

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “340B Program Im-
5 provement and Integrity Act of 2007”.

1 **SEC. 2. EXPANDED PARTICIPATION IN SECTION 340B PRO-**
2 **GRAM.**

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

7 “(M) A children’s hospital excluded from
8 the Medicare prospective payment system pur-
9 suant to section 1886(d)(1)(B)(iii) of the Social
10 Security Act which would meet the require-
11 ments of subparagraph (L), including the dis-
12 proportionate share adjustment percentage re-
13 quirement under clause (ii) of such subpara-
14 graph, if the hospital were a subsection (d) hos-
15 pital as defined by section 1886(d)(1)(B) of the
16 Social Security Act.

17 “(N) An entity that is a critical access hos-
18 pital (as determined under section 1820(e)(2)
19 of the Social Security Act), and that meets the
20 requirements of subparagraph (L)(i).

21 “(O) An entity that is a rural referral cen-
22 ter, as defined by section 1886(d)(5)(C)(i) of
23 the Social Security Act, or a sole community
24 hospital, as defined by section
25 1886(d)(5)(C)(iii) of such Act, and that both
26 meets the requirements of subparagraph (L)(i)

1 and has a disproportionate share adjustment
2 percentage equal to or greater than 8 percent.”.

3 (b) PROHIBITION ON GROUP PURCHASING ARRANGE-
4 MENTS.—Section 340B(a) of the Public Health Service
5 Act (42 U.S.C. 256b(a)) is amended—

6 (1) in paragraph (4)(L), by striking clause (iii);

7 and

8 (2) in paragraph (5)—

9 (A) by redesignating subparagraphs (C)
10 and (D) as subparagraphs (D) and (E); respec-
11 tively; and

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

14 “(C) PROHIBITING THE USE OF GROUP
15 PURCHASING ARRANGEMENTS.—

16 “(i) IN GENERAL.—A hospital de-
17 scribed in subparagraphs (L), (M), (N), or
18 (O) of paragraph (4) shall not obtain cov-
19 ered outpatient drugs through a group
20 purchasing organization or other group
21 purchasing arrangement, except as per-
22 mitted or provided for pursuant to clauses
23 (ii) or (iii).

1 “(ii) INPATIENT DRUGS.—Clause (i)
2 shall not apply to drugs purchased for in-
3 patient use.

4 “(iii) EXCEPTIONS.—The Secretary
5 shall establish reasonable exceptions to
6 clause (i)—

7 “(I) with respect to a covered
8 outpatient drug that is unavailable to
9 be purchased through the program
10 under this section due to a drug
11 shortage problem, manufacturer non-
12 compliance, or any other circumstance
13 beyond the hospital’s control;

14 “(II) to facilitate generic substi-
15 tution when a generic covered out-
16 patient drug is available at a lower
17 price; or

18 “(III) to reduce in other ways
19 the administrative burdens of man-
20 aging both inventories of drugs sub-
21 ject to this section and inventories of
22 drugs that are not subject to this sec-
23 tion, so long as the exceptions do not
24 create a duplicate discount problem in
25 violation of subparagraph (A) or a di-

1 version problem in violation of sub-
2 paragraph (B).”.

3 **SEC. 3. EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.**

4 (a) DEFINITIONS.—

5 (1) IN GENERAL.—Section 340B(b) of the Pub-
6 lic Health Service Act (42 U.S.C. 256b(b)) is
7 amended—

8 (A) by striking “In this section” and in-
9 serting the following:

10 “(1) IN GENERAL.—In this section”; and

11 (B) adding at the end the following:

12 “(2) COVERED DRUG.—In this section, the term
13 ‘covered drug’ means—

14 “(A) a ‘covered outpatient drug’ as defined
15 in section 1927(k)(2) of the Social Security
16 Act; and

17 “(B) notwithstanding the limiting defini-
18 tion set forth in section 1927(k)(3) of such Act,
19 a drug used in connection with an inpatient or
20 outpatient service provided by a hospital de-
21 scribed in subparagraph (L), (M), (N), or (O)
22 of subsection (a)(4), and enrolled to participate
23 in the drug discount program under this sec-
24 tion.”.

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

5 (A) by striking “covered outpatient drug”
6 each place that such appears and inserting
7 “covered drug”; and

8 (B) by striking “covered outpatient drugs”
9 each place that such appears and inserting
10 “covered drugs”.

11 (b) MEDICAID CREDITS ON INPATIENT DRUGS.—
12 Section 340B of the Public Health Service Act (42 U.S.C.
13 256b) is amended by striking subsection (c) and inserting
14 the following:

15 “(c) MEDICAID CREDITS ON INPATIENT DRUGS.—

16 “(1) IN GENERAL.—With respect to the cost re-
17 porting period covered by the most recently filed
18 Medicare cost report, a hospital described in sub-
19 paragraph (L), (M), (N), or (O) of subsection (a)(4)
20 and enrolled to participate in the drug discount pro-
21 gram under this section shall provide to each State
22 with an approved State plan under title XIX of the
23 Social Security Act—

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

1 vator multiple source drugs provided to Med-
2 icaid recipients for inpatient use; and

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

7 “(2) CALCULATION OF CREDITS.—

8 “(A) SINGLE SOURCE AND INNOVATOR
9 MULTIPLE SOURCE DRUGS.—For purposes of
10 paragraph (1)(A)—

11 “(i) the credit under such paragraph
12 shall be determined by multiplying—

13 “(I) the product of—

14 “(aa) the estimated annual
15 costs of single source and inno-
16 vator multiple source drugs pro-
17 vided by the hospital to Medicaid
18 recipients for inpatient use; and

19 “(bb) the average manufac-
20 turer price adjustment; and

21 “(II) the minimum rebate per-
22 centage described in section
23 1927(e)(1)(B) of the Social Security
24 Act;

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

7 “(I) the product of—

8 “(aa) the hospital’s actual
9 acquisition costs of all drugs pur-
10 chased during the cost reporting
11 period for inpatient use; and

12 “(bb)(AA) the Medicaid in-
13 patient drug charges as reported
14 on the hospital’s most recently
15 filed Medicare cost report; di-
16 vided by

17 “(BB) the total inpatient
18 drug charges reported on the cost
19 report; and

20 “(II) the percentage of the hos-
21 pital’s annual inpatient drug costs de-
22 scribed in subclause (I) that arise out
23 of the purchase of single source and
24 innovator multiple source drugs;

1 “(iii) the average manufacturer price
2 adjustment referred to in clause (i)(I)(bb)
3 shall be determined annually by the Sec-
4 retary for single source and innovator mul-
5 tiple source drugs by dividing on an aggre-
6 gate basis—

7 “(I) the average manufacturer
8 price as defined in section
9 1927(k)(1)(D) of the Social Security
10 Act, averaged across all covered drugs
11 reported to the Secretary pursuant to
12 section 1927(b)(3) of such Act; by

13 “(II) the average ceiling price
14 under this section for covered drugs
15 calculated pursuant to subsection
16 (a)(1); and

17 “(iv) the terms ‘single source drug’
18 and ‘innovator multiple source drug’ have
19 the meanings given such terms in section
20 1927(k)(7) of the Social Security Act.

21 “(B) NONINNOVATOR MULTIPLE SOURCE
22 DRUGS.—For purposes of subparagraph
23 (1)(B)—

24 “(i) the credit under such paragraph
25 shall be calculated by multiplying—

1 “(I) the product of—

2 “(aa) the estimated annual
3 costs to the hospital of noninno-
4 vator multiple source drugs pro-
5 vided to Medicaid recipients for
6 inpatient use; and

7 “(bb) the average manufac-
8 turer price adjustment; and

9 “(II) the applicable percentage as
10 defined in section 1927(c)(3)(B) of
11 the Social Security Act;

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

17 “(I) the product of—

18 “(aa) the hospital’s actual
19 acquisition cost of all drugs pur-
20 chased during the cost reporting
21 period for inpatient use; and

22 “(bb)(AA) the Medicaid in-
23 patient drug charges as reported
24 on the hospital’s most recently

1 filed Medicare cost report; di-
2 vided by

3 “(BB) total inpatient drug
4 charges reported on the cost re-
5 port; and

6 “(II) the percentage of the hos-
7 pital’s annual inpatient drug costs de-
8 scribed in subclause (I) arising out of
9 the purchase of noninnovator multiple
10 source drugs;

11 “(iii) the average manufacturer price
12 adjustment referred to in clause (i)(I)(bb)
13 shall be determined annually by the Sec-
14 retary for noninnovator multiple source
15 drugs by dividing on an aggregate basis—

16 “(I) the average manufacturer
17 price as defined in section
18 1927(k)(1)(D) of the Social Security
19 Act, averaged across all covered drugs
20 reported to the Secretary pursuant to
21 section 1927(b)(3) of such Act; by

22 “(II) the average ceiling price
23 under this section for covered drugs
24 calculated pursuant to subsection
25 (a)(1); and

1 “(iv) the term ‘noninnovator multiple
2 source drug’ has the meaning given such
3 term in section 1927(k)(7) of the Social
4 Security Act.

5 “(3) PAYMENT DEADLINE.—The credits pro-
6 vided by a hospital under paragraph (1) shall be
7 paid not later than 90 days after the date of the fil-
8 ing of the hospital’s most recently filed Medicare
9 cost report.

10 “(4) OPT-OUT.—A hospital shall not be re-
11 quired to provide the Medicaid credit required under
12 this subsection if the hospital is able to demonstrate
13 to the State that the credits would be less than or
14 equal to the loss of reimbursement under the State
15 plan resulting from the extension of discounts to in-
16 patient drugs under subsection (b)(2), or if the hos-
17 pital and State agree to an alternative arrangement.
18 Any dispute between the hospital and the State re-
19 garding the applicability of this paragraph shall be
20 adjudicated through the administrative dispute reso-
21 lution process described in subsection (e)(3).

22 “(5) OFFSET AGAINST MEDICAL ASSISTANCE.—
23 Amounts received by a State under this subsection
24 in any quarter shall be considered to be a reduction
25 in the amount expended under the State plan in the

1 quarter for medical assistance for purposes of sec-
 2 tion 1903(a)(1) of the Social Security Act.

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

10 **SEC. 4. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.**

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

14 “(e) IMPROVEMENTS IN PROGRAM INTEGRITY.—

15 “(1) MANUFACTURER COMPLIANCE.—

16 “(A) IN GENERAL.—From amounts appro-
 17 priated under paragraph (4), the Secretary
 18 shall carry out activities to provide for improve-
 19 ment in the compliance of manufacturers with
 20 the requirements of this section in order to pre-
 21 vent overcharges and other violations of the dis-
 22 counted pricing requirements specified in this
 23 section.

24 “(B) ACTIVITIES.—The activities described
 25 in subparagraph (A) shall include the following:

1 “(i) The development of a system to
2 enable the Secretary to verify the accuracy
3 of ceiling prices calculated by manufactur-
4 ers under subsection (a)(1) and charged to
5 covered entities, which shall include—

6 “(I) developing and publishing,
7 through an appropriate policy or regu-
8 latory issuance, precisely defined
9 standards and methodologies for the
10 calculation of ceiling prices under sub-
11 section (a)(1);

12 “(II) comparing regularly the
13 ceiling prices calculated by the Sec-
14 retary with the quarterly pricing data
15 that is reported by manufacturers to
16 the Secretary;

17 “(III) performing spot checks of
18 sales transactions by covered entities;
19 and

20 “(IV) inquiring into the cause of
21 any pricing discrepancies that may be
22 identified and either taking, or requir-
23 ing manufacturers to take, such cor-
24 rective action as is appropriate in re-
25 sponse to such price discrepancies.

1 “(ii) The establishment of procedures
2 for manufacturers to issue refunds to cov-
3 ered entities in the event that there is an
4 overcharge by the manufacturers, includ-
5 ing—

6 “(I) providing the Secretary with
7 an explanation of why and how the
8 overcharge occurred, how the refunds
9 will be calculated, and to whom the
10 refunds will be issued; and

11 “(II) oversight by the Secretary
12 to ensure that the refunds are issued
13 accurately and within a reasonable pe-
14 riod of time, both in routine instances
15 of retroactive adjustment to relevant
16 pricing data and exceptional cir-
17 cumstances such as erroneous or in-
18 tentional overcharging for covered
19 drugs.

20 “(iii) The provision of access, through
21 the Internet website of the Department of
22 Health and Human Services, to the appli-
23 cable ceiling prices for covered drugs as
24 calculated and verified by the Secretary in
25 accordance with this section, in a manner

1 (such as through the use of password pro-
2 tection) that limits such access to covered
3 entities and adequately ensures security
4 and the protection of privileged pricing
5 data from unauthorized redisclosure.

6 “(iv) The development of a mecha-
7 nism by which—

8 “(I) rebates and other discounts
9 provided by manufacturers to other
10 purchasers, subsequent to the sale of
11 covered drugs to covered entities, are
12 reported to the Secretary; and

13 “(II) appropriate credits and re-
14 funds are issued to covered entities if
15 such credits and refunds have the ef-
16 fect of lowering the applicable ceiling
17 price for the relevant quarter for the
18 drugs involved.

19 “(v) Selective auditing of manufactur-
20 ers and wholesalers to ensure the integrity
21 of the drug discount program under this
22 section.

23 “(vi) The imposition of sanctions in
24 the form of civil monetary penalties,
25 which—

1 “(I) shall be assessed according
2 to standards established in regulations
3 to be promulgated by the Secretary
4 within 180 days of the date of enact-
5 ment of this subsection;

6 “(II) shall not exceed \$5,000 for
7 each instance of overcharging a cov-
8 ered entity that may have occurred;
9 and

10 “(III) shall apply to any manu-
11 facturer with an agreement under this
12 section that knowingly and inten-
13 tionally charges a covered entity a
14 price for the purchase of a drug that
15 exceeds the maximum applicable price
16 under subsection (a)(1).

17 “(2) COVERED ENTITY COMPLIANCE.—

18 “(A) IN GENERAL.—From amounts appro-
19 priated under paragraph (4), the Secretary
20 shall carry out activities to provide for improve-
21 ment in compliance by covered entities with the
22 requirements of this section in order to prevent
23 diversion and other violations of the duplicate
24 discount requirements specified under sub-
25 section (a)(5).

1 “(B) ACTIVITIES.—The activities described
2 in subparagraph (A) shall include the following:

3 “(i) The development of procedures to
4 enable and require covered entities to regu-
5 larly update (at least annually) the infor-
6 mation on the Internet website of the De-
7 partment of Health and Human Services
8 relating to this section.

9 “(ii) The development of a system for
10 the Secretary to verify the accuracy of in-
11 formation regarding covered entities that is
12 listed on the website described in clause
13 (i).

14 “(iii) The development of more de-
15 tailed guidance describing methodologies
16 and options available to covered entities for
17 billing covered drugs to State Medicaid
18 agencies in a manner that avoids duplicate
19 discounts pursuant to subsection (a)(5)(A).

20 “(iv) The establishment of a single,
21 universal, and standardized identification
22 system by which each covered entity site
23 can be identified by manufacturers, dis-
24 tributors, covered entities and the Sec-
25 retary for purposes of facilitating the or-

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

4 “(v) The imposition of sanctions, as
5 determined appropriate by the Secretary,
6 in addition to the sanctions to which cov-
7 ered entities are subject to under sub-
8 section (a)(5)(D), through 1 or more of the
9 following actions:

10 “(I) Where a covered entity
11 knowingly and intentionally violates
12 subsection (a)(5)(B), the covered enti-
13 ty shall be required to pay a monetary
14 penalty to a manufacturer or manu-
15 facturers in the form of interest on
16 sums for which the covered entity is
17 found liable under subsection
18 (a)(5)(E), and such interest to be
19 compounded monthly and equal to the
20 current short-term interest rate as de-
21 termined by the Federal Reserve for
22 the time period for which the covered
23 entity is liable.

24 “(II) Where the Secretary deter-
25 mines that a violation of subsection

1 (a)(5)(B) was systematic and egre-
2 gious as well as knowing and inten-
3 tional, removing the covered entity
4 from the program under this section
5 and disqualifying the entity from re-
6 entry into the program for a reason-
7 able period of time to be determined
8 by the Secretary.

9 “(III) Referring matters to ap-
10 propriate Federal authorities within
11 the Food and Drug Administration,
12 the Office of Inspector General, or
13 other Federal agencies for consider-
14 ation of appropriate action under
15 other Federal law, such as the Pre-
16 scription Drug Marketing Act.

17 “(3) ADMINISTRATIVE DISPUTE RESOLUTION
18 PROCESS.—

19 “(A) IN GENERAL.—Not later than 180
20 days after the date of enactment of this sub-
21 section, the Secretary shall promulgate regula-
22 tions to establish and implement an administra-
23 tive process for the resolution of claims by cov-
24 ered entities that they have been overcharged
25 for drugs purchased under this section, and

1 claims by manufacturers, after the conduct of
2 audits as authorized by subsection (a)(5)(D), of
3 violations of subsections (a)(5)(A) or (a)(5)(B),
4 including appropriate procedures for the provi-
5 sion of remedies and enforcement of determina-
6 tions made pursuant to such process through
7 mechanisms and sanctions described in para-
8 graphs (1)(B) and (2)(B) of this subsection.
9 Such regulations shall also establish an admin-
10 istrative process for resolution of disputes de-
11 scribed in subsection (c)(4).

12 “(B) DEADLINES AND PROCEDURES.—
13 Regulations promulgated by the Secretary
14 under subparagraph (A) shall—

15 “(i) designate or establish a decision-
16 making official or decisionmaking body
17 within the Department of Health and
18 Human Services to be responsible for re-
19 viewing and finally resolving claims by cov-
20 ered entities that they have been charged
21 prices for covered drugs in excess of the
22 ceiling price described in subsection (a)(1),
23 and claims by manufacturers that viola-
24 tions of subsection (a)(5)(A) or (a)(5)(B)
25 have occurred;

1 “(ii) establish such deadlines and pro-
2 cedures as may be necessary to ensure that
3 claims shall be resolved fairly, efficiently,
4 and expeditiously;

5 “(iii) establish procedures by which a
6 covered entity may discover and obtain
7 such information and documents from
8 manufacturers and third parties as may be
9 relevant to demonstrate the merits of a
10 claim that charges for a manufacturer’s
11 product have exceeded the applicable ceil-
12 ing price under this section, and may sub-
13 mit such documents and information to the
14 administrative official or body responsible
15 for adjudicating such claim;

16 “(iv) require that a manufacturer
17 must conduct an audit of a covered entity
18 pursuant to subsection (a)(5)(D) as a pre-
19 requisite to initiating administrative dis-
20 pute resolution proceedings against a cov-
21 ered entity;

22 “(v) permit the official or body des-
23 ignated in clause (i), at the request of a
24 manufacturer or manufacturers, to consoli-
25 date claims brought by more than 1 manu-

1 facturer against the same covered entity
2 where, in the judgment of such official or
3 body, consolidation is appropriate and con-
4 sistent with the goals of fairness and econ-
5 omy of resources; and

6 “(vi) include provisions and proce-
7 dures to permit multiple covered entities to
8 jointly assert claims of overcharges by the
9 same manufacturer for the same drug or
10 drugs in one administrative proceeding,
11 and permit such claims to be asserted on
12 behalf of covered entities by associations or
13 organizations representing the interests of
14 such covered entities and of which the cov-
15 ered entities are members.

16 “(C) FINALITY OF ADMINISTRATIVE RESO-
17 LUTION.—The administrative resolution of a
18 claim or claims under the regulations promul-
19 gated under subparagraph (A) shall be a final
20 agency decision and shall be binding upon the
21 parties involved, unless invalidated by an order
22 of a court of competent jurisdiction.

23 “(4) AUTHORIZATION OF APPROPRIATIONS.—

24 There are authorized to be appropriated to carry out

1 this subsection, such sums as may be necessary for
2 fiscal year 2008, and each succeeding fiscal year.”.

3 (b) RELATED AMENDMENTS.—Section 340B(a)(1) of
4 the Public Health Service Act (42 U.S.C. 256b(a)) is
5 amended by adding at the end the following: “Each such
6 agreement shall require that the manufacturer furnish the
7 Secretary with reports, on a quarterly basis, of the price
8 for each covered drug subject to the agreement that, ac-
9 cording to the manufacturer, represents the maximum
10 price that covered entities may permissibly be required to
11 pay for the drug (referred to in this section as the ‘ceiling
12 price’), and shall require that the manufacturer offer each
13 covered entity covered drugs for purchase at or below the
14 applicable ceiling price if such drug is made available to
15 any other purchaser at any price.”.

16 **SEC. 5. OTHER IMPROVEMENTS.**

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

20 “(f) USE OF MULTIPLE CONTRACT PHARMACIES
21 PERMITTED.—Nothing in this section shall be construed
22 as prohibiting a covered entity from entering into con-
23 tracts with more than 1 pharmacy for the provision of cov-
24 ered drugs, including a contract that supplements the use

1 of an in-house pharmacy arrangement or requires the ap-
2 proval of the Secretary for entering into such a contract.

3 “(g) INTRAAGENCY COORDINATION.—The Secretary
4 shall establish specific measures, policies, and procedures
5 to ensure effective communication and coordination be-
6 tween the Centers for Medicare & Medicaid Services and
7 the Health Resources and Services Administration with
8 respect to all agency actions and all aspects of policy and
9 administration affecting or pertaining to the drug discount
10 program under this section and in which the functions and
11 responsibilities of those agency components are inter-
12 related or interdependent, including through the establish-
13 ment of a permanent working group that is composed of
14 representatives of both the Health Resources and Services
15 Administration and the Centers for Medicare & Medicaid
16 Services, to identify and oversee matters requiring such
17 coordination.”.

18 (b) EFFECTIVE DATES.—

19 (1) AMENDMENT.—Section 340B(d) of the
20 Public Health Service Act (42 U.S.C. 256b(d)) is
21 amended by striking “Veterans Health Care Act of
22 1992” and inserting “340B Program Improvement
23 and Integrity Act of 2007”.

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

4 (c) EFFECTIVENESS NOTWITHSTANDING OTHER
5 PROVISIONS OF LAW.—Notwithstanding any other provi-
6 sion of law, the amendments made by this Act shall be-
7 come effective on January 1, 2008, and shall be taken into
8 account in determining whether a manufacturer is deemed
9 to meet the requirements of section 340B(a) of the Public
10 Health Service Act (42 U.S.C. 256b(a)), and the require-
11 ments of section 1927(a)(5) of the Social Security Act (42
12 U.S.C. 1396r–8(a)(5)).

13 **SEC. 6. CONFORMING AMENDMENTS.**

14 Section 1927 of the Social Security Act (42 U.S.C.
15 1396r–8) is amended—

16 (1) in subsection (a)(5)—

17 (A) in subparagraph (A), by striking “cov-
18 ered outpatient” and inserting “covered”;

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

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

24 “(C) COVERED DRUG DEFINED.—In this
25 subsection, the term ‘covered drug’ means a

1 drug defined in section 340B(b)(2) of the Pub-
2 lic Health Service Act.”;

3 (D) in subparagraph (E), as so redesign-
4 dated, by striking “title VI of the Veterans
5 Health Care Act of 1992” and inserting “340B
6 Program Improvement and Integrity Act of
7 2007.”; and

8 (E) in subparagraph (F), as so redesign-
9 dated—

10 (i) by striking “as in effect imme-
11 diately after the enactment of this para-
12 graph” and inserting “as in effect upon
13 the effective date of the 340B Program
14 Improvement and Integrity Act of 2007.”;
15 and

16 (ii) by striking “after the date of the
17 enactment of this paragraph” and insert-
18 ing “after the date of enactment of such
19 Act.”;

20 (2) in subsection (c)(1)(C)(i)—

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

24 (B) by inserting after subclause (I) the fol-
25 lowing:

1 “(II) any prices charged for a
2 covered drug as defined in section
3 340B(b)(2) of the Public Health Serv-
4 ice Act;”;

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

7 “(D) CALCULATION FOR COVERED
8 DRUGS.—Notwithstanding any other provision
9 of this subsection, with respect to a covered
10 drug as defined in section 340B(b)(2) of the
11 Public Health Service Act, average manufac-
12 turer price means the average price paid to the
13 manufacturer for the drug in the United States
14 by wholesalers for drugs distributed to both the
15 retail pharmacy and acute care classes of trade,
16 after deducting customary prompt pay dis-
17 counts.”.

○