

108TH CONGRESS  
1ST SESSION

# H. R. \_\_\_\_\_

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## IN THE HOUSE OF REPRESENTATIVES

Mr. ALLEN introduced the following bill; which was referred to the Committee  
on \_\_\_\_\_

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### A BILL

To provide for substantial reductions in the price of prescription drugs purchased by States for its employees, retirees, and pharmaceutical assistance 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 “State and Local Access  
5 to Fair Prescription Drug Prices Act”.

6 **SEC. 2. FINDINGS AND PURPOSE.**

7 (a) FINDINGS.—

8 (1) The majority of States are facing their  
9 worst fiscal crisis since World War II. Soaring



1 healthcare costs are deepening the crisis. Healthcare  
2 costs grew an average of 11 percent in 2002 and are  
3 expected to grow to 13 percent in fiscal year 2004.  
4 Healthcare spending currently accounts for approxi-  
5 mately 30 percent of total State budgets.

6 (2) As the economy continues to struggle, State  
7 revenues continue to fall dramatically while spending  
8 pressure has grown. Thirty-seven States reduced fis-  
9 cal 2003 enacted budgets by nearly  
10 \$14,500,000,000, the largest spending cut since  
11 1979.

12 (3) State drug expenditures for public employ-  
13 ees, dependents and retirees, medicaid beneficiaries,  
14 and the uninsured are rising each year. As more  
15 Americans lose jobs and health care coverage for  
16 themselves and their dependents, States' share of  
17 medicaid costs grew by 13 percent in fiscal year  
18 2002. This growth is expected to rise by an esti-  
19 mated 8 percent in fiscal year 2003 and 4.9 percent  
20 in fiscal year 2004 based on governors' fiscal 2004  
21 budget proposals.

22 (4) In February 2002, the National Governor's  
23 Association passed a resolution urging Congress to  
24 review Federal laws which may be contributing to  
25 the "high cost of prescription drugs".



1           (5) Several States and localities are currently  
2 seeking to reimport drugs from Canada and other  
3 foreign countries in an attempt to lower prescription  
4 drug costs.

5           (6) Foreign nations and Federally funded  
6 health care programs use purchasing power to ob-  
7 tain prescription drugs at low prices. States and lo-  
8 calities are not legally allowed to reimport prescrip-  
9 tion drugs. This Act will provide an appropriate al-  
10 ternative by allowing states and localities to pur-  
11 chase prescription drugs domestically at prices  
12 roughly equivalent to those available in foreign na-  
13 tions and Federally funded health care programs.

14           (7) Implementation of the policy set forth in  
15 this Act may reduce prices for brand name prescrip-  
16 tion drugs for many States and localities by up to  
17 40 percent.

18           (b) PURPOSE.—The purpose of this Act is to make  
19 prescription drugs available to States and local govern-  
20 ments and residents thereof at prices that are substan-  
21 tially lower than current United States prices.

22 **SEC. 3. PARTICIPATING MANUFACTURERS.**

23           (a) AVAILABILITY OF DRUGS FOR PURCHASE.—

24           (1) IN GENERAL.—Each participating manufac-  
25 turer of a covered outpatient drug shall make avail-

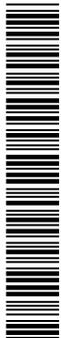


1       able for purchase in whole or in part by each State  
2       for the benefit of residents within the State whose  
3       cost of covered outpatient drugs are paid for by the  
4       State through a group health program, a retiree  
5       health program, a State or local pharmaceutical as-  
6       sistance program, or other similar program (includ-  
7       ing, to the extent provided under subsection (f)(2),  
8       a State medicaid program), such covered outpatient  
9       drug in the amount described in subsection (b) at  
10      the price described in subsection (c).

11           (2) DIRECT PURCHASES BY AGENTS.—The re-  
12      quirements of paragraph (1) shall apply in the case  
13      of purchases by an organization or agent of the  
14      State that directly purchases covered outpatient pre-  
15      scription drugs on behalf of the State, or on behalf  
16      of a county or municipality of such State, for resi-  
17      dents described in such paragraph.

18           (b) DESCRIPTION OF AMOUNT OF DRUGS.—The  
19      amount of a covered outpatient drug that a participating  
20      manufacturer shall make available for purchase by a State  
21      or local government (or agent thereof) is an amount equal  
22      to the aggregate amount of the covered outpatient drug  
23      sold or distributed to residents described in subsection (a)  
24      in that State.

25           (c) DESCRIPTION OF PRICE.—



1           (1) IN GENERAL.—The price at which a partici-  
2           pating manufacturer shall make a covered outpatient  
3           drug available for purchase by a pharmacy is a price  
4           no greater than the manufacturer's average foreign  
5           price.

6           (2) HANDLING FEE.—Nothing in this sub-  
7           section shall be construed to prevent a pharmacy  
8           from assessing a reasonable (as determined by the  
9           Secretary in consultation with pharmacy stake-  
10          holders) handling fee in connection with the provi-  
11          sion of covered outpatient prescription drugs to resi-  
12          dents described in subsection (a)(1).

13          (d) ENFORCEMENT.—

14           (1) IN GENERAL.—The Secretary, any whole-  
15           saler or retailer in the United States, or any resident  
16           described in subsection (a)(1) that is aggrieved by a  
17           violation of this Act may bring a civil action in a  
18           United States district court against a manufacturer  
19           or other person that violates this Act for an order  
20           enjoining the violation and awarding damages in the  
21           amount that is equal to 3 times the amount of the  
22           value of the difference between—

23                   (A) the price that the manufacturer or  
24           other person sold a covered outpatient prescrip-



1           tion drug to the wholesaler, retailer, or indi-  
2           vidual; and

3                   (B) the manufacturer's average foreign  
4           price for the prescription drug.

5           (2) REPEAT VIOLATIONS.—The United States  
6           shall debar a manufacturer of drugs or biologicals  
7           that commits repeated violations of the provisions of  
8           this Act.

9           (e) APPLICATION TO LOCAL GOVERNMENTS.—The  
10          provisions of this section shall apply with respect to the  
11          purchase of covered outpatient drugs by local governments  
12          if such purchase was made for the benefit of individuals  
13          within the jurisdiction of the local government whose cost  
14          of covered outpatient drugs are paid for by the local gov-  
15          ernment (or agent thereof) through a group health pro-  
16          gram, a retiree health program, a local pharmaceutical as-  
17          sistance program, or other similar program, in the same  
18          manner as such provisions apply to States.

19          (f) RELATION TO MEDICAID REBATE AGREEMENT.—  
20          A State, with respect to its provision of medical assistance  
21          for covered outpatient drugs under title XIX of the Social  
22          Security Act, may elect for a year (or other period speci-  
23          fied by the Secretary) either of the following to apply (and  
24          such election shall apply to all such covered outpatient  
25          drugs under such title):



1 (1) CONTINUATION OF REBATE AGREEMENT.—

2 (A) IN GENERAL.—The provisions of sec-  
3 tion 1927 of such Act (42 U.S.C. 1396r-8)  
4 shall continue to apply.

5 (B) DISREGARD OF MANUFACTURER'S AV-  
6 ERAGE FOREIGN PRICE IN DETERMINING BEST  
7 PRICE UNDER REBATE AGREEMENT.—The price  
8 under subsection (c) at which a participating  
9 manufacturer makes a covered outpatient drug  
10 available under this Act shall be disregarded for  
11 purposes of determining the best price under a  
12 rebate agreement under such section 1927 of  
13 the Social Security Act.

14 (2) USE OF MANUFACTURER'S FOREIGN  
15 PRICE.—The provisions of such section do not apply  
16 and such drugs shall be made available for purposes  
17 of such title in the quantities under subsection (b)  
18 and at the prices specified under subsection (c).

19 (g) RULE OF CONSTRUCTION.—Nothing in this sec-  
20 tion shall be construed to prevent a State or local govern-  
21 ment from implementing programs that provide for the  
22 purchase and distribution of outpatient drugs at prices  
23 that are lower than the price provided for under subsection  
24 (c).



1 **SEC. 4. ADMINISTRATION.**

2 The Secretary shall issue such regulations as may be  
3 necessary to implement this Act within 180 days after the  
4 date of the enactment of this Act.

5 **SEC. 5. REPORTS TO CONGRESS REGARDING EFFECTIVE-**  
6 **NESS OF ACT.**

7 (a) IN GENERAL.—Not later than 2 years after the  
8 date of the enactment of this Act, and annually thereafter,  
9 the Secretary shall report to the Congress regarding the  
10 effectiveness of this Act in—

11 (1) protecting States and local governments  
12 from drug price inflation, and

13 (2) making prescription drugs available to State  
14 and local government employees, retirees, and bene-  
15 ficiaries at substantially reduced prices.

16 (b) CONSULTATION.—In preparing such reports, the  
17 Secretary shall consult with public health experts, affected  
18 industries, organizations representing consumers and  
19 older Americans, and other interested persons.

20 (c) RECOMMENDATIONS.—The Secretary shall in-  
21 clude in such reports any recommendations the Secretary  
22 considers appropriate for changes in this Act to further  
23 reduce the cost of covered outpatient drugs to States.

24 **SEC. 6. DEFINITIONS.**

25 In this Act:

26 (1) AVERAGE FOREIGN PRICE.—



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

8 (i) any rebate, contract term or condi-  
9 tion, or other arrangement (whether with  
10 the purchaser or other persons) that has  
11 the effect of reducing the amount realized  
12 by the manufacturer on the sale of the  
13 drugs;

14 (ii) adjustments for any differences in  
15 dosage, formulation, or other relevant  
16 characteristics of the drugs; and

17 (iii) any other contract or side agree-  
18 ment that has the effect of adjusting the  
19 effective price of the drug, including agree-  
20 ments to purchase non-drug products.

21 (B) EXEMPT TRANSACTIONS.—The Sec-  
22 retary may, by regulation, exempt from the cal-  
23 culation of the average foreign price of a drug  
24 those prices realized by a manufacturer in  
25 transactions that are entered into for charitable



1 purposes, for research purposes, or under other  
2 unusual circumstances, if the Secretary deter-  
3 mines that the exemption is in the public inter-  
4 est and is consistent with the purposes of this  
5 Act.

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

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

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

19 (5) PARTICIPATING MANUFACTURER.—The  
20 term “participating manufacturer” means any man-  
21 ufacturer of drugs or biologicals that, on or after the  
22 date of the enactment of this Act, enters into a con-  
23 tract or agreement with the United States for the  
24 sale or distribution of covered outpatient drugs to  
25 the United States.



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

3 **SEC. 7. EFFECTIVE DATE.**

4           This Act shall apply on and after January 1, 2005,  
5 without regard to whether or not final regulations to carry  
6 out this Act have been promulgated by such date.

