

110TH CONGRESS
1ST SESSION

H. R. 2606

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

JUNE 7, 2007

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

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.

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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “340B Program Improvement and Integrity Act of 2007”.

6 (b) **TABLE OF CONTENTS.**—The table of contents of
7 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.

1 **SEC. 2. EXPANDED PARTICIPATION IN 340B PROGRAM.**

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

6 “(M) A children’s hospital excluded from
7 the Medicare prospective payment system pur-
8 suant to section 1886(d)(1)(B)(iii) of the Social
9 Security Act (42 U.S.C. 1395ww(d)(1)(B)(iii))
10 which would meet the requirements of sub-
11 section (a)(4)(L), including the disproportionate
12 share adjustment percentage requirement under
13 clause (ii), if the hospital were a subsection (d)
14 hospital as defined by Section 1886(d)(1)(B) of
15 the Social Security Act.

16 “(N) An entity that is a critical access hos-
17 pital (as determined under section 1820(e)(2)
18 of the Social Security Act (42 U.S.C. 1395i-
19 4(e)(2))).

20 “(O) An entity receiving funds under title
21 V of the Social Security Act (relating to mater-
22 nal and child health) for the provision of health
23 services.

1 “(P) An entity receiving funds under sub-
2 part I of part B of title XIX of the Public
3 Health Service Act (relating to comprehensive
4 mental health services) for the provision of com-
5 munity mental health services.

6 “(Q) An entity receiving funds under sub-
7 part II of such part B (relating to the preven-
8 tion and treatment of substance abuse) for the
9 provision of treatment services for substance
10 abuse.

11 “(R) An entity that is a medicare-depend-
12 ent, small rural hospital (as defined in section
13 1886(d)(5)(G)(iv) of the Social Security Act).

14 “(S) An entity that is a sole community
15 hospital (as defined in section
16 1886(d)(5)(D)(iii) of the Social Security Act).

17 “(T) An entity that is classified as a rural
18 referral center under section 1886(d)(5)(C) of
19 the Social Security Act.”.

20 (b) PROHIBITION ON GROUP PURCHASING ARRANGE-
21 MENTS.—Section 340B(a) of such Act (42 U.S.C.
22 256b(a)) is amended—

23 (1) in paragraph (4)(L)—

24 (A) by adding “and” at the end of clause

25 (i);

1 (B) by striking “; and” at the end of
2 clause (ii) and inserting a period; and

3 (C) by striking clause (iii);

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

8 “(C) PROHIBITING USE OF GROUP PUR-
9 CHASING ARRANGEMENTS.—

10 “(i) A hospital described in subpara-
11 graph (L), (M), (N), (R), (S), or (T) of
12 subsection (a)(4) shall not obtain covered
13 outpatient drugs through a group pur-
14 chasing organization or other group pur-
15 chasing arrangement, except as permitted
16 or provided pursuant to clause (ii) or (iii).

17 “(ii) Clause (i) shall not apply to
18 drugs purchased for inpatient use.

19 “(iii) The Secretary shall establish
20 reasonable exceptions to the requirement of
21 clause (i)—

22 “(I) with respect to a covered
23 outpatient drug that is unavailable to
24 be purchased through the program
25 under this section due to a drug

1 shortage problem, manufacturer non-
2 compliance, or any other reason be-
3 yond the hospital's control;

4 “(II) to facilitate generic substi-
5 tution when a generic covered out-
6 patient drug is available at a lower
7 price; or

8 “(III) to reduce in other ways
9 the administrative burdens of man-
10 aging both inventories of drugs ob-
11 tained under this section and not
12 under this section, if such exception
13 does not create a duplicate discount
14 problem in violation of subparagraph
15 (A) or a diversion problem in violation
16 of subparagraph (B).”.

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

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

20 (1) in subsection (b)—

21 (A) by designating the matter beginning
22 “In this section” as a paragraph (1) with the
23 heading “IN GENERAL” ; and

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

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

3 “(A) means a covered outpatient drug (as
4 defined in section 1927(k)(2) of the Social Se-
5 curity Act); and

6 “(B) includes, notwithstanding the section
7 1927(k)(3)(A) of such Act, a drug used in con-
8 nection with an inpatient or outpatient service
9 provided by a hospital described in subpara-
10 graph (L), (M), (N), (R), (S), or (T) of sub-
11 section (a)(4) that is enrolled to participate in
12 the drug discount program under this section.”;
13 and

14 (2) in paragraphs (5), (7), and (9), by striking
15 “outpatient” each place it appears.

16 (b) MEDICAID CREDITS ON INPATIENT DRUGS.—
17 Subsection (c) of section 340B of the Public Health Serv-
18 ice Act (42 U.S.C. 256b(c)) is amended to read as follows:

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

20 “(1) IN GENERAL.—For the cost reporting pe-
21 riod covered by the most recently filed Medicare cost
22 report under title XVIII of the Social Security Act,
23 a hospital described in subparagraph (L), (M), (N),
24 (R), (S), or (T) of subsection (a)(4) and enrolled to
25 participate in the drug discount program under this

1 section shall provide to each State under its plan
2 under title XIX of such Act —

3 “(A) a credit on the estimated annual
4 costs to such hospital of single source and inno-
5 vator multiple source drugs provided to Med-
6 icaid recipients for inpatient use; and

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

11 “(2) CALCULATION OF CREDITS.—

12 “(A) SINGLE SOURCE AND INNOVATOR
13 MULTIPLE SOURCE DRUGS.—For purposes of
14 paragraph (1)(A)—

15 “(i) the credit under such paragraph
16 shall be equal to the product of—

17 “(I) the estimated annual costs
18 of single source and innovator mul-
19 tiple source drugs provided by the
20 hospital to Medicaid recipients for in-
21 patient use;

22 “(II) the average manufacturer
23 price adjustment; and

24 “(III) the minimum rebate per-
25 centage described in section

1 1927(e)(1)(B) of the Social Security
2 Act;

3 “(ii) the estimated annual costs of
4 single source drugs and innovator multiple
5 source drugs provided by the hospital to
6 Medicaid recipients for inpatient use under
7 clause (i)(I) shall be equal to the product
8 of—

9 “(I) the hospital’s actual acquisi-
10 tion costs of all drugs purchased dur-
11 ing the cost reporting period for inpa-
12 tient use;

13 “(II) the Medicaid inpatient drug
14 charges as reported on the hospital’s
15 most recently filed Medicare cost re-
16 port divided by total inpatient drug
17 charges reported on the cost report;
18 and

19 “(III) the percent of the hos-
20 pital’s annual inpatient drug costs de-
21 scribed in subclause (I) arising out of
22 the purchase of single source and in-
23 novator multiple source drugs;

24 “(iii) the average manufacturer price
25 adjustment referenced in clause (i)(II)

1 shall be determined annually by the Sec-
2 retary for single source and innovator mul-
3 tiple source drugs by dividing on an aggre-
4 gate basis the average manufacturer price
5 as defined in section 1927(k)(1)(D) of the
6 Social Security Act, averaged across all
7 covered drugs reported to the Secretary
8 pursuant to section 1927(b)(3) of such Act
9 by the average 340B ceiling price for cov-
10 ered drugs calculated pursuant to sub-
11 section (a)(1); and

12 “(iv) the terms ‘single source drug’
13 and ‘innovator multiple source drug’ have
14 the meanings given such terms in section
15 1927(k)(7) of the Social Security Act.

16 “(B) NONINNOVATOR MULTIPLE SOURCE
17 DRUGS.—For purposes of subparagraph
18 (1)(B)—

19 “(i) the credit under such paragraph
20 shall be calculated by multiplying—

21 “(I) the estimated annual costs
22 to the hospital of noninnovator mul-
23 tiple source drugs provided to Med-
24 icaid recipients for inpatient use,

1 “(II) the average manufacturer
2 price adjustment, and

3 “(III) the applicable percentage
4 as defined in section 1927(e)(3)(B) of
5 the Social Security Act;

6 “(ii) the estimated annual costs to a
7 hospital of noninnovator multiple source
8 drugs provided to Medicaid recipients for
9 inpatient use under clause (i)(I) shall be
10 equal to the product of—

11 “(I) the hospital’s actual acquisi-
12 tion cost of all drugs purchased dur-
13 ing the cost reporting period for inpa-
14 tient use;

15 “(II) the Medicaid inpatient drug
16 charges as reported on the hospital’s
17 most recently filed Medicare cost re-
18 port divided by total inpatient drug
19 charges reported on the cost report;

20 “(III) the percent of the hos-
21 pital’s annual inpatient drug costs de-
22 scribed in subclause (I) arising out of
23 the purchase of noninnovator multiple
24 source drugs;

1 “(iii) the average manufacturer price
2 adjustment referenced in clause (i)(II)
3 shall be determined annually by the Sec-
4 retary for noninnovator multiple source
5 drugs by dividing on an aggregate basis
6 the average manufacturer price as defined
7 in Section 1927(k)(1)(D) of the Social Se-
8 curity Act, averaged across all covered
9 drugs reported to the Secretary pursuant
10 to Section 1927(b)(3) of such Act by the
11 average 340B ceiling price for covered
12 drugs calculated pursuant to section
13 340B(a)(1) of the Public Health Service
14 Act; and

15 “(iv) the term ‘noninnovator multiple
16 source drug’ has the meaning given such
17 term in section 1927(k)(7) of the Social
18 Security Act.

19 “(3) PAYMENT DEADLINE.—The credits pro-
20 vided by a hospital under paragraph (1) shall be
21 paid within 90 days of the filing of the hospital’s
22 most recently filed Medicare cost report.

23 “(4) OPT OUT.—A hospital shall not be re-
24 quired to provide the Medicaid credit required under
25 paragraph (1) if—

1 “(A) it can demonstrate to the State that
2 the amount of the credit would not exceed the
3 loss of reimbursement under the State plan re-
4 sulting from the extension of discounts to inpa-
5 tient drugs under subsection (b)(2); or

6 “(B) the hospital and State agree to an al-
7 ternative arrangement.

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

12 “(5) OFFSET AGAINST MEDICAL ASSISTANCE.—
13 Amounts received by a State under this subsection
14 in any quarter shall be considered to be a reduction
15 in the amount expended under the State plan in the
16 quarter for medical assistance for purposes of sec-
17 tion 1903(a)(1) of the Social Security Act.

18 “(6) REFERENCES TO SOCIAL SECURITY ACT
19 PROVISIONS.—Notwithstanding any other provision
20 of law, all references to provisions of the Social Se-
21 curity Act in this section shall be deemed to be ref-
22 erences to the Social Security Act as in effect on the
23 effective date of the 340B Program Improvement
24 Act of 2007.”.

1 (c) CONFORMING AMENDMENTS.—Section 1927 of
2 the Social Security Act (42 U.S.C. 1396r-8), is amend-
3 ed—

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

8 (2) in subsection (a)(5)(D), by striking “title
9 VI of the Veterans Health Care Act of 1992” and
10 inserting “the 340B Program Improvement and In-
11 tegrity Act of 2007”;

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

16 “(II) any prices charged for a
17 covered drug as defined in section
18 340B(b)(2) of the Public Health Serv-
19 ice Act;”; and

20 (4) in subsection (k)(1)—

21 (A) in subparagraph (A), by striking “sub-
22 subparagraph (B)” and inserting “subparagraph
23 (B) and (D)”;

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

1 “(D) CALCULATION FOR COVERED
2 DRUGS.—With respect to a covered drug (as de-
3 fined in section 340B(b)(2) of the Public
4 Health Service Act), the average manufacturer
5 price is the average price paid to the manufac-
6 turer for the drug in the United States by
7 wholesalers for drugs distributed to both the re-
8 tail pharmacy and acute care classes of trade,
9 after deducting customary prompt pay dis-
10 counts.”.

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

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

15 “(e) IMPROVEMENTS IN PROGRAM INTEGRITY.—

16 “(1) MANUFACTURER COMPLIANCE.—

17 “(A) IN GENERAL.—From amounts appro-
18 priated under paragraph (4), the Secretary
19 shall provide for improvements in compliance by
20 manufacturers with the requirements of this
21 section in order to prevent overcharges and
22 other violations of the discounted pricing re-
23 quirements specified in this section.

1 “(B) IMPROVEMENTS.—The improvements
2 described in subparagraph (A) shall include the
3 following:

4 “(i) The development of a system to
5 enable the Secretary to verify the accuracy
6 of ceiling prices calculated by manufactur-
7 ers under subsection (a)(1) and charged to
8 covered entities, which shall include the
9 following:

10 “(I) Developing and publishing
11 through an appropriate policy or regu-
12 latory issuance, precisely defined
13 standards and methodology for the
14 calculation of ceiling prices under
15 such subsection.

16 “(II) Comparing regularly the
17 ceiling prices calculated by the Sec-
18 retary with the quarterly pricing data
19 that is reported by manufacturers to
20 the Secretary.

21 “(III) Performing spot checks of
22 sales transactions by covered entities.

23 “(IV) Inquiring into the cause of
24 any pricing discrepancies that may be
25 identified and either taking, or requir-

1 ing manufacturers to take, such cor-
2 rective action as is appropriate in re-
3 sponse to such price discrepancies.

4 “(ii) The establishment of procedures
5 for manufacturers to issue refunds to cov-
6 ered entities in the event that there is an
7 overcharge by the manufacturers, including
8 the following:

9 “(I) Providing the Secretary with
10 an explanation of why and how the
11 overcharge occurred, how the refunds
12 will be calculated, and to whom the
13 refunds will be issued.

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

23 “(iii) The provision of access through
24 the Internet website of the Department of
25 Health and Human Services to the applica-

1 ble ceiling prices for covered drugs as cal-
2 culated and verified by the Secretary in ac-
3 cordance with this section, in a manner
4 (such as through the use of password pro-
5 tection) that limits such access to covered
6 entities and adequately assures security
7 and protection of privileged pricing data
8 from unauthorized re-disclosure.

9 “(iv) The development of a mecha-
10 nism by which—

11 “(I) rebates and other discounts
12 provided by manufacturers to other
13 purchasers subsequent to the sale of
14 covered drugs to covered entities are
15 reported to the Secretary, and

16 “(II) appropriate credits and re-
17 funds are issued to covered entities if
18 such discounts or rebates have the ef-
19 fect of lowering the applicable ceiling
20 price for the relevant quarter for the
21 drugs involved.

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

1 “(vi) The imposition of sanctions in
2 the form of civil monetary penalties,
3 which—

4 “(I) shall be assessed according
5 to standards established in regulations
6 to be promulgated by the Secretary
7 within 180 days of enactment of this
8 subsection;

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

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

20 “(2) COVERED ENTITY COMPLIANCE.—

21 “(A) IN GENERAL.—From amounts appro-
22 priated under paragraph (4), the Secretary
23 shall provide for improvements in compliance by
24 covered entities with the requirements of this
25 section in order to prevent diversion and other

1 violations of the duplicate discount require-
2 ments specified under subsection (a)(5).

3 “(B) IMPROVEMENTS.—The improvements
4 described in subparagraph (A) shall include the
5 following:

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

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

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

23 “(iv) The establishment of a single,
24 universal, and standardized identification
25 system by which each covered entity site

1 can be identified by manufacturers, dis-
2 tributors, covered entities, and the Sec-
3 retary for purposes of facilitating the or-
4 dering, purchasing, and delivery of covered
5 drugs under this section, including the
6 processing of chargebacks for such drugs.

7 “(v) The imposition of sanctions, in
8 appropriate cases as determined by the
9 Secretary, additional to those to which cov-
10 ered entities are subject under subpara-
11 graph (a)(5)(D), through one or more of
12 the following actions:

13 “(I) Where a covered entity
14 knowingly and intentionally violates
15 subparagraph (a)(5)(E), the covered
16 entity shall be required to pay a mon-
17 etary penalty to a manufacturer or
18 manufacturers in the form of interest
19 on sums for which the covered entity
20 is found liable under paragraph
21 (a)(5)(E), such interest to be com-
22 pounded monthly and equal to the
23 current short term interest rate as de-
24 termined by the Federal Reserve for

1 the time period for which the covered
2 entity is liable.

3 “(II) Where the Secretary deter-
4 mines a violation of subparagraph
5 (a)(5)(B) was systematic and egre-
6 gious as well as knowing and inten-
7 tional, removing the covered entity
8 from the drug discount program
9 under this section and disqualifying
10 the entity from re-entry into such pro-
11 gram for a reasonable period of time
12 to be determined by the Secretary.

13 “(III) Referring matters to ap-
14 propriate Federal authorities within
15 the Food and Drug Administration,
16 the Office of Inspector General of De-
17 partment of Health and Human Serv-
18 ices, or other Federal agencies for
19 consideration of appropriate action
20 under other Federal statutes, such as
21 the Prescription Drug Marketing Act
22 (21 U.S.C. 353).

23 “(3) ADMINISTRATIVE DISPUTE RESOLUTION
24 PROCESS.—

1 “(A) IN GENERAL.—Not later than 180
2 days after the date of enactment of this sub-
3 section, the Secretary shall promulgate regula-
4 tions to establish and implement an administra-
5 tive process for the resolution of claims by cov-
6 ered entities that they have been overcharged
7 for drugs purchased under this section, and
8 claims by manufacturers, after the conduct of
9 audits as authorized by subsection (a)(5)(D), of
10 violations of subsections (a)(5)(A) or (a)(5)(B),
11 including appropriate procedures for the provi-
12 sion of remedies and enforcement of determina-
13 tions made pursuant to such process through
14 mechanisms and sanctions described in para-
15 graphs (1)(B) and (2)(B).

16 “(B) DEADLINES AND PROCEDURES.—
17 Regulations promulgated by the Secretary
18 under subparagraph (A) shall—

19 “(i) designate or establish a decision-
20 making official or decision-making body
21 within the Department of Health and
22 Human Services to be responsible for re-
23 viewing and finally resolving claims by cov-
24 ered entities that they have been charged
25 prices for covered drugs in excess of the

1 ceiling price described in subsection (a)(1),
2 and claims by manufacturers that viola-
3 tions of subsection (a)(5)(A) or (a)(5)(B)
4 have occurred;

5 “(ii) establish such deadlines and pro-
6 cedures as may be necessary to ensure that
7 claims shall be resolved fairly, efficiently,
8 and expeditiously;

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

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

1 “(v) permit the official or body des-
2 ignated in clause (i), at the request of a
3 manufacturer or manufacturers, to consoli-
4 date claims brought by more than one
5 manufacturer against the same covered en-
6 tity where, in the judgment of such official
7 or body, consolidation is appropriate and
8 consistent with the goals of fairness and
9 economy of resources; and

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

20 “(C) FINALITY OF ADMINISTRATIVE RESO-
21 LUTION.—The administrative resolution of a
22 claim or claims under the regulations promul-
23 gated under subparagraph (A) shall be a final
24 agency decision and shall be binding upon the

1 parties involved, unless invalidated by an order
2 of a court of competent jurisdiction.

3 “(4) AUTHORIZATION OF APPROPRIATIONS.—

4 There are authorized to be appropriated to carry out
5 this subsection, such sums as may be necessary for
6 fiscal year 2008 and each succeeding fiscal year.”.

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

9 (1) in subsection (a)(1), by adding at the end
10 the following: “Each such agreement shall require
11 that the manufacturer furnish the Secretary with re-
12 ports, on a quarterly basis, of the price for each cov-
13 ered drug subject to the agreement that, according
14 to the manufacturer, represents the maximum price
15 that covered entities may permissibly be required to
16 pay for the drug (referred to in this section as the
17 ‘ceiling price’), and shall require that the manufac-
18 turer offer each covered entity covered drugs for
19 purchase at or below the applicable ceiling price if
20 such drug is made available to any other purchaser
21 at any price.”; and

22 (2) in the first sentence of subsection (a)(5)(E),
23 as redesignated by section 2(b), by inserting “after
24 audit as described in subparagraph (D) and” after
25 “finds,”.

1 **SEC. 5. OTHER IMPROVEMENTS IN 340B PROGRAM.**

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

6 “(f) **USE OF MULTIPLE CONTRACT PHARMACIES**
7 **PERMITTED.**—Nothing in this section shall be construed
8 as prohibiting a covered entity from entering into con-
9 tracts with more than one pharmacy for the provision of
10 covered drugs, including such a contract that supplements
11 the use of an in-house pharmacy arrangement or as re-
12 quiring the approval of the Secretary for entering into
13 such a contract.

14 “(g) **INTRA-AGENCY COORDINATION.**—The Secretary
15 shall establish specific measures, policies, and procedures
16 to ensure effective communication and coordination be-
17 tween the Centers for Medicare & Medicaid Services and
18 the Health Resources and Services Administration with
19 respect to all agency actions and all aspects of policy and
20 administration affecting or pertaining to the drug discount
21 program under this section and in which the functions and
22 responsibilities of those agency components are inter-
23 related or interdependent, including by establishment of
24 a permanent working group, composed of representatives
25 of both the Health Resources and Services Administration

1 and the Centers for Medicare & Medicaid Services, to iden-
2 tify and oversee matters requiring such coordination.”.

3 **SEC. 6. EFFECTIVE DATES.**

4 (a) **IN GENERAL.**—The amendments made by this
5 Act shall take effect on January 1, 2008, and shall apply
6 to drugs purchased on or after January 1, 2008.

7 (b) **GENERAL CONFORMING REFERENCE.**—Section
8 340B(d) of the Public Health Service Act (42 U.S.C.
9 256b(d)) is amended by striking “Veterans Health Care
10 Act of 1992” and inserting “the effective date of the 340B
11 Program Improvement and Integrity Act of 2007”.

12 (c) **EFFECTIVENESS.**—The amendments made by
13 this Act shall be effective, and shall be taken into account
14 in determining whether a manufacturer is deemed to meet
15 the requirements of section 340B(a) of the Public Health
16 Service Act (42 U.S.C. 256b(a)) and of section 1927(a)(5)
17 of the Social Security Act (42 U.S.C. 1396r–8(a)(5)), not-
18 withstanding any other provision of law.

○