111TH CONGRESS
1ST SESSION

S. 1239

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 SENATE OF THE UNITED STATES

JUNE 11, 2009

Mr. BINGAMAN (for himself, Mr. THUNE, and Mrs. GILLIBRAND) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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.

This Act may be cited as the ''340B Program Improvement and Integrity Act of 2009''.

SEC. 2. EXPANDED PARTICIPATION IN SECTION 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:

''(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 which would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, 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), and that meets the requirements of subparagraph (L)(i).

''(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i)

and has a disproportionate share adjustment percentage equal to or greater than 8 percent.''.

(b) EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended—

(1) in subsection (a), by striking ''outpatient'' each place that such appears in paragraphs (2), (5), (7), and (9); and

(2) in subsection (b)—

(A) by striking ''In this section'' and inserting the following:

''(A) IN GENERAL.—In this section''; and

(B) by adding at the end the following:

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

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

''(ii) includes, notwithstanding paragraph (3)(A) of such section 1927(k), a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled

to participate in the drug discount program under this section.

''(C) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.—The Secretary shall ensure that a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section shall have multiple options for purchasing covered drugs for inpatients including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer, and any other purchasing arrangements that the Secretary may deem appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.''.

(c) PROHIBITION ON GROUP PURCHASING ARRANGEMENTS.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended—

(1) in paragraph (4)(L)—

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

(B) in clause (ii), by striking ''; and'' and inserting a period; and

(C) by striking clause (iii); and

(2) in paragraph (5)—

(A) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E); respectively; and

(B) by inserting after subparagraph (B), the following:

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

''(i) IN GENERAL.—A hospital described in subparagraphs (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

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

''(iii) EXCEPTIONS.—The Secretary shall establish reasonable exceptions to 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 circumstance beyond the hospital's control;

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

"(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).".

(d) MEDICAID CREDITS ON INPATIENT DRUGS.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)) is amended by adding at the end the following:

''(E) MEDICAID CREDITS.—Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.''.

(e) INTEGRITY IMPROVEMENTS.—Subsection (c) of section 340B of the Public Health Service Act (42 U.S.C. 256b(c)) is amended to read as follows:

''(c) 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 manufactur-

ers 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 the date of enactment of the 340B Program Improvement and Integrity Act of 2009;

''(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 Sec-

retary 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.

''(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of the 340B Program Improvement and Integrity Act of 2009, the Secretary shall promulgate regula-

tions 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) DEADLINE AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

''(i) designate or establish a decision-making official or decision-making 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 viola-

tions 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 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 under clause (i), at the request of a manufacturer or manufacturers, to con-

solidate 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.''.

(f) CONFORMING AMENDMENTS.—

(1) SOCIAL SECURITY ACT.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8), is amended—

(A) in subsection (a)(5)—

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

(ii) by striking subparagraph (D); and

(iii) by redesignating subparagraph (E) as subparagraph (D);

(B) 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

(C) in subsection (k)(1)—

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

(ii) 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. The Secretary shall establish a mechanism for collecting the necessary data for the acute care class of trade from manufacturers.''.

(2) PUBLIC HEALTH SERVICE ACT.—Section 340B(a) of such Act (42 U.S.C. 256b(a)) is amended—

(A) 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

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

SEC. 3. 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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