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108TH CONGRESS
1ST SESSION

# H. R. 3299

To provide for prescription drugs at reduced prices to Medicare beneficiaries.

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IN THE HOUSE OF REPRESENTATIVES

OCTOBER 15, 2003

Mr. LARSON of Connecticut 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

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# A BILL

To provide for prescription drugs at reduced prices to Medicare 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 ''Medicare Prescription Drug Price Negotiation Act''.

**SEC. 2. AVAILABILITY OF PRESCRIPTION DRUGS FROM PARTICIPATING MANUFACTURERS AT NEGOTIATED PRICES.**

(a) IN GENERAL.—Each participating manufacturer of a covered outpatient drug shall make available for purchase by any qualified Federal health care provider, by each pharmacy, and by each provider of services, physician, practitioner, and supplier under the medicare program such covered outpatient drug in the amount described in subsection (b) at the price described in subsection (c).

(b) DESCRIPTION OF AMOUNT OF DRUGS.—The amount of a covered outpatient drug that a participating manufacturer shall make available for purchase under subsection (a) is the sum of—

(1) an amount equal to the aggregate amount of the covered outpatient drug dispensed by pharmacies to Medicare beneficiaries; and

(2) an amount equal to the aggregate amount of the covered outpatient drug dispensed through qualified Federal health care providers.

(c) DESCRIPTION OF PRICE.—

(1) IN GENERAL.—The price at which a participating manufacturer shall make a covered outpatient drug available for purchase under subsection (a) is a price that the Secretary, in conjunction with the

Secretary of Defense and the Secretary of Veterans Affairs, negotiate with the manufacturer.

(2) PROMOTION OF BREAKTHROUGH DRUGS.—

(A) IN GENERAL.—In conducting negotiations with participating manufacturers under paragraph (1), the Secretary shall take into account the goal of promoting the development of breakthrough drugs.

(B) DEFINITION.—For purposes of this paragraph, a drug is a ''breakthrough drug'' if the Secretary determines it is a new product that will make a significant and major improvement by reducing physical or mental illness, reducing mortality, or reducing disability, and that no other product is available to enrollees that achieves similar results for the same condition.

(d) ENFORCEMENT.—The United States shall debar a manufacturer of drugs or biologicals that does not comply with the provisions of this Act.

(e) DISPUTE RESOLUTION MECHANISM.—The Secretary shall establish a mechanism (such as an ombudsman) for the resolution of disputes between Medicare beneficiaries and prescription drug resellers and drug

manufacturers in order to protect such beneficiaries and to ensure that—

(1) prescription drug resellers are not artifically increasing prices charged to Medicare beneficiaries (above those negotiated under subsection (c)) in places where there is less competition (such as in rural areas); and

(2) such resellers are not colluding on prices in areas with more potential significant competition.

**SEC. 3. ADMINISTRATION.**

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

**SEC. 4. 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 Medicare beneficiaries from discriminatory pricing by drug manufacturers, and

(2) making prescription drugs available to Medicare 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 Medicare beneficiaries.

**SEC. 5. DEFINITIONS.**

In this Act:

(1) PROVIDER OF SERVICES.—The term ''provider of services'' has the meaning given that term in section 1861(u) of the Social Security Act (42 U.S.C. 1395x(u)).

(2) PHYSICIAN.—The term ''physician'' has the meaning given that term in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)).

(3) PRACTITIONER.—The term ''practitioner'' has the meaning given that term in section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)).

(4) SUPPLIER.—The term ''supplier'' has the meaning given that term under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)).

(5) 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)).

(6) 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.

(7) MEDICARE BENEFICIARY.—The term ''Medicare beneficiary'' means an individual entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title, or both.

(8) PARTICIPATING MANUFACTURER.—The term ''participating manufacturer'' means any manufacturer of drugs or biologicals that, on or after the date of the enactment of this title, enters into a contract or agreement with the United States for the sale or distribution of covered outpatient drugs to the United States.

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

**SEC. 6. EFFECTIVE DATE.**

The Secretary shall implement this Act as expeditiously as practicable and in a manner consistent with the obligations of the United States.

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