I

111TH CONGRESS
1ST SESSION

H. R. 444

To amend section 340B of the Public Health Service Act to revise and expand the drug discount program under that section to improve the provision of discounts on drug purchases for certain safety net providers.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 2009

Mr. RUSH (for himself, Mrs. EMERSON, and Mr. STUPAK) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend section 340B of the Public Health Service Act to revise and expand the drug discount program under that section to improve the provision of discounts on drug purchases for certain safety net providers.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''340B Program Improvement and Integrity Act of 2009''.

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

Sec. 1. Short title; table of contents.
Sec. 2. Expanded participation in 340B program.
Sec. 3. Extension of discounts to inpatient drugs.

Sec. 4. Improvements to 340B program integrity.
Sec. 5. Other improvements in 340B program.
Sec. 6. Effective dates.

SEC. 2. EXPANDED PARTICIPATION IN 340B PROGRAM.

(a) EXPANSION OF COVERED ENTITIES RECEIVING DISCOUNTED PRICES.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended by adding at the end the following new subparagraphs:

"(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)(iii)) which would meet the requirements of subsection (a)(4)(L), including the disproportionate share adjustment percentage requirement under clause (ii), if the hospital were a subsection (d) hospital as defined by Section 1886(d)(1)(B) of the Social Security Act.

"(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act (42 U.S.C. 1395i–4(c)(2)).

"(O) An entity receiving funds under title V of the Social Security Act (relating to maternal and child health) for the provision of health services.

''(P) An entity receiving funds under subpart I of part B of title XIX of the Public Health Service Act (relating to comprehensive mental health services) for the provision of community mental health services.

''(Q) An entity receiving funds under subpart II of such part B (relating to the prevention and treatment of substance abuse) for the provision of treatment services for substance abuse.

''(R) An entity that is a Medicare-dependent, small rural hospital (as defined in section 1886(d)(5)(G)(iv) of the Social Security Act).

''(S) An entity that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

''(T) An entity that is classified as a rural referral center under section 1886(d)(5)(C) of the Social Security Act.''.

(b) PROHIBITION ON GROUP PURCHASING ARRANGEMENTS.—Section 340B(a) of such Act (42 U.S.C. 256b(a)) is amended—

(1) in paragraph (4)(L)—

(A) by adding ''and'' at the end of clause (i);

(B) by striking ''; and'' at the end of clause (ii) and inserting a period; and

(C) by striking clause (iii);

(2) in subsection (a)(5), by redesignating the subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and by inserting after subparagraph (B) the following new subparagraph:

''(C) PROHIBITING USE OF GROUP PURCHASING ARRANGEMENTS.—

''(i) A hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided pursuant to clause (ii) or (iii).

''(ii) Clause (i) shall not apply to drugs purchased for inpatient use.

''(iii) The Secretary shall establish reasonable exceptions to the requirement of clause (i)—

''(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug

shortage problem, manufacturer noncompliance, or any other reason beyond the hospital's control;

"(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; and

"(III) to reduce in other ways the administrative burdens of managing both inventories of drugs obtained under this section and not under this section, if such exception does not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).".

SEC. 3. EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.

(a) IN GENERAL.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(1) in subsection (b)—

(A) by designating the matter beginning "In this section" as a paragraph (1) with the heading "IN GENERAL"; and

(B) by adding at the end the following new paragraph:

''(2) COVERED DRUG.—In this section, the term 'covered drug'—

''(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

''(B) includes, notwithstanding the section 1927(k)(3)(A) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.''; and

(2) in paragraphs (5), (7), and (9) of subsection (a), by striking ''outpatient'' each place it appears.

(b) MEDICAID CREDITS ON INPATIENT DRUGS.—Subsection (c) of section 340B of the Public Health Service Act (42 U.S.C. 256b(c)) is replaced as follows:

''(c) MEDICAID CREDITS ON INPATIENT DRUGS.—

''(1) IN GENERAL.—For the cost reporting period covered by the most recently filed Medicare cost report under title XVIII of the Social Security Act, a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) and enrolled to

participate in the drug discount program under this section shall provide to each State under its plan under title XIX of such Act—

"(A) a credit on the estimated annual costs to such hospital of single source and innovator multiple source drugs provided to Medicaid recipients for inpatient use; and

"(B) a credit on the estimated annual costs to such hospital of noninnovator multiple source drugs provided to Medicaid recipients for inpatient use.

"(2) AMOUNT OF CREDITS.—

"(A) SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of paragraph (1)(A)—

"(i) the credit under such paragraph shall be equal to the product of—

"(I) the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

"(II) the estimated percentage of the hospital's drug purchases attrib-

utable to Medicaid recipients for inpatient use; and

"(III) the minimum rebate percentage described in section 1927(c)(1)(B) of the Social Security Act;

"(ii) the reference in clause (i)(I) to the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

"(I) the annual quantity of each single source and innovator multiple source drug purchased during the cost reporting period, multiplied by

"(II) the average manufacturer price for that drug;

"(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid recipients for inpatient use; shall be equal to—

"(I) the Medicaid inpatient drug charges as reported on the hospital's

most recently filed Medicare cost report, divided by

"(II) total drug charges reported on the cost report; and

"(iv) the terms 'single source drug' and 'innovator multiple source drug' have the meanings given such terms in section 1927(k)(7) of the Social Security Act.

"(B) NONINNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of subparagraph (1)(B)—

"(i) the credit under such paragraph shall be equal to the product of—

"(I) the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

"(II) the estimated percentage of the hospital's drug purchases attributable to Medicaid recipients for inpatient use; and

"(III) the applicable percentage as defined in section 1927(c)(3)(B) of the Social Security Act;

''(ii) the reference in clause (i)(I) to the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

''(I) the annual quantity of each noninnovator multiple source drug purchased during the cost reporting period, multiplied by

''(II) the average manufacturer price for that drug;

''(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid recipients for inpatient use shall be equal to—

''(I) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report, divided by

''(II) total drug charges reported on the cost report; and

''(iv) the term 'noninnovator multiple source drug' has the meaning given such

term in section 1927(k)(7) of the Social Security Act.

''(3) CALCULATION OF CREDITS.—

''(A) IN GENERAL.—Not later than 30 days after receiving the information specified in subparagraph (B), the State shall calculate the credits owed by the hospital under paragraph (1) and provide the hospital with both the amounts and an explanation of how it calculated the credits. In performing the calculations specified in paragraphs (2)(A)(ii) and (2)(B)(ii), the State shall use the average manufacturer price applicable to the calendar quarter in which the drug was purchased by the hospital.

''(B) HOSPITAL PROVISION OF INFORMATION.—Not later than 30 days after the date of the filing of the hospital's most recently filed Medicare cost report, the hospital shall provide the State with the information described in paragraphs (2)(A)(ii) and (2)(B)(ii). With respect to each drug purchased during the cost reporting period, the hospital shall provide the dosage form, strength, package size, date of purchase and the number of units purchased.

''(4) PAYMENT DEADLINE.—The credits provided by a hospital under paragraph (1) shall be paid within 60 days after receiving the information specified in paragraph (3)(A).

''(5) OPT OUT.—A hospital shall not be required to provide the Medicaid credit required under paragraph (1) if—

''(A) it can demonstrate to the State that it will lose reimbursement under the State plan resulting from the extension of discounts to inpatient drugs under subsection (b)(2) and that the loss of reimbursement will exceed the amount of the credit otherwise owed by the hospital; or

''(B) the hospital and State agree to an alternative arrangement.

Any dispute between the hospital and the State under this paragraph shall be adjudicated through the administrative dispute resolution process under this section.

''(6) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this subsection in any quarter shall be considered to be a reduction in the amount expended under the State plan in the

quarter for medical assistance for purposes of section 1903(a)(1) of the Social Security Act.''.

(c) CONFORMING AMENDMENTS.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8), is amended—

(1) in subsection (a)(5)(A), by striking ''covered outpatient drugs'' and inserting ''covered drugs (as defined in section 340B(b)(2) of the Public Health Service Act)'';

(2) by striking subsection (a)(5)(D) in its entirety;

(3) in subsection (c)(1)(C)(i), by redesignating subclauses (II) through (IV) as subclauses (III) through (V), respectively and by inserting after subclause (I) the following new subclause:

''(II) any prices charged for a covered drug as defined in section 340B(b)(2) of the Public Health Service Act;''; and

(4) in subsection (k)(1)—

(A) in subparagraph (A), by striking ''subparagraph (B)'' and inserting ''subparagraphs (B) and (D)''; and

(B) by adding at the end the following new subparagraph:

"(D) CALCULATION FOR COVERED DRUGS.—With respect to a covered drug (as defined in section 340B(b)(2) of the Public Health Service Act), the average manufacturer price shall be determined in accordance with subparagraph (A) except that, in the event a covered drug is not distributed to the retail pharmacy class of trade, it shall mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts.".

SEC. 4. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.

(a) INTEGRITY IMPROVEMENTS.—Subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is replaced as follows:

"(d) IMPROVEMENTS IN PROGRAM INTEGRITY.—

"(1) MANUFACTURER COMPLIANCE.—

"(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and

other violations of the discounted pricing requirements specified in this section.

''(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

''(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

''(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

''(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

''(III) Performing spot checks of sales transactions by covered entities.

''(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

''(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

''(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

''(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs.

''(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

''(iv) The development of a mechanism by which—

''(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; and

''(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

''(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

''(vi) The imposition of sanctions in the form of civil monetary penalties, which—

''(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary within 180 days of enactment of this subsection;

''(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

''(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

''(2) COVERED ENTITY COMPLIANCE.—

''(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

''(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

''(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

''(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

''(iii) The development of more detailed guidance describing methodologies and options available to covered entities for

billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

''(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

''(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subparagraph (a)(5)(E), through one or more of the following actions:

''(I) Where a covered entity knowingly and intentionally violates subparagraph (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity

is found liable under paragraph (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

''(II) Where the Secretary determines a violation of subparagraph (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

''(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as

the Prescription Drug Marketing Act (21 U.S.C. 353).

"(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of this subsection, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

"(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

"(i) designate or establish a decision-making official or decisionmaking body within the Department of Health and

Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

''(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

''(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

''(iv) require that a manufacturer must conduct an audit of a covered entity

pursuant to subsection (a)(5)(D) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

''(v) permit the official or body designated in clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

''(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

''(C) FINALITY OF ADMINISTRATIVE RESOLUTION.—The administrative resolution of a

claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

''(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.''.

(b) CONFORMING AMENDMENTS.—Section 340B(a) of such Act (42 U.S.C. 256b(a)) is amended—

(1) in subsection (a)(1), by adding at the end the following: ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''; and

(2) in the first sentence of subsection (a)(5)(E), as redesignated by section 2(b), by inserting ''after audit as described in subparagraph (D) and'' after ''finds,''.

SEC. 5. OTHER IMPROVEMENTS IN 340B PROGRAM.

Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by section 4(a), is further amended by adding at the end the following new subsections:

''(f) USE OF MULTIPLE CONTRACT PHARMACIES PERMITTED.—Nothing in this section shall be construed as prohibiting a covered entity from entering into contracts with more than one pharmacy for the provision of covered drugs, including such a contract that supplements the use of an in-house pharmacy arrangement or as requiring the approval of the Secretary for entering into such a contract.

''(g) INTRA-AGENCY COORDINATION.—The Secretary shall establish specific measures, policies, and procedures to ensure effective communication and coordination between the Centers for Medicare & Medicaid Services and the Health Resources and Services Administration with respect to all agency actions and all aspects of policy and administration affecting or pertaining to the drug discount program under this section and in which the functions and

responsibilities of those agency components are interrelated or interdependent, including by establishment of a permanent working group, composed of representatives of both the Health Resources and Services Administration and the Centers for Medicare & Medicaid Services, to identify and oversee matters requiring such coordination.''.

SEC. 6. EFFECTIVE DATES.

(a) IN GENERAL.—The amendments made by this Act shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

(b) EFFECTIVENESS.—The amendments made by this Act shall be effective, and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) and of section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r–8(a)(5)), notwithstanding any other provision of law.

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