34 retary of the Treasury does not have adequate data
 35 for an individual in appropriate electronic form for
 36 the taxable year referred to in clause (i), the indi-
 37 vidual’s modified adjusted gross income shall be de-

1 terminated using the data in such form from the pre-
2 vious taxable year. Except as provided in regula-
3 tions prescribed by the Commissioner of Social Se-
4 curity in consultation with the Secretary, the pre-
5 ceding sentence shall cease to apply when adequate
6 data in appropriate electronic form are available for
7 the individual for the taxable year referred to in
8 clause (i), and proper adjustments shall be made to
9 the extent that the premium adjustments deter-
10 mined under the preceding sentence were inconsis-
11 tent with those determined using such taxable
12 year.

13 “(iii) NON-FILERS.—In the case of individuals
14 with respect to whom the Secretary of the Treasury
15 does not have adequate data in appropriate elec-
16 tronic form for either taxable year referred to in
17 clause (i) or clause (ii), the Commissioner of Social
18 Security, in consultation with the Secretary, shall
19 prescribe regulations which provide for the treat-
20 ment of the premium adjustment with respect to
21 such individual under this subsection, including
22 regulations which provide for—

23 “(I) the application of the highest applica-
24 ble percentage under paragraph (3)(C) to such
25 individual if the Commissioner has information
26 which indicates that such individual’s modified
27 adjusted gross income might exceed the thresh-
28 old amount for the taxable year referred to in
29 clause (i), and

30 “(II) proper adjustments in the case of the
31 application of an applicable percentage under
32 subclause (I) to such individual which is inconsis-
33 tent with such individual’s modified adjusted
34 gross income for such taxable year.

35 “(C) USE OF MORE RECENT TAXABLE YEAR.—

36 “(i) IN GENERAL.—The Commissioner of So-
37 cial Security in consultation with the Secretary of

1 the Treasury shall establish a procedures under
 2 which an individual's modified adjusted gross in-
 3 come shall, at the request of such individual, be de-
 4 termined under this subsection—

5 “(I) for a more recent taxable year than
 6 the taxable year otherwise used under subpara-
 7 graph (B), or

8 “(II) by such methodology as the Commis-
 9 sioner, in consultation with such Secretary, de-
 10 termines to be appropriate, which may include
 11 a methodology for aggregating or
 12 disaggregating information from tax returns in
 13 the case of marriage or divorce.

14 “(ii) STANDARD FOR GRANTING REQUESTS.—
 15 A request under clause (i)(I) to use a more recent
 16 taxable year may be granted only if—

17 “(I) the individual furnishes to such Com-
 18 missioner with respect to such year such docu-
 19 mentation, such as a copy of a filed Federal in-
 20 come tax return or an equivalent document, as
 21 the Commissioner specifies for purposes of de-
 22 termining the premium adjustment (if any)
 23 under this subsection; and

24 “(II) the individual's modified adjusted
 25 gross income for such year is significantly less
 26 than such income for the taxable year deter-
 27 mined under subparagraph (B) by reason of
 28 the death of such individual's spouse, the mar-
 29 riage or divorce of such individual, or other
 30 major life changing events specified in regula-
 31 tions prescribed by the Commissioner in con-
 32 sultation with the Secretary.

33 “(5) INFLATION ADJUSTMENT.—

34 “(A) IN GENERAL.—In the case of any calendar
 35 year beginning after 2007, each dollar amount in para-
 36 graph (2) or (3) shall be increased by an amount equal
 37 to—

1 “(i) such dollar amount, multiplied by

2 “(ii) the percentage (if any) by which the aver-
3 age of the Consumer Price Index for all urban con-
4 sumers (United States city average) for the 12-
5 month period ending with August of the preceding
6 calendar year exceeds such average for the 12-
7 month period ending with August 2006.

8 “(B) ROUNDING.—If any dollar amount after
9 being increased under subparagraph (A) is not a mul-
10 tiple of \$1,000, such dollar amount shall be rounded to
11 the nearest multiple of \$1,000.

12 “(6) JOINT RETURN DEFINED.—For purposes of this
13 subsection, the term ‘joint return’ has the meaning given
14 to such term by section 7701(a)(38) of the Internal Rev-
15 enue Code of 1986.”.

16 (b) CONFORMING AMENDMENTS.—

17 (1) Section 1839 (42 U.S.C. 1395r) is amended—

18 (A) in subsection (a)(2), by striking “and (f)” and
19 inserting “(f), and (i)”;

20 (B) in subsection (b), inserting “(without regard
21 to any adjustment under subsection (i))” after “sub-
22 section (a)”;

23 (C) in subsection (f)—

24 (i) by striking “and if” and inserting “if”; and

25 (ii) by inserting “and if the amount of the in-
26 dividual’s premium is not adjusted for such Janu-
27 ary under subsection (i),” after “section
28 1840(b)(1),”.

29 (2) Section 1844 (42 U.S.C. 1395w) is amended—

30 (A) in subsection (a)(1)—

31 (i) in subparagraph (B), by striking “plus” at
32 the end and inserting “minus”; and

33 (ii) by adding at the end the following new
34 subparagraph:

35 “(C) the aggregate amount of additional premium pay-
36 ments attributable to the application of section 1839(i);
37 plus”; and

1 (B) in subsection (c), by inserting before the pe-
 2 riod at the end the following: “and without regard to
 3 any premium adjustment under section 1839(i)”.

4 (c) REPORTING REQUIREMENTS FOR SECRETARY OF THE
 5 TREASURY.—

6 (1) IN GENERAL.—Subsection (l) of section 6103 of
 7 the Internal Revenue Code of 1986 (relating to disclosure
 8 of returns and return information for purposes other than
 9 tax administration), as amended by section 105(e), is
 10 amended by adding at the end the following new para-
 11 graph:

12 “(20) DISCLOSURE OF RETURN INFORMATION TO
 13 CARRY OUT MEDICARE PART B PREMIUM SUBSIDY ADJUST-
 14 MENT.—

15 “(A) IN GENERAL.—The Secretary shall, upon
 16 written request from the Commissioner of Social Secu-
 17 rity, disclose to officers, employees, and contractors of
 18 the Social Security Administration return information
 19 of a taxpayer whose premium (according to the records
 20 of the Secretary) may be subject to adjustment under
 21 section 1839(i) of the Social Security Act. Such return
 22 information shall be limited to—

23 “(i) taxpayer identity information with respect
 24 to such taxpayer,

25 “(ii) the filing status of such taxpayer,

26 “(iii) the adjusted gross income of such tax-
 27 payer,

28 “(iv) the amounts excluded from such tax-
 29 payer’s gross income under sections 135 and 911
 30 to the extent such information is available,

31 “(v) the interest received or accrued during
 32 the taxable year which is exempt from the tax im-
 33 posed by chapter 1 to the extent such information
 34 is available,

35 “(vi) the amounts excluded from such tax-
 36 payer’s gross income by sections 931 and 933 to
 37 the extent such information is available,

1 “(vii) such other information relating to the li-
2 ability of the taxpayer as is prescribed by the Sec-
3 retary by regulation as might indicate in the case
4 of a taxpayer who is an individual described in sub-
5 section (i)(4)(B)(iii) of section 1839 of the Social
6 Security Act that the amount of the premium of
7 the taxpayer under such section may be subject to
8 adjustment under subsection (i) of such section and
9 the amount of such adjustment, and

10 “(viii) the taxable year with respect to which
11 the preceding information relates.

12 “(B) RESTRICTION ON USE OF DISCLOSED INFOR-
13 MATION.—Return information disclosed under subpara-
14 graph (A) may be used by officers, employees, and con-
15 tractors of the Social Security Administration only for
16 the purposes of, and to the extent necessary in, estab-
17 lishing the appropriate amount of any premium adjust-
18 ment under such section 1839(i).”

19 (2) CONFORMING AMENDMENTS.—

20 (A) Paragraph (3) of section 6103(a) of such
21 Code, as amended by section 105(e)(1), is amended by
22 striking “or (19)” and inserting “(19), or (20)”.

23 (B) Paragraph (4) of section 6103(p) of such
24 Code, as amended by section 105(e)(3), is amended by
25 striking “(l)(16), (17), or (19)” each place it appears
26 and inserting “(l)(16), (17), (19), or (20)”.

27 (C) Paragraph (2) of section 7213(a) of such
28 Code, as amended by section 105(e)(4), is amended by
29 striking “or (19)” and inserting “(19), or (20)”.

1 **TITLE IX—ADMINISTRATIVE IM-**
 2 **PROVEMENTS, REGULATORY RE-**
 3 **DUCTION, AND CONTRACTING**
 4 **REFORM**

5 **SEC. 900. ADMINISTRATIVE IMPROVEMENTS WITHIN**
 6 **THE CENTERS FOR MEDICARE & MEDICAID**
 7 **SERVICES (CMS).**

8 (a) COORDINATED ADMINISTRATION OF MEDICARE PRE-
 9 SCRIPTURE DRUG AND MEDICARE ADVANTAGE PROGRAMS.—
 10 Title XVIII (42 U.S.C. 1395 et seq.), as amended by section
 11 721, is amended by inserting after 1807 the following new sec-
 12 tion:

13 “PROVISIONS RELATING TO ADMINISTRATION

14 “SEC. 1808. (a) COORDINATED ADMINISTRATION OF
 15 MEDICARE PRESCRIPTION DRUG AND MEDICARE ADVANTAGE
 16 PROGRAMS.—

17 “(1) IN GENERAL.—There is within the Centers for
 18 Medicare & Medicaid Services a center to carry out the du-
 19 ties described in paragraph (3).

20 “(2) DIRECTOR.—Such center shall be headed by a di-
 21 rector who shall report directly to the Administrator of the
 22 Centers for Medicare & Medicaid Services.

23 “(3) DUTIES.—The duties described in this paragraph
 24 are the following:

25 “(A) The administration of parts C and D.

26 “(B) The provision of notice and information
 27 under section 1804.

28 “(C) Such other duties as the Secretary may
 29 specify.

30 “(4) DEADLINE.—The Secretary shall ensure that the
 31 center is carrying out the duties described in paragraph (3)
 32 by not later than January 1, 2008.”.

33 (b) MANAGEMENT STAFF FOR THE CENTERS FOR MEDI-
 34 CARE & MEDICAID SERVICES.—Such section is further amend-
 35 ed by adding at the end the following new subsection:

36 “(b) EMPLOYMENT OF MANAGEMENT STAFF.—

1 “(1) IN GENERAL.—The Secretary may employ, within
2 the Centers for Medicare & Medicaid Services, such individ-
3 uals as management staff as the Secretary determines to
4 be appropriate. With respect to the administration of parts
5 C and D, such individuals shall include individuals with pri-
6 vate sector expertise in negotiations with health benefits
7 plans.

8 “(2) ELIGIBILITY.—To be eligible for employment
9 under paragraph (1) an individual shall be required to have
10 demonstrated, by their education and experience (either in
11 the public or private sector), superior expertise in at least
12 one of the following areas:

13 “(A) The review, negotiation, and administration of
14 health care contracts.

15 “(B) The design of health care benefit plans.

16 “(C) Actuarial sciences.

17 “(D) Compliance with health plan contracts.

18 “(E) Consumer education and decision making.

19 “(F) Any other area specified by the Secretary that
20 requires specialized management or other expertise.

21 “(3) RATES OF PAYMENT.—

22 “(A) PERFORMANCE-RELATED PAY.—Subject to
23 subparagraph (B), the Secretary shall establish the
24 rate of pay for an individual employed under paragraph
25 (1). Such rate shall take into account expertise, experi-
26 ence, and performance.

27 “(B) LIMITATION.—In no case may the rate of
28 compensation determined under subparagraph (A) ex-
29 ceed the highest rate of basic pay for the Senior Execu-
30 tive Service under section 5382(b) of title 5, United
31 States Code.”.

32 (c) REQUIREMENT FOR DEDICATED ACTUARY FOR PRI-
33 VATE HEALTH PLANS.—Section 1117(b) (42 U.S.C. 1317(b))
34 is amended by adding at the end the following new paragraph:

35 “(3) In the office of the Chief Actuary there shall be an
36 actuary whose duties relate exclusively to the programs under

1 parts C and D of title XVIII and related provisions of such
2 title.”.

3 (d) INCREASE IN GRADE TO EXECUTIVE LEVEL III FOR
4 THE ADMINISTRATOR OF THE CENTERS FOR MEDICARE &
5 MEDICAID SERVICES.—

6 (1) IN GENERAL.—Section 5314 of title 5, United
7 States Code, is amended by adding at the end the fol-
8 lowing:

9 “Administrator of the Centers for Medicare & Med-
10 icaid Services.”.

11 (2) CONFORMING AMENDMENT.—Section 5315 of such
12 title is amended by striking “Administrator of the Health
13 Care Financing Administration.”.

14 (3) EFFECTIVE DATE.—The amendments made by
15 this subsection take effect on January 1, 2004.

16 (e) CONFORMING AMENDMENTS RELATING TO HEALTH
17 CARE FINANCING ADMINISTRATION.—

18 (1) AMENDMENTS TO THE SOCIAL SECURITY ACT.—
19 The Social Security Act is amended—

20 (A) in section 1117 (42 U.S.C. 1317)—

21 (i) in the heading to read as follows:

22 “APPOINTMENT OF THE ADMINISTRATOR AND CHIEF ACTUARY
23 OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES”;

24 (ii) in subsection (a), by striking “Health Care
25 Financing Administration” and inserting “Centers
26 for Medicare & Medicaid Services”; and

27 (iii) in subsection (b)(1)—

28 (I) by striking “Health Care Financing
29 Administration” and inserting “Centers for
30 Medicare & Medicaid Services”; and

31 (II) by striking “Administration” and in-
32 serting “Centers”;

33 (B) in section 1140(a) (42 U.S.C. 1320b–10(a))—

34 (i) in paragraph (1), by striking “Health Care
35 Financing Administration” both places it appears
36 in the matter following subparagraph (B) and in-

1 serting “Centers for Medicare & Medicaid Serv-
2 ices”;

3 (ii) in paragraph (1)(A)—

4 (I) by striking “Health Care Financing
5 Administration” and inserting “Centers for
6 Medicare & Medicaid Services”; and

7 (II) by striking “HCFA” and inserting
8 “CMS”; and

9 (iii) in paragraph (1)(B), by striking “Health
10 Care Financing Administration” both places it ap-
11 pears and inserting “Centers for Medicare & Med-
12 icaid Services”;

13 (C) in section 1142(b)(3) (42 U.S.C. 1320b-
14 12(b)(3)), by striking “Health Care Financing Admin-
15 istration” and inserting “Centers for Medicare & Med-
16 icaid Services”;

17 (D) in section 1817(b) (42 U.S.C. 1395i(b))—

18 (i) by striking “Health Care Financing Ad-
19 ministration”, both in the fifth sentence of the
20 matter preceding paragraph (1) and in the second
21 sentence of the matter following paragraph (4), and
22 inserting “Centers for Medicare & Medicaid Serv-
23 ices”; and

24 (ii) by striking “Chief Actuarial Officer” in
25 the second sentence of the matter following para-
26 graph (4) and inserting “Chief Actuary”;

27 (E) in section 1841(b) (42 U.S.C. 1395t(b))—

28 (i) by striking “Health Care Financing Ad-
29 ministration”, both in the fifth sentence of the
30 matter preceding paragraph (1) and in the second
31 sentence of the matter following paragraph (4), and
32 inserting “Centers for Medicare & Medicaid Serv-
33 ices”; and

34 (ii) by striking “Chief Actuarial Officer” in
35 the second sentence of the matter following para-
36 graph (4) and inserting “Chief Actuary”;

1 (F) in section 1852(a)(5) (42 U.S.C. 1395w-
 2 22(a)(5)), by striking “Health Care Financing Admin-
 3 stration” in the matter following subparagraph (B)
 4 and inserting “Centers for Medicare & Medicaid Serv-
 5 ices”;

6 (G) in section 1853 (42 U.S.C. 1395w-23)—

7 (i) in subsection (b)(4), by striking “Health
 8 Care Financing Administration” in the first sen-
 9 tence and inserting “Centers for Medicare & Med-
 10 icaid Services”; and

11 (ii) in subsection (c)(7), by striking “Health
 12 Care Financing Administration” in the last sen-
 13 tence and inserting “Centers for Medicare & Med-
 14 icaid Services”;

15 (H) in section 1854(a)(5)(A) (42 U.S.C. 1395w-
 16 24(a)(5)(A)), by striking “Health Care Financing
 17 Administration” and inserting “Centers for Medicare &
 18 Medicaid Services”;

19 (I) in section 1857(d)(4)(A)(ii) (42 U.S.C.
 20 1395w-27(d)(4)(A)(ii)), by striking “Health Care Fi-
 21 nancing Administration” and inserting “Secretary”;

22 (J) in section 1862(b)(5)(A)(ii) (42 U.S.C.
 23 1395y(b)(5)(A)(ii)), by striking “Health Care Financ-
 24 ing Administration” and inserting “Centers for Medi-
 25 care & Medicaid Services”;

26 (K) in section 1927(e)(4) (42 U.S.C. 1396r-
 27 8(e)(4)), by striking “HCFA” and inserting “The Sec-
 28 retary”;

29 (L) in section 1927(f)(2) (42 U.S.C. 1396r-
 30 8(f)(2)), by striking “HCFA” and inserting “The Sec-
 31 retary”; and

32 (M) in section 2104(g)(3) (42 U.S.C.
 33 1397dd(g)(3)) by inserting “or CMS Form 64 or CMS
 34 Form 21, as the case may be,” after “HCFA Form 64
 35 or HCFA Form 21”.

36 (2) AMENDMENTS TO THE PUBLIC HEALTH SERVICE
 37 ACT.—The Public Health Service Act is amended—

1 (A) in section 501(d)(18) (42 U.S.C.
2 290aa(d)(18)), by striking “Health Care Financing Ad-
3 ministration” and inserting “Centers for Medicare &
4 Medicaid Services”;

5 (B) in section 507(b)(6) (42 U.S.C. 290bb(b)(6)),
6 by striking “Health Care Financing Administration”
7 and inserting “Centers for Medicare & Medicaid Serv-
8 ices”;

9 (C) in section 916 (42 U.S.C. 299b-5)—

10 (i) in subsection (b)(2), by striking “Health
11 Care Financing Administration” and inserting
12 “Centers for Medicare & Medicaid Services”; and

13 (ii) in subsection (c)(2), by striking “Health
14 Care Financing Administration” and inserting
15 “Centers for Medicare & Medicaid Services”;

16 (D) in section 921(c)(3)(A) (42 U.S.C.
17 299c(c)(3)(A)), by striking “Health Care Financing
18 Administration” and inserting “Centers for Medicare &
19 Medicaid Services”;

20 (E) in section 1318(a)(2) (42 U.S.C. 300e-
21 17(a)(2)), by striking “Health Care Financing Admin-
22 istration” and inserting “Centers for Medicare & Med-
23 icaid Services”;

24 (F) in section 2102(a)(7) (42 U.S.C. 300aa-
25 2(a)(7)), by striking “Health Care Financing Adminis-
26 tration” and inserting “Centers for Medicare & Med-
27 icaid Services”; and

28 (G) in section 2675(a) (42 U.S.C. 300ff-75(a)),
29 by striking “Health Care Financing Administration” in
30 the first sentence and inserting “Centers for Medicare
31 & Medicaid Services”.

32 (3) AMENDMENTS TO THE INTERNAL REVENUE CODE
33 OF 1986.—Section 6103(l)(12) of the Internal Revenue
34 Code of 1986 is amended—

35 (A) in subparagraph (B), by striking “Health
36 Care Financing Administration” in the matter pre-

1 ceding clause (i) and inserting “Centers for Medicare
2 & Medicaid Services”; and

3 (B) in subparagraph (C)—

4 (i) by striking “HEALTH CARE FINANCING AD-
5 MINISTRATION” in the heading and inserting “CEN-
6 TERS FOR MEDICARE & MEDICAID SERVICES”; and

7 (ii) by striking “Health Care Financing Ad-
8 ministration” in the matter preceding clause (i)
9 and inserting “Centers for Medicare & Medicaid
10 Services”.

11 (4) AMENDMENTS TO TITLE 10, UNITED STATES
12 CODE.—Title 10, United States Code, is amended—

13 (A) in section 1086(d)(4), by striking “adminis-
14 trator of the Health Care Financing Administration” in
15 the last sentence and inserting “Administrator of the
16 Centers for Medicare & Medicaid Services”; and

17 (B) in section 1095(k)(2), by striking “Health
18 Care Financing Administration” in the second sentence
19 and inserting “Centers for Medicare & Medicaid Ser-
20 vices”.

21 (5) AMENDMENTS TO THE ALZHEIMER’S DISEASE AND
22 RELATED DEMENTIAS SERVICES RESEARCH ACT OF 1992.—
23 The Alzheimer’s Disease and Related Dementias Research
24 Act of 1992 (42 U.S.C. 11271 et seq.) is amended—

25 (A) in the heading of subpart 3 of part D to read
26 as follows:

27 “Subpart 3—Responsibilities of the Centers for Medicare &
28 Medicaid Services”;

29 (B) in section 937 (42 U.S.C. 11271)—

30 (i) in subsection (a), by striking “National
31 Health Care Financing Administration” and insert-
32 ing “Centers for Medicare & Medicaid Services”;

33 (ii) in subsection (b)(1), by striking “Health
34 Care Financing Administration” and inserting
35 “Centers for Medicare & Medicaid Services”;

1 (iii) in subsection (b)(2), by striking “Health
2 Care Financing Administration” and inserting
3 “Centers for Medicare & Medicaid Services”; and

4 (iv) in subsection (c), by striking “Health
5 Care Financing Administration” and inserting
6 “Centers for Medicare & Medicaid Services”; and

7 (C) in section 938 (42 U.S.C. 11272), by striking
8 “Health Care Financing Administration” and inserting
9 “Centers for Medicare & Medicaid Services”.

10 (6) MISCELLANEOUS AMENDMENTS.—

11 (A) REHABILITATION ACT OF 1973.—Section
12 202(b)(8) of the Rehabilitation Act of 1973 (29 U.S.C.
13 762(b)(8)) is amended by striking “Health Care Fi-
14 nancing Administration” and inserting “Centers for
15 Medicare & Medicaid Services”.

16 (B) INDIAN HEALTH CARE IMPROVEMENT ACT.—
17 Section 405(d)(1) of the Indian Health Care Improve-
18 ment Act (25 U.S.C. 1645(d)(1)) is amended by strik-
19 ing “Health Care Financing Administration” in the
20 matter preceding subparagraph (A) and inserting
21 “Centers for Medicare & Medicaid Services”.

22 (C) INDIVIDUALS WITH DISABILITIES EDUCATION
23 ACT.—Section 644(b)(5) of the Individuals with Dis-
24 abilities Education Act (20 U.S.C. 1444(b)(5)) is
25 amended by striking “Health Care Financing Adminis-
26 tration” and inserting “Centers for Medicare & Med-
27 icaid Services”.

28 (D) THE HOME HEALTH CARE AND ALZHEIMER’S
29 DISEASE AMENDMENTS OF 1990.—Section 302(a)(9) of
30 the Home Health Care and Alzheimer’s Disease
31 Amendments of 1990 (42 U.S.C. 242q–1(a)(9)) is
32 amended by striking “Health Care Financing Adminis-
33 tration” and inserting “Centers for Medicare & Med-
34 icaid Services”.

35 (E) THE CHILDREN’S HEALTH ACT OF 2000.—Sec-
36 tion 2503(a) of the Children’s Health Act of 2000 (42
37 U.S.C. 247b–3a(a)) is amended by striking “Health

1 Care Financing Administration” and inserting “Cen-
2 ters for Medicare & Medicaid Services”.

3 (F) THE NATIONAL INSTITUTES OF HEALTH REVI-
4 TALIZATION ACT OF 1993.—Section 1909 of the Na-
5 tional Institutes of Health Revitalization Act of 1993
6 (42 U.S.C. 299a note) is amended by striking “Health
7 Care Financing Administration” and inserting “Cen-
8 ters for Medicare & Medicaid Services”.

9 (G) THE OMNIBUS BUDGET RECONCILIATION ACT
10 OF 1990.—Section 4359(d) of the Omnibus Budget
11 Reconciliation Act of 1990 (42 U.S.C. 1395b–3(d)) is
12 amended by striking “Health Care Financing Adminis-
13 tration” and inserting “Centers for Medicare & Med-
14 icaid Services”.

15 (H) THE MEDICARE, MEDICAID, AND SCHIP BENE-
16 FITS IMPROVEMENT AND PROTECTION ACT OF 2000.—
17 Section 104(d)(4) of the Medicare, Medicaid, and
18 SCHIP Benefits Improvement and Protection Act of
19 2000 (42 U.S.C. 1395m note) is amended by striking
20 “Health Care Financing Administration” and inserting
21 “Health Care”.

22 (7) ADDITIONAL AMENDMENT.—Section 403 of the
23 Act entitled, “An Act to authorize certain appropriations
24 for the territories of the United States, to amend certain
25 Acts relating thereto, and for other purposes”, enacted Oc-
26 tober 15, 1977 (48 U.S.C. 1574–1; 48 U.S.C. 1421q–1),
27 is amended by striking “Health Care Financing Adminis-
28 tration” and inserting “Centers for Medicare & Medicaid
29 Services”.

30 **Subtitle A—Regulatory Reform**

31 **SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.**

32 (a) CONSTRUCTION.—Nothing in this title shall be
33 construed—

34 (1) to compromise or affect existing legal remedies for
35 addressing fraud or abuse, whether it be criminal prosecu-
36 tion, civil enforcement, or administrative remedies, includ-

1 ing under sections 3729 through 3733 of title 31, United
 2 States Code (commonly known as the “False Claims Act”);
 3 or

4 (2) to prevent or impede the Department of Health
 5 and Human Services in any way from its ongoing efforts
 6 to eliminate waste, fraud, and abuse in the medicare pro-
 7 gram.

8 Furthermore, the consolidation of medicare administrative con-
 9 tracting set forth in this division does not constitute consolida-
 10 tion of the Federal Hospital Insurance Trust Fund and the
 11 Federal Supplementary Medical Insurance Trust Fund or re-
 12 flect any position on that issue.

13 (b) DEFINITION OF SUPPLIER.—Section 1861 (42 U.S.C.
 14 1395x) is amended by inserting after subsection (c) the fol-
 15 lowing new subsection:

16 “Supplier

17 “(d) The term ‘supplier’ means, unless the context other-
 18 wise requires, a physician or other practitioner, a facility, or
 19 other entity (other than a provider of services) that furnishes
 20 items or services under this title.”.

21 **SEC. 902. ISSUANCE OF REGULATIONS.**

22 (a) REGULAR TIMELINE FOR PUBLICATION OF FINAL
 23 RULES.—

24 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
 25 1395hh(a)) is amended by adding at the end the following
 26 new paragraph:

27 “(3)(A) The Secretary, in consultation with the Director
 28 of the Office of Management and Budget, shall establish and
 29 publish a regular timeline for the publication of final regula-
 30 tions based on the previous publication of a proposed regulation
 31 or an interim final regulation.

32 “(B) Such timeline may vary among different regulations
 33 based on differences in the complexity of the regulation, the
 34 number and scope of comments received, and other relevant
 35 factors, but shall not be longer than 3 years except under ex-
 36 ceptional circumstances. If the Secretary intends to vary such
 37 timeline with respect to the publication of a final regulation,

1 the Secretary shall cause to have published in the Federal Reg-
2 ister notice of the different timeline by not later than the
3 timeline previously established with respect to such regulation.
4 Such notice shall include a brief explanation of the justification
5 for such variation.

6 “(C) In the case of interim final regulations, upon the ex-
7 piration of the regular timeline established under this para-
8 graph for the publication of a final regulation after opportunity
9 for public comment, the interim final regulation shall not con-
10 tinue in effect unless the Secretary publishes (at the end of the
11 regular timeline and, if applicable, at the end of each suc-
12 ceeding 1-year period) a notice of continuation of the regulation
13 that includes an explanation of why the regular timeline (and
14 any subsequent 1-year extension) was not complied with. If
15 such a notice is published, the regular timeline (or such
16 timeline as previously extended under this paragraph) for publi-
17 cation of the final regulation shall be treated as having been
18 extended for 1 additional year.

19 “(D) The Secretary shall annually submit to Congress a
20 report that describes the instances in which the Secretary failed
21 to publish a final regulation within the applicable regular
22 timeline under this paragraph and that provides an explanation
23 for such failures.”.

24 (2) EFFECTIVE DATE.—The amendment made by
25 paragraph (1) shall take effect on the date of the enact-
26 ment of this Act. The Secretary shall provide for an appro-
27 priate transition to take into account the backlog of pre-
28 viously published interim final regulations.

29 (b) LIMITATIONS ON NEW MATTER IN FINAL REGULA-
30 TIONS.—

31 (1) IN GENERAL.—Section 1871(a) (42 U.S.C.
32 1395hh(a)), as amended by subsection (a), is amended by
33 adding at the end the following new paragraph:

34 “(4) If the Secretary publishes a final regulation that in-
35 cludes a provision that is not a logical outgrowth of a pre-
36 viously published notice of proposed rulemaking or interim final
37 rule, such provision shall be treated as a proposed regulation

1 and shall not take effect until there is the further opportunity
 2 for public comment and a publication of the provision again as
 3 a final regulation.”.

4 (2) EFFECTIVE DATE.—The amendment made by
 5 paragraph (1) shall apply to final regulations published on
 6 or after the date of the enactment of this Act.

7 **SEC. 903. COMPLIANCE WITH CHANGES IN REGULA-**
 8 **TIONS AND POLICIES.**

9 (a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE
 10 CHANGES.—

11 (1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh),
 12 as amended by section 902(a), is amended by adding at the
 13 end the following new subsection:

14 “(e)(1)(A) A substantive change in regulations, manual in-
 15 structions, interpretative rules, statements of policy, or guide-
 16 lines of general applicability under this title shall not be applied
 17 (by extrapolation or otherwise) retroactively to items and serv-
 18 ices furnished before the effective date of the change, unless
 19 the Secretary determines that—

20 “(i) such retroactive application is necessary to comply
 21 with statutory requirements; or

22 “(ii) failure to apply the change retroactively would be
 23 contrary to the public interest.”.

24 (2) EFFECTIVE DATE.—The amendment made by
 25 paragraph (1) shall apply to substantive changes issued on
 26 or after the date of the enactment of this Act.

27 (b) TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE
 28 CHANGES AFTER NOTICE.—

29 (1) IN GENERAL.—Section 1871(e)(1), as added by
 30 subsection (a), is amended by adding at the end the fol-
 31 lowing:

32 “(B)(i) Except as provided in clause (ii), a substantive
 33 change referred to in subparagraph (A) shall not become effec-
 34 tive before the end of the 30-day period that begins on the date
 35 that the Secretary has issued or published, as the case may be,
 36 the substantive change.

1 “(ii) The Secretary may provide for such a substantive
2 change to take effect on a date that precedes the end of the
3 30-day period under clause (i) if the Secretary finds that waiv-
4 er of such 30-day period is necessary to comply with statutory
5 requirements or that the application of such 30-day period is
6 contrary to the public interest. If the Secretary provides for an
7 earlier effective date pursuant to this clause, the Secretary
8 shall include in the issuance or publication of the substantive
9 change a finding described in the first sentence, and a brief
10 statement of the reasons for such finding.

11 “(C) No action shall be taken against a provider of serv-
12 ices or supplier with respect to noncompliance with such a sub-
13 stantive change for items and services furnished before the ef-
14 fective date of such a change.”.

15 (2) EFFECTIVE DATE.—The amendment made by
16 paragraph (1) shall apply to compliance actions undertaken
17 on or after the date of the enactment of this Act.

18 (c) RELIANCE ON GUIDANCE.—

19 (1) IN GENERAL.—Section 1871(e), as added by sub-
20 section (a), is further amended by adding at the end the
21 following new paragraph:

22 “(2)(A) If—

23 “(i) a provider of services or supplier follows the writ-
24 ten guidance (which may be transmitted electronically) pro-
25 vided by the Secretary or by a medicare contractor (as de-
26 fined in section 1889(g)) acting within the scope of the
27 contractor’s contract authority, with respect to the fur-
28 nishing of items or services and submission of a claim for
29 benefits for such items or services with respect to such pro-
30 vider or supplier;

31 “(ii) the Secretary determines that the provider of
32 services or supplier has accurately presented the cir-
33 cumstances relating to such items, services, and claim to
34 the contractor in writing; and

35 “(iii) the guidance was in error;

36 the provider of services or supplier shall not be subject to any
37 penalty or interest under this title or the provisions of title XI

1 insofar as they relate to this title (including interest under a
2 repayment plan under section 1893 or otherwise) relating to
3 the provision of such items or service or such claim if the pro-
4 vider of services or supplier reasonably relied on such guidance.

5 “(B) Subparagraph (A) shall not be construed as pre-
6 venting the recoupment or repayment (without any additional
7 penalty) relating to an overpayment insofar as the overpayment
8 was solely the result of a clerical or technical operational
9 error.”.

10 (2) EFFECTIVE DATE.—The amendment made by
11 paragraph (1) shall take effect on the date of the enact-
12 ment of this Act and shall only apply to a penalty or inter-
13 est imposed with respect to guidance provided on or after
14 July 24, 2003.

15 **SEC. 904. REPORTS AND STUDIES RELATING TO REGU-**
16 **LATORY REFORM.**

17 (a) GAO STUDY ON ADVISORY OPINION AUTHORITY.—

18 (1) STUDY.—The Comptroller General of the United
19 States shall conduct a study to determine the feasibility
20 and appropriateness of establishing in the Secretary au-
21 thority to provide legally binding advisory opinions on ap-
22 propriate interpretation and application of regulations to
23 carry out the medicare program under title XVIII of the
24 Social Security Act. Such study shall examine the appro-
25 priate timeframe for issuing such advisory opinions, as well
26 as the need for additional staff and funding to provide such
27 opinions.

28 (2) REPORT.—The Comptroller General shall submit
29 to Congress a report on the study conducted under para-
30 graph (1) by not later than 1 year after the date of the
31 enactment of this Act.

32 (b) REPORT ON LEGAL AND REGULATORY INCONSIST-
33 ENCIES.—Section 1871 (42 U.S.C. 1395hh), as amended by
34 section 903(a)(1), is amended by adding at the end the fol-
35 lowing new subsection:

36 “(f)(1) Not later than 2 years after the date of the enact-
37 ment of this subsection, and every 3 years thereafter, the Sec-

1 retary shall submit to Congress a report with respect to the ad-
 2 ministration of this title and areas of inconsistency or conflict
 3 among the various provisions under law and regulation.

4 “(2) In preparing a report under paragraph (1), the Sec-
 5 retary shall collect—

6 “(A) information from individuals entitled to benefits
 7 under part A or enrolled under part B, or both, providers
 8 of services, and suppliers and from the Medicare Bene-
 9 ficiary Ombudsman with respect to such areas of inconsis-
 10 tency and conflict; and

11 “(B) information from medicare contractors that
 12 tracks the nature of written and telephone inquiries.

13 “(3) A report under paragraph (1) shall include a descrip-
 14 tion of efforts by the Secretary to reduce such inconsistency or
 15 conflicts, and recommendations for legislation or administrative
 16 action that the Secretary determines appropriate to further re-
 17 duce such inconsistency or conflicts.”.

18 **Subtitle B—Contracting Reform**

19 **SEC. 911. INCREASED FLEXIBILITY IN MEDICARE AD-** 20 **MINISTRATION.**

21 (a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE AD-
 22 MINISTRATION.—

23 (1) IN GENERAL.—Title XVIII is amended by insert-
 24 ing after section 1874 the following new section:

25 “CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

26 “SEC. 1874A. (a) AUTHORITY.—

27 “(1) AUTHORITY TO ENTER INTO CONTRACTS.—The
 28 Secretary may enter into contracts with any eligible entity
 29 to serve as a medicare administrative contractor with re-
 30 spect to the performance of any or all of the functions de-
 31 scribed in paragraph (4) or parts of those functions (or, to
 32 the extent provided in a contract, to secure performance
 33 thereof by other entities).

34 “(2) ELIGIBILITY OF ENTITIES.—An entity is eligible
 35 to enter into a contract with respect to the performance of
 36 a particular function described in paragraph (4) only if—

1 “(A) the entity has demonstrated capability to
2 carry out such function;

3 “(B) the entity complies with such conflict of in-
4 terest standards as are generally applicable to Federal
5 acquisition and procurement;

6 “(C) the entity has sufficient assets to financially
7 support the performance of such function; and

8 “(D) the entity meets such other requirements as
9 the Secretary may impose.

10 “(3) MEDICARE ADMINISTRATIVE CONTRACTOR DE-
11 FINED.—For purposes of this title and title XI—

12 “(A) IN GENERAL.—The term ‘medicare adminis-
13 trative contractor’ means an agency, organization, or
14 other person with a contract under this section.

15 “(B) APPROPRIATE MEDICARE ADMINISTRATIVE
16 CONTRACTOR.—With respect to the performance of a
17 particular function in relation to an individual entitled
18 to benefits under part A or enrolled under part B, or
19 both, a specific provider of services or supplier (or class
20 of such providers of services or suppliers), the ‘appro-
21 priate’ medicare administrative contractor is the medi-
22 care administrative contractor that has a contract
23 under this section with respect to the performance of
24 that function in relation to that individual, provider of
25 services or supplier or class of provider of services or
26 supplier.

27 “(4) FUNCTIONS DESCRIBED.—The functions referred
28 to in paragraphs (1) and (2) are payment functions (in-
29 cluding the function of developing local coverage determina-
30 tions, as defined in section 1869(f)(2)(B)), provider serv-
31 ices functions, and functions relating to services furnished
32 to individuals entitled to benefits under part A or enrolled
33 under part B, or both, as follows:

34 “(A) DETERMINATION OF PAYMENT AMOUNTS.—
35 Determining (subject to the provisions of section 1878
36 and to such review by the Secretary as may be provided
37 for by the contracts) the amount of the payments re-

1 quired pursuant to this title to be made to providers of
2 services, suppliers and individuals.

3 “(B) MAKING PAYMENTS.—Making payments de-
4 scribed in subparagraph (A) (including receipt, dis-
5 bursement, and accounting for funds in making such
6 payments).

7 “(C) BENEFICIARY EDUCATION AND ASSIST-
8 ANCE.—Providing education and outreach to individ-
9 uals entitled to benefits under part A or enrolled under
10 part B, or both, and providing assistance to those indi-
11 viduals with specific issues, concerns, or problems.

12 “(D) PROVIDER CONSULTATIVE SERVICES.—Pro-
13 viding consultative services to institutions, agencies,
14 and other persons to enable them to establish and
15 maintain fiscal records necessary for purposes of this
16 title and otherwise to qualify as providers of services or
17 suppliers.

18 “(E) COMMUNICATION WITH PROVIDERS.—Com-
19 municating to providers of services and suppliers any
20 information or instructions furnished to the medicare
21 administrative contractor by the Secretary, and facili-
22 tating communication between such providers and sup-
23 pliers and the Secretary.

24 “(F) PROVIDER EDUCATION AND TECHNICAL AS-
25 SISTANCE.—Performing the functions relating to pro-
26 vider education, training, and technical assistance.

27 “(G) ADDITIONAL FUNCTIONS.—Performing such
28 other functions, including (subject to paragraph (5))
29 functions under the Medicare Integrity Program under
30 section 1893, as are necessary to carry out the pur-
31 poses of this title.

32 “(5) RELATIONSHIP TO MIP CONTRACTS.—

33 “(A) NONDUPLICATION OF DUTIES.—In entering
34 into contracts under this section, the Secretary shall
35 assure that functions of medicare administrative con-
36 tractors in carrying out activities under parts A and B
37 do not duplicate activities carried out under a contract

1 entered into under the Medicare Integrity Program
2 under section 1893. The previous sentence shall not
3 apply with respect to the activity described in section
4 1893(b)(5) (relating to prior authorization of certain
5 items of durable medical equipment under section
6 1834(a)(15)).

7 “(B) CONSTRUCTION.—An entity shall not be
8 treated as a medicare administrative contractor merely
9 by reason of having entered into a contract with the
10 Secretary under section 1893.

11 “(6) APPLICATION OF FEDERAL ACQUISITION REGULA-
12 TION.—Except to the extent inconsistent with a specific re-
13 quirement of this section, the Federal Acquisition Regula-
14 tion applies to contracts under this section.

15 “(b) CONTRACTING REQUIREMENTS.—

16 “(1) USE OF COMPETITIVE PROCEDURES.—

17 “(A) IN GENERAL.—Except as provided in laws
18 with general applicability to Federal acquisition and
19 procurement or in subparagraph (B), the Secretary
20 shall use competitive procedures when entering into
21 contracts with medicare administrative contractors
22 under this section, taking into account performance
23 quality as well as price and other factors.

24 “(B) RENEWAL OF CONTRACTS.—The Secretary
25 may renew a contract with a medicare administrative
26 contractor under this section from term to term with-
27 out regard to section 5 of title 41, United States Code,
28 or any other provision of law requiring competition, if
29 the medicare administrative contractor has met or ex-
30 ceeded the performance requirements applicable with
31 respect to the contract and contractor, except that the
32 Secretary shall provide for the application of competi-
33 tive procedures under such a contract not less fre-
34 quently than once every 5 years.

35 “(C) TRANSFER OF FUNCTIONS.—The Secretary
36 may transfer functions among medicare administrative
37 contractors consistent with the provisions of this para-

1 graph. The Secretary shall ensure that performance
2 quality is considered in such transfers. The Secretary
3 shall provide public notice (whether in the Federal Reg-
4 ister or otherwise) of any such transfer (including a de-
5 scription of the functions so transferred, a description
6 of the providers of services and suppliers affected by
7 such transfer, and contact information for the contrac-
8 tors involved).

9 “(D) INCENTIVES FOR QUALITY.—The Secretary
10 shall provide incentives for medicare administrative
11 contractors to provide quality service and to promote
12 efficiency.

13 “(2) COMPLIANCE WITH REQUIREMENTS.—No con-
14 tract under this section shall be entered into with any
15 medicare administrative contractor unless the Secretary
16 finds that such medicare administrative contractor will per-
17 form its obligations under the contract efficiently and effec-
18 tively and will meet such requirements as to financial re-
19 sponsibility, legal authority, quality of services provided,
20 and other matters as the Secretary finds pertinent.

21 “(3) PERFORMANCE REQUIREMENTS.—

22 “(A) DEVELOPMENT OF SPECIFIC PERFORMANCE
23 REQUIREMENTS.—

24 “(i) IN GENERAL.—The Secretary shall de-
25 velop contract performance requirements to carry
26 out the specific requirements applicable under this
27 title to a function described in subsection (a)(4)
28 and shall develop standards for measuring the ex-
29 tent to which a contractor has met such require-
30 ments.

31 “(ii) CONSULTATION.—In developing such per-
32 formance requirements and standards for measure-
33 ment, the Secretary shall consult with providers of
34 services, organizations representative of bene-
35 ficiaries under this title, and organizations and
36 agencies performing functions necessary to carry

1 out the purposes of this section with respect to
2 such performance requirements.

3 “(iii) PUBLICATION OF STANDARDS.—The
4 Secretary shall make such performance require-
5 ments and measurement standards available to the
6 public.

7 “(B) CONSIDERATIONS.—The Secretary shall in-
8 clude, as one of the standards developed under sub-
9 paragraph (A), provider and beneficiary satisfaction
10 levels.

11 “(C) INCLUSION IN CONTRACTS.—All contractor
12 performance requirements shall be set forth in the con-
13 tract between the Secretary and the appropriate medi-
14 care administrative contractor. Such performance
15 requirements—

16 “(i) shall reflect the performance requirements
17 published under subparagraph (A), but may include
18 additional performance requirements;

19 “(ii) shall be used for evaluating contractor
20 performance under the contract; and

21 “(iii) shall be consistent with the written state-
22 ment of work provided under the contract.

23 “(4) INFORMATION REQUIREMENTS.—The Secretary
24 shall not enter into a contract with a medicare administra-
25 tive contractor under this section unless the contractor
26 agrees—

27 “(A) to furnish to the Secretary such timely infor-
28 mation and reports as the Secretary may find nec-
29 essary in performing his functions under this title; and

30 “(B) to maintain such records and afford such ac-
31 cess thereto as the Secretary finds necessary to assure
32 the correctness and verification of the information and
33 reports under subparagraph (A) and otherwise to carry
34 out the purposes of this title.

35 “(5) SURETY BOND.—A contract with a medicare ad-
36 ministrative contractor under this section may require the
37 medicare administrative contractor, and any of its officers

1 or employees certifying payments or disbursing funds pur-
2 suant to the contract, or otherwise participating in carrying
3 out the contract, to give surety bond to the United States
4 in such amount as the Secretary may deem appropriate.

5 “(c) TERMS AND CONDITIONS.—

6 “(1) IN GENERAL.—A contract with any medicare ad-
7 ministrative contractor under this section may contain such
8 terms and conditions as the Secretary finds necessary or
9 appropriate and may provide for advances of funds to the
10 medicare administrative contractor for the making of pay-
11 ments by it under subsection (a)(4)(B).

12 “(2) PROHIBITION ON MANDATES FOR CERTAIN DATA
13 COLLECTION.—The Secretary may not require, as a condi-
14 tion of entering into, or renewing, a contract under this
15 section, that the medicare administrative contractor match
16 data obtained other than in its activities under this title
17 with data used in the administration of this title for pur-
18 poses of identifying situations in which the provisions of
19 section 1862(b) may apply.

20 “(d) LIMITATION ON LIABILITY OF MEDICARE ADMINIS-
21 TRATIVE CONTRACTORS AND CERTAIN OFFICERS.—

22 “(1) CERTIFYING OFFICER.—No individual designated
23 pursuant to a contract under this section as a certifying of-
24 ficer shall, in the absence of the reckless disregard of the
25 individual’s obligations or the intent by that individual to
26 defraud the United States, be liable with respect to any
27 payments certified by the individual under this section.

28 “(2) DISBURSING OFFICER.—No disbursing officer
29 shall, in the absence of the reckless disregard of the offi-
30 cer’s obligations or the intent by that officer to defraud the
31 United States, be liable with respect to any payment by
32 such officer under this section if it was based upon an au-
33 thorization (which meets the applicable requirements for
34 such internal controls established by the Comptroller Gen-
35 eral of the United States) of a certifying officer designated
36 as provided in paragraph (1) of this subsection.

1 “(3) LIABILITY OF MEDICARE ADMINISTRATIVE CON-
2 TRACTOR.—

3 “(A) IN GENERAL.—No medicare administrative
4 contractor shall be liable to the United States for a
5 payment by a certifying or disbursing officer unless, in
6 connection with such payment, the medicare adminis-
7 trative contractor acted with reckless disregard of its
8 obligations under its medicare administrative contract
9 or with intent to defraud the United States.

10 “(B) RELATIONSHIP TO FALSE CLAIMS ACT.—
11 Nothing in this subsection shall be construed to limit
12 liability for conduct that would constitute a violation of
13 sections 3729 through 3731 of title 31, United States
14 Code.

15 “(4) INDEMNIFICATION BY SECRETARY.—

16 “(A) IN GENERAL.—Subject to subparagraphs (B)
17 and (D), in the case of a medicare administrative con-
18 tractor (or a person who is a director, officer, or em-
19 ployee of such a contractor or who is engaged by the
20 contractor to participate directly in the claims adminis-
21 tration process) who is made a party to any judicial or
22 administrative proceeding arising from or relating di-
23 rectly to the claims administration process under this
24 title, the Secretary may, to the extent the Secretary de-
25 termines to be appropriate and as specified in the con-
26 tract with the contractor, indemnify the contractor and
27 such persons.

28 “(B) CONDITIONS.—The Secretary may not pro-
29 vide indemnification under subparagraph (A) insofar as
30 the liability for such costs arises directly from conduct
31 that is determined by the judicial proceeding or by the
32 Secretary to be criminal in nature, fraudulent, or
33 grossly negligent. If indemnification is provided by the
34 Secretary with respect to a contractor before a deter-
35 mination that such costs arose directly from such con-
36 duct, the contractor shall reimburse the Secretary for
37 costs of indemnification.

1 “(C) SCOPE OF INDEMNIFICATION.—Indemnifica-
2 tion by the Secretary under subparagraph (A) may in-
3 clude payment of judgments, settlements (subject to
4 subparagraph (D)), awards, and costs (including rea-
5 sonable legal expenses).

6 “(D) WRITTEN APPROVAL FOR SETTLEMENTS OR
7 COMPROMISES.—A contractor or other person described
8 in subparagraph (A) may not propose to negotiate a
9 settlement or compromise of a proceeding described in
10 such subparagraph without the prior written approval
11 of the Secretary to negotiate such settlement or com-
12 promise. Any indemnification under subparagraph (A)
13 with respect to amounts paid under a settlement or
14 compromise of a proceeding described in such subpara-
15 graph are conditioned upon prior written approval by
16 the Secretary of the final settlement or compromise.

17 “(E) CONSTRUCTION.—Nothing in this paragraph
18 shall be construed—

19 “(i) to change any common law immunity that
20 may be available to a medicare administrative con-
21 tractor or person described in subparagraph (A); or

22 “(ii) to permit the payment of costs not other-
23 wise allowable, reasonable, or allocable under the
24 Federal Acquisition Regulation.”.

25 (2) CONSIDERATION OF INCORPORATION OF CURRENT
26 LAW STANDARDS.—In developing contract performance re-
27 quirements under section 1874A(b) of the Social Security
28 Act, as inserted by paragraph (1), the Secretary shall con-
29 sider inclusion of the performance standards described in
30 sections 1816(f)(2) of such Act (relating to timely proc-
31 essing of reconsiderations and applications for exemptions)
32 and section 1842(b)(2)(B) of such Act (relating to timely
33 review of determinations and fair hearing requests), as
34 such sections were in effect before the date of the enact-
35 ment of this Act.

1 (b) CONFORMING AMENDMENTS TO SECTION 1816 (RE-
 2 LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42
 3 U.S.C. 1395h) is amended as follows:

4 (1) The heading is amended to read as follows:
 5 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART A”.

6 (2) Subsection (a) is amended to read as follows:

7 “(a) The administration of this part shall be conducted
 8 through contracts with medicare administrative contractors
 9 under section 1874A.”.

10 (3) Subsection (b) is repealed.

11 (4) Subsection (c) is amended—

12 (A) by striking paragraph (1); and

13 (B) in each of paragraphs (2)(A) and (3)(A), by
 14 striking “agreement under this section” and inserting
 15 “contract under section 1874A that provides for mak-
 16 ing payments under this part”.

17 (5) Subsections (d) through (i) are repealed.

18 (6) Subsections (j) and (k) are each amended—

19 (A) by striking “An agreement with an agency or
 20 organization under this section” and inserting “A con-
 21 tract with a medicare administrative contractor under
 22 section 1874A with respect to the administration of
 23 this part”; and

24 (B) by striking “such agency or organization” and
 25 inserting “such medicare administrative contractor”
 26 each place it appears.

27 (7) Subsection (l) is repealed.

28 (c) CONFORMING AMENDMENTS TO SECTION 1842 (RE-
 29 LATING TO CARRIERS).—Section 1842 (42 U.S.C. 1395u) is
 30 amended as follows:

31 (1) The heading is amended to read as follows:
 32 “PROVISIONS RELATING TO THE ADMINISTRATION OF PART B”.

33 (2) Subsection (a) is amended to read as follows:

34 “(a) The administration of this part shall be conducted
 35 through contracts with medicare administrative contractors
 36 under section 1874A.”.

37 (3) Subsection (b) is amended—

- 1 (A) by striking paragraph (1);
- 2 (B) in paragraph (2)—
- 3 (i) by striking subparagraphs (A) and (B);
- 4 (ii) in subparagraph (C), by striking “car-
- 5 riers” and inserting “medicare administrative con-
- 6 tractors”; and
- 7 (iii) by striking subparagraphs (D) and (E);
- 8 (C) in paragraph (3)—
- 9 (i) in the matter before subparagraph (A), by
- 10 striking “Each such contract shall provide that the
- 11 carrier” and inserting “The Secretary”;
- 12 (ii) by striking “will” the first place it appears
- 13 in each of subparagraphs (A), (B), (F), (G), (H),
- 14 and (L) and inserting “shall”;
- 15 (iii) in subparagraph (B), in the matter before
- 16 clause (i), by striking “to the policyholders and
- 17 subscribers of the carrier” and inserting “to the
- 18 policyholders and subscribers of the medicare ad-
- 19 ministrative contractor”;
- 20 (iv) by striking subparagraphs (C), (D), and
- 21 (E);
- 22 (v) in subparagraph (H)—
- 23 (I) by striking “if it makes determinations
- 24 or payments with respect to physicians’ serv-
- 25 ices,” in the matter preceding clause (i); and
- 26 (II) by striking “carrier” and inserting
- 27 “medicare administrative contractor” in clause
- 28 (i);
- 29 (vi) by striking subparagraph (I);
- 30 (vii) in subparagraph (L), by striking the
- 31 semicolon and inserting a period;
- 32 (viii) in the first sentence, after subparagraph
- 33 (L), by striking “and shall contain” and all that
- 34 follows through the period; and
- 35 (ix) in the seventh sentence, by inserting
- 36 “medicare administrative contractor,” after “car-
- 37 rier,”;

1 (D) by striking paragraph (5);

2 (E) in paragraph (6)(D)(iv), by striking “carrier”
 3 and inserting “medicare administrative contractor”;
 4 and

5 (F) in paragraph (7), by striking “the carrier”
 6 and inserting “the Secretary” each place it appears.

7 (4) Subsection (c) is amended—

8 (A) by striking paragraph (1);

9 (B) in paragraph (2)(A), by striking “contract
 10 under this section which provides for the disbursement
 11 of funds, as described in subsection (a)(1)(B),” and in-
 12 serting “contract under section 1874A that provides for
 13 making payments under this part”;

14 (C) in paragraph (3)(A), by striking “subsection
 15 (a)(1)(B)” and inserting “section 1874A(a)(3)(B)”;

16 (D) in paragraph (4), in the matter preceding sub-
 17 paragraph (A), by striking “carrier” and inserting
 18 “medicare administrative contractor”; and

19 (E) by striking paragraphs (5) and (6).

20 (5) Subsections (d), (e), and (f) are repealed.

21 (6) Subsection (g) is amended by striking “carrier or
 22 carriers” and inserting “medicare administrative contractor
 23 or contractors”.

24 (7) Subsection (h) is amended—

25 (A) in paragraph (2)—

26 (i) by striking “Each carrier having an agree-
 27 ment with the Secretary under subsection (a)” and
 28 inserting “The Secretary”; and

29 (ii) by striking “Each such carrier” and in-
 30 serting “The Secretary”;

31 (B) in paragraph (3)(A)—

32 (i) by striking “a carrier having an agreement
 33 with the Secretary under subsection (a)” and in-
 34 serting “medicare administrative contractor having
 35 a contract under section 1874A that provides for
 36 making payments under this part”; and

1 (ii) by striking “such carrier” and inserting
2 “such contractor”;

3 (C) in paragraph (3)(B)—

4 (i) by striking “a carrier” and inserting “a
5 medicare administrative contractor” each place it
6 appears; and

7 (ii) by striking “the carrier” and inserting
8 “the contractor” each place it appears; and

9 (D) in paragraphs (5)(A) and (5)(B)(iii), by strik-
10 ing “carriers” and inserting “medicare administrative
11 contractors” each place it appears.

12 (8) Subsection (l) is amended—

13 (A) in paragraph (1)(A)(iii), by striking “carrier”
14 and inserting “medicare administrative contractor”;
15 and

16 (B) in paragraph (2), by striking “carrier” and in-
17 serting “medicare administrative contractor”.

18 (9) Subsection (p)(3)(A) is amended by striking “car-
19 rier” and inserting “medicare administrative contractor”.

20 (10) Subsection (q)(1)(A) is amended by striking “car-
21 rier”.

22 (d) EFFECTIVE DATE; TRANSITION RULE.—

23 (1) EFFECTIVE DATE.—

24 (A) IN GENERAL.—Except as otherwise provided
25 in this subsection, the amendments made by this sec-
26 tion shall take effect on October 1, 2005, and the Sec-
27 retary is authorized to take such steps before such date
28 as may be necessary to implement such amendments on
29 a timely basis.

30 (B) CONSTRUCTION FOR CURRENT CONTRACTS.—

31 Such amendments shall not apply to contracts in effect
32 before the date specified under subparagraph (A) that
33 continue to retain the terms and conditions in effect on
34 such date (except as otherwise provided under this Act,
35 other than under this section) until such date as the
36 contract is let out for competitive bidding under such
37 amendments.

1 (C) DEADLINE FOR COMPETITIVE BIDDING.—The
2 Secretary shall provide for the letting by competitive
3 bidding of all contracts for functions of medicare ad-
4 ministrative contractors for annual contract periods
5 that begin on or after October 1, 2011.

6 (2) GENERAL TRANSITION RULES.—

7 (A) AUTHORITY TO CONTINUE TO ENTER INTO
8 NEW AGREEMENTS AND CONTRACTS AND WAIVER OF
9 PROVIDER NOMINATION PROVISIONS DURING TRANSI-
10 TION.—Prior to October 1, 2005, the Secretary may,
11 consistent with subparagraph (B), continue to enter
12 into agreements under section 1816 and contracts
13 under section 1842 of the Social Security Act (42
14 U.S.C. 1395h, 1395u). The Secretary may enter into
15 new agreements under section 1816 prior to October 1,
16 2005, without regard to any of the provider nomination
17 provisions of such section.

18 (B) APPROPRIATE TRANSITION.—The Secretary
19 shall take such steps as are necessary to provide for an
20 appropriate transition from agreements under section
21 1816 and contracts under section 1842 of the Social
22 Security Act (42 U.S.C. 1395h, 1395u) to contracts
23 under section 1874A, as added by subsection (a)(1).

24 (3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS
25 UNDER CURRENT CONTRACTS AND AGREEMENTS AND
26 UNDER TRANSITION CONTRACTS.—Notwithstanding the
27 amendments made by this section, the provisions contained
28 in the exception in section 1893(d)(2) of the Social Secu-
29 rity Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply
30 during the period that begins on the date of the enactment
31 of this Act and ends on October 1, 2011, and any reference
32 in such provisions to an agreement or contract shall be
33 deemed to include a contract under section 1874A of such
34 Act, as inserted by subsection (a)(1), that continues the ac-
35 tivities referred to in such provisions.

36 (e) REFERENCES.—On and after the effective date pro-
37 vided under subsection (d)(1), any reference to a fiscal inter-

1 mediary or carrier under title XI or XVIII of the Social Secu-
2 rity Act (or any regulation, manual instruction, interpretative
3 rule, statement of policy, or guideline issued to carry out such
4 titles) shall be deemed a reference to a medicare administrative
5 contractor (as provided under section 1874A of the Social Se-
6 curity Act).

7 (f) SECRETARIAL SUBMISSION OF LEGISLATIVE PRO-
8 POSAL.—Not later than 6 months after the date of the enact-
9 ment of this Act, the Secretary shall submit to the appropriate
10 committees of Congress a legislative proposal providing for
11 such technical and conforming amendments in the law as are
12 required by the provisions of this section.

13 (g) REPORTS ON IMPLEMENTATION.—

14 (1) PLAN FOR IMPLEMENTATION.—By not later than
15 October 1, 2004, the Secretary shall submit a report to
16 Congress and the Comptroller General of the United States
17 that describes the plan for implementation of the amend-
18 ments made by this section. The Comptroller General shall
19 conduct an evaluation of such plan and shall submit to
20 Congress, not later than 6 months after the date the report
21 is received, a report on such evaluation and shall include
22 in such report such recommendations as the Comptroller
23 General deems appropriate.

24 (2) STATUS OF IMPLEMENTATION.—The Secretary
25 shall submit a report to Congress not later than October
26 1, 2008, that describes the status of implementation of
27 such amendments and that includes a description of the
28 following:

29 (A) The number of contracts that have been com-
30 petitively bid as of such date.

31 (B) The distribution of functions among contracts
32 and contractors.

33 (C) A timeline for complete transition to full com-
34 petition.

35 (D) A detailed description of how the Secretary
36 has modified oversight and management of medicare
37 contractors to adapt to full competition.

1 **SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY**
 2 **FOR MEDICARE ADMINISTRATIVE CONTRAC-**
 3 **TORS.**

4 (a) IN GENERAL.—Section 1874A, as added by section
 5 911(a)(1), is amended by adding at the end the following new
 6 subsection:

7 “(e) REQUIREMENTS FOR INFORMATION SECURITY.—

8 “(1) DEVELOPMENT OF INFORMATION SECURITY PRO-
 9 GRAM.—A medicare administrative contractor that per-
 10 forms the functions referred to in subparagraphs (A) and
 11 (B) of subsection (a)(4) (relating to determining and mak-
 12 ing payments) shall implement a contractor-wide informa-
 13 tion security program to provide information security for
 14 the operation and assets of the contractor with respect to
 15 such functions under this title. An information security
 16 program under this paragraph shall meet the requirements
 17 for information security programs imposed on Federal
 18 agencies under paragraphs (1) through (8) of section
 19 3544(b) of title 44, United States Code (other than the re-
 20 quirements under paragraphs (2)(D)(i), (5)(A), and (5)(B)
 21 of such section).

22 “(2) INDEPENDENT AUDITS.—

23 “(A) PERFORMANCE OF ANNUAL EVALUATIONS.—

24 Each year a medicare administrative contractor that
 25 performs the functions referred to in subparagraphs
 26 (A) and (B) of subsection (a)(4) (relating to deter-
 27 mining and making payments) shall undergo an evalua-
 28 tion of the information security of the contractor with
 29 respect to such functions under this title. The evalua-
 30 tion shall—

31 “(i) be performed by an entity that meets such
 32 requirements for independence as the Inspector
 33 General of the Department of Health and Human
 34 Services may establish; and

35 “(ii) test the effectiveness of information secu-
 36 rity control techniques of an appropriate subset of
 37 the contractor’s information systems (as defined in

1 section 3502(8) of title 44, United States Code) re-
2 lating to such functions under this title and an as-
3 sessment of compliance with the requirements of
4 this subsection and related information security
5 policies, procedures, standards and guidelines, in-
6 cluding policies and procedures as may be pre-
7 scribed by the Director of the Office of Manage-
8 ment and Budget and applicable information secu-
9 rity standards promulgated under section 11331 of
10 title 40, United States Code.

11 “(B) DEADLINE FOR INITIAL EVALUATION.—

12 “(i) NEW CONTRACTORS.—In the case of a
13 medicare administrative contractor covered by this
14 subsection that has not previously performed the
15 functions referred to in subparagraphs (A) and (B)
16 of subsection (a)(4) (relating to determining and
17 making payments) as a fiscal intermediary or car-
18 rier under section 1816 or 1842, the first inde-
19 pendent evaluation conducted pursuant to subpara-
20 graph (A) shall be completed prior to commencing
21 such functions.

22 “(ii) OTHER CONTRACTORS.—In the case of a
23 medicare administrative contractor covered by this
24 subsection that is not described in clause (i), the
25 first independent evaluation conducted pursuant to
26 subparagraph (A) shall be completed within 1 year
27 after the date the contractor commences functions
28 referred to in clause (i) under this section.

29 “(C) REPORTS ON EVALUATIONS.—

30 “(i) TO THE DEPARTMENT OF HEALTH AND
31 HUMAN SERVICES.—The results of independent
32 evaluations under subparagraph (A) shall be sub-
33 mitted promptly to the Inspector General of the
34 Department of Health and Human Services and to
35 the Secretary.

36 “(ii) TO CONGRESS.—The Inspector General
37 of the Department of Health and Human Services

1 shall submit to Congress annual reports on the re-
 2 sults of such evaluations, including assessments of
 3 the scope and sufficiency of such evaluations.

4 “(iii) AGENCY REPORTING.—The Secretary
 5 shall address the results of such evaluations in re-
 6 ports required under section 3544(c) of title 44,
 7 United States Code.”.

8 (b) APPLICATION OF REQUIREMENTS TO FISCAL INTER-
 9 MEDIARIES AND CARRIERS.—

10 (1) IN GENERAL.—The provisions of section
 11 1874A(e)(2) of the Social Security Act (other than sub-
 12 paragraph (B)), as added by subsection (a), shall apply to
 13 each fiscal intermediary under section 1816 of the Social
 14 Security Act (42 U.S.C. 1395h) and each carrier under
 15 section 1842 of such Act (42 U.S.C. 1395u) in the same
 16 manner as they apply to medicare administrative contrac-
 17 tors under such provisions.

18 (2) DEADLINE FOR INITIAL EVALUATION.—In the case
 19 of such a fiscal intermediary or carrier with an agreement
 20 or contract under such respective section in effect as of the
 21 date of the enactment of this Act, the first evaluation
 22 under section 1874A(e)(2)(A) of the Social Security Act
 23 (as added by subsection (a)), pursuant to paragraph (1),
 24 shall be completed (and a report on the evaluation sub-
 25 mitted to the Secretary) by not later than 1 year after such
 26 date.

27 **Subtitle C—Education and Outreach**

28 **SEC. 921. PROVIDER EDUCATION AND TECHNICAL AS-**
 29 **SISTANCE.**

30 (a) COORDINATION OF EDUCATION FUNDING.—

31 (1) IN GENERAL.—Title XVIII is amended by insert-
 32 ing after section 1888 the following new section:

33 “PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

34 “SEC. 1889. (a) COORDINATION OF EDUCATION FUND-
 35 ING.—The Secretary shall coordinate the educational activities
 36 provided through medicare contractors (as defined in sub-
 37 section (g), including under section 1893) in order to maximize

1 the effectiveness of Federal education efforts for providers of
2 services and suppliers.”.

3 (2) EFFECTIVE DATE.—The amendment made by
4 paragraph (1) shall take effect on the date of the enact-
5 ment of this Act.

6 (3) REPORT.—Not later than October 1, 2004, the
7 Secretary shall submit to Congress a report that includes
8 a description and evaluation of the steps taken to coordi-
9 nate the funding of provider education under section
10 1889(a) of the Social Security Act, as added by paragraph
11 (1).

12 (b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
13 ANCE.—

14 (1) IN GENERAL.—Section 1874A, as added by section
15 911(a)(1) and as amended by section 912(a), is amended
16 by adding at the end the following new subsection:

17 “(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
18 ANCE IN PROVIDER EDUCATION AND OUTREACH.—The Sec-
19 retary shall use specific claims payment error rates or similar
20 methodology of medicare administrative contractors in the
21 processing or reviewing of medicare claims in order to give such
22 contractors an incentive to implement effective education and
23 outreach programs for providers of services and suppliers.”.

24 (2) APPLICATION TO FISCAL INTERMEDIARIES AND
25 CARRIERS.—The provisions of section 1874A(f) of the So-
26 cial Security Act, as added by paragraph (1), shall apply
27 to each fiscal intermediary under section 1816 of the Social
28 Security Act (42 U.S.C. 1395h) and each carrier under
29 section 1842 of such Act (42 U.S.C. 1395u) in the same
30 manner as they apply to medicare administrative contrac-
31 tors under such provisions.

32 (3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—
33 Not later than October 1, 2004, the Comptroller General
34 of the United States shall submit to Congress and to the
35 Secretary a report on the adequacy of the methodology
36 under section 1874A(f) of the Social Security Act, as added
37 by paragraph (1), and shall include in the report such rec-

1 ommendations as the Comptroller General determines ap-
2 propriate with respect to the methodology.

3 (4) REPORT ON USE OF METHODOLOGY IN ASSESSING
4 CONTRACTOR PERFORMANCE.—Not later than October 1,
5 2004, the Secretary shall submit to Congress a report that
6 describes how the Secretary intends to use such method-
7 ology in assessing medicare contractor performance in im-
8 plementing effective education and outreach programs, in-
9 cluding whether to use such methodology as a basis for per-
10 formance bonuses. The report shall include an analysis of
11 the sources of identified errors and potential changes in
12 systems of contractors and rules of the Secretary that could
13 reduce claims error rates.

14 (c) PROVISION OF ACCESS TO AND PROMPT RESPONSES
15 FROM MEDICARE ADMINISTRATIVE CONTRACTORS.—

16 (1) IN GENERAL.—Section 1874A, as added by section
17 911(a)(1) and as amended by section 912(a) and sub-
18 section (b), is further amended by adding at the end the
19 following new subsection:

20 “(g) COMMUNICATIONS WITH BENEFICIARIES, PROVIDERS
21 OF SERVICES AND SUPPLIERS.—

22 “(1) COMMUNICATION STRATEGY.—The Secretary
23 shall develop a strategy for communications with individ-
24 uals entitled to benefits under part A or enrolled under
25 part B, or both, and with providers of services and sup-
26 pliers under this title.

27 “(2) RESPONSE TO WRITTEN INQUIRIES.—Each medi-
28 care administrative contractor shall, for those providers of
29 services and suppliers which submit claims to the con-
30 tractor for claims processing and for those individuals enti-
31 tled to benefits under part A or enrolled under part B, or
32 both, with respect to whom claims are submitted for claims
33 processing, provide general written responses (which may
34 be through electronic transmission) in a clear, concise, and
35 accurate manner to inquiries of providers of services, sup-
36 pliers, and individuals entitled to benefits under part A or
37 enrolled under part B, or both, concerning the programs

1 under this title within 45 business days of the date of re-
2 ceipt of such inquiries.

3 “(3) RESPONSE TO TOLL-FREE LINES.—The Secretary
4 shall ensure that each medicare administrative contractor
5 shall provide, for those providers of services and suppliers
6 which submit claims to the contractor for claims processing
7 and for those individuals entitled to benefits under part A
8 or enrolled under part B, or both, with respect to whom
9 claims are submitted for claims processing, a toll-free tele-
10 phone number at which such individuals, providers of serv-
11 ices, and suppliers may obtain information regarding bill-
12 ing, coding, claims, coverage, and other appropriate infor-
13 mation under this title.

14 “(4) MONITORING OF CONTRACTOR RESPONSES.—

15 “(A) IN GENERAL.—Each medicare administrative
16 contractor shall, consistent with standards developed by
17 the Secretary under subparagraph (B)—

18 “(i) maintain a system for identifying who
19 provides the information referred to in paragraphs
20 (2) and (3); and

21 “(ii) monitor the accuracy, consistency, and
22 timeliness of the information so provided.

23 “(B) DEVELOPMENT OF STANDARDS.—

24 “(i) IN GENERAL.—The Secretary shall estab-
25 lish and make public standards to monitor the ac-
26 curacy, consistency, and timeliness of the informa-
27 tion provided in response to written and telephone
28 inquiries under this subsection. Such standards
29 shall be consistent with the performance require-
30 ments established under subsection (b)(3).

31 “(ii) EVALUATION.—In conducting evaluations
32 of individual medicare administrative contractors,
33 the Secretary shall take into account the results of
34 the monitoring conducted under subparagraph (A)
35 taking into account as performance requirements
36 the standards established under clause (i). The
37 Secretary shall, in consultation with organizations

1 representing providers of services, suppliers, and
 2 individuals entitled to benefits under part A or en-
 3 rolled under part B, or both, establish standards
 4 relating to the accuracy, consistency, and timeliness
 5 of the information so provided.

6 “(C) DIRECT MONITORING.—Nothing in this para-
 7 graph shall be construed as preventing the Secretary
 8 from directly monitoring the accuracy, consistency, and
 9 timeliness of the information so provided.

10 “(5) AUTHORIZATION OF APPROPRIATIONS.—There
 11 are authorized to be appropriated such sums as are nec-
 12 essary to carry out this subsection.”.

13 (2) EFFECTIVE DATE.—The amendment made by
 14 paragraph (1) shall take effect October 1, 2004.

15 (3) APPLICATION TO FISCAL INTERMEDIARIES AND
 16 CARRIERS.—The provisions of section 1874A(g) of the So-
 17 cial Security Act, as added by paragraph (1), shall apply
 18 to each fiscal intermediary under section 1816 of the Social
 19 Security Act (42 U.S.C. 1395h) and each carrier under
 20 section 1842 of such Act (42 U.S.C. 1395u) in the same
 21 manner as they apply to medicare administrative contrac-
 22 tors under such provisions.

23 (d) IMPROVED PROVIDER EDUCATION AND TRAINING.—

24 (1) IN GENERAL.—Section 1889, as added by sub-
 25 section (a), is amended by adding at the end the following
 26 new subsections:

27 “(b) ENHANCED EDUCATION AND TRAINING.—

28 “(1) ADDITIONAL RESOURCES.—There are authorized
 29 to be appropriated to the Secretary (in appropriate part
 30 from the Federal Hospital Insurance Trust Fund and the
 31 Federal Supplementary Medical Insurance Trust Fund)
 32 such sums as may be necessary for fiscal years beginning
 33 with fiscal year 2005.

34 “(2) USE.—The funds made available under para-
 35 graph (1) shall be used to increase the conduct by medicare
 36 contractors of education and training of providers of serv-
 37 ices and suppliers regarding billing, coding, and other ap-

1 appropriate items and may also be used to improve the accu-
 2 racy, consistency, and timeliness of contractor responses.

3 “(c) TAILORING EDUCATION AND TRAINING ACTIVITIES
 4 FOR SMALL PROVIDERS OR SUPPLIERS.—

5 “(1) IN GENERAL.—Insofar as a medicare contractor
 6 conducts education and training activities, it shall tailor
 7 such activities to meet the special needs of small providers
 8 of services or suppliers (as defined in paragraph (2)). Such
 9 education and training activities for small providers of serv-
 10 ices and suppliers may include the provision of technical as-
 11 sistance (such as review of billing systems and internal con-
 12 trols to determine program compliance and to suggest more
 13 efficient and effective means of achieving such compliance).

14 “(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—
 15 In this subsection, the term ‘small provider of services or
 16 supplier’ means—

17 “(A) a provider of services with fewer than 25 full-
 18 time-equivalent employees; or

19 “(B) a supplier with fewer than 10 full-time-equiv-
 20 alent employees.”.

21 (2) EFFECTIVE DATE.—The amendment made by
 22 paragraph (1) shall take effect on October 1, 2004.

23 (e) REQUIREMENT TO MAINTAIN INTERNET WEBSITES.—

24 (1) IN GENERAL.—Section 1889, as added by sub-
 25 section (a) and as amended by subsection (d), is further
 26 amended by adding at the end the following new sub-
 27 section:

28 “(d) INTERNET WEBSITES; FAQs.—The Secretary, and
 29 each medicare contractor insofar as it provides services (includ-
 30 ing claims processing) for providers of services or suppliers,
 31 shall maintain an Internet website which—

32 “(1) provides answers in an easily accessible format to
 33 frequently asked questions, and

34 “(2) includes other published materials of the con-
 35 tractor,

1 that relate to providers of services and suppliers under the pro-
 2 grams under this title (and title XI insofar as it relates to such
 3 programs).”.

4 (2) EFFECTIVE DATE.—The amendment made by
 5 paragraph (1) shall take effect on October 1, 2004.

6 (f) ADDITIONAL PROVIDER EDUCATION PROVISIONS.—

7 (1) IN GENERAL.—Section 1889, as added by sub-
 8 section (a) and as amended by subsections (d) and (e), is
 9 further amended by adding at the end the following new
 10 subsections:

11 “(e) ENCOURAGEMENT OF PARTICIPATION IN EDUCATION
 12 PROGRAM ACTIVITIES.—A medicare contractor may not use a
 13 record of attendance at (or failure to attend) educational activi-
 14 ties or other information gathered during an educational pro-
 15 gram conducted under this section or otherwise by the Sec-
 16 retary to select or track providers of services or suppliers for
 17 the purpose of conducting any type of audit or prepayment re-
 18 view.

19 “(f) CONSTRUCTION.—Nothing in this section or section
 20 1893(g) shall be construed as providing for disclosure by a
 21 medicare contractor—

22 “(1) of the screens used for identifying claims that will
 23 be subject to medical review; or

24 “(2) of information that would compromise pending
 25 law enforcement activities or reveal findings of law enforce-
 26 ment-related audits.

27 “(g) DEFINITIONS.—For purposes of this section, the
 28 term ‘medicare contractor’ includes the following:

29 “(1) A medicare administrative contractor with a con-
 30 tract under section 1874A, including a fiscal intermediary
 31 with a contract under section 1816 and a carrier with a
 32 contract under section 1842.

33 “(2) An eligible entity with a contract under section
 34 1893.

35 Such term does not include, with respect to activities of a spe-
 36 cific provider of services or supplier an entity that has no au-

1 thority under this title or title IX with respect to such activities
2 and such provider of services or supplier.”.

3 (2) EFFECTIVE DATE.—The amendment made by
4 paragraph (1) shall take effect on the date of the enact-
5 ment of this Act.

6 **SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE**
7 **DEMONSTRATION PROGRAM.**

8 (a) ESTABLISHMENT.—

9 (1) IN GENERAL.—The Secretary shall establish a
10 demonstration program (in this section referred to as the
11 “demonstration program”) under which technical assist-
12 ance described in paragraph (2) is made available, upon re-
13 quest and on a voluntary basis, to small providers of serv-
14 ices or suppliers in order to improve compliance with the
15 applicable requirements of the programs under medicare
16 program under title XVIII of the Social Security Act (in-
17 cluding provisions of title XI of such Act insofar as they
18 relate to such title and are not administered by the Office
19 of the Inspector General of the Department of Health and
20 Human Services).

21 (2) FORMS OF TECHNICAL ASSISTANCE.—The tech-
22 nical assistance described in this paragraph is—

23 (A) evaluation and recommendations regarding
24 billing and related systems; and

25 (B) information and assistance regarding policies
26 and procedures under the medicare program, including
27 coding and reimbursement.

28 (3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—
29 In this section, the term “small providers of services or
30 suppliers” means—

31 (A) a provider of services with fewer than 25 full-
32 time-equivalent employees; or

33 (B) a supplier with fewer than 10 full-time-equa-
34 lent employees.

35 (b) QUALIFICATION OF CONTRACTORS.—In conducting the
36 demonstration program, the Secretary shall enter into contracts
37 with qualified organizations (such as peer review organizations

1 or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 921(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

9 (c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

15 (d) GAO EVALUATION.—Not later than 2 years after the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

28 (e) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

35 (f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, from amounts not otherwise appro-

1 priated in the Treasury, such sums as may be necessary to
2 carry out this section.

3 **SEC. 923. MEDICARE BENEFICIARY OMBUDSMAN.**

4 (a) IN GENERAL.—Section 1808, as added and amended
5 by section 900, is amended by adding at the end the following
6 new subsection:

7 “(c) MEDICARE BENEFICIARY OMBUDSMAN.—

8 “(1) IN GENERAL.—The Secretary shall appoint with-
9 in the Department of Health and Human Services a Medi-
10 care Beneficiary Ombudsman who shall have expertise and
11 experience in the fields of health care and education of
12 (and assistance to) individuals entitled to benefits under
13 this title.

14 “(2) DUTIES.—The Medicare Beneficiary Ombudsman
15 shall—

16 “(A) receive complaints, grievances, and requests
17 for information submitted by individuals entitled to
18 benefits under part A or enrolled under part B, or
19 both, with respect to any aspect of the medicare pro-
20 gram;

21 “(B) provide assistance with respect to complaints,
22 grievances, and requests referred to in subparagraph
23 (A), including—

24 “(i) assistance in collecting relevant informa-
25 tion for such individuals, to seek an appeal of a de-
26 cision or determination made by a fiscal inter-
27 mediary, carrier, MA organization, or the Sec-
28 retary;

29 “(ii) assistance to such individuals with any
30 problems arising from disenrollment from an MA
31 plan under part C; and

32 “(iii) assistance to such individuals in pre-
33 senting information under section 1839(i)(4)(C)
34 (relating to income-related premium adjustment;
35 and

36 “(C) submit annual reports to Congress and the
37 Secretary that describe the activities of the Office and

1 that include such recommendations for improvement in
2 the administration of this title as the Ombudsman de-
3 termines appropriate.

4 The Ombudsman shall not serve as an advocate for any in-
5 creases in payments or new coverage of services, but may
6 identify issues and problems in payment or coverage poli-
7 cies.

8 “(3) WORKING WITH HEALTH INSURANCE COUN-
9 SELING PROGRAMS.—To the extent possible, the Ombuds-
10 man shall work with health insurance counseling programs
11 (receiving funding under section 4360 of Omnibus Budget
12 Reconciliation Act of 1990) to facilitate the provision of in-
13 formation to individuals entitled to benefits under part A
14 or enrolled under part B, or both regarding MA plans and
15 changes to those plans. Nothing in this paragraph shall
16 preclude further collaboration between the Ombudsman and
17 such programs.”.

18 (b) DEADLINE FOR APPOINTMENT.—By not later than 1
19 year after the date of the enactment of this Act, the Secretary
20 shall appoint the Medicare Beneficiary Ombudsman under sec-
21 tion 1808(c) of the Social Security Act, as added by subsection
22 (a).

23 (c) FUNDING.—There are authorized to be appropriated to
24 the Secretary (in appropriate part from the Federal Hospital
25 Insurance Trust Fund, established under section 1817 of the
26 Social Security Act (42 U.S.C. 1395i), and the Federal Supple-
27 mentary Medical Insurance Trust Fund, established under sec-
28 tion 1841 of such Act (42 U.S.C. 1395t)) to carry out section
29 1808(c) of such Act (relating to the Medicare Beneficiary Om-
30 budsman), as added by subsection (a), such sums as are nec-
31 essary for fiscal year 2004 and each succeeding fiscal year.

32 (d) USE OF CENTRAL, TOLL-FREE NUMBER (1-800-
33 MEDICARE).—

34 (1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE
35 HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—
36 Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by
37 adding at the end the following: “The Secretary shall pro-

1 vide, through the toll-free telephone number 1–800–MEDI-
 2 CARE, for a means by which individuals seeking informa-
 3 tion about, or assistance with, such programs who phone
 4 such toll-free number are transferred (without charge) to
 5 appropriate entities for the provision of such information or
 6 assistance. Such toll-free number shall be the toll-free num-
 7 ber listed for general information and assistance in the an-
 8 nual notice under subsection (a) instead of the listing of
 9 numbers of individual contractors.”.

10 (2) MONITORING ACCURACY.—

11 (A) STUDY.—The Comptroller General of the
 12 United States shall conduct a study to monitor the ac-
 13 curacy and consistency of information provided to indi-
 14 viduals entitled to benefits under part A or enrolled
 15 under part B, or both, through the toll-free telephone
 16 number 1–800–MEDICARE, including an assessment
 17 of whether the information provided is sufficient to an-
 18 swer questions of such individuals. In conducting the
 19 study, the Comptroller General shall examine the edu-
 20 cation and training of the individuals providing infor-
 21 mation through such number.

22 (B) REPORT.—Not later than 1 year after the
 23 date of the enactment of this Act, the Comptroller Gen-
 24 eral shall submit to Congress a report on the study
 25 conducted under subparagraph (A).

26 **SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION**
 27 **PROGRAM.**

28 (a) IN GENERAL.—The Secretary shall establish a dem-
 29 onstration program (in this section referred to as the “dem-
 30 onstration program”) under which medicare specialists em-
 31 ployed by the Department of Health and Human Services pro-
 32 vide advice and assistance to individuals entitled to benefits
 33 under part A of title XVIII of the Social Security Act, or en-
 34 rolled under part B of such title, or both, regarding the medi-
 35 care program at the location of existing local offices of the So-
 36 cial Security Administration.

37 (b) LOCATIONS.—

1 (1) IN GENERAL.—The demonstration program shall
 2 be conducted in at least 6 offices or areas. Subject to para-
 3 graph (2), in selecting such offices and areas, the Secretary
 4 shall provide preference for offices with a high volume of
 5 visits by individuals referred to in subsection (a).

6 (2) ASSISTANCE FOR RURAL BENEFICIARIES.—The
 7 Secretary shall provide for the selection of at least 2 rural
 8 areas to participate in the demonstration program. In con-
 9 ducting the demonstration program in such rural areas, the
 10 Secretary shall provide for medicare specialists to travel
 11 among local offices in a rural area on a scheduled basis.

12 (c) DURATION.—The demonstration program shall be con-
 13 ducted over a 3-year period.

14 (d) EVALUATION AND REPORT.—

15 (1) EVALUATION.—The Secretary shall provide for an
 16 evaluation of the demonstration program. Such evaluation
 17 shall include an analysis of—

18 (A) utilization of, and satisfaction of those individ-
 19 uals referred to in subsection (a) with, the assistance
 20 provided under the program; and

21 (B) the cost-effectiveness of providing beneficiary
 22 assistance through out-stationing medicare specialists
 23 at local offices of the Social Security Administration.

24 (2) REPORT.—The Secretary shall submit to Congress
 25 a report on such evaluation and shall include in such report
 26 recommendations regarding the feasibility of permanently
 27 out-stationing medicare specialists at local offices of the So-
 28 cial Security Administration.

29 **SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN**
 30 **NOTICES TO BENEFICIARIES ABOUT**
 31 **SKILLED NURSING FACILITY BENEFITS.**

32 (a) IN GENERAL.—The Secretary shall provide that in
 33 medicare beneficiary notices provided (under section 1806(a) of
 34 the Social Security Act, 42 U.S.C. 1395b-7(a)) with respect to
 35 the provision of post-hospital extended care services under part
 36 A of title XVIII of the Social Security Act, there shall be in-
 37 cluded information on the number of days of coverage of such

1 services remaining under such part for the medicare beneficiary
2 and spell of illness involved.

3 (b) EFFECTIVE DATE.—Subsection (a) shall apply to no-
4 tices provided during calendar quarters beginning more than 6
5 months after the date of the enactment of this Act.

6 **SEC. 926. INFORMATION ON MEDICARE-CERTIFIED**
7 **SKILLED NURSING FACILITIES IN HOSPITAL**
8 **DISCHARGE PLANS.**

9 (a) AVAILABILITY OF DATA.—The Secretary shall publicly
10 provide information that enables hospital discharge planners,
11 medicare beneficiaries, and the public to identify skilled nursing
12 facilities that are participating in the medicare program.

13 (b) INCLUSION OF INFORMATION IN CERTAIN HOSPITAL
14 DISCHARGE PLANS.—

15 (1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C.
16 1395x(ee)(2)(D)) is amended—

17 (A) by striking “hospice services” and inserting
18 “hospice care and post-hospital extended care services”;
19 and

20 (B) by inserting before the period at the end the
21 following: “and, in the case of individuals who are like-
22 ly to need post-hospital extended care services, the
23 availability of such services through facilities that par-
24 ticipate in the program under this title and that serve
25 the area in which the patient resides”.

26 (2) EFFECTIVE DATE.—The amendments made by
27 paragraph (1) shall apply to discharge plans made on or
28 after such date as the Secretary shall specify, but not later
29 than 6 months after the date the Secretary provides for
30 availability of information under subsection (a).

31 **Subtitle D—Appeals and Recovery**

32 **SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDI-**
33 **CARE APPEALS.**

34 (a) TRANSITION PLAN.—

35 (1) IN GENERAL.—Not later than April 1, 2004, the
36 Commissioner of Social Security and the Secretary shall de-
37 velop and transmit to Congress and the Comptroller Gen-

1 eral of the United States a plan under which the functions
 2 of administrative law judges responsible for hearing cases
 3 under title XVIII of the Social Security Act (and related
 4 provisions in title XI of such Act) are transferred from the
 5 responsibility of the Commissioner and the Social Security
 6 Administration to the Secretary and the Department of
 7 Health and Human Services.

8 (2) CONTENTS.—The plan shall include information
 9 on the following:

10 (A) WORKLOAD.—The number of such administra-
 11 tive law judges and support staff required now and in
 12 the future to hear and decide such cases in a timely
 13 manner, taking into account the current and antici-
 14 pated claims volume, appeals, number of beneficiaries,
 15 and statutory changes.

16 (B) COST PROJECTIONS AND FINANCING.—Fund-
 17 ing levels required for fiscal year 2005 and subsequent
 18 fiscal years to carry out the functions transferred
 19 under the plan.

20 (C) TRANSITION TIMETABLE.—A timetable for the
 21 transition.

22 (D) REGULATIONS.—The establishment of specific
 23 regulations to govern the appeals process.

24 (E) CASE TRACKING.—The development of a uni-
 25 fied case tracking system that will facilitate the mainte-
 26 nance and transfer of case specific data across both the
 27 fee-for-service and managed care components of the
 28 medicare program.

29 (F) FEASIBILITY OF PRECEDENTIAL AUTHOR-
 30 ITY.—The feasibility of developing a process to give de-
 31 cisions of the Departmental Appeals Board in the De-
 32 partment of Health and Human Services addressing
 33 broad legal issues binding, precedential authority.

34 (G) ACCESS TO ADMINISTRATIVE LAW JUDGES.—
 35 The feasibility of—

36 (i) filing appeals with administrative law
 37 judges electronically; and

1 (ii) conducting hearings using tele- or video-
2 conference technologies.

3 (H) INDEPENDENCE OF ADMINISTRATIVE LAW
4 JUDGES.—The steps that should be taken to ensure the
5 independence of administrative law judges consistent
6 with the requirements of subsection (b)(2).

7 (I) GEOGRAPHIC DISTRIBUTION.—The steps that
8 should be taken to provide for an appropriate geo-
9 graphic distribution of administrative law judges
10 throughout the United States to carry out subsection
11 (b)(3).

12 (J) HIRING.—The steps that should be taken to
13 hire administrative law judges (and support staff) to
14 carry out subsection (b)(4).

15 (K) PERFORMANCE STANDARDS.—The appro-
16 priateness of establishing performance standards for
17 administrative law judges with respect to timelines for
18 decisions in cases under title XVIII of the Social Secu-
19 rity Act taking into account requirements under sub-
20 section (b)(2) for the independence of such judges and
21 consistent with the applicable provisions of title 5,
22 United States Code relating to impartiality.

23 (L) SHARED RESOURCES.—The steps that should
24 be taken to carry out subsection (b)(6) (relating to the
25 arrangements with the Commissioner of Social Security
26 to share office space, support staff, and other re-
27 sources, with appropriate reimbursement).

28 (M) TRAINING.—The training that should be pro-
29 vided to administrative law judges with respect to laws
30 and regulations under title XVIII of the Social Security
31 Act.

32 (3) ADDITIONAL INFORMATION.—The plan may also
33 include recommendations for further congressional action,
34 including modifications to the requirements and deadlines
35 established under section 1869 of the Social Security Act
36 (42 U.S.C. 1395ff) (as amended by this Act).

1 (4) GAO EVALUATION.—The Comptroller General of
2 the United States shall evaluate the plan and, not later
3 than the date that is 6 months after the date on which the
4 plan is received by the Comptroller General, shall submit
5 to Congress a report on such evaluation.

6 (b) TRANSFER OF ADJUDICATION AUTHORITY.—

7 (1) IN GENERAL.—Not earlier than July 1, 2005, and
8 not later than October 1, 2005, the Commissioner of Social
9 Security and the Secretary shall implement the transition
10 plan under subsection (a) and transfer the administrative
11 law judge functions described in such subsection from the
12 Social Security Administration to the Secretary.

13 (2) ASSURING INDEPENDENCE OF JUDGES.—The Sec-
14 retary shall assure the independence of administrative law
15 judges performing the administrative law judge functions
16 transferred under paragraph (1) from the Centers for
17 Medicare & Medicaid Services and its contractors. In order
18 to assure such independence, the Secretary shall place such
19 judges in an administrative office that is organizationally
20 and functionally separate from such Centers. Such judges
21 shall report to, and be under the general supervision of, the
22 Secretary, but shall not report to, or be subject to super-
23 vision by, another officer of the Department of Health and
24 Human Services.

25 (3) GEOGRAPHIC DISTRIBUTION.—The Secretary shall
26 provide for an appropriate geographic distribution of ad-
27 ministrative law judges performing the administrative law
28 judge functions transferred under paragraph (1) through-
29 out the United States to ensure timely access to such
30 judges.

31 (4) HIRING AUTHORITY.—Subject to the amounts pro-
32 vided in advance in appropriations Acts, the Secretary shall
33 have authority to hire administrative law judges to hear
34 such cases, taking into consideration those judges with ex-
35 pertise in handling medicare appeals and in a manner con-
36 sistent with paragraph (3), and to hire support staff for
37 such judges.

1 (5) FINANCING.—Amounts payable under law to the
 2 Commissioner for administrative law judges performing the
 3 administrative law judge functions transferred under para-
 4 graph (1) from the Federal Hospital Insurance Trust Fund
 5 and the Federal Supplementary Medical Insurance Trust
 6 Fund shall become payable to the Secretary for the func-
 7 tions so transferred.

8 (6) SHARED RESOURCES.—The Secretary shall enter
 9 into such arrangements with the Commissioner as may be
 10 appropriate with respect to transferred functions of admin-
 11 istrative law judges to share office space, support staff, and
 12 other resources, with appropriate reimbursement from the
 13 Trust Funds described in paragraph (5).

14 (c) INCREASED FINANCIAL SUPPORT.—In addition to any
 15 amounts otherwise appropriated, to ensure timely action on ap-
 16 peals before administrative law judges and the Departmental
 17 Appeals Board consistent with section 1869 of the Social Secu-
 18 rity Act (42 U.S.C. 1395ff) (as amended by this Act), there are
 19 authorized to be appropriated (in appropriate part from the
 20 Federal Hospital Insurance Trust Fund, established under sec-
 21 tion 1817 of the Social Security Act (42 U.S.C. 1395i), and
 22 the Federal Supplementary Medical Insurance Trust Fund, es-
 23 tablished under section 1841 of such Act (42 U.S.C. 1395t))
 24 to the Secretary such sums as are necessary for fiscal year
 25 2005 and each subsequent fiscal year to—

26 (1) increase the number of administrative law judges
 27 (and their staffs) under subsection (b)(4);

28 (2) improve education and training opportunities for
 29 administrative law judges (and their staffs); and

30 (3) increase the staff of the Departmental Appeals
 31 Board.

32 (d) CONFORMING AMENDMENT.—Section 1869(f)(2)(A)(i)
 33 (42 U.S.C. 1395ff(f)(2)(A)(i)) is amended by striking “of the
 34 Social Security Administration”.

35 **SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.**

36 (a) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

1 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
2 1395ff(b)) is amended—

3 (A) in paragraph (1)(A), by inserting “, subject to
4 paragraph (2),” before “to judicial review of the Sec-
5 retary’s final decision”; and

6 (B) by adding at the end the following new para-
7 graph:

8 “(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—

9 “(A) IN GENERAL.—The Secretary shall establish
10 a process under which a provider of services or supplier
11 that furnishes an item or service or an individual enti-
12 tled to benefits under part A or enrolled under part B,
13 or both, who has filed an appeal under paragraph (1)
14 (other than an appeal filed under paragraph (1)(F)(i))
15 may obtain access to judicial review when a review enti-
16 ty (described in subparagraph (D)), on its own motion
17 or at the request of the appellant, determines that the
18 Departmental Appeals Board does not have the author-
19 ity to decide the question of law or regulation relevant
20 to the matters in controversy and that there is no ma-
21 terial issue of fact in dispute. The appellant may make
22 such request only once with respect to a question of law
23 or regulation for a specific matter in dispute in a case
24 of an appeal.

25 “(B) PROMPT DETERMINATIONS.—If, after or co-
26 incident with appropriately filing a request for an ad-
27 ministrative hearing, the appellant requests a deter-
28 mination by the appropriate review entity that the De-
29 partmental Appeals Board does not have the authority
30 to decide the question of law or regulations relevant to
31 the matters in controversy and that there is no mate-
32 rial issue of fact in dispute, and if such request is ac-
33 companied by the documents and materials as the ap-
34 propriate review entity shall require for purposes of
35 making such determination, such review entity shall
36 make a determination on the request in writing within
37 60 days after the date such review entity receives the

1 request and such accompanying documents and mate-
2 rials. Such a determination by such review entity shall
3 be considered a final decision and not subject to review
4 by the Secretary.

5 “(C) ACCESS TO JUDICIAL REVIEW.—

6 “(i) IN GENERAL.—If the appropriate review
7 entity—

8 “(I) determines that there are no material
9 issues of fact in dispute and that the only
10 issues to be adjudicated are ones of law or reg-
11 ulation that the Departmental Appeals Board
12 does not have authority to decide; or

13 “(II) fails to make such determination
14 within the period provided under subparagraph
15 (B),

16 then the appellant may bring a civil action as de-
17 scribed in this subparagraph.

18 “(ii) DEADLINE FOR FILING.—Such action
19 shall be filed, in the case described in—

20 “(I) clause (i)(I), within 60 days of the
21 date of the determination described in such
22 clause; or

23 “(II) clause (i)(II), within 60 days of the
24 end of the period provided under subparagraph
25 (B) for the determination.

26 “(iii) VENUE.—Such action shall be brought
27 in the district court of the United States for the ju-
28 dicial district in which the appellant is located (or,
29 in the case of an action brought jointly by more
30 than one applicant, the judicial district in which
31 the greatest number of applicants are located) or in
32 the District Court for the District of Columbia.

33 “(iv) INTEREST ON ANY AMOUNTS IN CON-
34 TROVERSY.—Where a provider of services or sup-
35 plier is granted judicial review pursuant to this
36 paragraph, the amount in controversy (if any) shall
37 be subject to annual interest beginning on the first

1 day of the first month beginning after the 60-day
 2 period as determined pursuant to clause (ii) and
 3 equal to the rate of interest on obligations issued
 4 for purchase by the Federal Supplementary Med-
 5 ical Insurance Trust Fund for the month in which
 6 the civil action authorized under this paragraph is
 7 commenced, to be awarded by the reviewing court
 8 in favor of the prevailing party. No interest award-
 9 ed pursuant to the preceding sentence shall be
 10 deemed income or cost for the purposes of deter-
 11 mining reimbursement due providers of services or
 12 suppliers under this title.

13 “(D) REVIEW ENTITY DEFINED.—For purposes of
 14 this subsection, the term ‘review entity’ means an enti-
 15 ty of up to three reviewers who are administrative law
 16 judges or members of the Departmental Appeals Board
 17 selected for purposes of making determinations under
 18 this paragraph.”.

19 (2) CONFORMING AMENDMENT.—Section
 20 1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amend-
 21 ed to read as follows:

22 “(ii) REFERENCE TO EXPEDITED ACCESS TO
 23 JUDICIAL REVIEW.—For the provision relating to
 24 expedited access to judicial review, see paragraph
 25 (2).”.

26 (b) APPLICATION TO PROVIDER AGREEMENT DETERMINA-
 27 TIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is
 28 amended—

29 (1) by inserting “(A)” after “(h)(1)”; and

30 (2) by adding at the end the following new subpara-
 31 graph:

32 “(B) An institution or agency described in subparagraph
 33 (A) that has filed for a hearing under subparagraph (A) shall
 34 have expedited access to judicial review under this subpara-
 35 graph in the same manner as providers of services, suppliers,
 36 and individuals entitled to benefits under part A or enrolled
 37 under part B, or both, may obtain expedited access to judicial

1 review under the process established under section 1869(b)(2).
 2 Nothing in this subparagraph shall be construed to affect the
 3 application of any remedy imposed under section 1819 during
 4 the pendency of an appeal under this subparagraph.”.

5 (c) EXPEDITED REVIEW OF CERTAIN PROVIDER AGREE-
 6 MENT DETERMINATIONS.—

7 (1) TERMINATION AND CERTAIN OTHER IMMEDIATE
 8 REMEDIES.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)),
 9 as amended by subsection (b), is amended by adding at the
 10 end the following new subparagraph:

11 “(C)(i) The Secretary shall develop and implement a proc-
 12 ess to expedite proceedings under this subsection in which—

13 “(I) the remedy of termination of participation has
 14 been imposed;

15 “(II) a remedy described in clause (i) or (iii) of section
 16 1819(h)(2)(B) has been imposed, but only if such remedy
 17 has been imposed on an immediate basis; or

18 “(III) a determination has been made as to a finding
 19 of substandard quality of care that results in the loss of ap-
 20 proval of a skilled nursing facility’s nurse aide training pro-
 21 gram.

22 “(ii) Under such process under clause (i), priority shall be
 23 provided in cases of termination described in clause (i)(I).

24 “(iii) Nothing in this subparagraph shall be construed to
 25 affect the application of any remedy imposed under section
 26 1819 during the pendency of an appeal under this subpara-
 27 graph.”.

28 (2) WAIVER OF DISAPPROVAL OF NURSE-AIDE TRAIN-
 29 ING PROGRAMS.—Sections 1819(f)(2) and section
 30 1919(f)(2) (42 U.S.C. 1395i–3(f)(2) and 1396r(f)(2)) are
 31 each amended—

32 (A) in subparagraph (B)(iii), by striking “sub-
 33 paragraph (C)” and inserting “subparagraphs (C) and
 34 (D)”; and

35 (B) by adding at the end the following new sub-
 36 paragraph:

1 “(D) WAIVER OF DISAPPROVAL OF NURSE-AIDE
 2 TRAINING PROGRAMS.—Upon application of a nursing
 3 facility, the Secretary may waive the application of sub-
 4 paragraph (B)(iii)(I)(c) if the imposition of the civil
 5 monetary penalty was not related to the quality of care
 6 provided to residents of the facility. Nothing in this
 7 subparagraph shall be construed as eliminating any re-
 8 quirement upon a facility to pay a civil monetary pen-
 9 alty described in the preceding sentence.”

10 (3) INCREASED FINANCIAL SUPPORT.—In addition to
 11 any amounts otherwise appropriated, to reduce by 50 per-
 12 cent the average time for administrative determinations on
 13 appeals under section 1866(h) of the Social Security Act
 14 (42 U.S.C. 1395cc(h)), there are authorized to be appro-
 15 priated (in appropriate part from the Federal Hospital In-
 16 surance Trust Fund, established under section 1817 of the
 17 Social Security Act (42 U.S.C. 1395i), and the Federal
 18 Supplementary Medical Insurance Trust Fund, established
 19 under section 1841 of such Act (42 U.S.C. 1395t)) to the
 20 Secretary such additional sums for fiscal year 2004 and
 21 each subsequent fiscal year as may be necessary. The pur-
 22 poses for which such amounts are available include increas-
 23 ing the number of administrative law judges (and their
 24 staffs) and the appellate level staff at the Departmental
 25 Appeals Board of the Department of Health and Human
 26 Services and educating such judges and staffs on long-term
 27 care issues.

28 (d) EFFECTIVE DATE.—The amendments made by this
 29 section shall apply to appeals filed on or after October 1, 2004.

30 **SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.**

31 (a) REQUIRING FULL AND EARLY PRESENTATION OF EVI-
 32 DENCE.—

33 (1) IN GENERAL.—Section 1869(b) (42 U.S.C.
 34 1395ff(b)), as amended by section 932(a), is further
 35 amended by adding at the end the following new para-
 36 graph:

1 “(3) REQUIRING FULL AND EARLY PRESENTATION OF
2 EVIDENCE BY PROVIDERS.—A provider of services or sup-
3 plier may not introduce evidence in any appeal under this
4 section that was not presented at the reconsideration con-
5 ducted by the qualified independent contractor under sub-
6 section (c), unless there is good cause which precluded the
7 introduction of such evidence at or before that reconsider-
8 ation.”.

9 (2) EFFECTIVE DATE.—The amendment made by
10 paragraph (1) shall take effect on October 1, 2004.

11 (b) USE OF PATIENTS’ MEDICAL RECORDS.—Section
12 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended by
13 inserting “(including the medical records of the individual in-
14 volved)” after “clinical experience”.

15 (c) NOTICE REQUIREMENTS FOR MEDICARE APPEALS.—

16 (1) INITIAL DETERMINATIONS AND REDETERMINA-
17 TIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)) is amended
18 by adding at the end the following new paragraphs:

19 “(4) REQUIREMENTS OF NOTICE OF DETERMINA-
20 TIONS.—With respect to an initial determination insofar as
21 it results in a denial of a claim for benefits—

22 “(A) the written notice on the determination shall
23 include—

24 “(i) the reasons for the determination, includ-
25 ing whether a local medical review policy or a local
26 coverage determination was used;

27 “(ii) the procedures for obtaining additional
28 information concerning the determination, includ-
29 ing the information described in subparagraph (B);
30 and

31 “(iii) notification of the right to seek a rede-
32 termination or otherwise appeal the determination
33 and instructions on how to initiate such a redeter-
34 mination under this section;

35 “(B) such written notice shall be provided in
36 printed form and written in a manner calculated to be

1 understood by the individual entitled to benefits under
2 part A or enrolled under part B, or both; and

3 “(C) the individual provided such written notice
4 may obtain, upon request, information on the specific
5 provision of the policy, manual, or regulation used in
6 making the redetermination.

7 “(5) REQUIREMENTS OF NOTICE OF REDETERMINA-
8 TIONS.—With respect to a redetermination insofar as it re-
9 sults in a denial of a claim for benefits—

10 “(A) the written notice on the redetermination
11 shall include—

12 “(i) the specific reasons for the redetermina-
13 tion;

14 “(ii) as appropriate, a summary of the clinical
15 or scientific evidence used in making the redeter-
16 mination;

17 “(iii) a description of the procedures for ob-
18 taining additional information concerning the rede-
19 termination; and

20 “(iv) notification of the right to appeal the re-
21 determination and instructions on how to initiate
22 such an appeal under this section;

23 “(B) such written notice shall be provided in
24 printed form and written in a manner calculated to be
25 understood by the individual entitled to benefits under
26 part A or enrolled under part B, or both; and

27 “(C) the individual provided such written notice
28 may obtain, upon request, information on the specific
29 provision of the policy, manual, or regulation used in
30 making the redetermination.”.

31 (2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42
32 U.S.C. 1395ff(c)(3)(E)) is amended—

33 (A) by inserting “be written in a manner cal-
34 culated to be understood by the individual entitled to
35 benefits under part A or enrolled under part B, or
36 both, and shall include (to the extent appropriate)”
37 after “in writing;” and

1 (B) by inserting “and a notification of the right to
2 appeal such determination and instructions on how to
3 initiate such appeal under this section” after “such de-
4 cision,”.

5 (3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d))
6 is amended—

7 (A) in the heading, by inserting “; NOTICE” after
8 “SECRETARY”; and

9 (B) by adding at the end the following new para-
10 graph:

11 “(4) NOTICE.—Notice of the decision of an adminis-
12 trative law judge shall be in writing in a manner calculated
13 to be understood by the individual entitled to benefits
14 under part A or enrolled under part B, or both, and shall
15 include—

16 “(A) the specific reasons for the determination (in-
17 cluding, to the extent appropriate, a summary of the
18 clinical or scientific evidence used in making the deter-
19 mination);

20 “(B) the procedures for obtaining additional infor-
21 mation concerning the decision; and

22 “(C) notification of the right to appeal the deci-
23 sion and instructions on how to initiate such an appeal
24 under this section.”.

25 (4) SUBMISSION OF RECORD FOR APPEAL.—Section
26 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) is amended
27 by striking “prepare” and inserting “submit” and by strik-
28 ing “with respect to” and all that follows through “and rel-
29 evant policies”.

30 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

31 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDE-
32 PENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C.
33 1395ff(c)(3)) is amended—

34 (A) in subparagraph (A), by striking “sufficient
35 training and expertise in medical science and legal mat-
36 ters” and inserting “sufficient medical, legal, and other

1 expertise (including knowledge of the program under
2 this title) and sufficient staffing”; and

3 (B) by adding at the end the following new sub-
4 paragraph:

5 “(K) INDEPENDENCE REQUIREMENTS.—

6 “(i) IN GENERAL.—Subject to clause (ii), a
7 qualified independent contractor shall not conduct
8 any activities in a case unless the entity—

9 “(I) is not a related party (as defined in
10 subsection (g)(5));

11 “(II) does not have a material familial, fi-
12 nancial, or professional relationship with such a
13 party in relation to such case; and

14 “(III) does not otherwise have a conflict of
15 interest with such a party.

16 “(ii) EXCEPTION FOR REASONABLE COM-
17 PENSATION.—Nothing in clause (i) shall be con-
18 strued to prohibit receipt by a qualified inde-
19 pendent contractor of compensation from the Sec-
20 retary for the conduct of activities under this sec-
21 tion if the compensation is provided consistent with
22 clause (iii).

23 “(iii) LIMITATIONS ON ENTITY COMPENSA-
24 TION.—Compensation provided by the Secretary to
25 a qualified independent contractor in connection
26 with reviews under this section shall not be contin-
27 gent on any decision rendered by the contractor or
28 by any reviewing professional.”.

29 (2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—
30 Section 1869 (42 U.S.C. 1395ff) is amended—

31 (A) by amending subsection (c)(3)(D) to read as
32 follows:

33 “(D) QUALIFICATIONS FOR REVIEWERS.—The re-
34 quirements of subsection (g) shall be met (relating to
35 qualifications of reviewing professionals).”; and

36 (B) by adding at the end the following new sub-
37 section:

1 “(g) QUALIFICATIONS OF REVIEWERS.—

2 “(1) IN GENERAL.—In reviewing determinations under
3 this section, a qualified independent contractor shall assure
4 that—

5 “(A) each individual conducting a review shall
6 meet the qualifications of paragraph (2);

7 “(B) compensation provided by the contractor to
8 each such reviewer is consistent with paragraph (3);
9 and

10 “(C) in the case of a review by a panel described
11 in subsection (c)(3)(B) composed of physicians or other
12 health care professionals (each in this subsection re-
13 ferred to as a ‘reviewing professional’), a reviewing pro-
14 fessional meets the qualifications described in para-
15 graph (4) and, where a claim is regarding the fur-
16 nishing of treatment by a physician (allopathic or os-
17 teopathic) or the provision of items or services by a
18 physician (allopathic or osteopathic), a reviewing pro-
19 fessional shall be a physician (allopathic or osteo-
20 pathic).

21 “(2) INDEPENDENCE.—

22 “(A) IN GENERAL.—Subject to subparagraph (B),
23 each individual conducting a review in a case shall—

24 “(i) not be a related party (as defined in para-
25 graph (5));

26 “(ii) not have a material familial, financial, or
27 professional relationship with such a party in the
28 case under review; and

29 “(iii) not otherwise have a conflict of interest
30 with such a party.

31 “(B) EXCEPTION.—Nothing in subparagraph (A)
32 shall be construed to—

33 “(i) prohibit an individual, solely on the basis
34 of a participation agreement with a fiscal inter-
35 mediary, carrier, or other contractor, from serving
36 as a reviewing professional if—

1 “(I) the individual is not involved in the
2 provision of items or services in the case under
3 review;

4 “(II) the fact of such an agreement is dis-
5 closed to the Secretary and the individual enti-
6 tled to benefits under part A or enrolled under
7 part B, or both, or such individual’s authorized
8 representative, and neither party objects; and

9 “(III) the individual is not an employee of
10 the intermediary, carrier, or contractor and
11 does not provide services exclusively or pri-
12 marily to or on behalf of such intermediary,
13 carrier, or contractor;

14 “(ii) prohibit an individual who has staff privi-
15 leges at the institution where the treatment in-
16 volved takes place from serving as a reviewer mere-
17 ly on the basis of having such staff privileges if the
18 existence of such privileges is disclosed to the Sec-
19 retary and such individual (or authorized represent-
20 ative), and neither party objects; or

21 “(iii) prohibit receipt of compensation by a re-
22 viewing professional from a contractor if the com-
23 pensation is provided consistent with paragraph
24 (3).

25 For purposes of this paragraph, the term ‘participation
26 agreement’ means an agreement relating to the provi-
27 sion of health care services by the individual and does
28 not include the provision of services as a reviewer
29 under this subsection.

30 “(3) LIMITATIONS ON REVIEWER COMPENSATION.—
31 Compensation provided by a qualified independent con-
32 tractor to a reviewer in connection with a review under this
33 section shall not be contingent on the decision rendered by
34 the reviewer.

35 “(4) LICENSURE AND EXPERTISE.—Each reviewing
36 professional shall be—

1 “(A) a physician (allopathic or osteopathic) who is
2 appropriately credentialed or licensed in one or more
3 States to deliver health care services and has medical
4 expertise in the field of practice that is appropriate for
5 the items or services at issue; or

6 “(B) a health care professional who is legally au-
7 thorized in one or more States (in accordance with
8 State law or the State regulatory mechanism provided
9 by State law) to furnish the health care items or serv-
10 ices at issue and has medical expertise in the field of
11 practice that is appropriate for such items or services.

12 “(5) RELATED PARTY DEFINED.—For purposes of this
13 section, the term ‘related party’ means, with respect to a
14 case under this title involving a specific individual entitled
15 to benefits under part A or enrolled under part B, or both,
16 any of the following:

17 “(A) The Secretary, the medicare administrative
18 contractor involved, or any fiduciary, officer, director,
19 or employee of the Department of Health and Human
20 Services, or of such contractor.

21 “(B) The individual (or authorized representative).

22 “(C) The health care professional that provides
23 the items or services involved in the case.

24 “(D) The institution at which the items or services
25 (or treatment) involved in the case are provided.

26 “(E) The manufacturer of any drug or other item
27 that is included in the items or services involved in the
28 case.

29 “(F) Any other party determined under any regu-
30 lations to have a substantial interest in the case in-
31 volved.”.

32 (3) REDUCING MINIMUM NUMBER OF QUALIFIED
33 INDEPENDENT CONTRACTORS.—Section 1869(c)(4) (42
34 U.S.C. 1395ff(c)(4)) is amended by striking “not fewer
35 than 12 qualified independent contractors under this sub-
36 section” and inserting “a sufficient number of qualified
37 independent contractors (but not fewer than 4 such con-

tractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection”.

(4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA (114 Stat. 2763A–534).

(5) TRANSITION.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:

“(h) CONDUCT OF PREPAYMENT REVIEW.—

“(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—

“(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.

“(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT REVIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.

“(C) CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.

1 “(D) RANDOM PREPAYMENT REVIEW.—For pur-
 2 poses of this subsection, the term ‘random prepayment
 3 review’ means a demand for the production of records
 4 or documentation absent cause with respect to a claim.

5 “(2) LIMITATIONS ON NON-RANDOM PREPAYMENT RE-
 6 VIEW.—

7 “(A) LIMITATIONS ON INITIATION OF NON-RAN-
 8 DOM PREPAYMENT REVIEW.—A medicare administra-
 9 tive contractor may not initiate non-random prepay-
 10 ment review of a provider of services or supplier based
 11 on the initial identification by that provider of services
 12 or supplier of an improper billing practice unless there
 13 is a likelihood of sustained or high level of payment
 14 error under section 1893(f)(3)(A).

15 “(B) TERMINATION OF NON-RANDOM PREPAY-
 16 MENT REVIEW.—The Secretary shall issue regulations
 17 relating to the termination, including termination
 18 dates, of non-random prepayment review. Such regula-
 19 tions may vary such a termination date based upon the
 20 differences in the circumstances triggering prepayment
 21 review.”.

22 (b) EFFECTIVE DATE.—

23 (1) IN GENERAL.—Except as provided in this sub-
 24 section, the amendment made by subsection (a) shall take
 25 effect 1 year after the date of the enactment of this Act.

26 (2) DEADLINE FOR PROMULGATION OF CERTAIN REG-
 27 ULATIONS.—The Secretary shall first issue regulations
 28 under section 1874A(h) of the Social Security Act, as
 29 added by subsection (a), by not later than 1 year after the
 30 date of the enactment of this Act.

31 (3) APPLICATION OF STANDARD PROTOCOLS FOR RAN-
 32 DOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of
 33 the Social Security Act, as added by subsection (a), shall
 34 apply to random prepayment reviews conducted on or after
 35 such date (not later than 1 year after the date of the enact-
 36 ment of this Act) as the Secretary shall specify.

1 (c) APPLICATION TO FISCAL INTERMEDIARIES AND CAR-
 2 RIERS.—The provisions of section 1874A(h) of the Social Secu-
 3 rity Act, as added by subsection (a), shall apply to each fiscal
 4 intermediary under section 1816 of the Social Security Act (42
 5 U.S.C. 1395h) and each carrier under section 1842 of such Act
 6 (42 U.S.C. 1395u) in the same manner as they apply to medi-
 7 care administrative contractors under such provisions.

8 **SEC. 935. RECOVERY OF OVERPAYMENTS.**

9 (a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is
 10 amended by adding at the end the following new subsection:

11 “(f) RECOVERY OF OVERPAYMENTS.—

12 “(1) USE OF REPAYMENT PLANS.—

13 “(A) IN GENERAL.—If the repayment, within 30
 14 days by a provider of services or supplier, of an over-
 15 payment under this title would constitute a hardship
 16 (as described in subparagraph (B)), subject to subpara-
 17 graph (C), upon request of the provider of services or
 18 supplier the Secretary shall enter into a plan with the
 19 provider of services or supplier for the repayment
 20 (through offset or otherwise) of such overpayment over
 21 a period of at least 6 months but not longer than 3
 22 years (or not longer than 5 years in the case of extreme
 23 hardship, as determined by the Secretary). Interest
 24 shall accrue on the balance through the period of re-
 25 payment. Such plan shall meet terms and conditions
 26 determined to be appropriate by the Secretary.

27 “(B) HARDSHIP.—

28 “(i) IN GENERAL.—For purposes of subpara-
 29 graph (A), the repayment of an overpayment (or
 30 overpayments) within 30 days is deemed to con-
 31 stitute a hardship if—

32 “(I) in the case of a provider of services
 33 that files cost reports, the aggregate amount of
 34 the overpayments exceeds 10 percent of the
 35 amount paid under this title to the provider of
 36 services for the cost reporting period covered by
 37 the most recently submitted cost report; or

1 “(II) in the case of another provider of
2 services or supplier, the aggregate amount of
3 the overpayments exceeds 10 percent of the
4 amount paid under this title to the provider of
5 services or supplier for the previous calendar
6 year.

7 “(ii) RULE OF APPLICATION.—The Secretary
8 shall establish rules for the application of this sub-
9 paragraph in the case of a provider of services or
10 supplier that was not paid under this title during
11 the previous year or was paid under this title only
12 during a portion of that year.

13 “(iii) TREATMENT OF PREVIOUS OVERPAY-
14 MENTS.—If a provider of services or supplier has
15 entered into a repayment plan under subparagraph
16 (A) with respect to a specific overpayment amount,
17 such payment amount under the repayment plan
18 shall not be taken into account under clause (i)
19 with respect to subsequent overpayment amounts.

20 “(C) EXCEPTIONS.—Subparagraph (A) shall not
21 apply if—

22 “(i) the Secretary has reason to suspect that
23 the provider of services or supplier may file for
24 bankruptcy or otherwise cease to do business or
25 discontinue participation in the program under this
26 title; or

27 “(ii) there is an indication of fraud or abuse
28 committed against the program.

29 “(D) IMMEDIATE COLLECTION IF VIOLATION OF
30 REPAYMENT PLAN.—If a provider of services or sup-
31 plier fails to make a payment in accordance with a re-
32 payment plan under this paragraph, the Secretary may
33 immediately seek to offset or otherwise recover the
34 total balance outstanding (including applicable interest)
35 under the repayment plan.

36 “(E) RELATION TO NO FAULT PROVISION.—Noth-
37 ing in this paragraph shall be construed as affecting

1 the application of section 1870(c) (relating to no ad-
2 justment in the cases of certain overpayments).

3 “(2) LIMITATION ON RECOUPMENT.—

4 “(A) IN GENERAL.—In the case of a provider of
5 services or supplier that is determined to have received
6 an overpayment under this title and that seeks a recon-
7 sideration by a qualified independent contractor on
8 such determination under section 1869(b)(1), the Sec-
9 retary may not take any action (or authorize any other
10 person, including any medicare contractor, as defined
11 in subparagraph (C)) to recoup the overpayment until
12 the date the decision on the reconsideration has been
13 rendered. If the provisions of section 1869(b)(1) (pro-
14 viding for such a reconsideration by a qualified inde-
15 pendent contractor) are not in effect, in applying the
16 previous sentence any reference to such a reconsider-
17 ation shall be treated as a reference to a redetermina-
18 tion by the fiscal intermediary or carrier involved.

19 “(B) COLLECTION WITH INTEREST.—Insofar as
20 the determination on such appeal is against the pro-
21 vider of services or supplier, interest on the overpay-
22 ment shall accrue on and after the date of the original
23 notice of overpayment. Insofar as such determination
24 against the provider of services or supplier is later re-
25 versed, the Secretary shall provide for repayment of the
26 amount recouped plus interest at the same rate as
27 would apply under the previous sentence for the period
28 in which the amount was recouped.

29 “(C) MEDICARE CONTRACTOR DEFINED.—For
30 purposes of this subsection, the term ‘medicare con-
31 tractor’ has the meaning given such term in section
32 1889(g).

33 “(3) LIMITATION ON USE OF EXTRAPOLATION.—A
34 medicare contractor may not use extrapolation to determine
35 overpayment amounts to be recovered by recoupment, off-
36 set, or otherwise unless the Secretary determines that—

1 “(A) there is a sustained or high level of payment
2 error; or

3 “(B) documented educational intervention has
4 failed to correct the payment error.

5 There shall be no administrative or judicial review under sec-
6 tion 1869, section 1878, or otherwise, of determinations by the
7 Secretary of sustained or high levels of payment errors under
8 this paragraph.

9 “(4) PROVISION OF SUPPORTING DOCUMENTATION.—
10 In the case of a provider of services or supplier with respect
11 to which amounts were previously overpaid, a medicare con-
12 tractor may request the periodic production of records or
13 supporting documentation for a limited sample of sub-
14 mitted claims to ensure that the previous practice is not
15 continuing.

16 “(5) CONSENT SETTLEMENT REFORMS.—

17 “(A) IN GENERAL.—The Secretary may use a con-
18 sent settlement (as defined in subparagraph (D)) to
19 settle a projected overpayment.

20 “(B) OPPORTUNITY TO SUBMIT ADDITIONAL IN-
21 FORMATION BEFORE CONSENT SETTLEMENT OFFER.—
22 Before offering a provider of services or supplier a con-
23 sent settlement, the Secretary shall—

24 “(i) communicate to the provider of services or
25 supplier—

26 “(I) that, based on a review of the medical
27 records requested by the Secretary, a prelimi-
28 nary evaluation of those records indicates that
29 there would be an overpayment;

30 “(II) the nature of the problems identified
31 in such evaluation; and

32 “(III) the steps that the provider of serv-
33 ices or supplier should take to address the
34 problems; and

35 “(ii) provide for a 45-day period during which
36 the provider of services or supplier may furnish ad-

1 ditional information concerning the medical records
2 for the claims that had been reviewed.

3 “(C) CONSENT SETTLEMENT OFFER.—The Sec-
4 retary shall review any additional information furnished
5 by the provider of services or supplier under subpara-
6 graph (B)(ii). Taking into consideration such informa-
7 tion, the Secretary shall determine if there still appears
8 to be an overpayment. If so, the Secretary—

9 “(i) shall provide notice of such determination
10 to the provider of services or supplier, including an
11 explanation of the reason for such determination;
12 and

13 “(ii) in order to resolve the overpayment, may
14 offer the provider of services or supplier—

15 “(I) the opportunity for a statistically
16 valid random sample; or

17 “(II) a consent settlement.

18 The opportunity provided under clause (ii)(I) does not
19 waive any appeal rights with respect to the alleged
20 overpayment involved.

21 “(D) CONSENT SETTLEMENT DEFINED.—For pur-
22 poses of this paragraph, the term ‘consent settlement’
23 means an agreement between the Secretary and a pro-
24 vider of services or supplier whereby both parties agree
25 to settle a projected overpayment based on less than a
26 statistically valid sample of claims and the provider of
27 services or supplier agrees not to appeal the claims in-
28 volved.

29 “(6) NOTICE OF OVER-UTILIZATION OF CODES.—The
30 Secretary shall establish, in consultation with organizations
31 representing the classes of providers of services and sup-
32 pliers, a process under which the Secretary provides for no-
33 tice to classes of providers of services and suppliers served
34 by the contractor in cases in which the contractor has iden-
35 tified that particular billing codes may be overutilized by
36 that class of providers of services or suppliers under the

1 programs under this title (or provisions of title XI insofar
2 as they relate to such programs).

3 “(7) PAYMENT AUDITS.—

4 “(A) WRITTEN NOTICE FOR POST-PAYMENT AU-
5 DITS.—Subject to subparagraph (C), if a medicare con-
6 tractor decides to conduct a post-payment audit of a
7 provider of services or supplier under this title, the con-
8 tractor shall provide the provider of services or supplier
9 with written notice (which may be in electronic form)
10 of the intent to conduct such an audit.

11 “(B) EXPLANATION OF FINDINGS FOR ALL AU-
12 DITS.—Subject to subparagraph (C), if a medicare con-
13 tractor audits a provider of services or supplier under
14 this title, the contractor shall—

15 “(i) give the provider of services or supplier a
16 full review and explanation of the findings of the
17 audit in a manner that is understandable to the
18 provider of services or supplier and permits the de-
19 velopment of an appropriate corrective action plan;

20 “(ii) inform the provider of services or supplier
21 of the appeal rights under this title as well as con-
22 sent settlement options (which are at the discretion
23 of the Secretary);

24 “(iii) give the provider of services or supplier
25 an opportunity to provide additional information to
26 the contractor; and

27 “(iv) take into account information provided,
28 on a timely basis, by the provider of services or
29 supplier under clause (iii).

30 “(C) EXCEPTION.—Subparagraphs (A) and (B)
31 shall not apply if the provision of notice or findings
32 would compromise pending law enforcement activities,
33 whether civil or criminal, or reveal findings of law en-
34 forcement-related audits.

35 “(8) STANDARD METHODOLOGY FOR PROBE SAM-
36 PLING.—The Secretary shall establish a standard method-
37 ology for medicare contractors to use in selecting a sample

1 of claims for review in the case of an abnormal billing pat-
2 tern.”.

3 (b) EFFECTIVE DATES AND DEADLINES.—

4 (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1)
5 of the Social Security Act, as added by subsection (a), shall
6 apply to requests for repayment plans made after the date
7 of the enactment of this Act.

8 (2) LIMITATION ON RECOUPMENT.—Section
9 1893(f)(2) of the Social Security Act, as added by sub-
10 section (a), shall apply to actions taken after the date of
11 the enactment of this Act.

12 (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of
13 the Social Security Act, as added by subsection (a), shall
14 apply to statistically valid random samples initiated after
15 the date that is 1 year after the date of the enactment of
16 this Act.

17 (4) PROVISION OF SUPPORTING DOCUMENTATION.—
18 Section 1893(f)(4) of the Social Security Act, as added by
19 subsection (a), shall take effect on the date of the enact-
20 ment of this Act.

21 (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of
22 the Social Security Act, as added by subsection (a), shall
23 apply to consent settlements entered into after the date of
24 the enactment of this Act.

25 (6) NOTICE OF OVERUTILIZATION.—Not later than 1
26 year after the date of the enactment of this Act, the Sec-
27 retary shall first establish the process for notice of over-
28 utilization of billing codes under section 1893A(f)(6) of the
29 Social Security Act, as added by subsection (a).

30 (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the
31 Social Security Act, as added by subsection (a), shall apply
32 to audits initiated after the date of the enactment of this
33 Act.

34 (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—
35 Not later than 1 year after the date of the enactment of
36 this Act, the Secretary shall first establish a standard
37 methodology for selection of sample claims for abnormal

1 billing patterns under section 1893(f)(8) of the Social Se-
 2 curity Act, as added by subsection (a).

3 **SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF**
 4 **APPEAL.**

5 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is
 6 amended—

7 (1) by adding at the end of the heading the following:
 8 “; ENROLLMENT PROCESSES”; and

9 (2) by adding at the end the following new subsection:
 10 “(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERV-
 11 ICES AND SUPPLIERS.—

12 “(1) ENROLLMENT PROCESS.—

13 “(A) IN GENERAL.—The Secretary shall establish
 14 by regulation a process for the enrollment of providers
 15 of services and suppliers under this title.

16 “(B) DEADLINES.—The Secretary shall establish
 17 by regulation procedures under which there are dead-
 18 lines for actions on applications for enrollment (and, if
 19 applicable, renewal of enrollment). The Secretary shall
 20 monitor the performance of medicare administrative
 21 contractors in meeting the deadlines established under
 22 this subparagraph.

23 “(C) CONSULTATION BEFORE CHANGING PRO-
 24 VIDER ENROLLMENT FORMS.—The Secretary shall con-
 25 sult with providers of services and suppliers before
 26 making changes in the provider enrollment forms re-
 27 quired of such providers and suppliers to be eligible to
 28 submit claims for which payment may be made under
 29 this title.

30 “(2) HEARING RIGHTS IN CASES OF DENIAL OR NON-
 31 RENEWAL.—A provider of services or supplier whose appli-
 32 cation to enroll (or, if applicable, to renew enrollment)
 33 under this title is denied may have a hearing and judicial
 34 review of such denial under the procedures that apply
 35 under subsection (h)(1)(A) to a provider of services that is
 36 dissatisfied with a determination by the Secretary.”.

37 (b) EFFECTIVE DATES.—

1 (1) ENROLLMENT PROCESS.—The Secretary shall pro-
 2 vide for the establishment of the enrollment process under
 3 section 1866(j)(1) of the Social Security Act, as added by
 4 subsection (a)(2), within 6 months after the date of the en-
 5 actment of this Act.

6 (2) CONSULTATION.—Section 1866(j)(1)(C) of the So-
 7 cial Security Act, as added by subsection (a)(2), shall apply
 8 with respect to changes in provider enrollment forms made
 9 on or after January 1, 2004.

10 (3) HEARING RIGHTS.—Section 1866(j)(2) of the So-
 11 cial Security Act, as added by subsection (a)(2), shall apply
 12 to denials occurring on or after such date (not later than
 13 1 year after the date of the enactment of this Act) as the
 14 Secretary specifies.

15 **SEC. 937. PROCESS FOR CORRECTION OF MINOR ER-**
 16 **RORS AND OMISSIONS WITHOUT PURSUING**
 17 **APPEALS PROCESS.**

18 (a) CLAIMS.—The Secretary shall develop, in consultation
 19 with appropriate medicare contractors (as defined in section
 20 1889(g) of the Social Security Act, as inserted by section
 21 301(a)(1)) and representatives of providers of services and sup-
 22 pliers, a process whereby, in the case of minor errors or omis-
 23 sions (as defined by the Secretary) that are detected in the sub-
 24 mission of claims under the programs under title XVIII of such
 25 Act, a provider of services or supplier is given an opportunity
 26 to correct such an error or omission without the need to initiate
 27 an appeal. Such process shall include the ability to resubmit
 28 corrected claims.

29 (b) DEADLINE.—Not later than 1 year after the date of
 30 the enactment of this Act, the Secretary shall first develop the
 31 process under subsection (a).

32 **SEC. 938. PRIOR DETERMINATION PROCESS FOR CER-**
 33 **TAIN ITEMS AND SERVICES; ADVANCE BENE-**
 34 **FICIARY NOTICES.**

35 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff(b)), as
 36 amended by section 933(d)(2)(B), is further amended by add-
 37 ing at the end the following new subsection:

1 “(h) PRIOR DETERMINATION PROCESS FOR CERTAIN
2 ITEMS AND SERVICES.—

3 “(1) ESTABLISHMENT OF PROCESS.—

4 “(A) IN GENERAL.—With respect to a medicare
5 administrative contractor that has a contract under
6 section 1874A that provides for making payments
7 under this title with respect to physicians’ services (as
8 defined in section 1848(j)(3)), the Secretary shall es-
9 tablish a prior determination process that meets the re-
10 quirements of this subsection and that shall be applied
11 by such contractor in the case of eligible requesters.

12 “(B) ELIGIBLE REQUESTER.—For purposes of
13 this subsection, each of the following shall be an eligi-
14 ble requester:

15 “(i) A participating physician, but only with
16 respect to physicians’ services to be furnished to an
17 individual who is entitled to benefits under this title
18 and who has consented to the physician making the
19 request under this subsection for those physicians’
20 services.

21 “(ii) An individual entitled to benefits under
22 this title, but only with respect to a physicians’
23 service for which the individual receives, from a
24 physician, an advance beneficiary notice under sec-
25 tion 1879(a).

26 “(2) SECRETARIAL FLEXIBILITY.—The Secretary shall
27 establish by regulation reasonable limits on the physicians’
28 services for which a prior determination of coverage may be
29 requested under this subsection. In establishing such limits,
30 the Secretary may consider the dollar amount involved with
31 respect to the physicians’ service, administrative costs and
32 burdens, and other relevant factors.

33 “(3) REQUEST FOR PRIOR DETERMINATION.—

34 “(A) IN GENERAL.—Subject to paragraph (2),
35 under the process established under this subsection an
36 eligible requester may submit to the contractor a re-
37 quest for a determination, before the furnishing of a

1 physicians' service, as to whether the physicians' serv-
 2 ice is covered under this title consistent with the appli-
 3 cable requirements of section 1862(a)(1)(A) (relating
 4 to medical necessity).

5 “(B) ACCOMPANYING DOCUMENTATION.—The Sec-
 6 retary may require that the request be accompanied by
 7 a description of the physicians' service, supporting doc-
 8 umentation relating to the medical necessity for the
 9 physicians' service, and any other appropriate docu-
 10 mentation. In the case of a request submitted by an eli-
 11 gible requester who is described in paragraph
 12 (1)(B)(ii), the Secretary may require that the request
 13 also be accompanied by a copy of the advance bene-
 14 ficiary notice involved.

15 “(4) RESPONSE TO REQUEST.—

16 “(A) IN GENERAL.—Under such process, the con-
 17 tractor shall provide the eligible requester with written
 18 notice of a determination as to whether—

19 “(i) the physicians' service is so covered;

20 “(ii) the physicians' service is not so covered;

21 or

22 “(iii) the contractor lacks sufficient informa-
 23 tion to make a coverage determination with respect
 24 to the physicians' service.

25 “(B) CONTENTS OF NOTICE FOR CERTAIN DETER-
 26 MINATIONS.—

27 “(i) NONCOVERAGE.—If the contractor makes
 28 the determination described in subparagraph
 29 (A)(ii), the contractor shall include in the notice a
 30 brief explanation of the basis for the determination,
 31 including on what national or local coverage or
 32 noncoverage determination (if any) the determina-
 33 tion is based, and a description of any applicable
 34 rights under subsection (a).

35 “(ii) INSUFFICIENT INFORMATION.—If the
 36 contractor makes the determination described in
 37 subparagraph (A)(iii), the contractor shall include

1 in the notice a description of the additional infor-
2 mation required to make the coverage determina-
3 tion.

4 “(C) DEADLINE TO RESPOND.—Such notice shall
5 be provided within the same time period as the time pe-
6 riod applicable to the contractor providing notice of ini-
7 tial determinations on a claim for benefits under sub-
8 section (a)(2)(A).

9 “(D) INFORMING BENEFICIARY IN CASE OF PHYSI-
10 CIAN REQUEST.—In the case of a request by a partici-
11 pating physician under paragraph (1)(B)(i), the process
12 shall provide that the individual to whom the physi-
13 cians’ service is proposed to be furnished shall be in-
14 formed of any determination described in subparagraph
15 (A)(ii) (relating to a determination of non-coverage)
16 and the right (referred to in paragraph (6)(B)) to ob-
17 tain the physicians’ service and have a claim submitted
18 for the physicians’ service.

19 “(5) BINDING NATURE OF POSITIVE DETERMINA-
20 TION.—If the contractor makes the determination described
21 in paragraph (4)(A)(i), such determination shall be binding
22 on the contractor in the absence of fraud or evidence of
23 misrepresentation of facts presented to the contractor.

24 “(6) LIMITATION ON FURTHER REVIEW.—

25 “(A) IN GENERAL.—Contractor determinations de-
26 scribed in paragraph (4)(A)(ii) or (4)(A)(iii) (relating
27 to pre-service claims) are not subject to further admin-
28 istrative appeal or judicial review under this section or
29 otherwise.

30 “(B) DECISION NOT TO SEEK PRIOR DETERMINA-
31 TION OR NEGATIVE DETERMINATION DOES NOT IMPACT
32 RIGHT TO OBTAIN SERVICES, SEEK REIMBURSEMENT,
33 OR APPEAL RIGHTS.—Nothing in this subsection shall
34 be construed as affecting the right of an individual
35 who—

1 “(i) decides not to seek a prior determination
2 under this subsection with respect to physicians’
3 services; or

4 “(ii) seeks such a determination and has re-
5 ceived a determination described in paragraph
6 (4)(A)(ii),

7 from receiving (and submitting a claim for) such physi-
8 cians’ services and from obtaining administrative or ju-
9 dicial review respecting such claim under the other ap-
10 plicable provisions of this section. Failure to seek a
11 prior determination under this subsection with respect
12 to physicians’ service shall not be taken into account in
13 such administrative or judicial review.

14 “(C) NO PRIOR DETERMINATION AFTER RECEIPT
15 OF SERVICES.—Once an individual is provided physi-
16 cians’ services, there shall be no prior determination
17 under this subsection with respect to such physicians’
18 services.”.

19 (b) EFFECTIVE DATE; SUNSET; TRANSITION.—

20 (1) EFFECTIVE DATE.—The Secretary shall establish
21 the prior determination process under the amendment
22 made by subsection (a) in such a manner as to provide for
23 the acceptance of requests for determinations under such
24 process filed not later than 18 months after the date of the
25 enactment of this Act.

26 (2) SUNSET.—Such prior determination process shall
27 not apply to requests filed after the end of the 5-year pe-
28 riod beginning on the first date on which requests for de-
29 terminations under such process are accepted.

30 (3) TRANSITION.—During the period in which the
31 amendment made by subsection (a) has become effective
32 but contracts are not provided under section 1874A of the
33 Social Security Act with medicare administrative contrac-
34 tors, any reference in section 1869(g) of such Act (as
35 added by such amendment) to such a contractor is deemed
36 a reference to a fiscal intermediary or carrier with an

1 agreement under section 1816, or contract under section
2 1842, respectively, of such Act.

3 (4) LIMITATION ON APPLICATION TO SGR.—For pur-
4 poses of applying section 1848(f)(2)(D) of the Social Secu-
5 rity Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment
6 made by subsection (a) shall not be considered to be a
7 change in law or regulation.

8 (c) PROVISIONS RELATING TO ADVANCE BENEFICIARY
9 NOTICES; REPORT ON PRIOR DETERMINATION PROCESS.—

10 (1) DATA COLLECTION.—The Secretary shall establish
11 a process for the collection of information on the instances
12 in which an advance beneficiary notice (as defined in para-
13 graph (5)) has been provided and on instances in which a
14 beneficiary indicates on such a notice that the beneficiary
15 does not intend to seek to have the item or service that is
16 the subject of the notice furnished.

17 (2) OUTREACH AND EDUCATION.—The Secretary shall
18 establish a program of outreach and education for bene-
19 ficiaries and providers of services and other persons on the
20 appropriate use of advance beneficiary notices and coverage
21 policies under the medicare program.

22 (3) GAO REPORT ON USE OF ADVANCE BENEFICIARY
23 NOTICES.—Not later than 18 months after the date on
24 which section 1869(h) of the Social Security Act (as added
25 by subsection (a)) takes effect, the Comptroller General of
26 the United States shall submit to Congress a report on the
27 use of advance beneficiary notices under title XVIII of such
28 Act. Such report shall include information concerning the
29 providers of services and other persons that have provided
30 such notices and the response of beneficiaries to such no-
31 tices.

32 (4) GAO REPORT ON USE OF PRIOR DETERMINATION
33 PROCESS.—Not later than 36 months after the date on
34 which section 1869(h) of the Social Security Act (as added
35 by subsection (a)) takes effect, the Comptroller General of
36 the United States shall submit to Congress a report on the

1 use of the prior determination process under such section.

2 Such report shall include—

3 (A) information concerning—

4 (i) the number and types of procedures for
5 which a prior determination has been sought;

6 (ii) determinations made under the process;

7 (iii) the percentage of beneficiaries prevailing;

8 (iv) in those cases in which the beneficiaries
9 do not prevail, the reasons why such beneficiaries
10 did not prevail; and

11 (v) changes in receipt of services resulting
12 from the application of such process;

13 (B) an evaluation of whether the process was use-
14 ful for physicians (and other suppliers) and bene-
15 ficiaries, whether it was timely, and whether the
16 amount of information required was burdensome to
17 physicians and beneficiaries; and

18 (C) recommendations for improvements or con-
19 tinuation of such process.

20 (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In
21 this subsection, the term “advance beneficiary notice”
22 means a written notice provided under section 1879(a) of
23 the Social Security Act (42 U.S.C. 1395pp(a)) to an indi-
24 vidual entitled to benefits under part A or enrolled under
25 part B of title XVIII of such Act before items or services
26 are furnished under such part in cases where a provider of
27 services or other person that would furnish the item or
28 service believes that payment will not be made for some or
29 all of such items or services under such title.

30 **SEC. 939. APPEALS BY PROVIDERS WHEN THERE IS NO**
31 **OTHER PARTY AVAILABLE.**

32 (a) IN GENERAL.—Section 1870 (42 U.S.C. 1395gg) is
33 amended by adding at the end the following new subsection:

34 “(h) Notwithstanding subsection (f) or any other provision
35 of law, the Secretary shall permit a provider of services or sup-
36 plier to appeal any determination of the Secretary under this
37 title relating to services rendered under this title to an indi-

1 vidual who subsequently dies if there is no other party available
2 to appeal such determination.”.

3 (b) EFFECTIVE DATE.—The amendment made by sub-
4 section (a) shall take effect on the date of the enactment of this
5 Act and shall apply to items and services furnished on or after
6 such date.

7 **SEC. 940. REVISIONS TO APPEALS TIMEFRAMES AND**
8 **AMOUNTS.**

9 (a) TIMEFRAMES.—Section 1869 (42 U.S.C. 1395ff) is
10 amended—

11 (1) in subsection (a)(3)(C)(ii), by striking “30-day pe-
12 riod” each place it appears and inserting “60-day period”;
13 and

14 (2) in subsection (c)(3)(C)(i), by striking “30-day pe-
15 riod” and inserting “60-day period”.

16 (b) AMOUNTS.—

17 (1) IN GENERAL.—Section 1869(b)(1)(E) (42 U.S.C.
18 1395ff(b)(1)(E)) is amended by adding at the end the fol-
19 lowing new clause:

20 “(iii) ADJUSTMENT OF DOLLAR AMOUNTS.—

21 For requests for hearings or judicial review made
22 in a year after 2004, the dollar amounts specified
23 in clause (i) shall be equal to such dollar amounts
24 increased by the percentage increase in the medical
25 care component of the consumer price index for all
26 urban consumers (U.S. city average) for July 2003
27 to the July preceding the year involved. Any
28 amount determined under the previous sentence
29 that is not a multiple of \$10 shall be rounded to
30 the nearest multiple of \$10.”.

31 (2) CONFORMING AMENDMENTS.—(A) Section
32 1852(g)(5) (42 U.S.C. 1395w-22(g)(5)) is amended by
33 adding at the end the following: “The provisions of section
34 1869(b)(1)(E)(iii) shall apply with respect to dollar
35 amounts specified in the first 2 sentences of this paragraph
36 in the same manner as they apply to the dollar amounts
37 specified in section 1869(b)(1)(E)(i).”.

1 (B) Section 1876(b)(5)(B) (42 U.S.C. 1395mm(b)(5)(B))
 2 is amended by adding at the end the following: “The provisions
 3 of section 1869(b)(1)(E)(iii) shall apply with respect to dollar
 4 amounts specified in the first 2 sentences of this subparagraph
 5 in the same manner as they apply to the dollar amounts speci-
 6 fied in section 1869(b)(1)(E)(i).”.

7 **SEC. 940A. MEDIATION PROCESS FOR LOCAL COV-**
 8 **ERAGE DETERMINATIONS.**

9 (a) IN GENERAL.—Section 1869 (42 U.S.C. 1395ff), as
 10 amended by section 938(a), is amended by adding at the end
 11 the following new subsection:

12 “(i) MEDIATION PROCESS FOR LOCAL COVERAGE DETER-
 13 MINATIONS.—

14 “(1) ESTABLISHMENT OF PROCESS.—The Secretary
 15 shall establish a mediation process under this subsection
 16 through the use of a physician trained in mediation and
 17 employed by the Centers for Medicare & Medicaid Services.

18 “(2) RESPONSIBILITY OF MEDIATOR.—Under the
 19 process established in paragraph (1), such a mediator shall
 20 mediate in disputes between groups representing providers
 21 of services, suppliers (as defined in section 1861(d)), and
 22 the medical director for a medicare administrative con-
 23 tractor whenever the regional administrator (as defined by
 24 the Secretary) involved determines that there was a system-
 25 atic pattern and a large volume of complaints from such
 26 groups regarding decisions of such director or there is a
 27 complaint from the co-chair of the advisory committee for
 28 that contractor to such regional administrator regarding
 29 such dispute.”.

30 (b) INCLUSION IN MAC CONTRACTS.—Section
 31 1874A(b)(3)(A)(i), as added by section 911(a)(1), is amended
 32 by adding at the end the following: “Such requirements shall
 33 include specific performance duties expected of a medical direc-
 34 tor of a medicare administrative contractor, including require-
 35 ments relating to professional relations and the availability of
 36 such director to conduct medical determination activities within
 37 the jurisdiction of such a contractor.”.

1 **Subtitle E—Miscellaneous Provisions**

2 **SEC. 941. POLICY DEVELOPMENT REGARDING EVALUA-** 3 **TION AND MANAGEMENT (E & M) DOCU-** 4 **MENTATION GUIDELINES.**

5 (a) IN GENERAL.—The Secretary may not implement any
 6 new or modified documentation guidelines (which for purposes
 7 of this section includes clinical examples) for evaluation and
 8 management physician services under the title XVIII of the So-
 9 cial Security Act on or after the date of the enactment of this
 10 Act unless the Secretary—

11 (1) has developed the guidelines in collaboration with
 12 practicing physicians (including both generalists and spe-
 13 cialists) and provided for an assessment of the proposed
 14 guidelines by the physician community;

15 (2) has established a plan that contains specific goals,
 16 including a schedule, for improving the use of such guide-
 17 lines;

18 (3) has conducted appropriate and representative pilot
 19 projects under subsection (b) to test such guidelines;

20 (4) finds, based on reports submitted under subsection
 21 (b)(5) with respect to pilot projects conducted for such or
 22 related guidelines, that the objectives described in sub-
 23 section (c) will be met in the implementation of such guide-
 24 lines; and

25 (5) has established, and is implementing, a program to
 26 educate physicians on the use of such guidelines and that
 27 includes appropriate outreach.

28 The Secretary shall make changes to the manner in which ex-
 29 isting evaluation and management documentation guidelines
 30 are implemented to reduce paperwork burdens on physicians.

31 (b) PILOT PROJECTS TO TEST MODIFIED OR NEW EVAL-
 32 UATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

33 (1) IN GENERAL.—With respect to proposed new or
 34 modified documentation guidelines referred to in subsection
 35 (a), the Secretary shall conduct under this subsection ap-
 36 propriate and representative pilot projects to test the pro-
 37 posed guidelines.

1 (2) LENGTH AND CONSULTATION.—Each pilot project
2 under this subsection shall—

3 (A) be voluntary;

4 (B) be of sufficient length as determined by the
5 Secretary (but in no case to exceed 1 year) to allow for
6 preparatory physician and medicare contractor edu-
7 cation, analysis, and use and assessment of potential
8 evaluation and management guidelines; and

9 (C) be conducted, in development and throughout
10 the planning and operational stages of the project, in
11 consultation with practicing physicians (including both
12 generalists and specialists).

13 (3) RANGE OF PILOT PROJECTS.—Of the pilot projects
14 conducted under this subsection with respect to proposed
15 new or modified documentation guidelines—

16 (A) at least one shall focus on a peer review meth-
17 od by physicians (not employed by a medicare con-
18 tractor) which evaluates medical record information for
19 claims submitted by physicians identified as statistical
20 outliers relative to codes used for billing purposes for
21 such services;

22 (B) at least one shall focus on an alternative
23 method to detailed guidelines based on physician docu-
24 mentation of face to face encounter time with a patient;

25 (C) at least one shall be conducted for services
26 furnished in a rural area and at least one for services
27 furnished outside such an area; and

28 (D) at least one shall be conducted in a setting
29 where physicians bill under physicians' services in
30 teaching settings and at least one shall be conducted in
31 a setting other than a teaching setting.

32 (4) STUDY OF IMPACT.—Each pilot project shall ex-
33 amine the effect of the proposed guidelines on—

34 (A) different types of physician practices, includ-
35 ing those with fewer than 10 full-time-equivalent em-
36 ployees (including physicians); and

1 (B) the costs of physician compliance, including
2 education, implementation, auditing, and monitoring.

3 (5) REPORT ON PILOT PROJECTS.—Not later than 6
4 months after the date of completion of pilot projects carried
5 out under this subsection with respect to a proposed guide-
6 line described in paragraph (1), the Secretary shall submit
7 to Congress a report on the pilot projects. Each such report
8 shall include a finding by the Secretary of whether the ob-
9 jectives described in subsection (c) will be met in the imple-
10 mentation of such proposed guideline.

11 (c) OBJECTIVES FOR EVALUATION AND MANAGEMENT
12 GUIDELINES.—The objectives for modified evaluation and man-
13 agement documentation guidelines developed by the Secretary
14 shall be to—

15 (1) identify clinically relevant documentation needed to
16 code accurately and assess coding levels accurately;

17 (2) decrease the level of non-clinically pertinent and
18 burdensome documentation time and content in the physi-
19 cian's medical record;

20 (3) increase accuracy by reviewers; and

21 (4) educate both physicians and reviewers.

22 (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOC-
23 UMENTATION FOR PHYSICIAN CLAIMS.—

24 (1) STUDY.—The Secretary shall carry out a study of
25 the matters described in paragraph (2).

26 (2) MATTERS DESCRIBED.—The matters referred to in
27 paragraph (1) are—

28 (A) the development of a simpler, alternative sys-
29 tem of requirements for documentation accompanying
30 claims for evaluation and management physician serv-
31 ices for which payment is made under title XVIII of
32 the Social Security Act; and

33 (B) consideration of systems other than current
34 coding and documentation requirements for payment
35 for such physician services.

36 (3) CONSULTATION WITH PRACTICING PHYSICIANS.—
37 In designing and carrying out the study under paragraph

1 (1), the Secretary shall consult with practicing physicians,
 2 including physicians who are part of group practices and
 3 including both generalists and specialists.

4 (4) APPLICATION OF HIPAA UNIFORM CODING RE-
 5 QUIREMENTS.—In developing an alternative system under
 6 paragraph (2), the Secretary shall consider requirements of
 7 administrative simplification under part C of title XI of the
 8 Social Security Act.

9 (5) REPORT TO CONGRESS.—(A) Not later than Octo-
 10 ber 1, 2005, the Secretary shall submit to Congress a re-
 11 port on the results of the study conducted under paragraph
 12 (1).

13 (B) The Medicare Payment Advisory Commission shall
 14 conduct an analysis of the results of the study included in
 15 the report under subparagraph (A) and shall submit a re-
 16 port on such analysis to Congress.

17 (e) STUDY ON APPROPRIATE CODING OF CERTAIN EX-
 18 TENDED OFFICE VISITS.—The Secretary shall conduct a study
 19 of the appropriateness of coding in cases of extended office vis-
 20 its in which there is no diagnosis made. Not later than October
 21 1, 2005, the Secretary shall submit a report to Congress on
 22 such study and shall include recommendations on how to code
 23 appropriately for such visits in a manner that takes into ac-
 24 count the amount of time the physician spent with the patient.

25 (f) DEFINITIONS.—In this section—

26 (1) the term “rural area” has the meaning given that
 27 term in section 1886(d)(2)(D) of the Social Security Act
 28 (42 U.S.C. 1395ww(d)(2)(D)); and

29 (2) the term “teaching settings” are those settings de-
 30 scribed in section 415.150 of title 42, Code of Federal Reg-
 31 ulations.

32 **SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECH-**
 33 **NOLOGY AND COVERAGE.**

34 (a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Sec-
 35 tion 1868 (42 U.S.C. 1395ee) is amended—

36 (1) by adding at the end of the heading the following:
 37 “; COUNCIL FOR TECHNOLOGY AND INNOVATION”;

1 (2) by inserting “PRACTICING PHYSICIANS ADVISORY
2 COUNCIL.—(1)” after “(a)”;

3 (3) in paragraph (1), as so redesignated under para-
4 graph (2), by striking “in this section” and inserting “in
5 this subsection”;

6 (4) by redesignating subsections (b) and (c) as para-
7 graphs (2) and (3), respectively; and

8 (5) by adding at the end the following new subsection:

9 “(b) COUNCIL FOR TECHNOLOGY AND INNOVATION.—

10 “(1) ESTABLISHMENT.—The Secretary shall establish
11 a Council for Technology and Innovation within the Cen-
12 ters for Medicare & Medicaid Services (in this section re-
13 ferred to as ‘CMS’).

14 “(2) COMPOSITION.—The Council shall be composed
15 of senior CMS staff and clinicians and shall be chaired by
16 the Executive Coordinator for Technology and Innovation
17 (appointed or designated under paragraph (4)).

18 “(3) DUTIES.—The Council shall coordinate the activi-
19 ties of coverage, coding, and payment processes under this
20 title with respect to new technologies and procedures, in-
21 cluding new drug therapies, and shall coordinate the ex-
22 change of information on new technologies between CMS
23 and other entities that make similar decisions.

24 “(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY
25 AND INNOVATION.—The Secretary shall appoint (or des-
26 ignate) a noncareer appointee (as defined in section
27 3132(a)(7) of title 5, United States Code) who shall serve
28 as the Executive Coordinator for Technology and Innova-
29 tion. Such executive coordinator shall report to the Admin-
30 istrator of CMS, shall chair the Council, shall oversee the
31 execution of its duties, and shall serve as a single point of
32 contact for outside groups and entities regarding the cov-
33 erage, coding, and payment processes under this title.”.

34 (b) METHODS FOR DETERMINING PAYMENT BASIS FOR
35 NEW LAB TESTS.—Section 1833(h) (42 U.S.C. 13951(h)) is
36 amended by adding at the end the following:

1 “(8)(A) The Secretary shall establish by regulation proce-
2 dures for determining the basis for, and amount of, payment
3 under this subsection for any clinical diagnostic laboratory test
4 with respect to which a new or substantially revised HCPCS
5 code is assigned on or after January 1, 2005 (in this para-
6 graph referred to as ‘new tests’).

7 “(B) Determinations under subparagraph (A) shall be
8 made only after the Secretary—

9 “(i) makes available to the public (through an Internet
10 website and other appropriate mechanisms) a list that in-
11 cludes any such test for which establishment of a payment
12 amount under this subsection is being considered for a
13 year;

14 “(ii) on the same day such list is made available,
15 causes to have published in the Federal Register notice of
16 a meeting to receive comments and recommendations (and
17 data on which recommendations are based) from the public
18 on the appropriate basis under this subsection for estab-
19 lishing payment amounts for the tests on such list;

20 “(iii) not less than 30 days after publication of such
21 notice convenes a meeting, that includes representatives of
22 officials of the Centers for Medicare & Medicaid Services
23 involved in determining payment amounts, to receive such
24 comments and recommendations (and data on which the
25 recommendations are based);

26 “(iv) taking into account the comments and rec-
27 ommendations (and accompanying data) received at such
28 meeting, develops and makes available to the public
29 (through an Internet website and other appropriate mecha-
30 nisms) a list of proposed determinations with respect to the
31 appropriate basis for establishing a payment amount under
32 this subsection for each such code, together with an expla-
33 nation of the reasons for each such determination, the data
34 on which the determinations are based, and a request for
35 public written comments on the proposed determination;
36 and

1 “(v) taking into account the comments received during
2 the public comment period, develops and makes available to
3 the public (through an Internet website and other appro-
4 priate mechanisms) a list of final determinations of the
5 payment amounts for such tests under this subsection, to-
6 gether with the rationale for each such determination, the
7 data on which the determinations are based, and responses
8 to comments and suggestions received from the public.

9 “(C) Under the procedures established pursuant to sub-
10 paragraph (A), the Secretary shall—

11 “(i) set forth the criteria for making determinations
12 under subparagraph (A); and

13 “(ii) make available to the public the data (other than
14 proprietary data) considered in making such determina-
15 tions.

16 “(D) The Secretary may convene such further public meet-
17 ings to receive public comments on payment amounts for new
18 tests under this subsection as the Secretary deems appropriate.

19 “(E) For purposes of this paragraph:

20 “(i) The term ‘HCPCS’ refers to the Health Care Pro-
21 cedure Coding System.

22 “(ii) A code shall be considered to be ‘substantially re-
23 vised’ if there is a substantive change to the definition of
24 the test or procedure to which the code applies (such as a
25 new analyte or a new methodology for measuring an exist-
26 ing analyte-specific test).”.

27 (c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA
28 COLLECTION FOR USE IN THE MEDICARE INPATIENT PAY-
29 MENT SYSTEM.—

30 (1) STUDY.—The Comptroller General of the United
31 States shall conduct a study that analyzes which external
32 data can be collected in a shorter timeframe by the Centers
33 for Medicare & Medicaid Services for use in computing pay-
34 ments for inpatient hospital services. The study may in-
35 clude an evaluation of the feasibility and appropriateness of
36 using quarterly samples or special surveys or any other
37 methods. The study shall include an analysis of whether

1 other executive agencies, such as the Bureau of Labor Sta-
 2 tistics in the Department of Commerce, are best suited to
 3 collect this information.

4 (2) REPORT.—By not later than October 1, 2004, the
 5 Comptroller General shall submit a report to Congress on
 6 the study under paragraph (1).

7 **SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN**
 8 **SERVICES UNDER MEDICARE SECONDARY**
 9 **PAYOR (MSP) PROVISIONS.**

10 (a) IN GENERAL.—The Secretary shall not require a hos-
 11 pital (including a critical access hospital) to ask questions (or
 12 obtain information) relating to the application of section
 13 1862(b) of the Social Security Act (relating to medicare sec-
 14 ondary payor provisions) in the case of reference laboratory
 15 services described in subsection (b), if the Secretary does not
 16 impose such requirement in the case of such services furnished
 17 by an independent laboratory.

18 (b) REFERENCE LABORATORY SERVICES DESCRIBED.—
 19 Reference laboratory services described in this subsection are
 20 clinical laboratory diagnostic tests (or the interpretation of
 21 such tests, or both) furnished without a face-to-face encounter
 22 between the individual entitled to benefits under part A or en-
 23 rolled under part B, or both, and the hospital involved and in
 24 which the hospital submits a claim only for such test or inter-
 25 pretation.

26 **SEC. 944. EMTALA IMPROVEMENTS.**

27 (a) PAYMENT FOR EMTALA-MANDATED SCREENING AND
 28 STABILIZATION SERVICES.—

29 (1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
 30 amended by inserting after subsection (c) the following new
 31 subsection:

32 “(d) For purposes of subsection (a)(1)(A), in the case of
 33 any item or service that is required to be provided pursuant to
 34 section 1867 to an individual who is entitled to benefits under
 35 this title, determinations as to whether the item or service is
 36 reasonable and necessary shall be made on the basis of the in-
 37 formation available to the treating physician or practitioner (in-

1 cluding the patient’s presenting symptoms or complaint) at the
2 time the item or service was ordered or furnished by the physi-
3 cian or practitioner (and not on the patient’s principal diag-
4 nosis). When making such determinations with respect to such
5 an item or service, the Secretary shall not consider the fre-
6 quency with which the item or service was provided to the pa-
7 tient before or after the time of the admission or visit.”.

8 (2) EFFECTIVE DATE.—The amendment made by
9 paragraph (1) shall apply to items and services furnished
10 on or after January 1, 2004.

11 (b) NOTIFICATION OF PROVIDERS WHEN EMTALA IN-
12 VESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C.
13 1395dd(d)) is amended by adding at the end the following new
14 paragraph:

15 “(4) NOTICE UPON CLOSING AN INVESTIGATION.—The
16 Secretary shall establish a procedure to notify hospitals and
17 physicians when an investigation under this section is
18 closed.”.

19 (c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN
20 EMTALA CASES INVOLVING TERMINATION OF PARTICIPA-
21 TION.—

22 (1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C.
23 1395dd(d)(3)) is amended—

24 (A) in the first sentence, by inserting “or in termi-
25 nating a hospital’s participation under this title” after
26 “in imposing sanctions under paragraph (1)”; and

27 (B) by adding at the end the following new sen-
28 tences: “Except in the case in which a delay would
29 jeopardize the health or safety of individuals, the Sec-
30 retary shall also request such a review before making
31 a compliance determination as part of the process of
32 terminating a hospital’s participation under this title
33 for violations related to the appropriateness of a med-
34 ical screening examination, stabilizing treatment, or an
35 appropriate transfer as required by this section, and
36 shall provide a period of 5 days for such review. The
37 Secretary shall provide a copy of the organization’s re-

1 port to the hospital or physician consistent with con-
 2 fidentiality requirements imposed on the organization
 3 under such part B.”.

4 (2) EFFECTIVE DATE.—The amendments made by
 5 paragraph (1) shall apply to terminations of participation
 6 initiated on or after the date of the enactment of this Act.

7 **SEC. 945. EMERGENCY MEDICAL TREATMENT AND**
 8 **LABOR ACT (EMTALA) TECHNICAL ADVISORY**
 9 **GROUP.**

10 (a) ESTABLISHMENT.—The Secretary shall establish a
 11 Technical Advisory Group (in this section referred to as the
 12 “Advisory Group”) to review issues related to the Emergency
 13 Medical Treatment and Labor Act (EMTALA) and its imple-
 14 mentation. In this section, the term “EMTALA” refers to the
 15 provisions of section 1867 of the Social Security Act (42 U.S.C.
 16 1395dd).

17 (b) MEMBERSHIP.—The Advisory Group shall be com-
 18 posed of 19 members, including the Administrator of the Cen-
 19 ters for Medicare & Medicaid Services and the Inspector Gen-
 20 eral of the Department of Health and Human Services and of
 21 which—

22 (1) 4 shall be representatives of hospitals, including at
 23 least one public hospital, that have experience with the ap-
 24 plication of EMTALA and at least 2 of which have not
 25 been cited for EMTALA violations;

26 (2) 7 shall be practicing physicians drawn from the
 27 fields of emergency medicine, cardiology or cardiothoracic
 28 surgery, orthopedic surgery, neurosurgery, pediatrics or a
 29 pediatric subspecialty, obstetrics-gynecology, and psychi-
 30 atry, with not more than one physician from any particular
 31 field;

32 (3) 2 shall represent patients;

33 (4) 2 shall be staff involved in EMTALA investiga-
 34 tions from different regional offices of the Centers for
 35 Medicare & Medicaid Services; and

36 (5) 1 shall be from a State survey office involved in
 37 EMTALA investigations and 1 shall be from a peer review

1 organization, both of whom shall be from areas other than
2 the regions represented under paragraph (4).

3 In selecting members described in paragraphs (1) through (3),
4 the Secretary shall consider qualified individuals nominated by
5 organizations representing providers and patients.

6 (c) GENERAL RESPONSIBILITIES.—The Advisory Group—

7 (1) shall review EMTALA regulations;

8 (2) may provide advice and recommendations to the
9 Secretary with respect to those regulations and their appli-
10 cation to hospitals and physicians;

11 (3) shall solicit comments and recommendations from
12 hospitals, physicians, and the public regarding the imple-
13 mentation of such regulations; and

14 (4) may disseminate information on the application of
15 such regulations to hospitals, physicians, and the public.

16 (d) ADMINISTRATIVE MATTERS.—

17 (1) CHAIRPERSON.—The members of the Advisory
18 Group shall elect a member to serve as chairperson of the
19 Advisory Group for the life of the Advisory Group.

20 (2) MEETINGS.—The Advisory Group shall first meet
21 at the direction of the Secretary. The Advisory Group shall
22 then meet twice per year and at such other times as the
23 Advisory Group may provide.

24 (e) TERMINATION.—The Advisory Group shall terminate
25 30 months after the date of its first meeting.

26 (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Sec-
27 retary shall establish the Advisory Group notwithstanding any
28 limitation that may apply to the number of advisory committees
29 that may be established (within the Department of Health and
30 Human Services or otherwise).

31 **SEC. 946. AUTHORIZING USE OF ARRANGEMENTS TO**
32 **PROVIDE CORE HOSPICE SERVICES IN CER-**
33 **TAIN CIRCUMSTANCES.**

34 (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C.
35 1395x(dd)(5)) is amended by adding at the end the following:

36 “(D) In extraordinary, exigent, or other non-routine cir-
37 cumstances, such as unanticipated periods of high patient

1 loads, staffing shortages due to illness or other events, or tem-
 2 porary travel of a patient outside a hospice program’s service
 3 area, a hospice program may enter into arrangements with an-
 4 other hospice program for the provision by that other program
 5 of services described in paragraph (2)(A)(ii)(I). The provisions
 6 of paragraph (2)(A)(ii)(II) shall apply with respect to the serv-
 7 ices provided under such arrangements.

8 “(E) A hospice program may provide services described in
 9 paragraph (1)(A) other than directly by the program if the
 10 services are highly specialized services of a registered profes-
 11 sional nurse and are provided non-routinely and so infrequently
 12 so that the provision of such services directly would be imprac-
 13 ticable and prohibitively expensive.”.

14 (b) CONFORMING PAYMENT PROVISION.—Section 1814(i)
 15 (42 U.S.C. 1395f(i)), as amended by section 512(b), is amend-
 16 ed by adding at the end the following new paragraph:

17 “(5) In the case of hospice care provided by a hospice pro-
 18 gram under arrangements under section 1861(dd)(5)(D) made
 19 by another hospice program, the hospice program that made
 20 the arrangements shall bill and be paid for the hospice care.”.

21 (c) EFFECTIVE DATE.—The amendments made by this
 22 section shall apply to hospice care provided on or after the date
 23 of the enactment of this Act.

24 **SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHO-**
 25 **GENS STANDARD TO CERTAIN HOSPITALS.**

26 (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc), as
 27 amended by section 506, is amended—

28 (1) in subsection (a)(1)—

29 (A) in subparagraph (T), by striking “and” at the
 30 end;

31 (B) in subparagraph (U), by striking the period at
 32 the end and inserting “, and”; and

33 (C) by inserting after subparagraph (U) the fol-
 34 lowing new subparagraph:

35 “(V) in the case of hospitals that are not otherwise
 36 subject to the Occupational Safety and Health Act of 1970
 37 (or a State occupational safety and health plan that is ap-

1 proved under 18(b) of such Act), to comply with the
 2 Bloodborne Pathogens standard under section 1910.1030
 3 of title 29 of the Code of Federal Regulations (or as subse-
 4 quently redesignated).”; and

5 (2) by adding at the end of subsection (b) the fol-
 6 lowing new paragraph:

7 “(4)(A) A hospital that fails to comply with the require-
 8 ment of subsection (a)(1)(V) (relating to the Bloodborne
 9 Pathogens standard) is subject to a civil money penalty in an
 10 amount described in subparagraph (B), but is not subject to
 11 termination of an agreement under this section.

12 “(B) The amount referred to in subparagraph (A) is an
 13 amount that is similar to the amount of civil penalties that may
 14 be imposed under section 17 of the Occupational Safety and
 15 Health Act of 1970 for a violation of the Bloodborne Pathogens
 16 standard referred to in subsection (a)(1)(U) by a hospital that
 17 is subject to the provisions of such Act.

18 “(C) A civil money penalty under this paragraph shall be
 19 imposed and collected in the same manner as civil money pen-
 20 alties under subsection (a) of section 1128A are imposed and
 21 collected under that section.”.

22 (b) EFFECTIVE DATE.—The amendments made by this
 23 subsection (a) shall apply to hospitals as of July 1, 2004.

24 **SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND**
 25 **CORRECTIONS.**

26 (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY
 27 COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i)
 28 of section 1114 (42 U.S.C. 1314)—

29 (A) is transferred to section 1862 and added at the
 30 end of such section; and

31 (B) is redesignated as subsection (j).

32 (2) Section 1862 (42 U.S.C. 1395y) is amended—

33 (A) in the last sentence of subsection (a), by striking
 34 “established under section 1114(f)”; and

35 (B) in subsection (j), as so transferred and
 36 redesignated—

37 (i) by striking “under subsection (f)”; and

1 (ii) by striking “section 1862(a)(1)” and inserting
2 “subsection (a)(1)”.

3 (b) TERMINOLOGY CORRECTIONS.—(1) Section
4 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)) is amended—

5 (A) in subclause (III), by striking “policy” and insert-
6 ing “determination”; and

7 (B) in subclause (IV), by striking “medical review
8 policies” and inserting “coverage determinations”.

9 (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C))
10 is amended by striking “policy” and “POLICY” and inserting
11 “determination” each place it appears and “DETERMINATION”,
12 respectively.

13 (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42
14 U.S.C. 1395ff(f)(4)) is amended—

15 (1) in subparagraph (A)(iv), by striking “subclause
16 (I), (II), or (III)” and inserting “clause (i), (ii), or (iii)”;

17 (2) in subparagraph (B), by striking “clause (i)(IV)”
18 and “clause (i)(III)” and inserting “subparagraph (A)(iv)”
19 and “subparagraph (A)(iii)”, respectively; and

20 (3) in subparagraph (C), by striking “clause (i)”,
21 “subclause (IV)” and “subparagraph (A)” and inserting
22 “subparagraph (A)”, “clause (iv)” and “paragraph
23 (1)(A)”, respectively each place it appears.

24 (d) OTHER CORRECTIONS.—Effective as if included in the
25 enactment of section 521(c) of BIPA, section 1154(e) (42
26 U.S.C. 1320c-3(e)) is amended by striking paragraph (5).

27 (e) EFFECTIVE DATE.—Except as otherwise provided, the
28 amendments made by this section shall be effective as if in-
29 cluded in the enactment of BIPA.

30 **SEC. 949. CONFORMING AUTHORITY TO WAIVE A PRO-**
31 **GRAM EXCLUSION.**

32 The first sentence of section 1128(c)(3)(B) (42 U.S.C.
33 1320a-7(c)(3)(B)) is amended to read as follows: “Subject to
34 subparagraph (G), in the case of an exclusion under subsection
35 (a), the minimum period of exclusion shall be not less than five
36 years, except that, upon the request of the administrator of a
37 Federal health care program (as defined in section 1128B(f))

1 who determines that the exclusion would impose a hardship on
 2 individuals entitled to benefits under part A of title XVIII or
 3 enrolled under part B of such title, or both, the Secretary may,
 4 after consulting with the Inspector General of the Department
 5 of Health and Human Services, waive the exclusion under sub-
 6 section (a)(1), (a)(3), or (a)(4) with respect to that program
 7 in the case of an individual or entity that is the sole community
 8 physician or sole source of essential specialized services in a
 9 community.”.

10 **SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.**

11 (a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is
 12 amended by adding at the end, after the subsection transferred
 13 and redesignated by section 948(a), the following new sub-
 14 section:

15 “(k)(1) Subject to paragraph (2), a group health plan (as
 16 defined in subsection (a)(1)(A)(v)) providing supplemental or
 17 secondary coverage to individuals also entitled to services under
 18 this title shall not require a medicare claims determination
 19 under this title for dental benefits specifically excluded under
 20 subsection (a)(12) as a condition of making a claims deter-
 21 mination for such benefits under the group health plan.

22 “(2) A group health plan may require a claims determina-
 23 tion under this title in cases involving or appearing to involve
 24 inpatient dental hospital services or dental services expressly
 25 covered under this title pursuant to actions taken by the Sec-
 26 retary.”.

27 (b) EFFECTIVE DATE.—The amendment made by sub-
 28 section (a) shall take effect on the date that is 60 days after
 29 the date of the enactment of this Act.

30 **SEC. 951. FURNISHING HOSPITALS WITH INFORMATION**
 31 **TO COMPUTE DSH FORMULA.**

32 Beginning not later than 1 year after the date of the en-
 33 actment of this Act, the Secretary shall arrange to furnish to
 34 subsection (d) hospitals (as defined in section 1886(d)(1)(B) of
 35 the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data
 36 necessary for such hospitals to compute the number of patient
 37 days used in computing the disproportionate patient percentage

1 under such section for that hospital for the current cost report-
 2 ing year. Such data shall also be furnished to other hospitals
 3 which would qualify for additional payments under part A of
 4 title XVIII of the Social Security Act on the basis of such data.

5 **SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.**

6 (a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C.
 7 1395u(b)(6)(A)) is amended by striking “or (ii) (where the
 8 service was provided in a hospital, critical access hospital, clinic,
 9 or other facility) to the facility in which the service was pro-
 10 vided if there is a contractual arrangement between such physi-
 11 cian or other person and such facility under which such facility
 12 submits the bill for such service,” and inserting “or (ii) where
 13 the service was provided under a contractual arrangement be-
 14 tween such physician or other person and an entity, to the enti-
 15 ty if, under the contractual arrangement, the entity submits the
 16 bill for the service and the contractual arrangement meets such
 17 program integrity and other safeguards as the Secretary may
 18 determine to be appropriate,”.

19 (b) CONFORMING AMENDMENT.—The second sentence of
 20 section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by
 21 striking “except to an employer or facility as described in
 22 clause (A)” and inserting “except to an employer or entity as
 23 described in subparagraph (A)”.

24 (c) EFFECTIVE DATE.—The amendments made by this
 25 section shall apply to payments made on or after the date of
 26 the enactment of this Act.

27 **SEC. 953. OTHER PROVISIONS.**

28 (a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.—

29 (1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not
 30 later than 6 months after the date of the enactment of this
 31 Act, the Comptroller General of the United States shall
 32 submit to Congress a report on the appropriateness of the
 33 updates in the conversion factor under subsection (d)(3) of
 34 section 1848 of the Social Security Act (42 U.S.C. 1395w-
 35 4), including the appropriateness of the sustainable growth
 36 rate formula under subsection (f) of such section for 2002
 37 and succeeding years. Such report shall examine the sta-

1 bility and predictability of such updates and rate and alter-
2 natives for the use of such rate in the updates.

3 (2) PHYSICIAN COMPENSATION GENERALLY.—Not
4 later than 12 months after the date of the enactment of
5 this Act, the Comptroller General shall submit to Congress
6 a report on all aspects of physician compensation for serv-
7 ices furnished under title XVIII of the Social Security Act,
8 and how those aspects interact and the effect on appro-
9 priate compensation for physician services. Such report
10 shall review alternatives for the physician fee schedule
11 under section 1848 of such title (42 U.S.C. 1395w-4).

12 (b) ANNUAL PUBLICATION OF LIST OF NATIONAL COV-
13 ERAGE DETERMINATIONS.—The Secretary shall provide, in an
14 appropriate annual publication available to the public, a list of
15 national coverage determinations made under title XVIII of the
16 Social Security Act in the previous year and information on
17 how to get more information with respect to such determina-
18 tions.

19 (c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME
20 HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO
21 ARE NOT MEDICARE BENEFICIARIES.—Not later than 6
22 months after the date of the enactment of this Act, the Comp-
23 troller General of the United States shall submit to Congress
24 a report on the implications if there were flexibility in the ap-
25 plication of the medicare conditions of participation for home
26 health agencies with respect to groups or types of patients who
27 are not medicare beneficiaries. The report shall include an
28 analysis of the potential impact of such flexible application on
29 clinical operations and the recipients of such services and an
30 analysis of methods for monitoring the quality of care provided
31 to such recipients.

32 (d) OIG REPORT ON NOTICES RELATING TO USE OF
33 HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year
34 after the date of the enactment of this Act, the Inspector Gen-
35 eral of the Department of Health and Human Services shall
36 submit a report to Congress on—

1 (1) the extent to which hospitals provide notice to
 2 medicare beneficiaries in accordance with applicable re-
 3 quirements before they use the 60 lifetime reserve days de-
 4 scribed in section 1812(a)(1) of the Social Security Act (42
 5 U.S.C. 1395d(a)(1)); and

6 (2) the appropriateness and feasibility of hospitals pro-
 7 viding a notice to such beneficiaries before they completely
 8 exhaust such lifetime reserve days.

9 **TITLE X—MEDICAID AND**
 10 **MISCELLANEOUS PROVISIONS**
 11 **Subtitle A—Medicaid Provisions**

12 **SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOS-**
 13 **PITAL (DSH) PAYMENTS.**

14 (a) TEMPORARY INCREASE.—Section 1923(f)(3) (42
 15 U.S.C. 1396r-4(f)(3)) is amended—

16 (1) in subparagraph (A), by striking “subparagraph
 17 (B)” and inserting “subparagraphs (B) and (C)”; and

18 (2) by adding at the end the following new subpara-
 19 graphs:

20 “(C) SPECIAL, TEMPORARY INCREASE IN ALLOT-
 21 MENTS ON A ONE-TIME, NON-CUMULATIVE BASIS.—The
 22 DSH allotment for any State (other than a State with
 23 a DSH allotment determined under paragraph (5))—

24 “(i) for fiscal year 2004 is equal to 116 per-
 25 cent of the DSH allotment for the State for fiscal
 26 year 2003 under this paragraph, notwithstanding
 27 subparagraph (B); and

28 “(ii) for each succeeding fiscal year is equal to
 29 the DSH allotment for the State for fiscal year
 30 2004 or, in the case of fiscal years beginning with
 31 the fiscal year specified in subparagraph (D) for
 32 that State, the DSH allotment for the State for the
 33 previous fiscal year increased by the percentage
 34 change in the consumer price index for all urban
 35 consumers (all items; U.S. city average), for the
 36 previous fiscal year.

1 “(D) FISCAL YEAR SPECIFIED.—For purposes of
 2 subparagraph (C)(ii), the fiscal year specified in this
 3 subparagraph for a State is the first fiscal year for
 4 which the Secretary estimates that the DSH allotment
 5 for that State will equal (or no longer exceed) the DSH
 6 allotment for that State under the law as in effect be-
 7 fore the date of the enactment of this subparagraph.”.

8 (b) INCREASE IN FLOOR FOR TREATMENT AS A LOW DSH
 9 STATE.—Section 1923(f)(5) (42 U.S.C. 1396r-4(f)(5)) is
 10 amended—

11 (1) in the paragraph heading, by striking “EX-
 12 TREMELY”;

13 (2) by striking “In the case of” and inserting the fol-
 14 lowing:

15 “(A) FOR FISCAL YEARS 2001 THROUGH 2003 FOR
 16 EXTREMELY LOW DSH STATES.—In the case of”;

17 (3) by inserting “before fiscal year 2004” after “In
 18 subsequent years”; and

19 (4) by adding at the end the following:

20 “(B) FOR FISCAL YEAR 2004 AND SUBSEQUENT
 21 FISCAL YEARS.—In the case of a State in which the
 22 total expenditures under the State plan (including Fed-
 23 eral and State shares) for disproportionate share hos-
 24 pital adjustments under this section for fiscal year
 25 2000, as reported to the Administrator of the Centers
 26 for Medicare & Medicaid Services as of August 31,
 27 2003, is greater than 0 but less than 3 percent of the
 28 State’s total amount of expenditures under the State
 29 plan for medical assistance during the fiscal year, the
 30 DSH allotment for the State with respect to—

31 “(i) fiscal year 2004 shall be the DSH allot-
 32 ment for the State for fiscal year 2003 increased
 33 by 16 percent;

34 “(ii) each succeeding fiscal year before fiscal
 35 year 2009 shall be the DSH allotment for the State
 36 for the previous fiscal year increased by 16 percent;
 37 and

1 “(iii) fiscal year 2009 and any subsequent fis-
2 cal year, shall be the DSH allotment for the State
3 for the previous year subject to an increase for in-
4 flation as provided in paragraph (3)(A).”.

5 (c) ALLOTMENT ADJUSTMENT.—Section 1923(f) (42
6 U.S.C. 1396r-4(f)) is amended—

7 (1) in paragraph (3)(A), by striking “The DSH” and
8 inserting “Except as provided in paragraph (6), the DSH”;

9 (2) by redesignating paragraph (6) as paragraph (7);
10 and

11 (3) by inserting after paragraph (5) the following:

12 “(6) ALLOTMENT ADJUSTMENT.—Only with respect to
13 fiscal year 2004 or 2005, if a statewide waiver under sec-
14 tion 1115 is revoked or terminated before the end of either
15 such fiscal year and there is no DSH allotment for the
16 State, the Secretary shall—

17 “(A) permit the State whose waiver was revoked
18 or terminated to submit an amendment to its State
19 plan that would describe the methodology to be used by
20 the State (after the effective date of such revocation or
21 termination) to identify and make payments to dis-
22 proportionate share hospitals, including children’s hos-
23 pitals and institutions for mental diseases or other
24 mental health facilities (other than State-owned institu-
25 tions or facilities), on the basis of the proportion of pa-
26 tients served by such hospitals that are low-income pa-
27 tients with special needs; and

28 “(B) provide for purposes of this subsection for
29 computation of an appropriate DSH allotment for the
30 State for fiscal year 2004 or 2005 (or both) that would
31 not exceed the amount allowed under paragraph
32 (3)(B)(ii) and that does not result in greater expendi-
33 tures under this title than would have been made if
34 such waiver had not been revoked or terminated.

35 In determining the amount of an appropriate DSH allot-
36 ment under subparagraph (B) for a State, the Secretary
37 shall take into account the level of DSH expenditures for

1 the State for the fiscal year preceding the fiscal year in
2 which the waiver commenced.”.

3 (d) INCREASED REPORTING AND OTHER REQUIREMENTS
4 TO ENSURE THE APPROPRIATE USE OF MEDICAID DSH PAY-
5 MENT ADJUSTMENTS.—Section 1923 (42 U.S.C. 1396r–4) is
6 amended by adding at the end the following new subsection:

7 “(j) ANNUAL REPORTS AND OTHER REQUIREMENTS RE-
8 GARDING PAYMENT ADJUSTMENTS.—With respect to fiscal
9 year 2004 and each fiscal year thereafter, the Secretary shall
10 require a State, as a condition of receiving a payment under
11 section 1903(a)(1) with respect to a payment adjustment made
12 under this section, to do the following:

13 “(1) REPORT.—The State shall submit an annual re-
14 port that includes the following:

15 “(A) An identification of each disproportionate
16 share hospital that received a payment adjustment
17 under this section for the preceding fiscal year and the
18 amount of the payment adjustment made to such hos-
19 pital for the preceding fiscal year.

20 “(B) Such other information as the Secretary de-
21 termines necessary to ensure the appropriateness of the
22 payment adjustments made under this section for the
23 preceding fiscal year.

24 “(2) INDEPENDENT CERTIFIED AUDIT.—The State
25 shall annually submit to the Secretary an independent cer-
26 tified audit that verifies each of the following:

27 “(A) The extent to which hospitals in the State
28 have reduced their uncompensated care costs to reflect
29 the total amount of claimed expenditures made under
30 this section.

31 “(B) Payments under this section to hospitals that
32 comply with the requirements of subsection (g).

33 “(C) Only the uncompensated care costs of pro-
34 viding inpatient hospital and outpatient hospital serv-
35 ices to individuals described in paragraph (1)(A) of
36 such subsection are included in the calculation of the
37 hospital-specific limits under such subsection.

1 “(D) The State included all payments under this
2 title, including supplemental payments, in the calcula-
3 tion of such hospital-specific limits.

4 “(E) The State has separately documented and re-
5 tained a record of all of its costs under this title,
6 claimed expenditures under this title, uninsured costs
7 in determining payment adjustments under this section,
8 and any payments made on behalf of the uninsured
9 from payment adjustments under this section.”.

10 (e) CLARIFICATION REGARDING NON-REGULATION OF
11 TRANSFERS.—

12 (1) IN GENERAL.—Nothing in section 1903(w) of the
13 Social Security Act (42 U.S.C. 1396b(w)) shall be con-
14 strued by the Secretary as prohibiting a State’s use of
15 funds as the non-Federal share of expenditures under title
16 XIX of such Act where such funds are transferred from or
17 certified by a publicly-owned regional medical center lo-
18 cated in another State and described in paragraph (2), so
19 long as the Secretary determines that such use of funds is
20 proper and in the interest of the program under title XIX.

21 (2) CENTER DESCRIBED.—A center described in this
22 paragraph is a publicly-owned regional medical center
23 that—

24 (A) provides level 1 trauma and burn care serv-
25 ices;

26 (B) provides level 3 neonatal care services;

27 (C) is obligated to serve all patients, regardless of
28 State of origin;

29 (D) is located within a Standard Metropolitan Sta-
30 tistical Area (SMSA) that includes at least 3 States,
31 including the States described in paragraph (1);

32 (E) serves as a tertiary care provider for patients
33 residing within a 125 mile radius; and

34 (F) meets the criteria for a disproportionate share
35 hospital under section 1923 of such Act in at least one
36 State other than the one in which the center is located.

1 (3) EFFECTIVE PERIOD.—This subsection shall apply
2 through December 31, 2005.

3 **SEC. 1002. CLARIFICATION OF INCLUSION OF INPA-**
4 **TIENT DRUG PRICES CHARGED TO CERTAIN**
5 **PUBLIC HOSPITALS IN THE BEST PRICE EX-**
6 **EMPTIONS FOR THE MEDICAID DRUG RE-**
7 **BATE PROGRAM.**

8 (a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C.
9 1396r-8(c)(1)(C)(i)(I)) is amended by inserting before the
10 semicolon the following: “(including inpatient prices charged to
11 hospitals described in section 340B(a)(4)(L) of the Public
12 Health Service Act)”.

13 (b) ANTI-DIVERSION PROTECTION.—Section
14 1927(c)(1)(C) (42 U.S.C. 1396r-8(c)(1)(C)) is amended by
15 adding at the end the following:

16 “(iii) APPLICATION OF AUDITING AND REC-
17 ORDKEEPING REQUIREMENTS.—With respect to a
18 covered entity described in section 340B(a)(4)(L)
19 of the Public Health Service Act, any drug pur-
20 chased for inpatient use shall be subject to the au-
21 diting and recordkeeping requirements described in
22 section 340B(a)(5)(C) of the Public Health Service
23 Act.”.

24 **SEC. 1003. EXTENSION OF MORATORIUM.**

25 (a) IN GENERAL.—Section 6408(a)(3) of the Omnibus
26 Budget Reconciliation Act of 1989, as amended by section
27 13642 of the Omnibus Budget Reconciliation Act of 1993 and
28 section 4758 of the Balanced Budget Act of 1997, is
29 amended—

30 (1) by striking “until December 31, 2002”, and

31 (2) by striking “Kent Community Hospital Complex in
32 Michigan or.”

33 (b) EFFECTIVE DATES.—

34 (1) PERMANENT EXTENSION.—The amendment made
35 by subsection (a)(1) shall take effect as if included in the
36 amendment made by section 4758 of the Balanced Budget
37 Act of 1997.

1 (2) MODIFICATION.—The amendment made by sub-
 2 section (a)(2) shall take effect on the date of enactment of
 3 this Act.

4 **Subtitle B—Miscellaneous Provisions**

5 **SEC. 1011. FEDERAL REIMBURSEMENT OF EMERGENCY** 6 **HEALTH SERVICES FURNISHED TO UNDOCU-** 7 **MENTED ALIENS.**

8 (a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—

9 (1) IN GENERAL.—Out of any funds in the Treasury
 10 not otherwise appropriated, there are appropriated to the
 11 Secretary \$250,000,000 for each of fiscal years 2005
 12 through 2008 for the purpose of making allotments under
 13 this section for payments to eligible providers in States de-
 14 scribed in paragraph (1) or (2) of subsection (b).

15 (2) AVAILABILITY.—Funds appropriated under para-
 16 graph (1) shall remain available until expended.

17 (b) STATE ALLOTMENTS.—

18 (1) BASED ON PERCENTAGE OF UNDOCUMENTED
 19 ALIENS.—

20 (A) IN GENERAL.—Out of the amount appro-
 21 priated under subsection (a) for a fiscal year, the Sec-
 22 retary shall use \$167,000,000 of such amount to make
 23 allotments for such fiscal year in accordance with sub-
 24 paragraph (B).

25 (B) FORMULA.—The amount of the allotment for
 26 payments to eligible providers in each State for a fiscal
 27 year shall be equal to the product of—

28 (i) the total amount available for allotments
 29 under this paragraph for the fiscal year; and

30 (ii) the percentage of undocumented aliens re-
 31 siding in the State as compared to the total num-
 32 ber of such aliens residing in all States, as deter-
 33 mined by the Statistics Division of the Immigration
 34 and Naturalization Service, as of January 2003,
 35 based on the 2000 decennial census.

36 (2) BASED ON NUMBER OF UNDOCUMENTED ALIEN
 37 APPREHENSION STATES.—

1 (A) IN GENERAL.—Out of the amount appro-
 2 priated under subsection (a) for a fiscal year, the Sec-
 3 retary shall use \$83,000,000 of such amount to make
 4 allotments, in addition to amounts allotted under para-
 5 graph (1), for such fiscal year for each of the 6 States
 6 with the highest number of undocumented alien appre-
 7 hensions for such fiscal year.

8 (B) DETERMINATION OF ALLOTMENTS.—The
 9 amount of the allotment for each State described in
 10 subparagraph (A) for a fiscal year shall be equal to the
 11 product of—

12 (i) the total amount available for allotments
 13 under this paragraph for the fiscal year; and

14 (ii) the percentage of undocumented alien ap-
 15 prehensions in the State in that fiscal year as com-
 16 pared to the total of such apprehensions for all
 17 such States for the preceding fiscal year.

18 (C) DATA.—For purposes of this paragraph, the
 19 highest number of undocumented alien apprehensions
 20 for a fiscal year shall be based on the apprehension
 21 rates for the 4-consecutive-quarter period ending before
 22 the beginning of the fiscal year for which information
 23 is available for undocumented aliens in such States, as
 24 reported by the Department of Homeland Security.

25 (c) USE OF FUNDS.—

26 (1) AUTHORITY TO MAKE PAYMENTS.—From the allot-
 27 ments made for a State under subsection (b) for a fiscal
 28 year, the Secretary shall pay the amount (subject to the
 29 total amount available from such allotments) determined
 30 under paragraph (2) directly to eligible providers located in
 31 the State for the provision of eligible services to aliens de-
 32 scribed in paragraph (5) to the extent that the eligible pro-
 33 vider was not otherwise reimbursed (through insurance or
 34 otherwise) for such services during that fiscal year.

35 (2) DETERMINATION OF PAYMENT AMOUNTS.—

36 (A) IN GENERAL.—Subject to subparagraph (B),
 37 the payment amount determined under this paragraph

1 shall be an amount determined by the Secretary that
2 is equal to the lesser of—

- 3 (i) the amount that the provider demonstrates
4 was incurred for the provision of such services; or
5 (ii) amounts determined under a methodology
6 established by the Secretary for purposes of this
7 subsection.

8 (B) PRO-RATA REDUCTION.—If the amount of
9 funds allotted to a State under subsection (b) for a fis-
10 cal year is insufficient to ensure that each eligible pro-
11 vider in that State receives the amount of payment cal-
12 culated under subparagraph (A), the Secretary shall re-
13 duce that amount of payment with respect to each eli-
14 gible provider to ensure that the entire amount allotted
15 to the State for that fiscal year is paid to such eligible
16 providers.

17 (3) METHODOLOGY.—In establishing a methodology
18 under paragraph (2)(A)(ii), the Secretary—

19 (A) may establish different methodologies for
20 types of eligible providers;

21 (B) may base payments for hospital services on es-
22 timated hospital charges, adjusted to estimated cost,
23 through the application of hospital-specific cost-to-
24 charge ratios;

25 (C) shall provide for the election by a hospital to
26 receive either payments to the hospital for—

27 (i) hospital and physician services; or

28 (ii) hospital services and for a portion of the
29 on-call payments made by the hospital to physi-
30 cians; and

31 (D) shall make quarterly payments under this sec-
32 tion to eligible providers.

33 If a hospital makes the election under subparagraph (C)(i),
34 the hospital shall pass on payments for services of a physi-
35 cian to the physician and may not charge any administra-
36 tive or other fee with respect to such payments.

1 (4) LIMITATION ON USE OF FUNDS.—Payments made
2 to eligible providers in a State from allotments made under
3 subsection (b) for a fiscal year may only be used for costs
4 incurred in providing eligible services to aliens described in
5 paragraph (5).

6 (5) ALIENS DESCRIBED.—For purposes of paragraphs
7 (1) and (2), aliens described in this paragraph are any of
8 the following:

9 (A) Undocumented aliens.

10 (B) Aliens who have been paroled into the United
11 States at a United States port of entry for the purpose
12 of receiving eligible services.

13 (C) Mexican citizens permitted to enter the United
14 States for not more than 72 hours under the authority
15 of a biometric machine readable border crossing identi-
16 fication card (also referred to as a “laser visa”) issued
17 in accordance with the requirements of regulations pre-
18 scribed under section 101(a)(6) of the Immigration and
19 Nationality Act (8 U.S.C. 1101(a)(6)).

20 (d) APPLICATIONS; ADVANCE PAYMENTS.—

21 (1) DEADLINE FOR ESTABLISHMENT OF APPLICATION
22 PROCESS.—

23 (A) IN GENERAL.—Not later than September 1,
24 2004, the Secretary shall establish a process under
25 which eligible providers located in a State may request
26 payments under subsection (c).

27 (B) INCLUSION OF MEASURES TO COMBAT FRAUD
28 AND ABUSE.—The Secretary shall include in the proc-
29 ess established under subparagraph (A) measures to
30 ensure that inappropriate, excessive, or fraudulent pay-
31 ments are not made from the allotments determined
32 under subsection (b), including certification by the eli-
33 gible provider of the veracity of the payment request.

34 (2) ADVANCE PAYMENT; RETROSPECTIVE ADJUST-
35 MENT.—The process established under paragraph (1) may
36 provide for making payments under this section for each
37 quarter of a fiscal year on the basis of advance estimates

1 of expenditures submitted by applicants for such payments
 2 and such other investigation as the Secretary may find nec-
 3 essary, and for making reductions or increases in the pay-
 4 ments as necessary to adjust for any overpayment or un-
 5 derpayment for prior quarters of such fiscal year.

6 (e) DEFINITIONS.—In this section:

7 (1) ELIGIBLE PROVIDER.—The term “eligible pro-
 8 vider” means a hospital, physician, or provider of ambu-
 9 lance services (including an Indian Health Service facility
 10 whether operated by the Indian Health Service or by an In-
 11 dian tribe or tribal organization).

12 (2) ELIGIBLE SERVICES.—The term “eligible services”
 13 means health care services required by the application of
 14 section 1867 of the Social Security Act (42 U.S.C.
 15 1395dd), and related hospital inpatient and outpatient
 16 services and ambulance services (as defined by the Sec-
 17 retary).

18 (3) HOSPITAL.—The term “hospital” has the meaning
 19 given such term in section 1861(e) of the Social Security
 20 Act (42 U.S.C. 1395x(e)), except that such term shall in-
 21 clude a critical access hospital (as defined in section
 22 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1))).

23 (4) PHYSICIAN.—The term “physician” has the mean-
 24 ing given that term in section 1861(r) of the Social Secu-
 25 rity Act (42 U.S.C. 1395x(r)).

26 (5) INDIAN TRIBE; TRIBAL ORGANIZATION.—The
 27 terms “Indian tribe” and “tribal organization” have the
 28 meanings given such terms in section 4 of the Indian
 29 Health Care Improvement Act (25 U.S.C. 1603).

30 (6) STATE.—The term “State” means the 50 States
 31 and the District of Columbia.

32 **SEC. 1012. COMMISSION ON SYSTEMIC INTEROPER-**
 33 **ABILITY.**

34 (a) ESTABLISHMENT.—The Secretary shall establish a
 35 commission to be known as the “Commission on Systemic
 36 Interoperability” (in this section referred to as the “Commis-
 37 sion”).

1 (b) DUTIES.—

2 (1) IN GENERAL.—The Commission shall develop a
3 comprehensive strategy for the adoption and implementa-
4 tion of health care information technology standards, that
5 includes a timeline and prioritization for such adoption and
6 implementation.

7 (2) CONSIDERATIONS.—In developing the comprehen-
8 sive health care information technology strategy under
9 paragraph (1), the Commission shall consider—

10 (A) the costs and benefits of the standards, both
11 financial impact and quality improvement;

12 (B) the current demand on industry resources to
13 implement this Act and other electronic standards, in-
14 cluding HIPAA standards; and

15 (C) the most cost-effective and efficient means for
16 industry to implement the standards.

17 (3) NONINTERFERENCE.—In carrying out this section,
18 the Commission shall not interfere with any standards de-
19 velopment of adoption processes underway in the private or
20 public sector and shall not replicate activities related to
21 such standards or the national health information infra-
22 structure underway within the Department of Health and
23 Human Services.

24 (4) REPORT.—Not later than October 31, 2005, the
25 Commission shall submit to the Secretary and to Congress
26 a report describing the strategy developed under paragraph
27 (1), including an analysis of the matters considered under
28 paragraph (2).

29 (c) MEMBERSHIP.—

30 (1) NUMBER AND APPOINTMENT.—The Commission
31 shall be composed of 11 members appointed as follows:

32 (A) The President shall appoint 3 members, one of
33 whom the President shall designate as Chairperson.

34 (B) The Majority Leader of the Senate shall ap-
35 point 2 members.

36 (C) The Minority Leader of the Senate shall ap-
37 point 2 members.

1 (D) The Speaker of the House of Representatives
2 shall appoint 2 members.

3 (E) The Minority Leader of the House of Rep-
4 resentatives shall appoint 2 members.

5 (2) QUALIFICATIONS.—The membership of the Com-
6 mission shall include individuals with national recognition
7 for their expertise in health finance and economics, health
8 plans and integrated delivery systems, reimbursement of
9 health facilities, practicing physicians, practicing phar-
10 macists, and other providers of health services, health care
11 technology and information systems, and other related
12 fields, who provide a mix of different professionals, broad
13 geographic representation, and a balance between urban
14 and rural representatives.

15 (d) TERMS.—Each member shall be appointed for the life
16 of the Commission.

17 (e) COMPENSATION.—

18 (1) RATES OF PAY.—Members shall each be paid at a
19 rate not to exceed the daily equivalent of the rate of basic
20 pay for level IV of the Executive Schedule for each day (in-
21 cluding travel time) during which they are engaged in the
22 actual performance of duties vested in the Commission.

23 (2) PROHIBITION OF COMPENSATION OF FEDERAL EM-
24 PLOYEES.—Members of the Commission who are full-time
25 officers or employees of the United States or Members of
26 Congress may not receive additional pay, allowances, or
27 benefits by reason of their service on the Commission.

28 (3) TRAVEL EXPENSES.—Each member shall receive
29 travel expenses, including per diem in lieu of subsistence,
30 in accordance with applicable provisions under subchapter
31 I of chapter 57 of title 5, United States Code.

32 (f) QUORUM.—A majority of the members of the Commis-
33 sion shall constitute a quorum but a lesser number may hold
34 hearings.

35 (g) DIRECTOR AND STAFF OF COMMISSION; EXPERTS AND
36 CONSULTANTS.—

1 (1) DIRECTOR.—The Commission shall have a Direc-
2 tor who shall be appointed by the Chairperson. The Direc-
3 tor shall be paid at a rate not to exceed the rate of basic
4 pay for level IV of the Executive Schedule.

5 (2) STAFF.—With the approval of the Commission,
6 the Director may appoint and fix the pay of such additional
7 personnel as the Director considers appropriate.

8 (3) APPLICABILITY OF CERTAIN CIVIL SERVICE
9 LAWS.—The Director and staff of the Commission may be
10 appointed without regard to the provisions of title 5,
11 United States Code, governing appointments in the com-
12 petitive service, and may be paid without regard to the pro-
13 visions of chapter 51 and subchapter III of chapter 53 of
14 that title relating to classification and General Schedule
15 pay rates, except that an individual so appointed may not
16 receive pay in excess of level IV of the Executive Schedule.

17 (4) EXPERTS AND CONSULTANTS.—With the approval
18 of the Commission, the Director may procure temporary
19 and intermittent services under section 3109(b) of title 5,
20 United States Code.

21 (5) STAFF OF FEDERAL AGENCIES.—Upon request of
22 the Chairperson, the head of any Federal department or
23 agency may detail, on a reimbursable basis, any of the per-
24 sonnel of that department or agency to the Commission to
25 assist it in carrying out its duties under this Act.

26 (h) POWERS OF COMMISSION.—

27 (1) HEARINGS AND SESSIONS.—The Commission may,
28 for the purpose of carrying out this Act, hold hearings, sit
29 and act at times and places, take testimony, and receive
30 evidence as the Commission considers appropriate.

31 (2) POWERS OF MEMBERS AND AGENTS.—Any mem-
32 ber or agent of the Commission may, if authorized by the
33 Commission, take any action which the Commission is au-
34 thorized to take by this section.

35 (3) OBTAINING OFFICIAL DATA.—The Commission
36 may secure directly from any department or agency of the
37 United States information necessary to enable it to carry

1 out this Act. Upon request of the Chairperson of the Com-
 2 mission, the head of that department or agency shall fur-
 3 nish that information to the Commission.

4 (4) GIFTS, BEQUESTS, AND DEVICES.—The Commis-
 5 sion may accept, use, and dispose of gifts, bequests, or de-
 6 vices of services or property, both real and personal, for the
 7 purpose of aiding or facilitating the work of the Commis-
 8 sion. Gifts, bequests, or devises of money and proceeds
 9 from sales of other property received as gifts, bequests, or
 10 devises shall be deposited in the Treasury and shall be
 11 available for disbursement upon order of the Commission.
 12 For purposes of Federal income, estate, and gift taxes,
 13 property accepted under this subsection shall be considered
 14 as a gift, bequest, or devise to the United States.

15 (5) MAILS.—The Commission may use the United
 16 States mails in the same manner and under the same con-
 17 ditions as other departments and agencies of the United
 18 States.

19 (6) ADMINISTRATIVE SUPPORT SERVICES.—Upon the
 20 request of the Commission, the Administrator of General
 21 Services shall provide to the Commission, on a reimburs-
 22 able basis, the administrative support services necessary for
 23 the Commission to carry out its responsibilities under this
 24 Act.

25 (7) CONTRACT AUTHORITY.—The Commission may
 26 enter into contracts or make other arrangements, as may
 27 be necessary for the conduct of the work of the Commission
 28 (without regard to section 3709 of the Revised Statutes (41
 29 U.S.C. 5)).

30 (i) TERMINATION.—The Commission shall terminate on 30
 31 days after submitting its report pursuant to subsection (b)(3).

32 (j) AUTHORIZATION OF APPROPRIATIONS.—There is au-
 33 thorized to be appropriated such sums as may be necessary to
 34 carry out this section.

35 **SEC. 1013. RESEARCH ON OUTCOMES OF HEALTH CARE**
 36 **ITEMS AND SERVICES.**

37 (a) RESEARCH, DEMONSTRATIONS, AND EVALUATIONS.—

1 (1) IMPROVEMENT OF EFFECTIVENESS AND EFFI-
2 CIENCY.—

3 (A) IN GENERAL.—To improve the quality, effec-
4 tiveness, and efficiency of health care delivered pursu-
5 ant to the programs established under titles XVIII,
6 XIX, and XXI of the Social Security Act, the Secretary
7 acting through the Director of the Agency for
8 Healthcare Research and Quality (in this section re-
9 ferred to as the “Director”), shall conduct and support
10 research to meet the priorities and requests for sci-
11 entific evidence and information identified by such pro-
12 grams with respect to—

13 (i) the outcomes, comparative clinical effective-
14 ness, and appropriateness of health care items and
15 services (including prescription drugs); and

16 (ii) strategies for improving the efficiency and
17 effectiveness of such programs, including the ways
18 in which such items and services are organized,
19 managed, and delivered under such programs.

20 (B) SPECIFICATION.—To respond to priorities and
21 information requests in subparagraph (A), the Sec-
22 retary may conduct or support, by grant, contract, or
23 interagency agreement, research, demonstrations, eval-
24 uations, technology assessments, or other activities, in-
25 cluding the provision of technical assistance, scientific
26 expertise, or methodological assistance.

27 (2) PRIORITIES.—

28 (A) IN GENERAL.—The Secretary shall establish a
29 process to develop priorities that will guide the re-
30 search, demonstrations, and evaluation activities under-
31 taken pursuant to this section.

32 (B) INITIAL LIST.—Not later than 6 months after
33 the date of the enactment of this Act, the Secretary
34 shall establish an initial list of priorities for research
35 related to health care items and services (including pre-
36 scription drugs).

1 (C) PROCESS.—In carrying out subparagraph (A),
 2 the Secretary—

3 (i) shall ensure that there is broad and ongo-
 4 ing consultation with relevant stakeholders in iden-
 5 tifying the highest priorities for research, dem-
 6 onstrations, and evaluations to support and im-
 7 prove the programs established under titles XVIII,
 8 XIX, and XXI of the Social Security Act;

9 (ii) may include health care items and services
 10 which impose a high cost on such programs, as well
 11 as those which may be underutilized or overutilized
 12 and which may significantly improve the preven-
 13 tion, treatment, or cure of diseases and conditions
 14 (including chronic conditions) which impose high
 15 direct or indirect costs on patients or society; and

16 (iii) shall ensure that the research and activi-
 17 ties undertaken pursuant to this section are re-
 18 sponsive to the specified priorities and are con-
 19 ducted in a timely manner.

20 (3) EVALUATION AND SYNTHESIS OF SCIENTIFIC EVI-
 21 DENCE.—

22 (A) IN GENERAL.—The Secretary shall—

23 (i) evaluate and synthesize available scientific
 24 evidence related to health care items and services
 25 (including prescription drugs) identified as prior-
 26 ities in accordance with paragraph (2) with respect
 27 to the comparative clinical effectiveness, outcomes,
 28 appropriateness, and provision of such items and
 29 services (including prescription drugs);

30 (ii) identify issues for which existing scientific
 31 evidence is insufficient with respect to such health
 32 care items and services (including prescription
 33 drugs);

34 (iii) disseminate to prescription drug plans
 35 and MA–PD plans under part D of title XVIII of
 36 the Social Security Act, other health plans, and the

1 public the findings made under clauses (i) and (ii);
2 and

3 (iv) work in voluntary collaboration with public
4 and private sector entities to facilitate the develop-
5 ment of new scientific knowledge regarding health
6 care items and services (including prescription
7 drugs).

8 (B) INITIAL RESEARCH.—The Secretary shall
9 complete the evaluation and synthesis of the initial re-
10 search required by the priority list developed under
11 paragraph (2)(B) not later than 18 months after the
12 development of such list.

13 (C) DISSEMINATION.—

14 (i) IN GENERAL.—To enhance patient safety
15 and the quality of health care, the Secretary shall
16 make available and disseminate in appropriate for-
17 mats to prescription drugs plans under part D, and
18 MA–PD plans under part C, of title XVIII of the
19 Social Security Act, other health plans, and the
20 public the evaluations and syntheses prepared pur-
21 suant to subparagraph (A) and the findings of re-
22 search conducted pursuant to paragraph (1). In
23 carrying out this clause the Secretary, in order to
24 facilitate the availability of such evaluations and
25 syntheses or findings at every decision point in the
26 health care system, shall—

27 (I) present such evaluations and syntheses
28 or findings in a form that is easily understood
29 by the individuals receiving health care items
30 and services (including prescription drugs)
31 under such plans and periodically assess that
32 the requirements of this subclause have been
33 met; and

34 (II) provide such evaluations and syn-
35 theses or findings and other relevant informa-
36 tion through easily accessible and searchable

1 electronic mechanisms, and in hard copy for-
2 mats as appropriate.

3 (ii) RULE OF CONSTRUCTION.—Nothing in
4 this section shall be construed as—

5 (I) affecting the authority of the Secretary
6 or the Commissioner of Food and Drugs under
7 the Federal Food, Drug, and Cosmetic Act or
8 the Public Health Service Act; or

9 (II) conferring any authority referred to in
10 subclause (I) to the Director.

11 (D) ACCOUNTABILITY.—In carrying out this para-
12 graph, the Secretary shall implement activities in a
13 manner that—

14 (i) makes publicly available all scientific evi-
15 dence relied upon and the methodologies employed,
16 provided such evidence and method are not pro-
17 tected from public disclosure by section 1905 of
18 title 18, United States Code, or other applicable
19 law so that the results of the research, analyses, or
20 syntheses can be evaluated or replicated; and

21 (ii) ensures that any information needs and
22 unresolved issues identified in subparagraph (A)(ii)
23 are taken into account in priority-setting for future
24 research conducted by the Secretary.

25 (4) CONFIDENTIALITY.—

26 (A) IN GENERAL.—In making use of administra-
27 tive, clinical, and program data and information devel-
28 oped or collected with respect to the programs estab-
29 lished under titles XVIII, XIX, and XXI of the Social
30 Security Act, for purposes of carrying out the require-
31 ments of this section or the activities authorized under
32 title IX of the Public Health Service Act (42 U.S.C.
33 299 et seq.), such data and information shall be pro-
34 tected in accordance with the confidentiality require-
35 ments of title IX of the Public Health Service Act.

36 (B) RULE OF CONSTRUCTION.—Nothing in this
37 section shall be construed to require or permit the dis-

1 closure of data provided to the Secretary that is other-
2 wise protected from disclosure under the Federal Food,
3 Drug, and Cosmetic Act, section 1905 of title 18,
4 United States Code, or other applicable law.

5 (5) EVALUATIONS.—The Secretary shall conduct and
6 support evaluations of the activities carried out under this
7 section to determine the extent to which such activities
8 have had an effect on outcomes and utilization of health
9 care items and services.

10 (6) IMPROVING INFORMATION AVAILABLE TO HEALTH
11 CARE PROVIDERS, PATIENTS, AND POLICYMAKERS.—Not
12 later than 18 months after the date of enactment of this
13 Act, the Secretary shall identify options that could be un-
14 dertaken in voluntary collaboration with private and public
15 entities (as appropriate) for the—

16 (A) provision of more timely information through
17 the programs established under titles XVIII, XIX, and
18 XXI of the Social Security Act, regarding the outcomes
19 and quality of patient care, including clinical and pa-
20 tient-reported outcomes, especially with respect to
21 interventions and conditions for which clinical trials
22 would not be feasible or raise ethical concerns that are
23 difficult to address;

24 (B) acceleration of the adoption of innovation and
25 quality improvement under such programs; and

26 (C) development of management tools for the pro-
27 grams established under titles XIX and XXI of the So-
28 cial Security Act, and with respect to the programs es-
29 tablished under such titles, assess the feasibility of
30 using administrative or claims data, to—

31 (i) improve oversight by State officials;

32 (ii) support Federal and State initiatives to
33 improve the quality, safety, and efficiency of serv-
34 ices provided under such programs; and

35 (iii) provide a basis for estimating the fiscal
36 and coverage impact of Federal or State program
37 and policy changes.

1 (b) RECOMMENDATIONS.—

2 (1) DISCLAIMER.—In carrying out this section, the Di-
3 rector shall—

4 (A) not mandate national standards of clinical
5 practice or quality health care standards; and

6 (B) include in any recommendations resulting
7 from projects funded and published by the Director, a
8 corresponding reference to the prohibition described in
9 subparagraph (A).

10 (2) REQUIREMENT FOR IMPLEMENTATION.—Research,
11 evaluation, and communication activities performed pursu-
12 ant to this section shall reflect the principle that clinicians
13 and patients should have the best available evidence upon
14 which to make choices in health care items and services, in
15 providers, and in health care delivery systems, recognizing
16 that patient subpopulations and patient and physician pref-
17 erences may vary.

18 (3) RULE OF CONSTRUCTION.—Nothing in this section
19 shall be construed to provide the Director with authority to
20 mandate a national standard or require a specific approach
21 to quality measurement and reporting.

22 (c) RESEARCH WITH RESPECT TO DISSEMINATION.—The
23 Secretary, acting through the Director, may conduct or support
24 research with respect to improving methods of disseminating
25 information in accordance with subsection (a)(3)(C).

26 (d) LIMITATION ON CMS.—The Administrator of the Cen-
27 ters for Medicare & Medicaid Services may not use data ob-
28 tained in accordance with this section to withhold coverage of
29 a prescription drug.

30 (e) AUTHORIZATION OF APPROPRIATIONS.—There is au-
31 thorized to be appropriated to carry out this section,
32 \$50,000,000 for fiscal year 2004, and such sums as may be
33 necessary for each fiscal year thereafter.

34 **SEC. 1014. HEALTH CARE THAT WORKS FOR ALL AMERI-**
35 **CANS: CITIZENS HEALTH CARE WORKING**
36 **GROUP.**

37 (a) FINDINGS.—Congress finds the following:

1 (1) In order to improve the health care system, the
2 American public must engage in an informed national pub-
3 lic debate to make choices about the services they want cov-
4 ered, what health care coverage they want, and how they
5 are willing to pay for coverage.

6 (2) More than a trillion dollars annually is spent on
7 the health care system, yet—

8 (A) 41,000,000 Americans are uninsured;

9 (B) insured individuals do not always have access
10 to essential, effective services to improve and maintain
11 their health; and

12 (C) employers, who cover over 170,000,000 Ameri-
13 cans, find providing coverage increasingly difficult be-
14 cause of rising costs and double digit premium in-
15 creases.

16 (3) Despite increases in medical care spending that
17 are greater than the rate of inflation, population growth,
18 and Gross Domestic Product growth, there has not been a
19 commensurate improvement in our health status as a na-
20 tion.

21 (4) Health care costs for even just 1 member of a
22 family can be catastrophic, resulting in medical bills poten-
23 tially harming the economic stability of the entire family.

24 (5) Common life occurrences can jeopardize the ability
25 of a family to retain private coverage or jeopardize access
26 to public coverage.

27 (6) Innovations in health care access, coverage, and
28 quality of care, including the use of technology, have often
29 come from States, local communities, and private sector or-
30 ganizations, but more creative policies could tap this poten-
31 tial.

32 (7) Despite our Nation's wealth, the health care sys-
33 tem does not provide coverage to all Americans who want
34 it.

35 (b) PURPOSES.—The purposes of this section are—

36 (1) to provide for a nationwide public debate about im-
37 proving the health care system to provide every American

1 with the ability to obtain quality, affordable health care
2 coverage; and

3 (2) to provide for a vote by Congress on the rec-
4 ommendations that result from the debate.

5 (c) ESTABLISHMENT.—The Secretary, acting through the
6 Agency for Healthcare Research and Quality, shall establish an
7 entity to be known as the Citizens’ Health Care Working
8 Group (referred to in this section as the “Working Group”).

9 (d) MEMBERSHIP.—

10 (1) NUMBER AND APPOINTMENT.—The Working
11 Group shall be composed of 15 members. One member shall
12 be the Secretary. The Comptroller General of the United
13 States shall appoint 14 members.

14 (2) QUALIFICATIONS.—

15 (A) IN GENERAL.—The membership of the Work-
16 ing Group shall include—

17 (i) consumers of health services that represent
18 those individuals who have not had insurance with-
19 in 2 years of appointment, that have had chronic
20 illnesses, including mental illness, are disabled, and
21 those who receive insurance coverage through medi-
22 care and medicaid; and

23 (ii) individuals with expertise in financing and
24 paying for benefits and access to care, business and
25 labor perspectives, and providers of health care.

26 The membership shall reflect a broad geographic rep-
27 resentation and a balance between urban and rural rep-
28 resentatives.

29 (B) PROHIBITED APPOINTMENTS.—Members of
30 the Working Group shall not include Members of Con-
31 gress or other elected government officials (Federal,
32 State, or local). Individuals appointed to the Working
33 Group shall not be paid employees or representatives of
34 associations or advocacy organizations involved in the
35 health care system.

36 (e) PERIOD OF APPOINTMENT.—Members of the Working
37 Group shall be appointed for a life of the Working Group. Any

1 vacancies shall not affect the power and duties of the Working
2 Group but shall be filled in the same manner as the original
3 appointment.

4 (f) DESIGNATION OF THE CHAIRPERSON.—Not later than
5 15 days after the date on which all members of the Working
6 Group have been appointed under subsection (d)(1), the Comp-
7 troller General shall designate the chairperson of the Working
8 Group.

9 (g) SUBCOMMITTEES.—The Working Group may establish
10 subcommittees if doing so increases the efficiency of the Work-
11 ing Group in completing its tasks.

12 (h) DUTIES.—

13 (1) HEARINGS.—Not later than 90 days after the date
14 of the designation of the chairperson under subsection (f),
15 the Working Group shall hold hearings to examine—

16 (A) the capacity of the public and private health
17 care systems to expand coverage options;

18 (B) the cost of health care and the effectiveness
19 of care provided at all stages of disease;

20 (C) innovative State strategies used to expand
21 health care coverage and lower health care costs;

22 (D) local community solutions to accessing health
23 care coverage;

24 (E) efforts to enroll individuals currently eligible
25 for public or private health care coverage;

26 (F) the role of evidence-based medical practices
27 that can be documented as restoring, maintaining, or
28 improving a patient's health, and the use of technology
29 in supporting providers in improving quality of care
30 and lowering costs; and

31 (G) strategies to assist purchasers of health care,
32 including consumers, to become more aware of the im-
33 pact of costs, and to lower the costs of health care.

34 (2) ADDITIONAL HEARINGS.—The Working Group
35 may hold additional hearings on subjects other than those
36 listed in paragraph (1) so long as such hearings are deter-
37 mined to be necessary by the Working Group in carrying

1 out the purposes of this section. Such additional hearings
2 do not have to be completed within the time period speci-
3 fied in paragraph (1) but shall not delay the other activities
4 of the Working Group under this section.

5 (3) THE HEALTH REPORT TO THE AMERICAN PEO-
6 PLE.—Not later than 90 days after the hearings described
7 in paragraphs (1) and (2) are completed, the Working
8 Group shall prepare and make available to health care con-
9 sumers through the Internet and other appropriate public
10 channels, a report to be entitled, “The Health Report to
11 the American People”. Such report shall be understandable
12 to the general public and include—

13 (A) a summary of—

14 (i) health care and related services that may
15 be used by individuals throughout their life span;

16 (ii) the cost of health care services and their
17 medical effectiveness in providing better quality of
18 care for different age groups;

19 (iii) the source of coverage and payment, in-
20 cluding reimbursement, for health care services;

21 (iv) the reasons people are uninsured or
22 underinsured and the cost to taxpayers, purchasers
23 of health services, and communities when Ameri-
24 cans are uninsured or underinsured;

25 (v) the impact on health care outcomes and
26 costs when individuals are treated in all stages of
27 disease;

28 (vi) health care cost containment strategies;
29 and

30 (vii) information on health care needs that
31 need to be addressed;

32 (B) examples of community strategies to provide
33 health care coverage or access;

34 (C) information on geographic-specific issues relat-
35 ing to health care;

1 (D) information concerning the cost of care in dif-
 2 ferent settings, including institutional-based care and
 3 home and community-based care;

4 (E) a summary of ways to finance health care cov-
 5 erage; and

6 (F) the role of technology in providing future
 7 health care including ways to support the information
 8 needs of patients and providers.

9 (4) COMMUNITY MEETINGS.—

10 (A) IN GENERAL.—Not later than 1 year after the
 11 date on which all the members of the Working Group
 12 have been appointed under subsection (d)(1) and ap-
 13 propriations are first made available to carry out this
 14 section , the Working Group shall initiate health care
 15 community meetings throughout the United States (in
 16 this paragraph referred to as “community meetings”).
 17 Such community meetings may be geographically or re-
 18 gionally based and shall be completed within 180 days
 19 after the initiation of the first meeting.

20 (B) NUMBER OF MEETINGS.—The Working Group
 21 shall hold a sufficient number of community meetings
 22 in order to receive information that reflects—

23 (i) the geographic differences throughout the
 24 United States;

25 (ii) diverse populations; and

26 (iii) a balance among urban and rural popu-
 27 lations.

28 (C) MEETING REQUIREMENTS.—

29 (i) FACILITATOR.—A State health officer may
 30 be the facilitator at the community meetings.

31 (ii) ATTENDANCE.—At least 1 member of the
 32 Working Group shall attend and serve as chair of
 33 each community meeting. Other members may par-
 34 ticipate through interactive technology.

35 (iii) TOPICS.—The community meetings shall,
 36 at a minimum, address the following questions:

1 (I) What health care benefits and services
2 should be provided?

3 (II) How does the American public want
4 health care delivered?

5 (III) How should health care coverage be
6 financed?

7 (IV) What trade-offs are the American
8 public willing to make in either benefits or fi-
9 nancing to ensure access to affordable, high
10 quality health care coverage and services?

11 (iv) INTERACTIVE TECHNOLOGY.—The Work-
12 ing Group may encourage public participation in
13 community meetings through interactive technology
14 and other means as determined appropriate by the
15 Working Group.

16 (D) INTERIM REQUIREMENTS.—Not later than
17 180 days after the date of completion of the community
18 meetings, the Working Group shall prepare and make
19 available to the public through the Internet and other
20 appropriate public channels, an interim set of rec-
21 ommendations on health care coverage and ways to im-
22 prove and strengthen the health care system based on
23 the information and preferences expressed at the com-
24 munity meetings. There shall be a 90-day public com-
25 ment period on such recommendations.

26 (i) RECOMMENDATIONS.—Not later than 120 days after
27 the expiration of the public comment period described in sub-
28 section (h)(4)(D), the Working Group shall submit to Congress
29 and the President a final set of recommendations.

30 (j) ADMINISTRATION.—

31 (1) EXECUTIVE DIRECTOR.—There shall be an Execu-
32 tive Director of the Working Group who shall be appointed
33 by the chairperson of the Working Group in consultation
34 with the members of the Working Group.

35 (2) COMPENSATION.—While serving on the business of
36 the Working Group (including travel time), a member of
37 the Working Group shall be entitled to compensation at the

1 per diem equivalent of the rate provided for level IV of the
2 Executive Schedule under section 5315 of title 5, United
3 States Code, and while so serving away from home and the
4 member's regular place of business, a member may be al-
5 lowed travel expenses, as authorized by the chairperson of
6 the Working Group. For purposes of pay and employment
7 benefits, rights, and privileges, all personnel of the Working
8 Group shall be treated as if they were employees of the
9 Senate.

10 (3) INFORMATION FROM FEDERAL AGENCIES.—The
11 Working Group may secure directly from any Federal de-
12 partment or agency such information as the Working
13 Group considers necessary to carry out this section. Upon
14 request of the Working Group, the head of such depart-
15 ment or agency shall furnish such information.

16 (4) POSTAL SERVICES.—The Working Group may use
17 the United States mails in the same manner and under the
18 same conditions as other departments and agencies of the
19 Federal Government.

20 (k) DETAIL.—Not more than 10 Federal Government em-
21 ployees employed by the Department of Labor and 10 Federal
22 Government employees employed by the Department of Health
23 and Human Services may be detailed to the Working Group
24 under this section without further reimbursement. Any detail of
25 an employee shall be without interruption or loss of civil service
26 status or privilege.

27 (l) TEMPORARY AND INTERMITTENT SERVICES.—The
28 chairperson of the Working Group may procure temporary and
29 intermittent services under section 3109(b) of title 5, United
30 States Code, at rates for individuals which do not exceed the
31 daily equivalent of the annual rate of basic pay prescribed for
32 level V of the Executive Schedule under section 5316 of such
33 title.

34 (m) ANNUAL REPORT.—Not later than 1 year after the
35 date of enactment of this Act, and annually thereafter during
36 the existence of the Working Group, the Working Group shall
37 report to Congress and make public a detailed description of

1 the expenditures of the Working Group used to carry out its
2 duties under this section.

3 (n) SUNSET OF WORKING GROUP.—The Working Group
4 shall terminate on the date that is 2 years after the date on
5 which all the members of the Working Group have been ap-
6 pointed under subsection (d)(1) and appropriations are first
7 made available to carry out this section.

8 (o) ADMINISTRATION REVIEW AND COMMENTS.—Not later
9 than 45 days after receiving the final recommendations of the
10 Working Group under subsection (i), the President shall submit
11 a report to Congress which shall contain—

12 (1) additional views and comments on such rec-
13 ommendations; and

14 (2) recommendations for such legislation and adminis-
15 trative actions as the President considers appropriate.

16 (p) REQUIRED CONGRESSIONAL ACTION.—Not later than
17 45 days after receiving the report submitted by the President
18 under subsection (o), each committee of jurisdiction of Con-
19 gress, the Committee on Finance of the Senate, the Committee
20 on Health, Education, Labor, and Pensions of the Senate, the
21 Committee on Ways and Means of the House of Representa-
22 tives, the Committee on Energy and Commerce of the House
23 of Representatives, Committee on Education and the Workforce
24 of the House of Representatives, shall hold at least 1 hearing
25 on such report and on the final recommendations of the Work-
26 ing Group submitted under subsection (i).

27 (q) AUTHORIZATION OF APPROPRIATIONS.—

28 (1) IN GENERAL.—There are authorized to be appro-
29 priated to carry out this section, other than subsection
30 (h)(3), \$3,000,000 for each of fiscal years 2005 and 2006.

31 (2) HEALTH REPORT TO THE AMERICAN PEOPLE.—
32 There are authorized to be appropriated for the preparation
33 and dissemination of the Health Report to the American
34 People described in subsection (h)(3), such sums as may be
35 necessary for the fiscal year in which the report is required
36 to be submitted.

1 **SEC. 1015. FUNDING START-UP ADMINISTRATIVE COSTS**
 2 **FOR MEDICARE REFORM.**

3 (a) IN GENERAL.—There are appropriated to carry out
 4 this Act (including the amendments made by this Act), to be
 5 transferred from the Federal Hospital Insurance Trust Fund
 6 and the Federal Supplementary Medical Insurance Trust
 7 Fund—

8 (1) not to exceed \$1,000,000,000 for the Centers for
 9 Medicare & Medicaid Services; and

10 (2) not to exceed \$500,000,000 for the Social Security
 11 Administration.

12 (b) AVAILABILITY.—Amounts provided under subsection
 13 (a) shall remain available until September 30, 2005.

14 (c) APPLICATION.—From amounts provided under sub-
 15 section (a)(2), the Social Security Administration may reim-
 16 burse the Internal Revenue Service for expenses in carrying out
 17 this Act (and the amendments made by this Act).

18 (d) TRANSFER.—The President may transfer amounts
 19 provided under subsection (a) between the Centers for Medicare
 20 & Medicaid Services and the Social Security Administration.
 21 Notice of such transfers shall be transmitted within 15 days to
 22 the authorizing committees of the House of Representatives
 23 and of the Senate.

24 **SEC. 1016. HEALTH CARE INFRASTRUCTURE IMPROVE-**
 25 **MENT PROGRAM.**

26 Title XVIII is amended by adding at the end the following
 27 new section:

28 “HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

29 “SEC. 1897. (a) ESTABLISHMENT.—The Secretary shall
 30 establish a loan program that provides loans to qualifying hos-
 31 pitals for payment of the capital costs of projects described in
 32 subsection (d).

33 “(b) APPLICATION.—No loan may be provided under this
 34 section to a qualifying hospital except pursuant to an applica-
 35 tion that is submitted and approved in a time, manner, and
 36 form specified by the Secretary. A loan under this section shall

1 be on such terms and conditions and meet such requirements
2 as the Secretary determines appropriate.

3 “(c) SELECTION CRITERIA.—

4 “(1) IN GENERAL.—The Secretary shall establish cri-
5 teria for selecting among qualifying hospitals that apply for
6 a loan under this section. Such criteria shall consider the
7 extent to which the project for which loan is sought is na-
8 tionally or regionally significant, in terms of expanding or
9 improving the health care infrastructure of the United
10 States or the region or in terms of the medical benefit that
11 the project will have.

12 “(2) QUALIFYING HOSPITAL DEFINED.—For purposes
13 of this section, the term ‘qualifying hospital’ means a hos-
14 pital that—

15 “(A) is engaged in research in the causes, preven-
16 tion, and treatment of cancer; and

17 “(B) is designated as a cancer center for the Na-
18 tional Cancer Institute or is designated by the State as
19 the official cancer institute of the State.

20 “(d) PROJECTS.—A project described in this subsection is
21 a project of a qualifying hospital that is designed to improve
22 the health care infrastructure of the hospital, including con-
23 struction, renovation, or other capital improvements.

24 “(e) STATE AND LOCAL PERMITS.—The provision of a
25 loan under this section with respect to a project shall not—

26 “(1) relieve any recipient of the loan of any obligation
27 to obtain any required State or local permit or approval
28 with respect to the project;

29 “(2) limit the right of any unit of State or local gov-
30 ernment to approve or regulate any rate of return on pri-
31 vate equity invested in the project; or

32 “(3) otherwise supersede any State or local law (in-
33 cluding any regulation) applicable to the construction or
34 operation of the project.

35 “(f) FORGIVENESS OF INDEBTEDNESS.—The Secretary
36 may forgive a loan provided to a qualifying hospital under this
37 section under terms and conditions that are analogous to the

1 loan forgiveness provision for student loans under part D of
2 title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a
3 et seq.), except that the Secretary shall condition such forgive-
4 ness on the establishment by the hospital of—

5 “(A) an outreach program for cancer prevention,
6 early diagnosis, and treatment that provides services to
7 a substantial majority of the residents of a State or re-
8 gion, including residents of rural areas;

9 “(B) an outreach program for cancer prevention,
10 early diagnosis, and treatment that provides services to
11 multiple Indian tribes; and

12 “(C)(i) unique research resources (such as popu-
13 lation databases); or

14 “(ii) an affiliation with an entity that has unique
15 research resources.

16 “(g) FUNDING.—

17 “(1) IN GENERAL.—There are appropriated, out of
18 amounts in the Treasury not otherwise appropriated, to
19 carry out this section, \$200,000,000, to remain available
20 during the period beginning on July 1, 2004, and ending
21 on September 30, 2008.

22 “(2) ADMINISTRATIVE COSTS.—From funds made
23 available under paragraph (1), the Secretary may use, for
24 the administration of this section, not more than
25 \$2,000,000 for each of fiscal years 2004 through 2008.

26 “(3) AVAILABILITY.—Amounts appropriated under
27 this section shall be available for obligation on July 1,
28 2004.

29 “(h) REPORT TO CONGRESS.—Not later than 4 years after
30 the date of the enactment of this section, the Secretary shall
31 submit to Congress a report on the projects for which loans are
32 provided under this section and a recommendation as to wheth-
33 er the Congress should authorize the Secretary to continue
34 loans under this section beyond fiscal year 2008.”.

**TITLE XI—ACCESS TO
AFFORDABLE PHARMACEUTICALS
Subtitle A—Access to Affordable
Pharmaceuticals**

SEC. 1101. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.

(a) ABBREVIATED NEW DRUG APPLICATIONS.—Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) is amended—

(1) in paragraph (2)—

(A) by striking subparagraph (B) and inserting the following:

“(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

“(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

“(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

“(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

“(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

“(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

1 “(I) each owner of the patent that is the subject
2 of the certification (or a representative of the owner
3 designated to receive such a notice); and

4 “(II) the holder of the approved application under
5 subsection (b) for the drug that is claimed by the pat-
6 ent or a use of which is claimed by the patent (or a
7 representative of the holder designated to receive such
8 a notice).

9 “(iv) CONTENTS OF NOTICE.—A notice required under
10 this subparagraph shall—

11 “(I) state that an application that contains data
12 from bioavailability or bioequivalence studies has been
13 submitted under this subsection for the drug with re-
14 spect to which the certification is made to obtain ap-
15 proval to engage in the commercial manufacture, use,
16 or sale of the drug before the expiration of the patent
17 referred to in the certification; and

18 “(II) include a detailed statement of the factual
19 and legal basis of the opinion of the applicant that the
20 patent is invalid or will not be infringed.”; and

21 (B) by adding at the end the following subpara-
22 graph:

23 “(D)(i) An applicant may not amend or supplement an ap-
24 plication to seek approval of a drug referring to a different list-
25 ed drug from the listed drug identified in the application as
26 submitted to the Secretary.

27 “(ii) With respect to the drug for which an application is
28 submitted, nothing in this subsection prohibits an applicant
29 from amending or supplementing the application to seek ap-
30 proval of a different strength.

31 “(iii) Within 60 days after the date of the enactment of
32 the Medicare Prescription Drug, Improvement, and Moderniza-
33 tion Act of 2003, the Secretary shall issue guidance defining
34 the term ‘listed drug’ for purposes of this subparagraph.”; and

35 (2) in paragraph (5)—

36 (A) in subparagraph (B)—

1 (i) by striking “under the following” and in-
 2 serting “by applying the following to each certifi-
 3 cation made under paragraph (2)(A)(vii)”; and

4 (ii) in clause (iii)—

5 (I) in the first sentence, by striking “un-
 6 less” and all that follows and inserting “unless,
 7 before the expiration of 45 days after the date
 8 on which the notice described in paragraph
 9 (2)(B) is received, an action is brought for in-
 10 fringement of the patent that is the subject of
 11 the certification and for which information was
 12 submitted to the Secretary under subsection
 13 (b)(1) or (c)(2) before the date on which the
 14 application (excluding an amendment or sup-
 15 plement to the application), which the Sec-
 16 retary later determines to be substantially com-
 17 plete, was submitted.”; and

18 (II) in the second sentence—

19 (aa) by striking subclause (I) and in-
 20 serting the following:

21 “(I) if before the expiration of such period the dis-
 22 trict court decides that the patent is invalid or not in-
 23 fringed (including any substantive determination that
 24 there is no cause of action for patent infringement or
 25 invalidity), the approval shall be made effective on—

26 “(aa) the date on which the court enters judg-
 27 ment reflecting the decision; or

28 “(bb) the date of a settlement order or consent
 29 decree signed and entered by the court stating that
 30 the patent that is the subject of the certification is
 31 invalid or not infringed;”;

32 (bb) by striking subclause (II) and in-
 33 serting the following:

34 “(II) if before the expiration of such period the
 35 district court decides that the patent has been
 36 infringed—

1 “(aa) if the judgment of the district court is
2 appealed, the approval shall be made effective on—

3 “(AA) the date on which the court of ap-
4 peals decides that the patent is invalid or not
5 infringed (including any substantive determina-
6 tion that there is no cause of action for patent
7 infringement or invalidity); or

8 “(BB) the date of a settlement order or
9 consent decree signed and entered by the court
10 of appeals stating that the patent that is the
11 subject of the certification is invalid or not in-
12 fringed; or

13 “(bb) if the judgment of the district court is
14 not appealed or is affirmed, the approval shall be
15 made effective on the date specified by the district
16 court in a court order under section 271(e)(4)(A)
17 of title 35, United States Code;”;

18 (cc) in subclause (III), by striking “on
19 the date of such court decision.” and in-
20 serting “as provided in subclause (I); or”;

21 (dd) by inserting after subclause (III)
22 the following:

23 “(IV) if before the expiration of such period the
24 court grants a preliminary injunction prohibiting the
25 applicant from engaging in the commercial manufac-
26 ture or sale of the drug until the court decides the
27 issues of patent validity and infringement and if the
28 court decides that such patent has been infringed, the
29 approval shall be made effective as provided in sub-
30 clause (II).”; and

31 (ee) in the matter after and below sub-
32 clause (IV) (as added by item (dd)), by
33 striking “Until the expiration” and all that
34 follows;

35 (B) by redesignating subparagraphs (C) and (D)
36 as subparagraphs (E) and (F), respectively; and

1 (C) by inserting after subparagraph (B) the fol-
2 lowing:

3 “(C) CIVIL ACTION TO OBTAIN PATENT CER-
4 TAINTY.—

5 “(i) DECLARATORY JUDGMENT ABSENT IN-
6 FRINGEMENT ACTION.—

7 “(I) IN GENERAL.—No action may be
8 brought under section 2201 of title 28, United
9 States Code, by an applicant under paragraph
10 (2) for a declaratory judgment with respect to
11 a patent which is the subject of the certifi-
12 cation referred to in subparagraph (B)(iii)
13 unless—

14 “(aa) the forty-five day period referred
15 to in such subparagraph has expired;

16 “(bb) neither the owner of such patent
17 nor the holder of the approved application
18 under subsection (b) for the drug that is
19 claimed by the patent or a use of which is
20 claimed by the patent brought a civil action
21 against the applicant for infringement of
22 the patent before the expiration of such pe-
23 riod; and

24 “(cc) in any case in which the notice
25 provided under paragraph (2)(B) relates to
26 noninfringement, the notice was accom-
27 panied by a document described in sub-
28 clause (III).

29 “(II) FILING OF CIVIL ACTION.—If the
30 conditions described in items (aa), (bb), and as
31 applicable, (cc) of subclause (I) have been met,
32 the applicant referred to in such subclause
33 may, in accordance with section 2201 of title
34 28, United States Code, bring a civil action
35 under such section against the owner or holder
36 referred to in such subclause (but not against
37 any owner or holder that has brought such a

1 civil action against the applicant, unless that
2 civil action was dismissed without prejudice)
3 for a declaratory judgment that the patent is
4 invalid or will not be infringed by the drug for
5 which the applicant seeks approval, except that
6 such civil action may be brought for a declara-
7 tory judgment that the patent will not be in-
8 fringed only in a case in which the condition
9 described in subclause (I)(cc) is applicable. A
10 civil action referred to in this subclause shall be
11 brought in the judicial district where the de-
12 fendant has its principal place of business or a
13 regular and established place of business.

14 “(III) OFFER OF CONFIDENTIAL ACCESS
15 TO APPLICATION.—For purposes of subclause
16 (I)(cc), the document described in this sub-
17 clause is a document providing an offer of con-
18 fidential access to the application that is in the
19 custody of the applicant under paragraph (2)
20 for the purpose of determining whether an ac-
21 tion referred to in subparagraph (B)(iii) should
22 be brought. The document providing the offer
23 of confidential access shall contain such restric-
24 tions as to persons entitled to access, and on
25 the use and disposition of any information
26 accessed, as would apply had a protective order
27 been entered for the purpose of protecting
28 trade secrets and other confidential business in-
29 formation. A request for access to an applica-
30 tion under an offer of confidential access shall
31 be considered acceptance of the offer of con-
32 fidential access with the restrictions as to per-
33 sons entitled to access, and on the use and dis-
34 position of any information accessed, contained
35 in the offer of confidential access, and those re-
36 strictions and other terms of the offer of con-
37 fidential access shall be considered terms of an

1 enforceable contract. Any person provided an
2 offer of confidential access shall review the ap-
3 plication for the sole and limited purpose of
4 evaluating possible infringement of the patent
5 that is the subject of the certification under
6 paragraph (2)(A)(vii)(IV) and for no other pur-
7 pose, and may not disclose information of no
8 relevance to any issue of patent infringement to
9 any person other than a person provided an
10 offer of confidential access. Further, the appli-
11 cation may be redacted by the applicant to re-
12 move any information of no relevance to any
13 issue of patent infringement.

14 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-
15 TION.—

16 “(I) IN GENERAL.—If an owner of the
17 patent or the holder of the approved applica-
18 tion under subsection (b) for the drug that is
19 claimed by the patent or a use of which is
20 claimed by the patent brings a patent infringe-
21 ment action against the applicant, the appli-
22 cant may assert a counterclaim seeking an
23 order requiring the holder to correct or delete
24 the patent information submitted by the holder
25 under subsection (b) or (c) on the ground that
26 the patent does not claim either—

27 “(aa) the drug for which the applica-
28 tion was approved; or

29 “(bb) an approved method of using
30 the drug.

31 “(II) NO INDEPENDENT CAUSE OF AC-
32 TION.—Subclause (I) does not authorize the as-
33 sertion of a claim described in subclause (I) in
34 any civil action or proceeding other than a
35 counterclaim described in subclause (I).

1 “(iii) NO DAMAGES.—An applicant shall not
2 be entitled to damages in a civil action under
3 clause (i) or a counterclaim under clause (ii).”.

4 (b) APPLICATIONS GENERALLY.—Section 505 of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) is
6 amended—

7 (1) in subsection (b)—

8 (A) by striking paragraph (3) and inserting the
9 following:

10 “(3) NOTICE OF OPINION THAT PATENT IS INVALID OR
11 WILL NOT BE INFRINGED.—

12 “(A) AGREEMENT TO GIVE NOTICE.—An applicant
13 that makes a certification described in paragraph (2)(A)(iv)
14 shall include in the application a statement that the appli-
15 cant will give notice as required by this paragraph.

16 “(B) TIMING OF NOTICE.—An applicant that makes a
17 certification described in paragraph (2)(A)(iv) shall give
18 notice as required under this paragraph—

19 “(i) if the certification is in the application, not
20 later than 20 days after the date of the postmark on
21 the notice with which the Secretary informs the appli-
22 cant that the application has been filed; or

23 “(ii) if the certification is in an amendment or
24 supplement to the application, at the time at which the
25 applicant submits the amendment or supplement, re-
26 gardless of whether the applicant has already given no-
27 tice with respect to another such certification contained
28 in the application or in an amendment or supplement
29 to the application.

30 “(C) RECIPIENTS OF NOTICE.—An applicant required
31 under this paragraph to give notice shall give notice to—

32 “(i) each owner of the patent that is the subject
33 of the certification (or a representative of the owner
34 designated to receive such a notice); and

35 “(ii) the holder of the approved application under
36 this subsection for the drug that is claimed by the pat-
37 ent or a use of which is claimed by the patent (or a

1 representative of the holder designated to receive such
2 a notice).

3 “(D) CONTENTS OF NOTICE.—A notice required under
4 this paragraph shall—

5 “(i) state that an application that contains data
6 from bioavailability or bioequivalence studies has been
7 submitted under this subsection for the drug with re-
8 spect to which the certification is made to obtain ap-
9 proval to engage in the commercial manufacture, use,
10 or sale of the drug before the expiration of the patent
11 referred to in the certification; and

12 “(ii) include a detailed statement of the factual
13 and legal basis of the opinion of the applicant that the
14 patent is invalid or will not be infringed.”; and

15 (B)(i) by redesignating paragraph (4) as para-
16 graph (5); and

17 (ii) by inserting after paragraph (3) the following
18 paragraph:

19 “(4)(A) An applicant may not amend or supplement an
20 application referred to in paragraph (2) to seek approval of a
21 drug that is a different drug than the drug identified in the
22 application as submitted to the Secretary.

23 “(B) With respect to the drug for which such an applica-
24 tion is submitted, nothing in this subsection or subsection
25 (c)(3) prohibits an applicant from amending or supplementing
26 the application to seek approval of a different strength.”; and

27 (2) in subsection (c)(3)—

28 (A) in the first sentence, by striking “under the
29 following” and inserting “by applying the following to
30 each certification made under subsection (b)(2)(A)”;

31 (B) in subparagraph (C)—

32 (i) in the first sentence, by striking “unless”
33 and all that follows and inserting “unless, before
34 the expiration of 45 days after the date on which
35 the notice described in subsection (b)(3) is received,
36 an action is brought for infringement of the patent
37 that is the subject of the certification and for which

1 information was submitted to the Secretary under
2 paragraph (2) or subsection (b)(1) before the date
3 on which the application (excluding an amendment
4 or supplement to the application) was submitted.”;

5 (ii) in the second sentence—

6 (I) by striking “paragraph (3)(B)” and in-
7 serting “subsection (b)(3)”;

8 (II) by striking clause (i) and inserting the
9 following:

10 “(i) if before the expiration of such period the dis-
11 trict court decides that the patent is invalid or not in-
12 fringed (including any substantive determination that
13 there is no cause of action for patent infringement or
14 invalidity), the approval shall be made effective on—

15 “(I) the date on which the court enters judg-
16 ment reflecting the decision; or

17 “(II) the date of a settlement order or consent
18 decree signed and entered by the court stating that
19 the patent that is the subject of the certification is
20 invalid or not infringed;”;

21 (III) by striking clause (ii) and inserting
22 the following:

23 “(ii) if before the expiration of such period the dis-
24 trict court decides that the patent has been infringed—

25 “(I) if the judgment of the district court is ap-
26 pealed, the approval shall be made effective on—

27 “(aa) the date on which the court of ap-
28 peals decides that the patent is invalid or not
29 infringed (including any substantive determina-
30 tion that there is no cause of action for patent
31 infringement or invalidity); or

32 “(bb) the date of a settlement order or
33 consent decree signed and entered by the court
34 of appeals stating that the patent that is the
35 subject of the certification is invalid or not in-
36 fringed; or

1 “(II) if the judgment of the district court is
 2 not appealed or is affirmed, the approval shall be
 3 made effective on the date specified by the district
 4 court in a court order under section 271(e)(4)(A)
 5 of title 35, United States Code;”;

6 (IV) in clause (iii), by striking “on the
 7 date of such court decision.” and inserting “as
 8 provided in clause (i); or”;

9 (V) by inserting after clause (iii), the fol-
 10 lowing:

11 “(iv) if before the expiration of such period the
 12 court grants a preliminary injunction prohibiting the
 13 applicant from engaging in the commercial manufac-
 14 ture or sale of the drug until the court decides the
 15 issues of patent validity and infringement and if the
 16 court decides that such patent has been infringed, the
 17 approval shall be made effective as provided in clause
 18 (ii).”; and

19 (VI) in the matter after and below clause
 20 (iv) (as added by subclause (V)), by striking
 21 “Until the expiration” and all that follows; and

22 (iii) in the third sentence, by striking “para-
 23 graph (3)(B)” and inserting “subsection (b)(3)”;

24 (C) by redesignating subparagraph (D) as sub-
 25 paragraph (E); and

26 (D) by inserting after subparagraph (C) the fol-
 27 lowing:

28 “(D) CIVIL ACTION TO OBTAIN PATENT CER-
 29 TAINTY.—

30 “(i) DECLARATORY JUDGMENT ABSENT IN-
 31 FRINGEMENT ACTION.—

32 “(I) IN GENERAL.—No action may be
 33 brought under section 2201 of title 28, United
 34 States Code, by an applicant referred to in sub-
 35 section (b)(2) for a declaratory judgment with
 36 respect to a patent which is the subject of the

1 certification referred to in subparagraph (C)
2 unless—

3 “(aa) the forty-five day period referred
4 to in such subparagraph has expired;

5 “(bb) neither the owner of such patent
6 nor the holder of the approved application
7 under subsection (b) for the drug that is
8 claimed by the patent or a use of which is
9 claimed by the patent brought a civil action
10 against the applicant for infringement of
11 the patent before the expiration of such pe-
12 riod; and

13 “(cc) in any case in which the notice
14 provided under paragraph (2)(B) relates to
15 noninfringement, the notice was accom-
16 panied by a document described in sub-
17 clause (III).

18 “(II) FILING OF CIVIL ACTION.—If the
19 conditions described in items (aa), (bb), and as
20 applicable, (cc) of subclause (I) have been met,
21 the applicant referred to in such subclause
22 may, in accordance with section 2201 of title
23 28, United States Code, bring a civil action
24 under such section against the owner or holder
25 referred to in such subclause (but not against
26 any owner or holder that has brought such a
27 civil action against the applicant, unless that
28 civil action was dismissed without prejudice)
29 for a declaratory judgment that the patent is
30 invalid or will not be infringed by the drug for
31 which the applicant seeks approval, except that
32 such civil action may be brought for a declara-
33 tory judgment that the patent will not be in-
34 fringed only in a case in which the condition
35 described in subclause (I)(cc) is applicable. A
36 civil action referred to in this subclause shall be
37 brought in the judicial district where the de-

1 fendant has its principal place of business or a
2 regular and established place of business.

3 “(III) OFFER OF CONFIDENTIAL ACCESS
4 TO APPLICATION.—For purposes of subclause
5 (I)(cc), the document described in this sub-
6 clause is a document providing an offer of con-
7 fidential access to the application that is in the
8 custody of the applicant referred to in sub-
9 subsection (b)(2) for the purpose of determining
10 whether an action referred to in subparagraph
11 (C) should be brought. The document providing
12 the offer of confidential access shall contain
13 such restrictions as to persons entitled to ac-
14 cess, and on the use and disposition of any in-
15 formation accessed, as would apply had a pro-
16 tective order been entered for the purpose of
17 protecting trade secrets and other confidential
18 business information. A request for access to
19 an application under an offer of confidential ac-
20 cess shall be considered acceptance of the offer
21 of confidential access with the restrictions as to
22 persons entitled to access, and on the use and
23 disposition of any information accessed, con-
24 tained in the offer of confidential access, and
25 those restrictions and other terms of the offer
26 of confidential access shall be considered terms
27 of an enforceable contract. Any person provided
28 an offer of confidential access shall review the
29 application for the sole and limited purpose of
30 evaluating possible infringement of the patent
31 that is the subject of the certification under
32 subsection (b)(2)(A)(iv) and for no other pur-
33 pose, and may not disclose information of no
34 relevance to any issue of patent infringement to
35 any person other than a person provided an
36 offer of confidential access. Further, the appli-
37 cation may be redacted by the applicant to re-

1 move any information of no relevance to any
2 issue of patent infringement.

3 “(ii) COUNTERCLAIM TO INFRINGEMENT AC-
4 TION.—

5 “(I) IN GENERAL.—If an owner of the
6 patent or the holder of the approved applica-
7 tion under subsection (b) for the drug that is
8 claimed by the patent or a use of which is
9 claimed by the patent brings a patent infringe-
10 ment action against the applicant, the appli-
11 cant may assert a counterclaim seeking an
12 order requiring the holder to correct or delete
13 the patent information submitted by the holder
14 under subsection (b) or this subsection on the
15 ground that the patent does not claim either—

16 “(aa) the drug for which the applica-
17 tion was approved; or

18 “(bb) an approved method of using
19 the drug.

20 “(II) NO INDEPENDENT CAUSE OF AC-
21 TION.—Subclause (I) does not authorize the as-
22 sertion of a claim described in subclause (I) in
23 any civil action or proceeding other than a
24 counterclaim described in subclause (I).

25 “(iii) NO DAMAGES.—An applicant shall not
26 be entitled to damages in a civil action under
27 clause (i) or a counterclaim under clause (ii).”.

28 (c) APPLICABILITY.—

29 (1) IN GENERAL.—Except as provided in paragraphs
30 (2) and (3), the amendments made by subsections (a) and
31 (b) apply to any proceeding under section 505 of the Fed-
32 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) that
33 is pending on or after the date of the enactment of this Act
34 regardless of the date on which the proceeding was com-
35 menced or is commenced.

36 (2) NOTICE OF OPINION THAT PATENT IS INVALID OR
37 WILL NOT BE INFRINGED.—The amendments made by sub-

1 sections (a)(1) and (b)(1) apply with respect to any certifi-
 2 cation under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV)
 3 of section 505 of the Federal Food, Drug, and Cosmetic
 4 Act (21 U.S.C. 355) submitted on or after August 18,
 5 2003, in an application filed under subsection (b) or (j) of
 6 that section or in an amendment or supplement to an ap-
 7 plication filed under subsection (b) or (j) of that section.

8 (3) EFFECTIVE DATE OF APPROVAL.—The amend-
 9 ments made by subsections (a)(2)(A)(ii)(I) and (b)(2)(B)(i)
 10 apply with respect to any patent information submitted
 11 under subsection (b)(1) or (c)(2) of section 505 of the Fed-
 12 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355) on or
 13 after August 18, 2003.

14 (d) INFRINGEMENT ACTIONS.—Section 271(e) of title 35,
 15 United States Code, is amended by adding at the end the fol-
 16 lowing:

17 “(5) Where a person has filed an application described in
 18 paragraph (2) that includes a certification under subsection
 19 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal
 20 Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither
 21 the owner of the patent that is the subject of the certification
 22 nor the holder of the approved application under subsection (b)
 23 of such section for the drug that is claimed by the patent or
 24 a use of which is claimed by the patent brought an action for
 25 infringement of such patent before the expiration of 45 days
 26 after the date on which the notice given under subsection (b)(3)
 27 or (j)(2)(B) of such section was received, the courts of the
 28 United States shall, to the extent consistent with the Constitu-
 29 tion, have subject matter jurisdiction in any action brought by
 30 such person under section 2201 of title 28 for a declaratory
 31 judgment that such patent is invalid or not infringed.”.

32 **SEC. 1102. FORFEITURE OF 180-DAY EXCLUSIVITY PE-**
 33 **RIOD.**

34 (a) IN GENERAL.—Section 505(j)(5) of the Federal Food,
 35 Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as amended by
 36 section 1101) is amended—

1 (1) in subparagraph (B), by striking clause (iv) and
2 inserting the following:

3 “(iv) 180-DAY EXCLUSIVITY PERIOD.—

4 “(I) EFFECTIVENESS OF APPLICATION.—Subject
5 to subparagraph (D), if the application contains a cer-
6 tification described in paragraph (2)(A)(vii)(IV) and is
7 for a drug for which a first applicant has submitted an
8 application containing such a certification, the applica-
9 tion shall be made effective on the date that is 180
10 days after the date of the first commercial marketing
11 of the drug (including the commercial marketing of the
12 listed drug) by any first applicant.

13 “(II) DEFINITIONS.—In this paragraph:

14 “(aa) 180-DAY EXCLUSIVITY PERIOD.—The
15 term ‘180-day exclusivity period’ means the 180-
16 day period ending on the day before the date on
17 which an application submitted by an applicant
18 other than a first applicant could become effective
19 under this clause.

20 “(bb) FIRST APPLICANT.—As used in this sub-
21 section, the term ‘first applicant’ means an appli-
22 cant that, on the first day on which a substantially
23 complete application containing a certification de-
24 scribed in paragraph (2)(A)(vii)(IV) is submitted
25 for approval of a drug, submits a substantially
26 complete application that contains and lawfully
27 maintains a certification described in paragraph
28 (2)(A)(vii)(IV) for the drug.

29 “(cc) SUBSTANTIALLY COMPLETE APPLICA-
30 TION.—As used in this subsection, the term ‘sub-
31 stantially complete application’ means an applica-
32 tion under this subsection that on its face is suffi-
33 ciently complete to permit a substantive review and
34 contains all the information required by paragraph
35 (2)(A).

36 “(dd) TENTATIVE APPROVAL.—

1 “(AA) IN GENERAL.—The term ‘tentative
2 approval’ means notification to an applicant by
3 the Secretary that an application under this
4 subsection meets the requirements of para-
5 graph (2)(A), but cannot receive effective ap-
6 proval because the application does not meet
7 the requirements of this subparagraph, there is
8 a period of exclusivity for the listed drug under
9 subparagraph (F) or section 505A, or there is
10 a 7-year period of exclusivity for the listed drug
11 under section 527.

12 “(BB) LIMITATION.—A drug that is
13 granted tentative approval by the Secretary is
14 not an approved drug and shall not have an ef-
15 fective approval until the Secretary issues an
16 approval after any necessary additional review
17 of the application.”; and

18 (2) by inserting after subparagraph (C) the following:

19 “(D) FORFEITURE OF 180-DAY EXCLUSIVITY PE-
20 RIOD.—

21 “(i) DEFINITION OF FORFEITURE EVENT.—In
22 this subparagraph, the term ‘forfeiture event’, with
23 respect to an application under this subsection,
24 means the occurrence of any of the following:

25 “(I) FAILURE TO MARKET.—The first ap-
26 plicant fails to market the drug by the later
27 of—

28 “(aa) the earlier of the date that is—

29 “(AA) 75 days after the date on
30 which the approval of the application of
31 the first applicant is made effective
32 under subparagraph (B)(iii); or

33 “(BB) 30 months after the date of
34 submission of the application of the
35 first applicant; or

36 “(bb) with respect to the first appli-
37 cant or any other applicant (which other

1 applicant has received tentative approval),
2 the date that is 75 days after the date as
3 of which, as to each of the patents with re-
4 spect to which the first applicant submitted
5 and lawfully maintained a certification
6 qualifying the first applicant for the 180-
7 day exclusivity period under subparagraph
8 (B)(iv), at least 1 of the following has oc-
9 curred:

10 “(AA) In an infringement action
11 brought against that applicant with re-
12 spect to the patent or in a declaratory
13 judgment action brought by that appli-
14 cant with respect to the patent, a court
15 enters a final decision from which no
16 appeal (other than a petition to the Su-
17 preme Court for a writ of certiorari)
18 has been or can be taken that the pat-
19 ent is invalid or not infringed.

20 “(BB) In an infringement action
21 or a declaratory judgment action de-
22 scribed in subitem (AA), a court signs
23 a settlement order or consent decree
24 that enters a final judgment that in-
25 cludes a finding that the patent is in-
26 valid or not infringed.

27 “(CC) The patent information
28 submitted under subsection (b) or (c) is
29 withdrawn by the holder of the applica-
30 tion approved under subsection (b).

31 “(II) WITHDRAWAL OF APPLICATION.—
32 The first applicant withdraws the application
33 or the Secretary considers the application to
34 have been withdrawn as a result of a deter-
35 mination by the Secretary that the application
36 does not meet the requirements for approval
37 under paragraph (4).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37

“(III) AMENDMENT OF CERTIFICATION.—

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

“(IV) FAILURE TO OBTAIN TENTATIVE AP-

PROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

“(V) AGREEMENT WITH ANOTHER APPLI-

CANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 1 of the Clayton Act (15 U.S.C. 12), except that the term includes section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that that section applies to unfair methods of competition).

“(VI) EXPIRATION OF ALL PATENTS.—All

of the patents as to which the applicant sub-

1 mitted a certification qualifying it for the 180-
2 day exclusivity period have expired.

3 “(ii) FORFEITURE.—The 180-day exclusivity
4 period described in subparagraph (B)(iv) shall be
5 forfeited by a first applicant if a forfeiture event
6 occurs with respect to that first applicant.

7 “(iii) SUBSEQUENT APPLICANT.—If all first
8 applicants forfeit the 180-day exclusivity period
9 under clause (ii)—

10 “(I) approval of any application containing
11 a certification described in paragraph
12 (2)(A)(vii)(IV) shall be made effective in ac-
13 cordance with subparagraph (B)(iii); and

14 “(II) no applicant shall be eligible for a
15 180-day exclusivity period.”.

16 (b) EFFECTIVE DATE.—

17 (1) IN GENERAL.—Except as provided in paragraph
18 (2), the amendment made by subsection (a) shall be effec-
19 tive only with respect to an application filed under section
20 505(j) of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355(j)) after the date of the enactment of this Act
22 for a listed drug for which no certification under section
23 505(j)(2)(A)(vii)(IV) of that Act was made before the date
24 of the enactment of this Act.

25 (2) COLLUSIVE AGREEMENTS.—If a forfeiture event
26 described in section 505(j)(5)(D)(i)(V) of that Act occurs
27 in the case of an applicant, the applicant shall forfeit the
28 180-day period under section 505(j)(5)(B)(iv) of that Act
29 without regard to when the first certification under section
30 505(j)(2)(A)(vii)(IV) of that Act for the listed drug was
31 made.

32 (3) DECISION OF A COURT WHEN THE 180-DAY EXCLU-
33 SIVITY PERIOD HAS NOT BEEN TRIGGERED.—With respect
34 to an application filed before, on, or after the date of the
35 enactment of this Act for a listed drug for which a certifi-
36 cation under section 505(j)(2)(A)(vii)(IV) of that Act was
37 made before the date of the enactment of this Act and for

1 which neither of the events described in subclause (I) or
2 (II) of section 505(j)(5)(B)(iv) of that Act (as in effect on
3 the day before the date of the enactment of this Act) has
4 occurred on or before the date of the enactment of this Act,
5 the term “decision of a court” as used in clause (iv) of sec-
6 tion 505(j)(5)(B) of that Act means a final decision of a
7 court from which no appeal (other than a petition to the
8 Supreme Court for a writ of certiorari) has been or can be
9 taken.

10 **SEC. 1103. BIOAVAILABILITY AND BIOEQUIVALENCE.**

11 (a) IN GENERAL.—Section 505(j)(8) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is amended—

13 (1) by striking subparagraph (A) and inserting the fol-
14 lowing:

15 “(A)(i) The term ‘bioavailability’ means the rate and
16 extent to which the active ingredient or therapeutic ingre-
17 dient is absorbed from a drug and becomes available at the
18 site of drug action.

19 “(ii) For a drug that is not intended to be absorbed
20 into the bloodstream, the Secretary may assess bio-
21 availability by scientifically valid measurements intended to
22 reflect the rate and extent to which the active ingredient
23 or therapeutic ingredient becomes available at the site of
24 drug action.”; and

25 (2) by adding at the end the following:

26 “(C) For a drug that is not intended to be absorbed
27 into the bloodstream, the Secretary may establish alter-
28 native, scientifically valid methods to show bioequivalence if
29 the alternative methods are expected to detect a significant
30 difference between the drug and the listed drug in safety
31 and therapeutic effect.”.

32 (b) EFFECT OF AMENDMENT.—The amendment made by
33 subsection (a) does not alter the standards for approval of
34 drugs under section 505(j) of the Federal Food, Drug, and
35 Cosmetic Act (21 U.S.C. 355(j)).

SEC. 1104. CONFORMING AMENDMENTS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i), by striking “(j)(5)(D)(ii)” each place it appears and inserting “(j)(5)(F)(ii)”;

(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii), by striking “(j)(5)(D)” each place it appears and inserting “(j)(5)(F)”;

(3) in subsections (e) and (l), by striking “505(j)(5)(D)” each place it appears and inserting “505(j)(5)(F)”.

Subtitle B—Federal Trade Commission Review

SEC. 1111. DEFINITIONS.

In this subtitle:

(1) ANDA.—The term “ANDA” means an abbreviated drug application, as defined under section 201(aa) of the Federal Food, Drug, and Cosmetic Act.

(2) ASSISTANT ATTORNEY GENERAL.—The term “Assistant Attorney General” means the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice.

(3) BRAND NAME DRUG.—The term “brand name drug” means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including an application referred to in section 505(b)(2) of such Act.

(4) BRAND NAME DRUG COMPANY.—The term “brand name drug company” means the party that holds the approved application referred to in paragraph (3) for a brand name drug that is a listed drug in an ANDA, or a party that is the owner of a patent for which information is submitted for such drug under subsection (b) or (c) of section 505 of the Federal Food, Drug, and Cosmetic Act.

1 (5) COMMISSION.—The term “Commission” means the
2 Federal Trade Commission.

3 (6) GENERIC DRUG.—The term “generic drug” means
4 a drug for which an application under section 505(j) of the
5 Federal Food, Drug, and Cosmetic Act is approved.

6 (7) GENERIC DRUG APPLICANT.—The term “generic
7 drug applicant” means a person who has filed or received
8 approval for an ANDA under section 505(j) of the Federal
9 Food, Drug, and Cosmetic Act.

10 (8) LISTED DRUG.—The term “listed drug” means a
11 brand name drug that is listed under section 505(j)(7) of
12 the Federal Food, Drug, and Cosmetic Act.

13 **SEC. 1112. NOTIFICATION OF AGREEMENTS.**

14 (a) AGREEMENT WITH BRAND NAME DRUG COMPANY.—

15 (1) REQUIREMENT.—A generic drug applicant that
16 has submitted an ANDA containing a certification under
17 section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,
18 and Cosmetic Act and a brand name drug company that
19 enter into an agreement described in paragraph (2) shall
20 each file the agreement in accordance with subsection (c).
21 The agreement shall be filed prior to the date of the first
22 commercial marketing of the generic drug that is the sub-
23 ject of the ANDA.

24 (2) SUBJECT MATTER OF AGREEMENT.—An agree-
25 ment described in this paragraph between a generic drug
26 applicant and a brand name drug company is an agreement
27 regarding—

28 (A) the manufacture, marketing or sale of the
29 brand name drug that is the listed drug in the ANDA
30 involved;

31 (B) the manufacture, marketing, or sale of the ge-
32 neric drug for which the ANDA was submitted; or

33 (C) the 180-day period referred to in section
34 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cos-
35 metic Act as it applies to such ANDA or to any other
36 ANDA based on the same brand name drug.

1 (b) AGREEMENT WITH ANOTHER GENERIC DRUG APPLI-
2 CANT.—

3 (1) REQUIREMENT.—A generic drug applicant that
4 has submitted an ANDA containing a certification under
5 section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug,
6 and Cosmetic Act with respect to a listed drug and another
7 generic drug applicant that has submitted an ANDA con-
8 taining such a certification for the same listed drug shall
9 each file the agreement in accordance with subsection (c).
10 The agreement shall be filed prior to the date of the first
11 commercial marketing of either of the generic drugs for
12 which such ANDAs were submitted.

13 (2) SUBJECT MATTER OF AGREEMENT.—An agree-
14 ment described in this paragraph between two generic drug
15 applicants is an agreement regarding the 180-day period
16 referred to in section 505(j)(5)(B)(iv) of the Federal Food,
17 Drug, and Cosmetic Act as it applies to the ANDAs with
18 which the agreement is concerned.

19 (c) FILING.—

20 (1) AGREEMENT.—The parties that are required in
21 subsection (a) or (b) to file an agreement in accordance
22 with this subsection shall file with the Assistant Attorney
23 General and the Commission the text of any such agree-
24 ment, except that such parties are not required to file an
25 agreement that solely concerns—

- 26 (A) purchase orders for raw material supplies;
27 (B) equipment and facility contracts;
28 (C) employment or consulting contracts; or
29 (D) packaging and labeling contracts.

30 (2) OTHER AGREEMENTS.—The parties that are re-
31 quired in subsection (a) or (b) to file an agreement in ac-
32 cordance with this subsection shall file with the Assistant
33 Attorney General and the Commission the text of any
34 agreements between the parties that are not described in
35 such subsections and are contingent upon, provide a contin-
36 gent condition for, or are otherwise related to an agreement

1 that is required in subsection (a) or (b) to be filed in ac-
2 cordance with this subsection.

3 (3) DESCRIPTION.—In the event that any agreement
4 required in subsection (a) or (b) to be filed in accordance
5 with this subsection has not been reduced to text, each of
6 the parties involved shall file written descriptions of such
7 agreement that are sufficient to disclose all the terms and
8 conditions of the agreement.

9 **SEC. 1113. FILING DEADLINES.**

10 Any filing required under section 1112 shall be filed with
11 the Assistant Attorney General and the Commission not later
12 than 10 business days after the date the agreements are exe-
13 cuted.

14 **SEC. 1114. DISCLOSURE EXEMPTION.**

15 Any information or documentary material filed with the
16 Assistant Attorney General or the Commission pursuant to this
17 subtitle shall be exempt from disclosure under section 552 of
18 title 5, United States Code, and no such information or docu-
19 mentary material may be made public, except as may be rel-
20 evant to any administrative or judicial action or proceeding.
21 Nothing in this section is intended to prevent disclosure to ei-
22 ther body of the Congress or to any duly authorized committee
23 or subcommittee of the Congress.

24 **SEC. 1115. ENFORCEMENT.**

25 (a) CIVIL PENALTY.—Any brand name drug company or
26 generic drug applicant which fails to comply with any provision
27 of this subtitle shall be liable for a civil penalty of not more
28 than \$11,000, for each day during which such entity is in viola-
29 tion of this subtitle. Such penalty may be recovered in a civil
30 action brought by the United States, or brought by the Com-
31 mission in accordance with the procedures established in sec-
32 tion 16(a)(1) of the Federal Trade Commission Act (15 U.S.C.
33 56(a)).

34 (b) COMPLIANCE AND EQUITABLE RELIEF.—If any brand
35 name drug company or generic drug applicant fails to comply
36 with any provision of this subtitle, the United States district
37 court may order compliance, and may grant such other equi-

1 table relief as the court in its discretion determines necessary
2 or appropriate, upon application of the Assistant Attorney Gen-
3 eral or the Commission.

4 **SEC. 1116. RULEMAKING.**

5 The Commission, with the concurrence of the Assistant
6 Attorney General and by rule in accordance with section 553
7 of title 5, United States Code, consistent with the purposes of
8 this subtitle—

9 (1) may define the terms used in this subtitle;

10 (2) may exempt classes of persons or agreements from
11 the requirements of this subtitle; and

12 (3) may prescribe such other rules as may be nec-
13 essary and appropriate to carry out the purposes of this
14 subtitle.

15 **SEC. 1117. SAVINGS CLAUSE.**

16 Any action taken by the Assistant Attorney General or the
17 Commission, or any failure of the Assistant Attorney General
18 or the Commission to take action, under this subtitle shall not
19 at any time bar any proceeding or any action with respect to
20 any agreement between a brand name drug company and a ge-
21 neric drug applicant, or any agreement between generic drug
22 applicants, under any other provision of law, nor shall any fil-
23 ing under this subtitle constitute or create a presumption of
24 any violation of any competition laws.

25 **SEC. 1118. EFFECTIVE DATE.**

26 This subtitle shall—

27 (1) take effect 30 days after the date of the enactment
28 of this Act; and

29 (2) shall apply to agreements described in section
30 1112 that are entered into 30 days after the date of the
31 enactment of this Act.

1 **Subtitle C—Importation of** 2 **Prescription Drugs**

3 **SEC. 1121. IMPORTATION OF PRESCRIPTION DRUGS.**

4 (a) IN GENERAL.—Chapter VIII of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended
6 by striking section 804 and inserting the following:

7 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) IMPORTER.—The term ‘importer’ means a phar-
10 macist or wholesaler.

11 “(2) PHARMACIST.—The term ‘pharmacist’ means a
12 person licensed by a State to practice pharmacy, including
13 the dispensing and selling of prescription drugs.

14 “(3) PRESCRIPTION DRUG.—The term ‘prescription
15 drug’ means a drug subject to section 503(b), other than—

16 “(A) a controlled substance (as defined in section
17 102 of the Controlled Substances Act (21 U.S.C. 802));

18 “(B) a biological product (as defined in section
19 351 of the Public Health Service Act (42 U.S.C. 262));

20 “(C) an infused drug (including a peritoneal dialy-
21 sis solution);

22 “(D) an intravenously injected drug;

23 “(E) a drug that is inhaled during surgery; or

24 “(F) a drug which is a parenteral drug, the impor-
25 tation of which pursuant to subsection (b) is deter-
26 mined by the Secretary to pose a threat to the public
27 health, in which case section 801(d)(1) shall continue
28 to apply.

29 “(4) QUALIFYING LABORATORY.—The term ‘qualifying
30 laboratory’ means a laboratory in the United States that
31 has been approved by the Secretary for the purposes of this
32 section.

33 “(5) WHOLESALER.—

34 “(A) IN GENERAL.—The term ‘wholesaler’ means
35 a person licensed as a wholesaler or distributor of pre-

1 prescription drugs in the United States under section
2 503(e)(2)(A).

3 “(B) EXCLUSION.—The term ‘wholesaler’ does not
4 include a person authorized to import drugs under sec-
5 tion 801(d)(1).

6 “(b) REGULATIONS.—The Secretary, after consultation
7 with the United States Trade Representative and the Commis-
8 sioner of Customs, shall promulgate regulations permitting
9 pharmacists and wholesalers to import prescription drugs from
10 Canada into the United States.

11 “(c) LIMITATION.—The regulations under subsection (b)
12 shall—

13 “(1) require that safeguards be in place to ensure that
14 each prescription drug imported under the regulations com-
15 plies with section 505 (including with respect to being safe
16 and effective for the intended use of the prescription drug),
17 with sections 501 and 502, and with other applicable re-
18 quirements of this Act;

19 “(2) require that an importer of a prescription drug
20 under the regulations comply with subsections (d)(1) and
21 (e); and

22 “(3) contain any additional provisions determined by
23 the Secretary to be appropriate as a safeguard to protect
24 the public health or as a means to facilitate the importation
25 of prescription drugs.

26 “(d) INFORMATION AND RECORDS.—

27 “(1) IN GENERAL.—The regulations under subsection
28 (b) shall require an importer of a prescription drug under
29 subsection (b) to submit to the Secretary the following in-
30 formation and documentation:

31 “(A) The name and quantity of the active ingre-
32 dient of the prescription drug.

33 “(B) A description of the dosage form of the pre-
34 scription drug.

35 “(C) The date on which the prescription drug is
36 shipped.

1 “(D) The quantity of the prescription drug that is
2 shipped.

3 “(E) The point of origin and destination of the
4 prescription drug.

5 “(F) The price paid by the importer for the pre-
6 scription drug.

7 “(G) Documentation from the foreign seller
8 specifying—

9 “(i) the original source of the prescription
10 drug; and

11 “(ii) the quantity of each lot of the prescrip-
12 tion drug originally received by the seller from that
13 source.

14 “(H) The lot or control number assigned to the
15 prescription drug by the manufacturer of the prescrip-
16 tion drug.

17 “(I) The name, address, telephone number, and
18 professional license number (if any) of the importer.

19 “(J)(i) In the case of a prescription drug that is
20 shipped directly from the first foreign recipient of the
21 prescription drug from the manufacturer:

22 “(I) Documentation demonstrating that the
23 prescription drug was received by the recipient
24 from the manufacturer and subsequently shipped
25 by the first foreign recipient to the importer.

26 “(II) Documentation of the quantity of each
27 lot of the prescription drug received by the first
28 foreign recipient demonstrating that the quantity
29 being imported into the United States is not more
30 than the quantity that was received by the first for-
31 eign recipient.

32 “(III)(aa) In the case of an initial imported
33 shipment, documentation demonstrating that each
34 batch of the prescription drug in the shipment was
35 statistically sampled and tested for authenticity
36 and degradation.

1 “(bb) In the case of any subsequent shipment,
2 documentation demonstrating that a statistically
3 valid sample of the shipment was tested for authen-
4 ticity and degradation.

5 “(ii) In the case of a prescription drug that is not
6 shipped directly from the first foreign recipient of the
7 prescription drug from the manufacturer, documenta-
8 tion demonstrating that each batch in each shipment
9 offered for importation into the United States was sta-
10 tistically sampled and tested for authenticity and deg-
11 radation.

12 “(K) Certification from the importer or manufac-
13 turer of the prescription drug that the prescription
14 drug—

15 “(i) is approved for marketing in the United
16 States and is not adulterated or misbranded; and

17 “(ii) meets all labeling requirements under this
18 Act.

19 “(L) Laboratory records, including complete data
20 derived from all tests necessary to ensure that the pre-
21 scription drug is in compliance with established speci-
22 fications and standards.

23 “(M) Documentation demonstrating that the test-
24 ing required by subparagraphs (J) and (L) was con-
25 ducted at a qualifying laboratory.

26 “(N) Any other information that the Secretary de-
27 termines is necessary to ensure the protection of the
28 public health.

29 “(2) MAINTENANCE BY THE SECRETARY.—The Sec-
30 retary shall maintain information and documentation sub-
31 mitted under paragraph (1) for such period of time as the
32 Secretary determines to be necessary.

33 “(e) TESTING.—The regulations under subsection (b) shall
34 require—

35 “(1) that testing described in subparagraphs (J) and
36 (L) of subsection (d)(1) be conducted by the importer or

1 by the manufacturer of the prescription drug at a qualified
2 laboratory;

3 “(2) if the tests are conducted by the importer—

4 “(A) that information needed to—

5 “(i) authenticate the prescription drug being
6 tested; and

7 “(ii) confirm that the labeling of the prescrip-
8 tion drug complies with labeling requirements
9 under this Act;

10 be supplied by the manufacturer of the prescription
11 drug to the pharmacist or wholesaler; and

12 “(B) that the information supplied under subpara-
13 graph (A) be kept in strict confidence and used only for
14 purposes of testing or otherwise complying with this
15 Act; and

16 “(3) may include such additional provisions as the
17 Secretary determines to be appropriate to provide for the
18 protection of trade secrets and commercial or financial in-
19 formation that is privileged or confidential.

20 “(f) REGISTRATION OF FOREIGN SELLERS.—Any estab-
21 lishment within Canada engaged in the distribution of a pre-
22 scription drug that is imported or offered for importation into
23 the United States shall register with the Secretary the name
24 and place of business of the establishment and the name of the
25 United States agent for the establishment.

26 “(g) SUSPENSION OF IMPORTATION.—The Secretary shall
27 require that importations of a specific prescription drug or im-
28 portations by a specific importer under subsection (b) be imme-
29 diately suspended on discovery of a pattern of importation of
30 that specific prescription drug or by that specific importer of
31 drugs that are counterfeit or in violation of any requirement
32 under this section, until an investigation is completed and the
33 Secretary determines that the public is adequately protected
34 from counterfeit and violative prescription drugs being im-
35 ported under subsection (b).

36 “(h) APPROVED LABELING.—The manufacturer of a pre-
37 scription drug shall provide an importer written authorization

1 for the importer to use, at no cost, the approved labeling for
2 the prescription drug.

3 “(i) CHARITABLE CONTRIBUTIONS.—Notwithstanding any
4 other provision of this section, section 801(d)(1) continues to
5 apply to a prescription drug that is donated or otherwise sup-
6 plied at no charge by the manufacturer of the drug to a chari-
7 table or humanitarian organization (including the United Na-
8 tions and affiliates) or to a government of a foreign country.

9 “(j) WAIVER AUTHORITY FOR IMPORTATION BY INDIVID-
10 UALS.—

11 “(1) DECLARATIONS.—Congress declares that in the
12 enforcement against individuals of the prohibition of impor-
13 tation of prescription drugs and devices, the Secretary
14 should—

15 “(A) focus enforcement on cases in which the im-
16 portation by an individual poses a significant threat to
17 public health; and

18 “(B) exercise discretion to permit individuals to
19 make such importations in circumstances in which—

20 “(i) the importation is clearly for personal use;
21 and

22 “(ii) the prescription drug or device imported
23 does not appear to present an unreasonable risk to
24 the individual.

25 “(2) WAIVER AUTHORITY.—

26 “(A) IN GENERAL.—The Secretary may grant to
27 individuals, by regulation or on a case-by-case basis, a
28 waiver of the prohibition of importation of a prescrip-
29 tion drug or device or class of prescription drugs or de-
30 vices, under such conditions as the Secretary deter-
31 mines to be appropriate.

32 “(B) GUIDANCE ON CASE-BY-CASE WAIVERS.—The
33 Secretary shall publish, and update as necessary, guid-
34 ance that accurately describes circumstances in which
35 the Secretary will consistently grant waivers on a case-
36 by-case basis under subparagraph (A), so that individ-
37 uals may know with the greatest practicable degree of

1 certainty whether a particular importation for personal
2 use will be permitted.

3 “(3) DRUGS IMPORTED FROM CANADA.—In particular,
4 the Secretary shall by regulation grant individuals a waiver
5 to permit individuals to import into the United States a
6 prescription drug that—

7 “(A) is imported from a licensed pharmacy for
8 personal use by an individual, not for resale, in quan-
9 tities that do not exceed a 90-day supply;

10 “(B) is accompanied by a copy of a valid prescrip-
11 tion;

12 “(C) is imported from Canada, from a seller reg-
13 istered with the Secretary;

14 “(D) is a prescription drug approved by the Sec-
15 retary under chapter V;

16 “(E) is in the form of a final finished dosage that
17 was manufactured in an establishment registered under
18 section 510; and

19 “(F) is imported under such other conditions as
20 the Secretary determines to be necessary to ensure
21 public safety.

22 “(k) CONSTRUCTION.—Nothing in this section limits the
23 authority of the Secretary relating to the importation of pre-
24 scription drugs, other than with respect to section 801(d)(1) as
25 provided in this section.

26 “(l) EFFECTIVENESS OF SECTION.—

27 “(1) COMMENCEMENT OF PROGRAM.—This section
28 shall become effective only if the Secretary certifies to the
29 Congress that the implementation of this section will—

30 (A) pose no additional risk to the public’s health
31 and safety; and

32 (B) result in a significant reduction in the cost of
33 covered products to the American consumer.

34 “(2) TERMINATION OF PROGRAM.—

35 “(A) IN GENERAL.—If, after the date that is 1
36 year after the effective date of the regulations under
37 subsection (b) and before the date that is 18 months

1 after the effective date, the Secretary submits to Con-
2 gress a certification that, in the opinion of the Sec-
3 retary, based on substantial evidence obtained after the
4 effective date, the benefits of implementation of this
5 section do not outweigh any detriment of implementa-
6 tion of this section, this section shall cease to be effec-
7 tive as of the date that is 30 days after the date on
8 which the Secretary submits the certification.

9 “(B) PROCEDURE.—The Secretary shall not sub-
10 mit a certification under subparagraph (A) unless,
11 after a hearing on the record under sections 556 and
12 557 of title 5, United States Code, the Secretary—

13 “(i)(I) determines that it is more likely than
14 not that implementation of this section would result
15 in an increase in the risk to the public health and
16 safety;

17 “(II) identifies specifically, in qualitative and
18 quantitative terms, the nature of the increased risk;

19 “(III) identifies specifically the causes of the
20 increased risk; and

21 “(IV)(aa) considers whether any measures can
22 be taken to avoid, reduce, or mitigate the increased
23 risk; and

24 “(bb) if the Secretary determines that any
25 measures described in item (aa) would require ad-
26 ditional statutory authority, submits to Congress a
27 report describing the legislation that would be re-
28 quired;

29 “(ii) identifies specifically, in qualitative and
30 quantitative terms, the benefits that would result
31 from implementation of this section (including the
32 benefit of reductions in the cost of covered products
33 to consumers in the United States, allowing con-
34 sumers to procure needed medication that con-
35 sumers might not otherwise be able to procure
36 without foregoing other necessities of life); and

1 “(iii)(I) compares in specific terms the det-
 2 riment identified under clause (i) with the benefits
 3 identified under clause (ii); and

4 “(II) determines that the benefits do not out-
 5 weigh the detriment.

6 “(m) AUTHORIZATION OF APPROPRIATIONS.—There are
 7 authorized to be appropriated such sums as are necessary to
 8 carry out this section.”.

9 (b) CONFORMING AMENDMENTS.—The Federal Food,
 10 Drug, and Cosmetic Act is amended—

11 (1) in section 301(aa) (21 U.S.C. 331(aa)), by striking
 12 “covered product in violation of section 804” and inserting
 13 “prescription drug in violation of section 804”; and

14 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6)), by
 15 striking “covered product pursuant to section 804(a)” and
 16 inserting “prescription drug under section 804(b)”.

17 **SEC. 1122. STUDY AND REPORT ON IMPORTATION OF**
 18 **DRUGS.**

19 The Secretary, in consultation with appropriate govern-
 20 ment agencies, shall conduct a study on the importation of
 21 drugs into the United States pursuant to section 804 of the
 22 Federal Food, Drug, and Cosmetic Act (as added by section
 23 1121 of this Act). Not later than 12 months after the date of
 24 the enactment of this Act, the Secretary shall submit to the ap-
 25 propriate committees of the Congress a report providing the
 26 findings of such study.

27 **SEC. 1123. STUDY AND REPORT ON TRADE IN PHARMA-**
 28 **CEUTICALS.**

29 The President’s designees shall conduct a study and report
 30 on issues related to trade and pharmaceuticals.

31 **TITLE XII—TAX INCENTIVES FOR**
 32 **HEALTH AND RETIREMENT SE-**
 33 **CURITY**

34 **SEC. 1201. HEALTH SAVINGS ACCOUNTS.**

35 (a) IN GENERAL.—Part VII of subchapter B of chapter 1
 36 of the Internal Revenue Code of 1986 (relating to additional
 37 itemized deductions for individuals) is amended by redesignig-

1 nating section 223 as section 224 and by inserting after section
2 222 the following new section:

3 **“SEC. 223. HEALTH SAVINGS ACCOUNTS.**

4 “(a) DEDUCTION ALLOWED.—In the case of an individual
5 who is an eligible individual for any month during the taxable
6 year, there shall be allowed as a deduction for the taxable year
7 an amount equal to the aggregate amount paid in cash during
8 such taxable year by or on behalf of such individual to a health
9 savings account of such individual.

10 “(b) LIMITATIONS.—

11 “(1) IN GENERAL.—The amount allowable as a deduc-
12 tion under subsection (a) to an individual for the taxable
13 year shall not exceed the sum of the monthly limitations for
14 months during such taxable year that the individual is an
15 eligible individual.

16 “(2) MONTHLY LIMITATION.—The monthly limitation
17 for any month is $\frac{1}{12}$ of—

18 “(A) in the case of an eligible individual who has
19 self-only coverage under a high deductible health plan
20 as of the first day of such month, the lesser of—

21 “(i) the annual deductible under such cov-
22 erage, or

23 “(ii) \$2,250, or

24 “(B) in the case of an eligible individual who has
25 family coverage under a high deductible health plan as
26 of the first day of such month, the lesser of—

27 “(i) the annual deductible under such cov-
28 erage, or

29 “(ii) \$4,500.

30 “(3) ADDITIONAL CONTRIBUTIONS FOR INDIVIDUALS
31 55 OR OLDER.—

32 “(A) IN GENERAL.—In the case of an individual
33 who has attained age 55 before the close of the taxable
34 year, the applicable limitation under subparagraphs (A)
35 and (B) of paragraph (2) shall be increased by the ad-
36 ditional contribution amount.

1 “(B) ADDITIONAL CONTRIBUTION AMOUNT.—For
2 purposes of this section, the additional contribution
3 amount is the amount determined in accordance with
4 the following table:

“For taxable years beginning in:	The additional contribution amount is:
2004	\$500
2005	\$600
2006	\$700
2007	\$800
2008	\$900
2009 and thereafter	\$1,000.

5 “(4) COORDINATION WITH OTHER CONTRIBUTIONS.—
6 The limitation which would (but for this paragraph) apply
7 under this subsection to an individual for any taxable year
8 shall be reduced (but not below zero) by the sum of—

9 “(A) the aggregate amount paid for such taxable
10 year to Archer MSAs of such individual, and

11 “(B) the aggregate amount contributed to health
12 savings accounts of such individual which is excludable
13 from the taxpayer’s gross income for such taxable year
14 under section 106(d) (and such amount shall not be al-
15 lowed as a deduction under subsection (a)).

16 Subparagraph (A) shall not apply with respect to any indi-
17 vidual to whom paragraph (5) applies.

18 “(5) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In
19 the case of individuals who are married to each other, if
20 either spouse has family coverage—

21 “(A) both spouses shall be treated as having only
22 such family coverage (and if such spouses each have
23 family coverage under different plans, as having the
24 family coverage with the lowest annual deductible), and

25 “(B) the limitation under paragraph (1) (after the
26 application of subparagraph (A) and without regard to
27 any additional contribution amount under paragraph
28 (3))—

1 “(i) shall be reduced by the aggregate amount
2 paid to Archer MSAs of such spouses for the tax-
3 able year, and

4 “(ii) after such reduction, shall be divided
5 equally between them unless they agree on a dif-
6 ferent division.

7 “(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No
8 deduction shall be allowed under this section to any indi-
9 vidual with respect to whom a deduction under section 151
10 is allowable to another taxpayer for a taxable year begin-
11 ning in the calendar year in which such individual’s taxable
12 year begins.

13 “(7) MEDICARE ELIGIBLE INDIVIDUALS.—The limita-
14 tion under this subsection for any month with respect to
15 an individual shall be zero for the first month such indi-
16 vidual is entitled to benefits under title XVIII of the Social
17 Security Act and for each month thereafter.

18 “(c) DEFINITIONS AND SPECIAL RULES.—For purposes of
19 this section—

20 “(1) ELIGIBLE INDIVIDUAL.—

21 “(A) IN GENERAL.—The term ‘eligible individual’
22 means, with respect to any month, any individual if—

23 “(i) such individual is covered under a high
24 deductible health plan as of the 1st day of such
25 month, and

26 “(ii) such individual is not, while covered
27 under a high deductible health plan, covered under
28 any health plan—

29 “(I) which is not a high deductible health
30 plan, and

31 “(II) which provides coverage for any ben-
32 efit which is covered under the high deductible
33 health plan.

34 “(B) CERTAIN COVERAGE DISREGARDED.—Sub-
35 paragraph (A)(ii) shall be applied without regard to—

36 “(i) coverage for any benefit provided by per-
37 mitted insurance, and

1 “(ii) coverage (whether through insurance or
2 otherwise) for accidents, disability, dental care, vi-
3 sion care, or long-term care.

4 “(2) HIGH DEDUCTIBLE HEALTH PLAN.—

5 “(A) IN GENERAL.—The term ‘high deductible
6 health plan’ means a health plan—

7 “(i) which has an annual deductible which is
8 not less than—

9 “(I) \$1,000 for self-only coverage, and

10 “(II) twice the dollar amount in subclause
11 (I) for family coverage, and

12 “(ii) the sum of the annual deductible and the
13 other annual out-of-pocket expenses required to be
14 paid under the plan (other than for premiums) for
15 covered benefits does not exceed—

16 “(I) \$5,000 for self-only coverage, and

17 “(II) twice the dollar amount in subclause
18 (I) for family coverage.

19 “(B) EXCLUSION OF CERTAIN PLANS.—Such term
20 does not include a health plan if substantially all of its
21 coverage is coverage described in paragraph (1)(B).

22 “(C) SAFE HARBOR FOR ABSENCE OF PREVENTIVE
23 CARE DEDUCTIBLE.—A plan shall not fail to be treated
24 as a high deductible health plan by reason of failing to
25 have a deductible for preventive care (within the mean-
26 ing of section 1871 of the Social Security Act, except
27 as otherwise provided by the Secretary).

28 “(D) SPECIAL RULES FOR NETWORK PLANS.—In
29 the case of a plan using a network of providers—

30 “(i) ANNUAL OUT-OF-POCKET LIMITATION.—

31 Such plan shall not fail to be treated as a high de-
32 ductible health plan by reason of having an out-of-
33 pocket limitation for services provided outside of
34 such network which exceeds the applicable limita-
35 tion under subparagraph (A)(ii).

36 “(ii) ANNUAL DEDUCTIBLE.—Such plan’s an-
37 nual deductible for services provided outside of

1 such network shall not be taken into account for
2 purposes of subsection (b)(2).

3 “(3) PERMITTED INSURANCE.—The term ‘permitted
4 insurance’ means—

5 “(A) insurance if substantially all of the coverage
6 provided under such insurance relates to—

7 “(i) liabilities incurred under workers’ com-
8 pensation laws,

9 “(ii) tort liabilities,

10 “(iii) liabilities relating to ownership or use of
11 property, or

12 “(iv) such other similar liabilities as the Sec-
13 retary may specify by regulations,

14 “(B) insurance for a specified disease or illness,
15 and

16 “(C) insurance paying a fixed amount per day (or
17 other period) of hospitalization.

18 “(4) FAMILY COVERAGE.—The term ‘family coverage’
19 means any coverage other than self-only coverage.

20 “(5) ARCHER MSA.—The term ‘Archer MSA’ has the
21 meaning given such term in section 220(d).

22 “(d) HEALTH SAVINGS ACCOUNT.—For purposes of this
23 section—

24 “(1) IN GENERAL.—The term ‘health savings account’
25 means a trust created or organized in the United States as
26 a health savings account exclusively for the purpose of pay-
27 ing the qualified medical expenses of the account bene-
28 ficiary, but only if the written governing instrument cre-
29 ating the trust meets the following requirements:

30 “(A) Except in the case of a rollover contribution
31 described in subsection (f)(5) or section 220(f)(5), no
32 contribution will be accepted—

33 “(i) unless it is in cash, or

34 “(ii) to the extent such contribution, when
35 added to previous contributions to the trust for the
36 calendar year, exceeds the sum of—

1 “(I) the dollar amount in effect under sub-
2 section (b)(2)(B)(ii), and

3 “(II) the dollar amount in effect under
4 subsection (b)(3)(B).

5 “(B) The trustee is a bank (as defined in section
6 408(n)), an insurance company (as defined in section
7 816), or another person who demonstrates to the satis-
8 faction of the Secretary that the manner in which such
9 person will administer the trust will be consistent with
10 the requirements of this section.

11 “(C) No part of the trust assets will be invested
12 in life insurance contracts.

13 “(D) The assets of the trust will not be commin-
14 gled with other property except in a common trust fund
15 or common investment fund.

16 “(E) The interest of an individual in the balance
17 in his account is nonforfeitable.

18 “(2) QUALIFIED MEDICAL EXPENSES.—

19 “(A) IN GENERAL.—The term ‘qualified medical
20 expenses’ means, with respect to an account bene-
21 ficiary, amounts paid by such beneficiary for medical
22 care (as defined in section 213(d) for such individual,
23 the spouse of such individual, and any dependent (as
24 defined in section 152) of such individual, but only to
25 the extent such amounts are not compensated for by
26 insurance or otherwise.

27 “(B) HEALTH INSURANCE MAY NOT BE PUR-
28 CHASED FROM ACCOUNT.—Subparagraph (A) shall not
29 apply to any payment for insurance.

30 “(C) EXCEPTIONS.—Subparagraph (B) shall not
31 apply to any expense for coverage under—

32 “(i) a health plan during any period of con-
33 tinuation coverage required under any Federal law,

34 “(ii) a qualified long-term care insurance con-
35 tract (as defined in section 7702B(b)),

1 “(iii) a health plan during a period in which
2 the individual is receiving unemployment compensa-
3 tion under any Federal or State law, or

4 “(iv) in the case of an account beneficiary who
5 has attained the age specified in section 1811 of
6 the Social Security Act, any health insurance other
7 than a medicare supplemental policy (as defined in
8 section 1882 of the Social Security Act).

9 “(3) ACCOUNT BENEFICIARY.—The term ‘account
10 beneficiary’ means the individual on whose behalf the
11 health savings account was established.

12 “(4) CERTAIN RULES TO APPLY.—Rules similar to the
13 following rules shall apply for purposes of this section:

14 “(A) Section 219(d)(2) (relating to no deduction
15 for rollovers).

16 “(B) Section 219(f)(3) (relating to time when con-
17 tributions deemed made).

18 “(C) Except as provided in section 106(d), section
19 219(f)(5) (relating to employer payments).

20 “(D) Section 408(g) (relating to community prop-
21 erty laws).

22 “(E) Section 408(h) (relating to custodial ac-
23 counts).

24 “(e) TAX TREATMENT OF ACCOUNTS.—

25 “(1) IN GENERAL.—A health savings account is ex-
26 empt from taxation under this subtitle unless such account
27 has ceased to be a health savings account. Notwithstanding
28 the preceding sentence, any such account is subject to the
29 taxes imposed by section 511 (relating to imposition of tax
30 on unrelated business income of charitable, etc. organiza-
31 tions).

32 “(2) ACCOUNT TERMINATIONS.—Rules similar to the
33 rules of paragraphs (2) and (4) of section 408(e) shall
34 apply to health savings accounts, and any amount treated
35 as distributed under such rules shall be treated as not used
36 to pay qualified medical expenses.

37 “(f) TAX TREATMENT OF DISTRIBUTIONS.—

1 “(1) AMOUNTS USED FOR QUALIFIED MEDICAL EX-
2 PENSES.—Any amount paid or distributed out of a health
3 savings account which is used exclusively to pay qualified
4 medical expenses of any account beneficiary shall not be in-
5 cludible in gross income.

6 “(2) INCLUSION OF AMOUNTS NOT USED FOR QUALI-
7 FIED MEDICAL EXPENSES.—Any amount paid or distrib-
8 uted out of a health savings account which is not used ex-
9 clusively to pay the qualified medical expenses of the ac-
10 count beneficiary shall be included in the gross income of
11 such beneficiary.

12 “(3) EXCESS CONTRIBUTIONS RETURNED BEFORE
13 DUE DATE OF RETURN.—

14 “(A) IN GENERAL.—If any excess contribution is
15 contributed for a taxable year to any health savings ac-
16 count of an individual, paragraph (2) shall not apply
17 to distributions from the health savings accounts of
18 such individual (to the extent such distributions do not
19 exceed the aggregate excess contributions to all such
20 accounts of such individual for such year) if—

21 “(i) such distribution is received by the indi-
22 vidual on or before the last day prescribed by law
23 (including extensions of time) for filing such indi-
24 vidual’s return for such taxable year, and

25 “(ii) such distribution is accompanied by the
26 amount of net income attributable to such excess
27 contribution.

28 Any net income described in clause (ii) shall be in-
29 cluded in the gross income of the individual for the tax-
30 able year in which it is received.

31 “(B) EXCESS CONTRIBUTION.—For purposes of
32 subparagraph (A), the term ‘excess contribution’ means
33 any contribution (other than a rollover contribution de-
34 scribed in paragraph (5) or section 220(f)(5)) which is
35 neither excludable from gross income under section
36 106(d) nor deductible under this section.

1 “(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED
2 FOR QUALIFIED MEDICAL EXPENSES.—

3 “(A) IN GENERAL.—The tax imposed by this
4 chapter on the account beneficiary for any taxable year
5 in which there is a payment or distribution from a
6 health savings account of such beneficiary which is in-
7 cludible in gross income under paragraph (2) shall be
8 increased by 10 percent of the amount which is so in-
9 cludible.

10 “(B) EXCEPTION FOR DISABILITY OR DEATH.—
11 Subparagraph (A) shall not apply if the payment or
12 distribution is made after the account beneficiary be-
13 comes disabled within the meaning of section 72(m)(7)
14 or dies.

15 “(C) EXCEPTION FOR DISTRIBUTIONS AFTER
16 MEDICARE ELIGIBILITY.—Subparagraph (A) shall not
17 apply to any payment or distribution after the date on
18 which the account beneficiary attains the age specified
19 in section 1811 of the Social Security Act.

20 “(5) ROLLOVER CONTRIBUTION.—An amount is de-
21 scribed in this paragraph as a rollover contribution if it
22 meets the requirements of subparagraphs (A) and (B).

23 “(A) IN GENERAL.—Paragraph (2) shall not apply
24 to any amount paid or distributed from a health sav-
25 ings account to the account beneficiary to the extent
26 the amount received is paid into a health savings ac-
27 count for the benefit of such beneficiary not later than
28 the 60th day after the day on which the beneficiary re-
29 ceives the payment or distribution.

30 “(B) LIMITATION.—This paragraph shall not
31 apply to any amount described in subparagraph (A) re-
32 ceived by an individual from a health savings account
33 if, at any time during the 1-year period ending on the
34 day of such receipt, such individual received any other
35 amount described in subparagraph (A) from a health
36 savings account which was not includible in the individ-

1 ual's gross income because of the application of this
2 paragraph.

3 “(6) COORDINATION WITH MEDICAL EXPENSE DEDUC-
4 TION.—For purposes of determining the amount of the de-
5 duction under section 213, any payment or distribution out
6 of a health savings account for qualified medical expenses
7 shall not be treated as an expense paid for medical care.

8 “(7) TRANSFER OF ACCOUNT INCIDENT TO DI-
9 VORCE.—The transfer of an individual's interest in a health
10 savings account to an individual's spouse or former spouse
11 under a divorce or separation instrument described in sub-
12 paragraph (A) of section 71(b)(2) shall not be considered
13 a taxable transfer made by such individual notwithstanding
14 any other provision of this subtitle, and such interest shall,
15 after such transfer, be treated as a health savings account
16 with respect to which such spouse is the account bene-
17 ficiary.

18 “(8) TREATMENT AFTER DEATH OF ACCOUNT BENE-
19 FICIARY.—

20 “(A) TREATMENT IF DESIGNATED BENEFICIARY
21 IS SPOUSE.—If the account beneficiary's surviving
22 spouse acquires such beneficiary's interest in a health
23 savings account by reason of being the designated bene-
24 ficiary of such account at the death of the account ben-
25 eficiary, such health savings account shall be treated as
26 if the spouse were the account beneficiary.

27 “(B) OTHER CASES.—

28 “(i) IN GENERAL.— If, by reason of the death
29 of the account beneficiary, any person acquires the
30 account beneficiary's interest in a health savings
31 account in a case to which subparagraph (A) does
32 not apply—

33 “(I) such account shall cease to be a
34 health savings account as of the date of death,
35 and

36 “(II) an amount equal to the fair market
37 value of the assets in such account on such

1 date shall be includible if such person is not the
 2 estate of such beneficiary, in such person's
 3 gross income for the taxable year which in-
 4 cludes such date, or if such person is the estate
 5 of such beneficiary, in such beneficiary's gross
 6 income for the last taxable year of such bene-
 7 ficiary.

8 “(ii) SPECIAL RULES.—

9 “(I) REDUCTION OF INCLUSION FOR
 10 PREDEATH EXPENSES.—The amount includible
 11 in gross income under clause (i) by any person
 12 (other than the estate) shall be reduced by the
 13 amount of qualified medical expenses which
 14 were incurred by the decedent before the date
 15 of the decedent's death and paid by such per-
 16 son within 1 year after such date.

17 “(II) DEDUCTION FOR ESTATE TAXES.—
 18 An appropriate deduction shall be allowed
 19 under section 691(c) to any person (other than
 20 the decedent or the decedent's spouse) with re-
 21 spect to amounts included in gross income
 22 under clause (i) by such person.

23 “(g) COST-OF-LIVING ADJUSTMENT.—

24 “(1) IN GENERAL.—Each dollar amount in subsections
 25 (b)(2) and (c)(2)(A) shall be increased by an amount equal
 26 to—

27 “(A) such dollar amount, multiplied by

28 “(B) the cost-of-living adjustment determined
 29 under section 1(f)(3) for the calendar year in which
 30 such taxable year begins determined by substituting for
 31 ‘calendar year 1992’ in subparagraph (B) thereof—

32 “(i) except as provided in clause (ii), ‘calendar
 33 year 1997’, and

34 “(ii) in the case of each dollar amount in sub-
 35 section (c)(2)(A), ‘calendar year 2003’.

1 “(2) ROUNDING.—If any increase under paragraph (1)
2 is not a multiple of \$50, such increase shall be rounded to
3 the nearest multiple of \$50.

4 “(h) REPORTS.—The Secretary may require—

5 “(1) the trustee of a health savings account to make
6 such reports regarding such account to the Secretary and
7 to the account beneficiary with respect to contributions,
8 distributions, the return of excess contributions, and such
9 other matters as the Secretary determines appropriate, and

10 “(2) any person who provides an individual with a
11 high deductible health plan to make such reports to the
12 Secretary and to the account beneficiary with respect to
13 such plan as the Secretary determines appropriate.

14 The reports required by this subsection shall be filed at such
15 time and in such manner and furnished to such individuals at
16 such time and in such manner as may be required by the Sec-
17 retary.”.

18 (b) DEDUCTION ALLOWED WHETHER OR NOT INDI-
19 VIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of
20 section 62 of such Code is amended by inserting after para-
21 graph (18) the following new paragraph:

22 “(19) HEALTH SAVINGS ACCOUNTS.—The deduction
23 allowed by section 223.”.

24 (c) ROLLOVERS FROM ARCHER MSAS PERMITTED.—Sub-
25 paragraph (A) of section 220(f)(5) of such Code (relating to
26 rollover contribution) is amended by inserting “or a health sav-
27 ings account (as defined in section 223(d))” after “paid into
28 an Archer MSA”.

29 (d) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO
30 HEALTH SAVINGS ACCOUNTS.—

31 (1) EXCLUSION FROM INCOME TAX.—Section 106 of
32 such Code (relating to contributions by employer to acci-
33 dent and health plans) is amended by adding at the end
34 the following new subsection:

35 “(d) CONTRIBUTIONS TO HEALTH SAVINGS ACCOUNTS.—

36 “(1) IN GENERAL.—In the case of an employee who is
37 an eligible individual (as defined in section 223(c)(1)),

1 amounts contributed by such employee's employer to any
 2 health savings account (as defined in section 223(d)) of
 3 such employee shall be treated as employer-provided cov-
 4 erage for medical expenses under an accident or health
 5 plan to the extent such amounts do not exceed the limita-
 6 tion under section 223(b) (determined without regard to
 7 this subsection) which is applicable to such employee for
 8 such taxable year.

9 “(2) SPECIAL RULES.—Rules similar to the rules of
 10 paragraphs (2), (3), (4), and (5) of subsection (b) shall
 11 apply for purposes of this subsection.

12 “(3) CROSS REFERENCE.—

**“For penalty on failure by employer to make
 comparable contributions to the health savings
 accounts of comparable employees, see section
 4980G.”.**

13 (2) EXCLUSION FROM EMPLOYMENT TAXES.—

14 (A) RAILROAD RETIREMENT TAX.—Subsection (e)
 15 of section 3231 of such Code is amended by adding at
 16 the end the following new paragraph:

17 “(11) HEALTH SAVINGS ACCOUNT CONTRIBUTIONS.—
 18 The term ‘compensation’ shall not include any payment
 19 made to or for the benefit of an employee if at the time
 20 of such payment it is reasonable to believe that the em-
 21 ployee will be able to exclude such payment from income
 22 under section 106(d).”.

23 (B) UNEMPLOYMENT TAX.—Subsection (b) of sec-
 24 tion 3306 of such Code is amended by striking “or” at
 25 the end of paragraph (16), by striking the period at the
 26 end of paragraph (17) and inserting “; or”, and by in-
 27 serting after paragraph (17) the following new para-
 28 graph:

29 “(18) any payment made to or for the benefit of an
 30 employee if at the time of such payment it is reasonable
 31 to believe that the employee will be able to exclude such
 32 payment from income under section 106(d).”.

1 (C) WITHHOLDING TAX.—Subsection (a) of sec-
 2 tion 3401 of such Code is amended by striking “or” at
 3 the end of paragraph (20), by striking the period at the
 4 end of paragraph (21) and inserting “; or”, and by in-
 5 serting after paragraph (21) the following new para-
 6 graph:

7 “(22) any payment made to or for the benefit of an
 8 employee if at the time of such payment it is reasonable
 9 to believe that the employee will be able to exclude such
 10 payment from income under section 106(d).”.

11 (3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE
 12 SHOWN ON W-2.—Subsection (a) of section 6051 of such
 13 Code is amended by striking “and” at the end of para-
 14 graph (10), by striking the period at the end of paragraph
 15 (11) and inserting “, and”, and by inserting after para-
 16 graph (11) the following new paragraph:

17 “(12) the amount contributed to any health savings
 18 account (as defined in section 223(d)) of such employee or
 19 such employee’s spouse.”.

20 (4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE
 21 COMPARABLE HEALTH SAVINGS ACCOUNT CONTRIBU-
 22 TIONS.—

23 (A) IN GENERAL.—Chapter 43 of such Code is
 24 amended by adding after section 4980F the following
 25 new section:

26 **“SEC. 4980G. FAILURE OF EMPLOYER TO MAKE COM-**
 27 **PARABLE HEALTH SAVINGS ACCOUNT CON-**
 28 **TRIBUTIONS.**

29 “(a) GENERAL RULE.—In the case of an employer who
 30 makes a contribution to the health savings account of any em-
 31 ployee during a calendar year, there is hereby imposed a tax
 32 on the failure of such employer to meet the requirements of
 33 subsection (b) for such calendar year.

34 “(b) RULES AND REQUIREMENTS.—Rules and require-
 35 ments similar to the rules and requirements of section 4980E
 36 shall apply for purposes of this section.

1 “(c) REGULATIONS.—The Secretary shall issue regulations
2 to carry out the purposes of this section, including regulations
3 providing special rules for employers who make contributions to
4 Archer MSAs and health savings accounts during the calendar
5 year.”.

6 (B) CLERICAL AMENDMENT.—The table of sec-
7 tions for chapter 43 of such Code is amended by add-
8 ing after the item relating to section 4980F the fol-
9 lowing new item:

“Sec. 4980G. Failure of employer to make comparable health savings ac-
count contributions.”.

10 (e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 of
11 such Code (relating to tax on excess contributions to certain
12 tax-favored accounts and annuities) is amended—

13 (1) by striking “or” at the end of subsection (a)(3),
14 by inserting “or” at the end of subsection (a)(4), and by
15 inserting after subsection (a)(4) the following new para-
16 graph:

17 “(5) a health savings account (within the meaning of
18 section 223(d)),”, and

19 (2) by adding at the end the following new subsection:

20 “(g) EXCESS CONTRIBUTIONS TO HEALTH SAVINGS AC-
21 COUNTS.—For purposes of this section, in the case of health
22 savings accounts (within the meaning of section 223(d)), the
23 term ‘excess contributions’ means the sum of—

24 “(1) the aggregate amount contributed for the taxable
25 year to the accounts (other than a rollover contribution de-
26 scribed in section 220(f)(5) or 223(f)(5)) which is neither
27 excludable from gross income under section 106(d) nor al-
28 lowable as a deduction under section 223 for such year,
29 and

30 “(2) the amount determined under this subsection for
31 the preceding taxable year, reduced by the sum of—

32 “(A) the distributions out of the accounts which
33 were included in gross income under section 223(f)(2),
34 and

35 “(B) the excess (if any) of—

1 “(i) the maximum amount allowable as a de-
2 duction under section 223(b) (determined without
3 regard to section 106(d)) for the taxable year, over

4 “(ii) the amount contributed to the accounts
5 for the taxable year.

6 For purposes of this subsection, any contribution which is dis-
7 tributed out of the health savings account in a distribution to
8 which section 223(f)(3) applies shall be treated as an amount
9 not contributed.”.

10 (f) TAX ON PROHIBITED TRANSACTIONS.—

11 (1) Section 4975 of such Code (relating to tax on pro-
12 hibited transactions) is amended by adding at the end of
13 subsection (c) the following new paragraph:

14 “(6) SPECIAL RULE FOR HEALTH SAVINGS AC-
15 COUNTS.—An individual for whose benefit a health savings
16 account (within the meaning of section 223(d)) is estab-
17 lished shall be exempt from the tax imposed by this section
18 with respect to any transaction concerning such account
19 (which would otherwise be taxable under this section) if,
20 with respect to such transaction, the account ceases to be
21 a health savings account by reason of the application of
22 section 223(e)(2) to such account.”.

23 (2) Paragraph (1) of section 4975(e) of such Code is
24 amended by redesignating subparagraphs (E) and (F) as
25 subparagraphs (F) and (G), respectively, and by inserting
26 after subparagraph (D) the following new subparagraph:

27 “(E) a health savings account described in section
28 223(d),”.

29 (g) FAILURE TO PROVIDE REPORTS ON HEALTH SAVINGS
30 ACCOUNTS.—Paragraph (2) of section 6693(a) of such Code
31 (relating to reports) is amended by redesignating subpara-
32 graphs (C) and (D) as subparagraphs (D) and (E), respec-
33 tively, and by inserting after subparagraph (B) the following
34 new subparagraph:

35 “(C) section 223(h) (relating to health savings ac-
36 counts),”.

1 (h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUI-
 2 SITION EXPENSES.—Subparagraph (B) of section 848(e)(1) of
 3 such Code (defining specified insurance contract) is amended
 4 by striking “and” at the end of clause (iii), by striking the pe-
 5 riod at the end of clause (iv) and inserting “, and”, and by
 6 adding at the end the following new clause:

7 “(v) any contract which is a health savings ac-
 8 count (as defined in section 223(d)).”.

9 (i) HEALTH SAVINGS ACCOUNTS MAY BE OFFERED
 10 UNDER CAFETERIA PLANS.—Paragraph (2) of section 125(d)
 11 (relating to cafeteria plan defined) is amended by adding at the
 12 end the following new subparagraph:

13 “(D) EXCEPTION FOR HEALTH SAVINGS AC-
 14 COUNTS.—Subparagraph (A) shall not apply to a plan
 15 to the extent of amounts which a covered employee may
 16 elect to have the employer pay as contributions to a
 17 health savings account established on behalf of the em-
 18 ployee.”.

19 (j) CLERICAL AMENDMENT.—The table of sections for
 20 part VII of subchapter B of chapter 1 of such Code is amended
 21 by striking the last item and inserting the following:

“Sec. 223. Health savings accounts.

“Sec. 224. Cross reference.”.

22 (k) EFFECTIVE DATE.—The amendments made by this
 23 section shall apply to taxable years beginning after December
 24 31, 2003.

25 **SEC. 1202. EXCLUSION FROM GROSS INCOME OF CER-**
 26 **TAIN FEDERAL SUBSIDIES FOR PRESCRIP-**
 27 **TION DRUG PLANS.**

28 (a) IN GENERAL.—Part III of subchapter B of chapter 1
 29 of the Internal Revenue Code of 1986 is amended by inserting
 30 after section 139 the following new section:

31 **“SEC. 139A. FEDERAL SUBSIDIES FOR PRESCRIPTION**
 32 **DRUG PLANS.**

33 “Gross income shall not include any special subsidy pay-
 34 ment received under section 1860D–22 of the Social Security
 35 Act. This section shall not be taken into account for purposes

1 of determining whether any deduction is allowable with respect
2 to any cost taken into account in determining such payment.”.

3 (b) ALTERNATIVE MINIMUM TAX RELIEF.—Section
4 56(g)(4)(B) of such Code is amended by inserting “or 139A”
5 after “section 114”.

6 (c) CONFORMING AMENDMENT.—The table of sections for
7 part III of subchapter B of chapter 1 of such Code is amended
8 by inserting after the item relating to section 139 the following
9 new item:

“Sec. 139A. Federal subsidies for prescription drug plans.”.

10 (d) EFFECTIVE DATE.—The amendments made by this
11 section shall apply to taxable years ending after the date of the
12 enactment of this Act.

13 **SEC. 1203. EXCEPTION TO INFORMATION REPORTING**
14 **REQUIREMENTS RELATED TO CERTAIN**
15 **HEALTH ARRANGEMENTS.**

16 (a) IN GENERAL.—Section 6041 of the Internal Revenue
17 Code of 1986 (relating to information at source) is amended
18 by adding at the end the following new subsection:

19 “(f) SECTION DOES NOT APPLY TO CERTAIN HEALTH
20 ARRANGEMENTS.—This section shall not apply to any payment
21 for medical care (as defined in section 213(d)) made under—

22 “(1) a flexible spending arrangement (as defined in
23 section 106(c)(2)), or

24 “(2) a health reimbursement arrangement which is
25 treated as employer-provided coverage under an accident or
26 health plan for purposes of section 106.”.

27 (b) EFFECTIVE DATE.—The amendment made by this sec-
28 tion shall apply to payments made after December 31, 2002.