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108TH CONGRESS
1ST SESSION

H. R. 3662

To provide for substantial reductions in the price of prescription drugs purchased by States for its employees, retirees, and pharmaceutical assistance beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2003

Mr. ALLEN (for himself, Mr. WAXMAN, Mr. STARK, Mr. BROWN of Ohio, Mr. PALLONE, Mr. MARKEY, Mr. MEEHAN, Mr. BERRY, Mr. MICHAUD, Ms. SCHAKOWSKY, Mr. FRANK of Massachusetts, Mr. OLVER, Mr. CASE, Mrs. EMERSON, Mr. STUPAK, Mr. OBERSTAR, and Mr. MCGOVERN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''State and Local Access to Fair Prescription Drug Prices Act''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—

(1) The majority of States are facing their worst fiscal crisis since World War II. Soaring healthcare costs are deepening the crisis. Healthcare costs grew an average of 11 percent in 2002 and are expected to grow to 13 percent in fiscal year 2004. Healthcare spending currently accounts for approximately 30 percent of total State budgets.

(2) As the economy continues to struggle, State revenues continue to fall dramatically while spending pressure has grown. Thirty-seven States reduced fiscal 2003 enacted budgets by nearly $14,500,000,000, the largest spending cut since 1979.

(3) State drug expenditures for public employees, dependents and retirees, medicaid beneficiaries, and the uninsured are rising each year. As more Americans lose jobs and health care coverage for themselves and their dependents, States' share of medicaid costs grew by 13 percent in fiscal year 2002. This growth is expected to rise by an estimated 8 percent in fiscal year 2003 and 4.9 percent in fiscal year 2004 based on governors' fiscal 2004 budget proposals.

(4) In February 2002, the National Governor's Association passed a resolution urging Congress to

review Federal laws which may be contributing to the ''high cost of prescription drugs''.

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

(6) Foreign nations and Federally funded health care programs use purchasing power to obtain prescription drugs at low prices. States and localities are not legally allowed to reimport prescription drugs. This Act will provide an appropriate alternative by allowing states and localities to purchase prescription drugs domestically at prices roughly equivalent to those available in foreign nations and Federally funded health care programs.

(7) Implementation of the policy set forth in this Act may reduce prices for brand name prescription drugs for many States and localities by up to 40 percent.

(b) PURPOSE.—The purpose of this Act is to make prescription drugs available to States and local governments and residents thereof at prices that are substantially lower than current United States prices.

SEC. 3. PARTICIPATING MANUFACTURERS.

(a) AVAILABILITY OF DRUGS FOR PURCHASE.—

(1) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase in whole or in part by each State for the benefit of residents within the State whose cost of covered outpatient drugs are paid for by the State through a group health program, a retiree health program, a State or local pharmaceutical assistance program, or other similar program (including, to the extent provided under subsection (f)(2), a State medicaid program), such covered outpatient drug in the amount described in subsection (b) at the price described in subsection (c).

(2) DIRECT PURCHASES BY AGENTS.—The requirements of paragraph (1) shall apply in the case of purchases by an organization or agent of the State that directly purchases covered outpatient prescription drugs on behalf of the State, or on behalf of a county or municipality of such State, for residents described in such paragraph.

(b) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase by a State or local government (or agent thereof) is an amount equal to the aggregate amount of the covered outpatient drug

sold or distributed to residents described in subsection (a) in that State.

(c) DESCRIPTION OF PRICE.—

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

(2) HANDLING FEE.—Nothing in this subsection shall be construed to prevent a pharmacy from assessing a reasonable (as determined by the Secretary in consultation with pharmacy stakeholders) handling fee in connection with the provision of covered outpatient prescription drugs to residents described in subsection (a)(1).

(d) ENFORCEMENT.—

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

(A) the price that the manufacturer or other person sold a covered outpatient prescription drug to the wholesaler, retailer, or individual; and

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

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

(e) APPLICATION TO LOCAL GOVERNMENTS.—The provisions of this section shall apply with respect to the purchase of covered outpatient drugs by local governments if such purchase was made for the benefit of individuals within the jurisdiction of the local government whose cost of covered outpatient drugs are paid for by the local government (or agent thereof) through a group health program, a retiree health program, a local pharmaceutical assistance program, or other similar program, in the same manner as such provisions apply to States.

(f) RELATION TO MEDICAID REBATE AGREEMENT.—A State, with respect to its provision of medical assistance for covered outpatient drugs under title XIX of the Social Security Act, may elect for a year (or other period specified by the Secretary) either of the following to apply (and

such election shall apply to all such covered outpatient drugs under such title):

(1) CONTINUATION OF REBATE AGREEMENT.—

(A) IN GENERAL.—The provisions of section 1927 of such Act (42 U.S.C. 1396r–8) shall continue to apply.

(B) DISREGARD OF MANUFACTURER'S AVERAGE FOREIGN PRICE IN DETERMINING BEST PRICE UNDER REBATE AGREEMENT.—The price under subsection (c) at which a participating manufacturer makes a covered outpatient drug available under this Act shall be disregarded for purposes of determining the best price under a rebate agreement under such section 1927 of the Social Security Act.

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

(g) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a State or local government from implementing programs that provide for the purchase and distribution of outpatient drugs at prices

that are lower than the price provided for under subsection (c).

SEC. 4. ADMINISTRATION.

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

SEC. 5. REPORTS TO CONGRESS REGARDING EFFECTIVENESS OF ACT.

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

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

(2) making prescription drugs available to State and local government employees, retirees, and beneficiaries at substantially reduced prices.

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

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

SEC. 6. DEFINITIONS.

In this Act:

(1) AVERAGE FOREIGN PRICE.—

(A) IN GENERAL.—The term ''average foreign price'' means, with respect to a covered outpatient drug, the average price that the manufacturer of the drug realizes on the sale of drugs with the same active ingredient or ingredients that are consumed in covered foreign nations, taking into account—

(i) any rebate, contract term or condition, or other arrangement (whether with the purchaser or other persons) that has the effect of reducing the amount realized by the manufacturer on the sale of the drugs;

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

(iii) any other contract or side agreement that has the effect of adjusting the effective price of the drug, including agreements to purchase non-drug products.

(B) EXEMPT TRANSACTIONS.—The Secretary may, by regulation, exempt from the calculation of the average foreign price of a drug

those prices realized by a manufacturer in transactions that are entered into for charitable purposes, for research purposes, or under other unusual circumstances, if the Secretary determines that the exemption is in the public interest and is consistent with the purposes of this Act.

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

(3) COVERED OUTPATIENT DRUG.—The term ''covered outpatient drug'' has the meaning given that term in section 1927(k)(2) of the Social Security Act (42 U.S.C. 1396r–8(k)(2)).

(4) DEBAR.—The term ''debar'' means to exclude, pursuant to established administrative procedures, from Government contracting and subcontracting for a specified period of time commensurate with the seriousness of the failure or offense or the inadequacy of performance.

(5) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of the enactment of this Act, enters into a contract or agreement with the United States for the

sale or distribution of covered outpatient drugs to the United States.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

SEC. 7. EFFECTIVE DATE.

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

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