

108TH CONGRESS
1ST SESSION

H. R. 1400

To provide for substantial reductions in the price of prescription drugs for Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2003

Mr. ALLEN (for himself, Mr. BROWN of Ohio, Mr. BERRY, Ms. SCHAKOWSKY, Mr. CONYERS, Ms. ROYBAL-ALLARD, Mr. STARK, Ms. CORRINE BROWN of Florida, Mr. SERRANO, Mr. WAXMAN, Mr. KLECZKA, Mr. PALLONE, Mrs. MCCARTHY of New York, Ms. NORTON, Mr. KENNEDY of Rhode Island, Mr. HINCHEY, Mr. PASTOR, Mr. CASE, Ms. WOOLSEY, Mr. GREEN of Texas, Mrs. MALONEY, Mr. OBERSTAR, Mr. FROST, Mr. WEXLER, Mr. SABO, Mr. NADLER, Mr. McNULTY, Mr. MICHAUD, and Mr. KUCINICH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for substantial reductions in the price of prescription drugs for Medicare beneficiaries.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Prescription Drug
5 Fairness for Seniors Act of 2003”.

1 **SEC. 2. FINDINGS AND PURPOSES.**

2 (a) FINDINGS.—The Congress finds the following:

3 (1) Manufacturers of prescription drugs engage
4 in price discrimination practices that compel many
5 older Americans to pay substantially more for pre-
6 scription drugs than consumers in foreign nations
7 and the drug manufacturers' most favored U.S. cus-
8 tomers, such as health insurers, health maintenance
9 organizations, and the Federal Government.

10 (2) Older Americans who buy their own pre-
11 scription drugs often pay twice as much for prescrip-
12 tion drugs as consumers in foreign nations and the
13 drug manufacturers' most favored U.S. customers.
14 In some cases, older Americans pay 10 times more
15 for prescription drugs than such customers.

16 (3) The discriminatory pricing by major drug
17 manufacturers sustains their high profits (for exam-
18 ple, \$27,300,000,000 in 1999), but causes financial
19 hardship and impairs the health and well-being of
20 millions of older Americans. Many older Americans
21 are forced to choose between buying their food and
22 buying their medicines.

23 (4) Foreign nations and U.S. federally funded
24 health care programs use purchasing power to ob-
25 tain prescription drugs at low prices. Medicare bene-
26 ficiaries are denied this benefit and cannot obtain

1 their prescription drugs at the lower prices available
2 to such nations and programs.

3 (5) Implementation of the policy set forth in
4 this Act will reduce prices for brand name prescrip-
5 tion drugs for many Medicare beneficiaries by an av-
6 erage of 40 percent.

7 (6) In addition to substantially lowering the
8 costs of prescription drugs for older Americans, im-
9 plementation of the policy set forth in this Act will
10 significantly improve the health and well-being of
11 older Americans and lower the costs to the Federal
12 taxpayer of the Medicare program.

13 (7) Older Americans who are terminally ill and
14 receiving hospice care services represent some of the
15 most vulnerable individuals in our nation. Making
16 prescription drugs available to Medicare beneficiaries
17 under the care of Medicare-certified hospices will as-
18 sist in extending the benefits of lower prescription
19 drug prices to those most vulnerable and in need.

20 (b) PURPOSE.—The purpose of this Act is to protect
21 Medicare beneficiaries from discriminatory pricing by drug
22 manufacturers and to make prescription drugs available
23 to Medicare beneficiaries at substantially reduced prices.

1 **SEC. 3. PARTICIPATING MANUFACTURERS.**

2 (a) IN GENERAL.—Each participating manufacturer
3 of a covered outpatient drug shall make available for pur-
4 chase by each pharmacy such covered outpatient drug in
5 the amount described in subsection (b) at the price de-
6 scribed in subsection (c).

7 (b) DESCRIPTION OF AMOUNT OF DRUGS.—The
8 amount of a covered outpatient drug that a participating
9 manufacturer shall make available for purchase by a phar-
10 macy is an amount equal to the aggregate amount of the
11 covered outpatient drug sold or distributed by the phar-
12 macy to Medicare beneficiaries.

13 (c) DESCRIPTION OF PRICE.—The price at which a
14 participating manufacturer shall make a covered out-
15 patient drug available for purchase by a pharmacy is a
16 price no greater than the manufacturer's average foreign
17 price.

18 (d) ENFORCEMENT.—The United States shall debar
19 a manufacturer of drugs or biologicals that does not com-
20 ply with the provisions of this Act.

21 **SEC. 4. SPECIAL PROVISION WITH RESPECT TO HOSPICE**
22 **PROGRAMS.**

23 For purposes of determining the amount of a covered
24 outpatient drug that a participating manufacturer shall
25 make available for purchase by a pharmacy under section
26 3, there shall be included in the calculation of such

1 amount the amount of the covered outpatient drug sold
2 or distributed by a pharmacy to a hospice program. In
3 calculating such amount, only amounts of the covered out-
4 patient drug furnished to a Medicare beneficiary enrolled
5 in the hospice program shall be included.

6 **SEC. 5. ADMINISTRATION.**

7 The Secretary shall issue such regulations as may be
8 necessary to implement this Act.

9 **SEC. 6. REPORTS TO CONGRESS REGARDING EFFECTIVE-**
10 **NESS OF ACT.**

11 (a) IN GENERAL.—Not later than 2 years after the
12 date of the enactment of this Act, and annually thereafter,
13 the Secretary shall report to the Congress regarding the
14 effectiveness of this Act in—

15 (1) protecting Medicare beneficiaries from dis-
16 criminatory pricing by drug manufacturers, and

17 (2) making prescription drugs available to
18 Medicare beneficiaries at substantially reduced
19 prices.

20 (b) CONSULTATION.—In preparing such reports, the
21 Secretary shall consult with public health experts, affected
22 industries, organizations representing consumers and
23 older Americans, and other interested persons.

24 (c) RECOMMENDATIONS.—The Secretary shall in-
25 clude in such reports any recommendations the Secretary

1 considers appropriate for changes in this Act to further
2 reduce the cost of covered outpatient drugs to Medicare
3 beneficiaries.

4 **SEC. 7. DEFINITIONS.**

5 In this Act:

6 (1) AVERAGE FOREIGN PRICE.—

7 (A) IN GENERAL.—The term “average for-
8 eign price” means, with respect to a covered
9 outpatient drug, the average price that the
10 manufacturer of the drug realizes on the sale of
11 drugs with the same active ingredient or ingre-
12 dients that are consumed in covered foreign na-
13 tions, taking into account—

14 (i) any rebate, contract term or condi-
15 tion, or other arrangement (whether with
16 the purchaser or other persons) that has
17 the effect of reducing the amount realized
18 by the manufacturer on the sale of the
19 drugs; and

20 (ii) adjustments for any differences in
21 dosage, formulation, or other relevant
22 characteristics of the drugs.

23 (B) EXEMPT TRANSACTIONS.—The Sec-
24 retary may, by regulation, exempt from the cal-
25 culation of the average foreign price of a drug

1 those prices realized by a manufacturer in
2 transactions that are entered into for charitable
3 purposes, for research purposes, or under other
4 unusual circumstances, if the Secretary deter-
5 mines that the exemption is in the public inter-
6 est and is consistent with the purposes of this
7 Act.

8 (2) COVERED FOREIGN NATION.—The term
9 “covered foreign nation” means Canada, France,
10 Germany, Italy, Japan, and the United Kingdom.

11 (3) COVERED OUTPATIENT DRUG.—The term
12 “covered outpatient drug” has the meaning given
13 that term in section 1927(k)(2) of the Social Secu-
14 rity Act (42 U.S.C. 1396r–8(k)(2)).

15 (4) DEBAR.—The term “debar” means to ex-
16 clude, pursuant to established administrative proce-
17 dures, from Government contracting and subcon-
18 tracting for a specified period of time commensurate
19 with the seriousness of the failure or offense or the
20 inadequacy of performance.

21 (5) HOSPICE PROGRAM.—The term “hospice
22 program” has the meaning given that term under
23 section 1861(dd)(2) of the Social Security Act (42
24 U.S.C. 1395x(dd)(2)).

1 (6) MEDICARE BENEFICIARY.—The term
2 “Medicare beneficiary” means an individual entitled
3 to benefits under part A of title XVIII of the Social
4 Security Act or enrolled under part B of such title,
5 or both.

6 (7) PARTICIPATING MANUFACTURER.—The
7 term “participating manufacturer” means any man-
8 ufacturer of drugs or biologicals that, on or after the
9 date of the enactment of this Act, enters into a con-
10 tract or agreement with the United States for the
11 sale or distribution of covered outpatient drugs to
12 the United States.

13 (8) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services.

15 **SEC. 8. EFFECTIVE DATE.**

16 The Secretary shall implement this Act as expedi-
17 tiously as practicable and in a manner consistent with the
18 obligations of the United States.

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