II

110TH CONGRESS
1ST SESSION

S. 1376

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

IN THE SENATE OF THE UNITED STATES

MAY 14, 2007

Mr. BINGAMAN (for himself and Mr. THUNE) 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 the Public Health Service Act to revise and expand the drug discount program under section 340B of such Act 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 2007''.

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) 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), 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 di-

version problem in violation of subparagraph (B).''.

SEC. 3. EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.

(a) DEFINITIONS.—

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

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

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

(B) adding at the end the following:

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

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

''(B) notwithstanding the limiting definition set forth in section 1927(k)(3) of such Act, 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), and enrolled to participate in the drug discount program under this section.''.

(2) CONFORMING AMENDMENTS.—Paragraphs (2)(A), (5)(B), (5)(D), (5)(E), (7)(B), (7)(C), and (9) of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) are amended—

(A) by striking ''covered outpatient drug'' each place that such appears and inserting ''covered drug''; and

(B) by striking ''covered outpatient drugs'' each place that such appears and inserting ''covered drugs''.

(b) MEDICAID CREDITS ON INPATIENT DRUGS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by striking subsection (c) and inserting the following:

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

''(1) IN GENERAL.—With respect to the cost reporting period covered by the most recently filed Medicare cost report, a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) and enrolled to participate in the drug discount program under this section shall provide to each State with an approved State plan under title XIX of the Social Security Act—

''(A) a credit on the estimated annual costs to such hospital of single source and inno-

vator 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) CALCULATION OF CREDITS.—

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

''(i) the credit under such paragraph shall be determined by multiplying—

''(I) the product of—

''(aa) the estimated annual costs of single source and innovator multiple source drugs provided by the hospital to Medicaid recipients for inpatient use; and

''(bb) the average manufacturer price adjustment; and

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

"(ii) the estimated annual costs of single source drugs and innovator multiple source drugs provided by the hospital to Medicaid recipients for inpatient use under clause (i)(I)(aa) shall be determined by multiplying—

"(I) the product of—

"(aa) the hospital's actual acquisition costs of all drugs purchased during the cost reporting period for inpatient use; and

"(bb)(AA) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report; divided by

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

"(II) the percentage of the hospital's annual inpatient drug costs described in subclause (I) that arise out of the purchase of single source and innovator multiple source drugs;

"(iii) the average manufacturer price adjustment referred to in clause (i)(I)(bb) shall be determined annually by the Secretary for single source and innovator multiple source drugs by dividing on an aggregate basis—

"(I) the average manufacturer price as defined in section 1927(k)(1)(D) of the Social Security Act, averaged across all covered drugs reported to the Secretary pursuant to section 1927(b)(3) of such Act; by

"(II) the average ceiling price under this section for covered drugs calculated pursuant to subsection (a)(1); 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 calculated by multiplying—

"(I) the product of—

"(aa) the estimated annual costs to the hospital of noninnovator multiple source drugs provided to Medicaid recipients for inpatient use; and

"(bb) the average manufacturer price adjustment; and

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

"(ii) the estimated annual costs to a hospital of noninnovator multiple source drugs provided to Medicaid recipients for inpatient use under clause (i)(I)(aa) shall be determined by multiplying—

"(I) the product of—

"(aa) the hospital's actual acquisition cost of all drugs purchased during the cost reporting period for inpatient use; and

"(bb)(AA) the Medicaid inpatient drug charges as reported on the hospital's most recently

filed Medicare cost report; divided by

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

"(II) the percentage of the hospital's annual inpatient drug costs described in subclause (I) arising out of the purchase of noninnovator multiple source drugs;

"(iii) the average manufacturer price adjustment referred to in clause (i)(I)(bb) shall be determined annually by the Secretary for noninnovator multiple source drugs by dividing on an aggregate basis—

"(I) the average manufacturer price as defined in section 1927(k)(1)(D) of the Social Security Act, averaged across all covered drugs reported to the Secretary pursuant to section 1927(b)(3) of such Act; by

"(II) the average ceiling price under this section for covered drugs calculated pursuant to subsection (a)(1); 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) PAYMENT DEADLINE.—The credits provided by a hospital under paragraph (1) shall be paid not later than 90 days after the date of the filing of the hospital's most recently filed Medicare cost report.

"(4) OPT-OUT.—A hospital shall not be required to provide the Medicaid credit required under this subsection if the hospital is able to demonstrate to the State that the credits would be less than or equal to the loss of reimbursement under the State plan resulting from the extension of discounts to inpatient drugs under subsection (b)(2), or if the hospital and State agree to an alternative arrangement. Any dispute between the hospital and the State regarding the applicability of this paragraph shall be adjudicated through the administrative dispute resolution process described in subsection (e)(3).

"(5) 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.

''(6) EFFECTIVENESS NOTWITHSTANDING OTHER PROVISIONS OF LAW.—Notwithstanding any other provision of law, all references to provisions of the Social Security Act in this section shall be deemed to be references to the Social Security Act as in effect on the date of enactment of the 340B Program Improvement and Integrity Act of 2007.''.

SEC. 4. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.

(a) INTEGRITY IMPROVEMENTS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following:

''(e) IMPROVEMENTS IN PROGRAM INTEGRITY.—

''(1) MANUFACTURER COMPLIANCE.—

''(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall carry out activities to provide for improvement in the compliance of 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) ACTIVITIES.—The activities 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—

''(I) developing and publishing, through an appropriate policy or regulatory issuance, precisely defined standards and methodologies for the calculation of ceiling prices under subsection (a)(1);

''(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; and

''(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—

''(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; and

''(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 ensures security and the protection of privileged pricing data from unauthorized redisclosure.

''(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 credits and refunds 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 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 the 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 carry out activities to provide for improvement in compliance by covered entities with the requirements of this section in order to prevent diversion and other violations of the duplicate discount requirements specified under subsection (a)(5).

''(B) ACTIVITIES.—The activities 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 or-

dering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

''(v) The imposition of sanctions, as determined appropriate by the Secretary, in addition to the sanctions to which covered entities are subject to under subsection (a)(5)(D), through 1 or more of the following actions:

''(I) Where a covered entity knowingly and intentionally violates subsection (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 subsection (a)(5)(E), and 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 that a violation of subsection

(a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the program under this section and disqualifying the entity from reentry into the 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, or other Federal agencies for consideration of appropriate action under other Federal law, 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 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) of this subsection. Such regulations shall also establish an administrative process for resolution of disputes described in subsection (c)(4).

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

''(i) designate or establish a decisionmaking 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 1 manu-

facturer 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 2008, and each succeeding fiscal year.''.

(b) RELATED AMENDMENTS.—Section 340B(a)(1) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended 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.''.

SEC. 5. OTHER IMPROVEMENTS.

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

''(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 1 pharmacy for the provision of covered drugs, including a contract that supplements the use

of an in-house pharmacy arrangement or requires the approval of the Secretary for entering into such a contract.

''(g) INTRAAGENCY 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 through the establishment of a permanent working group that is 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.''.

(b) EFFECTIVE DATES.—

(1) AMENDMENT.—Section 340B(d) of the Public Health Service Act (42 U.S.C. 256b(d)) is amended by striking ''Veterans Health Care Act of 1992'' and inserting ''340B Program Improvement and Integrity Act of 2007''.

(2) APPLICATION OF ACT.—The amendments made by this Act shall apply to drugs purchased on or after January 1, 2008.

(c) EFFECTIVENESS NOTWITHSTANDING OTHER PROVISIONS OF LAW.—Notwithstanding any other provision of law, the amendments made by this Act shall become effective on January 1, 2008, 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 the requirements of section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r–8(a)(5)).

SEC. 6. CONFORMING AMENDMENTS.

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

(1) in subsection (a)(5)—

(A) in subparagraph (A), by striking ''covered outpatient'' and inserting ''covered'';

(B) by redesignating subparagraphs (C) through (E), as subparagraphs (D) through (F), respectively;

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

''(C) COVERED DRUG DEFINED.—In this subsection, the term 'covered drug' means a

drug defined in section 340B(b)(2) of the Public Health Service Act.'';

(D) in subparagraph (E), as so redesignated, by striking ''title VI of the Veterans Health Care Act of 1992'' and inserting ''340B Program Improvement and Integrity Act of 2007.''; and

(E) in subparagraph (F), as so redesignated—

(i) by striking ''as in effect immediately after the enactment of this paragraph'' and inserting ''as in effect upon the effective date of the 340B Program Improvement and Integrity Act of 2007,''; and

(ii) by striking ''after the date of the enactment of this paragraph'' and inserting ''after the date of enactment of such Act.'';

(2) in subsection (c)(1)(C)(i)—

(A) by redesignating subclauses (II) through (IV) as subclauses (III) through (V), respectively; and

(B) by inserting after subclause (I) the following:

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

(3) in subsection (k)(1), by adding at the end the following:

"(D) CALCULATION FOR COVERED DRUGS.—Notwithstanding any other provision of this subsection, with respect to a covered drug as defined in section 340B(b)(2) of the Public Health Service Act, average manufacturer price means the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to both the retail pharmacy and acute care classes of trade, after deducting customary prompt pay discounts.".

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