

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “340B Drug Pricing Integrity and Affordability for Pa-
4 tients Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Rebate conditions.
- Sec. 3. Amendments to the eligibility of subgrantees.
- Sec. 4. Additional definitions.
- Sec. 5. Contract pharmacies.
- Sec. 6. Transparency.
- Sec. 7. Ensuring affordability.
- Sec. 8. Hospital Child sites.
- Sec. 9. Contracting reforms.
- Sec. 10. Prime vendor program.
- Sec. 11. Transfer of civil penalty amounts collected.
- Sec. 12. Application; regulations and guidance.

7 **SEC. 2. REBATE CONDITIONS.**

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

10 (1) in paragraph (1)—

11 (A) by striking “(taking into account any
12 rebate or discount, as provided by the Sec-
13 retary)”;

14 (B) by striking “paragraph (2)” and in-
15 serting “paragraph (2)(A)”;

16 (2) in paragraph (2)—

1 (A) in the paragraph heading, by striking
2 “DEFINED” and inserting “; DISCOUNT AND RE-
3 BATE CONDITIONS”;

4 (B) in subparagraph (A), by redesignating
5 clauses (i) and (ii) as subclauses (I) and (II),
6 respectively, and adjusting the margins accord-
7 ingly;

8 (C) in subparagraph (B)—

9 (i) by redesignating clauses (i) and
10 (ii) as subclauses (I) and (II), respectively,
11 and adjusting the margins accordingly; and

12 (ii) in subclause (I), as so redesign-
13 ated, by striking “subparagraph (A)” and
14 inserting “clause (i)”;

15 (D) by redesignating subparagraphs (A)
16 and (B) as clauses (i) and (ii), respectively, and
17 adjusting the margins accordingly;

18 (E) by inserting before clause (i), as so re-
19 designated, the following:

20 “(A) REBATE PERCENTAGE DEFINED.—”;

21 and

22 (F) by adding at the end the following:

23 “(B) DISCOUNT AND REBATE CONDI-
24 TIONS.—

1 to patients of the covered entity,
2 consistent with paragraph (5)(B);

3 “(cc) submits standardized
4 claims documentation, as de-
5 scribed in clause (iii), to the
6 manufacturer or the delegated
7 contractor of the manufacturer
8 within 30 days of the date on
9 which the covered outpatient
10 drug is dispensed; and

11 “(dd) submits a signed at-
12 testation to, and documentation
13 demonstrating, compliance with
14 the requirements of items (aa)
15 and (bb), by a qualified rep-
16 resentative, to the Secretary and
17 the manufacturer on an annual
18 basis.

19 “(II) REQUIREMENTS FOR RE-
20 BATES.—A manufacturer may elect to
21 make the ceiling price available
22 through a retrospective rebate, where-
23 by the covered entity pays a non-ceil-
24 ing price acquisition cost for the cov-
25 ered outpatient drug at the time of

1 sale and the manufacturer later issues
2 a rebate accounting for the difference
3 between the actual acquisition cost
4 and the ceiling price for such drug,
5 provided that—

6 “(aa) the covered entity
7 shall submit a request for a re-
8 bate to the manufacturer or the
9 delegated contractor of the man-
10 ufacturer with the required
11 standardized claims documenta-
12 tion, as described in clause (iii),
13 within **[90]** days of the date on
14 such the drug is dispensed or ad-
15 ministered; and

16 “(bb) the manufacturer—

17 “(AA) pays all undis-
18 puted claims within 10 days
19 (except as provided in clause
20 (iii)(II)) of receiving a re-
21 quest under item (aa) by
22 issuing a rebate (either in
23 the form of a credit or cash
24 value) equal to the dif-
25 ference between the actual

6

1 acquisition cost and the ceil-
2 ing price; and
3 “(BB) with respect to
4 disputed claims, provides the
5 covered entity with the ra-
6 tionale and specific docu-
7 mentation for reasons the
8 claim is denied within a
9 minimum amount of time as
10 determined by the Secretary,
11 provides an opportunity for
12 the covered entity to submit
13 additional information to the
14 manufacturer or request re-
15 view of the disputed claim
16 by the Secretary, and in the
17 case that the covered entity
18 submits such additional in-
19 formation or as the Sec-
20 retary determines appro-
21 priate following secretarial
22 review of the disputed claim,
23 reconsiders the claim [with-
24 in a minimum amount of

1 time as determined by the
2 Secretary】.

3 “(III) REQUIREMENTS FOR A
4 CLAIMS REPOSITORY.—A manufac-
5 turer may elect to make the ceiling
6 price available through a discount of-
7 fered after the covered entity submits
8 standardized claims data described in
9 clause (iii) to a claims repository oper-
10 ated by the Secretary, which shall act
11 to prevent diversion and duplication of
12 discounts, and fulfill other require-
13 ments under this section, whereby—

14 “(aa) the covered entity
15 pays the ceiling price for a cov-
16 ered outpatient drug and—

17 “(AA) maintains a seg-
18 regated inventory system in
19 which covered outpatient
20 drugs purchased at the ceil-
21 ing price are physically dis-
22 tinguishable from such
23 drugs not purchased at the
24 ceiling price;

1 “(BB) establishes poli-
2 cies and procedures for iden-
3 tifying patients (as defined
4 in subsection (b)(3)) at the
5 time of dispensing to ensure
6 that drugs purchased at the
7 ceiling price are given only
8 to patients of the covered
9 entity, consistent with para-
10 graph (5)(B);

11 “(CC) submits stand-
12 ardized claims documenta-
13 tion, as described in clause
14 (iii), to the Secretary within
15 30 days of the date on which
16 the covered outpatient drug
17 is dispensed; and

18 “(DD) submits an at-
19 testation signed by a quali-
20 fied representative con-
21 firming compliance with the
22 requirements of subitems
23 (AA) and (BB), and docu-
24 mentation demonstrating
25 such compliance, to the Sec-

1 retary and the manufacturer
2 on an annual basis; and

3 “(bb) the Secretary, through
4 operation of the claims reposi-
5 tory—

6 “(AA) requests and re-
7 ceives, in the most efficient
8 and least burdensome man-
9 ner practicable, standardized
10 claims data;

11 “(BB) requests, re-
12 ceives, and maintains data
13 described in subitem (AA) in
14 a confidential manner;

15 “(CC) ensures that
16 claims-level data submis-
17 sions by covered entities are
18 complete and accurate, and
19 if not, obtain complete and
20 accurate data from the cov-
21 ered entity;

22 “(DD) notifies of any
23 violation described in
24 subitem (BB), and when
25 necessary to allow for reme-

1 diation, shares such data
2 with the purpose of pre-
3 venting any violations of this
4 section with, the covered en-
5 tity, the State Medicaid
6 agency, the manufacturer,
7 the Veterans Health Admin-
8 istration, and the Depart-
9 ment of Defense, as applica-
10 ble;

11 “(EE) allows covered
12 entities except those de-
13 scribed under subparagraph
14 (L), (M), (N), or (O) of
15 paragraph (4) the option of
16 submitting claims level data
17 on an aggregated retrospec-
18 tive basis that does not re-
19 quire the application of
20 modifiers on individual
21 claims or point-of-sale iden-
22 tification.

23 “(ii) COVERED ENTITIES PASSING
24 SAVINGS, DISCOUNTS, OR REBATES TO PA-
25 TIENTS.—Covered entities that elect to

1 make all outpatient drugs available to pa-
2 tients at a cost of not more than the ceil-
3 ing price (plus a nominal dispensing fee
4 that shall not exceed an amount deter-
5 mined by the Secretary) may opt to—

6 “(I) participate in the program
7 through a discount mechanism subject
8 to clause (i)(I);

9 “(II) participate in the program
10 through a rebate mechanism pursuant
11 to clause (i)(II), under which all un-
12 disputed claims will be paid [within 7
13 days of receiving a claim/upon receipt
14 of the claim]; or

15 “(III) participate in the program
16 through a claims repository pursuant
17 to clause (i)(III).

18 “(iii) STANDARDIZED CLAIMS DATA.—
19 The following data fields shall constitute
20 standardized claims data required to be
21 submitted by a covered entity for purposes
22 of claiming a discount or rebate as de-
23 scribed in clause (i):

24 “(I) Healthcare Encounter Data,
25 including the Billing Service Provider

1 ID, date of service, Rendering Physi-
2 cian ID, HCPCS Code, Diagnosis
3 COD, and Place of Service Code.

4 “(II) As appropriate for the set-
5 ting in which the drug is dispensed,
6 one of the following:

7 “(aa) For retail claims, the
8 Unique Transaction ID, RX
9 Identifier (RXID), Fill Number,
10 NDC11, Quantity, Unit of Meas-
11 ure, days supply, Ordering Physi-
12 cian NPI, CE Submitted (340B
13 ID), Pharmacy ID (DEA, HIN
14 or NPI), date of service, paid
15 date, BIN, PCN, GRP, and
16 Claims Modifiers.

17 “(bb) For medical claims,
18 the Unique Transaction ID,
19 NDC11, Quantity, Unit of Meas-
20 ure, days supply, Patient ID
21 (Tokenized), Ordering Physician
22 NPI, CE Submitter (340B ID or
23 NPI), CE Administration Loca-
24 tion (340B ID), CE Administra-
25 tion Location – Medical (NPI),

1 date of service, paid date, In-
2 sured's Plan Name or Program
3 Name, Insured's Policy Group or
4 FECA Number, and Claims
5 Modifiers.

6 “(III) Additional data as re-
7 quired by the Secretary to prevent di-
8 version, duplication of discounts, or
9 fulfill other requirements under this
10 section.

11 “(iv) RESPONSIBILITIES OF THE SEC-
12 RETARY.—As part of the auditing of cov-
13 ered entities and manufacturers, the Sec-
14 retary shall provide monitoring and over-
15 sight of each manufacturer's operation of
16 discount or rebate systems and covered en-
17 tities' participation in such systems, in-
18 cluding by reviewing the discount or rebate
19 conditions set by covered entities. Such
20 oversight shall include review for alleged
21 overcharges pursuant to subsection (d).”;

22 (3) by amending subparagraph (C) of para-
23 graph (5) to read as follows:

24 “(C) AUDITING.—A covered entity shall
25 permit the Secretary and the manufacturer of a

1 covered outpatient drug that is subject to an
2 agreement under this subsection with the entity
3 (acting in accordance with procedures estab-
4 lished by the Secretary relating only to the
5 number, duration, and scope of audits) to con-
6 duct routine audits and audits for cause, at the
7 Secretary's or the manufacturer's expense, with
8 the option to utilize the manufacturer's internal
9 auditing staff at either the Secretary's or man-
10 ufacturer's discretion, the records of the entity
11 that directly pertain to the entity's compliance
12 with the requirements described in subpara-
13 graphs (A) or (B) with respect to drugs of the
14 manufacturer.”;

15 (4) in paragraph (7)—

16 (A) in the paragraph heading, by striking
17 “OF CERTAIN” and inserting “AND RECERTIFI-
18 CATION OF”;

19 (B) in subparagraph (A)—

20 (i) by striking “this section” and in-
21 sserting “the 340B Drug Pricing Integrity
22 and Affordability for Patients Act”; and

23 (ii) by striking “subparagraphs (J)
24 and (K) of”;

1 (C) by amending subparagraph (B) to read
2 as follows:

3 “(B) INCLUSION OF PURCHASE AND PROF-
4 IT INFORMATION.—The process developed
5 under subparagraph (A) shall include a require-
6 ment that an entity described in subparagraph
7 (J) or (K) of paragraph (4) applying for certifi-
8 cation or recertification submit information to
9 the Secretary concerning the amount such enti-
10 ty expended for covered outpatient drugs, and,
11 in the case of recertification, the total revenues
12 generated for such covered outpatient drugs in
13 the preceding year.”;

14 (D) in subparagraph (C), by striking
15 “make available to all manufacturers of covered
16 outpatient drugs” and inserting “make publicly
17 available”;

18 (E) in subparagraph (D), by striking “sub-
19 paragraphs (J) and (K) of”;

20 (F) in subparagraph (E), by striking “a
21 not more frequent basis than” and inserting
22 “an”; and

23 (G) by adding at the end the following:

24 “(F) PENALTIES FOR MISREPRESENTA-
25 TIONS AND MISSTATEMENTS.—Any covered en-

1 tity that knowingly misrepresents or misstates
2 information under this section shall be subject
3 to a civil monetary penalty for each covered
4 outpatient drug that was unlawfully purchased
5 by the entity through the program under this
6 section as a result of an improper certification
7 or recertification, in an amount not to exceed 2
8 times the total amount of the discounts or re-
9 bates provided to the entity under paragraph
10 (2)(C) for any period during which the mis-
11 representations or misstatements applied.”; and
12 (5) in the heading of paragraph (10), by insert-
13 ing “OR REBATE” after “DISCOUNT”.

14 **SEC. 3. AMENDMENTS TO THE ELIGIBILITY OF SUB-**
15 **GRANTEES.**

16 Section 340B(a)(7) of the Public Health Service Act
17 (42 U.S.C. 256b(a)(7)) is amended—

18 (1) by redesignating subparagraph (E) as sub-
19 paragraph (G); and

20 (2) by inserting after subparagraph (D) the fol-
21 lowing:

22 “(E) SUBGRANTEE DATA SUBMISSIONS.—

23 The process developed under subparagraph (A)
24 shall include a requirement that an entity ap-

1 plying for certification under this paragraph
2 submit to the Secretary—

3 “(i) information on the grant received
4 by the entity under title XXVI that estab-
5 lishes the entity’s eligibility as a covered
6 entity described in paragraph (4)(J) or
7 under section 318 that establishes the enti-
8 ty’s eligibility as a covered entity described
9 in paragraph (4)(K);

10 “(ii) information regarding the enti-
11 ty’s status as a public or nonprofit entity;
12 and

13 “(iii) certification by the entity that—

14 “(I) revenues generated by par-
15 ticipation in the program under this
16 section are consistent with the scope
17 of the grant described in clause (i);
18 and

19 “(II) the patient population
20 treated by the entity is primarily low
21 income or uninsured.

22 **[(F) SUBGRANTEE LIMITATIONS.—**An
23 entity shall not be a covered entity described in
24 subparagraph (J) or (K) of paragraph (4) if the
25 entity receives only in-kind contributions pur-

1 chased with funds appropriated pursuant to
2 title XXVI or section 318, as applicable.”.]

3 **SEC. 4. ADDITIONAL DEFINITIONS.**

4 Section 340B(b) of the Public Health Service Act (42
5 U.S.C. 256b(b)) is amended by adding at the end the fol-
6 lowing:

7 “(3) PATIENT.—In this section, the term ‘pa-
8 tient’ means an individual who—

9 “(A) with respect to a covered entity and
10 each covered outpatient drug—

11 “(i) has received an outpatient health
12 care service at the covered entity within
13 the preceding 2 years;

14 “(ii) has a relationship with the cov-
15 ered entity such that the covered entity
16 creates and maintains an auditable medical
17 record in a form and manner consistent
18 with Federal and State law, that dem-
19 onstrates the existence of a patient rela-
20 tionship in accordance with this paragraph,
21 and maintains such record for a period of
22 at least 3 years, or longer if required by
23 Federal and State law; and

24 “(iii) received the prescription or
25 order for the covered outpatient drug from

1 a practitioner as a result of an outpatient
2 health care service described in clause (i)
3 or as a result of a referral; or

4 “(B) is registered in a State-operated
5 AIDS drug purchasing assistance program re-
6 ceiving financial assistance under title XXVI.

7 “(4) OUTPATIENT HEALTH CARE SERVICE.—In
8 this section, the term ‘*outpatient* health care service’
9 means an outpatient health care service—

10 “(A) that is paid by the insurer or third-
11 party payor as outpatient items and services (or
12 where third-party reimbursement is not made,
13 such items and services are deemed outpatient
14 if less than 24 hours have elapsed between such
15 individual’s hospital registration and discharge);
16 or

17 “(B) in the case of a covered entity de-
18 scribed in any of subparagraphs (A) through
19 (K) of subsection (a)(4), that is consistent with
20 the scope of the grant or designation described
21 in the applicable such subparagraph.

22 “(5) PRACTITIONER.—In this section, the term
23 ‘practitioner’ means a health care provider who—

24 “(A)(i) is an employee or independent con-
25 tractor of a covered entity, and the covered en-

1 tity bills for the outpatient health care service
2 and is responsible for the care furnished by the
3 practitioner; or

4 “(ii) furnishes the outpatient health care
5 service to the individual on behalf of the cov-
6 ered entity under an ongoing contractual obliga-
7 tion to the covered entity such that the covered
8 entity maintains clinical responsibility for the
9 health care provided to the individual that re-
10 sulted in the individual receiving a prescription
11 or order for the covered outpatient drug, if
12 state law prohibits or substantially limits the
13 ability of the covered entity to bill for services
14 of the practitioner; and

15 “(B) is not excluded, pursuant to section
16 1128 of the Social Security Act, from participa-
17 tion in the Medicare Program or a State health
18 care program as defined in section 1128(h) of
19 the Social Security Act.

20 “(6) SPECIFIED NONHOSPITAL COVERED ENTI-
21 TY.—

22 “(A) IN GENERAL.—In this section, the
23 term ‘specified nonhospital covered entity’
24 means a covered entity that—

1 “(i) is described in one of subpara-
2 graphs (B) through (K) of subsection
3 (a)(4), other than a covered entity de-
4 scribed in subparagraph (G) of such sub-
5 section, and—

6 “(I) has average annual oper-
7 ating revenues exceeding
8 \$1,000,000,000 calculated over the
9 most recent 3-year period for which
10 data are available, which revenue
11 threshold shall be adjusted for infla-
12 tion annually to reflect rate of change
13 in the Consumer Price Index for all
14 urban consumers published by the Bu-
15 reau of Labor Statistics; or

16 “(II) is an affiliate of a hospital;
17 or

18 “(ii) is described in subsection
19 (a)(4)(A) and becomes affiliated with a
20 hospital on or after **【December 1, 2025】**.

21 “(B) AFFILIATE.—

22 “(i) IN GENERAL.—For purposes of
23 subparagraph (A), the term ‘affiliate’
24 means an entity that, directly or indirectly,
25 controls, is controlled by, or is under com-

1 mon control with the referenced entity,
2 which may include the referenced entity's
3 parent.

4 “(ii) CONTROL.—For purposes of
5 clause (i), the term ‘control’ means the
6 power to direct the management and poli-
7 cies of an entity, directly or indirectly,
8 whether through the ownership of voting
9 securities, by contract, or otherwise.”.

10 **SEC. 5. CONTRACT PHARMACIES.**

11 Section 340B(a)(5) of the Public Health Service Act
12 (42 U.S.C. 256b(a)(5)) is amended by adding at the end
13 the following:

14 “(E) CONTRACT PHARMACIES.—

15 “(i) IN GENERAL.—Subject to the
16 conditions set forth in this subparagraph,
17 a covered entity may enter into written
18 agreements with contract pharmacies to
19 dispense to patients of such entity covered
20 outpatient drugs purchased by such entity
21 under the 340B program. Subject to such
22 conditions, a manufacturer of covered out-
23 patient drugs shall ship or facilitate ship-
24 ment of such drugs to contract pharmacies
25 at the request of such covered entity. Ex-

1 cept with respect to covered outpatient
2 drugs shipped to and dispensed by a con-
3 tract pharmacy as provided in this sub-
4 paragraph, and notwithstanding any other
5 provision in this section, a manufacturer of
6 covered outpatient drugs shall have no ob-
7 ligation to pay a discount or rebate under
8 this section with respect to covered out-
9 patient drugs delivered or otherwise trans-
10 ferred to any location other than a reg-
11 istered address of the covered entity (in-
12 cluding an entity pharmacy or child site
13 (as described in subparagraph (I)(i)), as
14 applicable) listed in the identification sys-
15 tem described in subsection (d)(2)(B)(iv).

16 “(ii) CONDITIONS FOR COVERED EN-
17 TITY USE OF CONTRACT PHARMACIES.—In
18 order for a covered entity to enter into a
19 written agreement with a contract phar-
20 macy to dispense to patients of such entity
21 covered outpatient drugs purchased by
22 such entity under the program under this
23 section, the entity shall—

24 “(I)(aa) be described in one of
25 subparagraphs (A) through (K) of

1 paragraph (4) and purchase covered
2 outpatient drugs for its patients with-
3 in the scope of the Federal grant,
4 project, or Federal grant-authorizing
5 statute, as applicable, that qualifies
6 such entity for participation in the
7 program under this section; or

8 “(bb) be described in one of sub-
9 paragraphs (L) through (O) of para-
10 graph (4);

11 “(II) establish and implement
12 compliance procedures to satisfy the
13 requirements described in subpara-
14 graphs (A), (B), (F), (G) (as applica-
15 ble), and (H) (as applicable) of para-
16 graph (5) and section 1193(d) of the
17 Social Security Act with respect to
18 covered outpatient drugs purchased by
19 the covered entity under this section,
20 including with respect to such drugs
21 dispensed by a contract pharmacy,
22 which compliance procedures shall be
23 considered records of the covered enti-
24 ty subject to audit under subpara-
25 graph (C);

1 “(III) prior to purchasing cov-
2 ered outpatient drugs subject to an
3 agreement under this section to be
4 shipped to or dispensed by such phar-
5 macy, register such pharmacy in the
6 identification system described in sub-
7 section (d)(2)(B)(iv) as a contract
8 pharmacy, to include such pharmacy’s
9 national provider identifier, and cer-
10 tify to the Secretary upon initial reg-
11 istration of such pharmacy in such
12 system and annually thereafter that
13 such pharmacy complies with all re-
14 quirements under this subparagraph,
15 including the covered entity compli-
16 ance procedures described in sub-
17 clause (II); and

18 “(IV) as applicable, comply with
19 the requirements and limitations set
20 forth in clauses (iii) through (vii) of
21 this subparagraph.

22 “(iii) LIMITATION ON CONTRACT
23 PHARMACIES FOR CERTAIN HOSPITAL COV-
24 ERED ENTITIES.—Notwithstanding clause
25 (ii), a covered entity described in para-

1 graph (4)(L), a free-standing cancer hos-
2 pital described in paragraph (4)(M), and a
3 rural referral center described in para-
4 graph (4)(O) may not enter into written
5 agreements with more than 5 contract
6 pharmacies to dispense covered outpatient
7 drugs purchased by the covered entity
8 under this section to patients of such enti-
9 ty under this subparagraph. For purposes
10 of this clause, a contract pharmacy shall
11 not include a mail order pharmacy.

12 “(iv) SERVICE AREA REQUIREMENT
13 FOR ELIGIBLE CONTRACT PHARMACIES.—
14 A contract pharmacy with which a covered
15 entity enters into a written agreement to
16 dispense covered outpatient drugs to pa-
17 tients of such entity subject to the condi-
18 tions in this subparagraph shall be located
19 in the service area of the covered entity (as
20 defined in clause (x)(IV)). Notwithstanding
21 any other provision in this subparagraph,
22 this clause (iv) shall not apply with respect
23 to a covered entity described in paragraph
24 (4)(G) or a contract pharmacy that is a
25 mail order pharmacy.

1 “(v) REQUIREMENTS FOR USE OF
2 MAIL ORDER PHARMACIES.—

3 “(I) IN GENERAL.—Notwith-
4 standing any other provision of this
5 section, a covered outpatient drug
6 subject to an agreement under this
7 section may be dispensed to a patient
8 of a covered entity through a mail
9 order pharmacy only if—

10 “(aa) the covered entity dis-
11 pensing such drug (or on whose
12 behalf such drug is dispensed)
13 through a mail order pharmacy
14 to such a patient is described in
15 one of subparagraphs (A)
16 through (K) of paragraph (4),
17 such entity is not a specified non-
18 hospital covered entity (as de-
19 fined in subsection (b)(6)), and,
20 except for a covered entity de-
21 scribed in paragraph (4)(G), the
22 patient dispensed such drug re-
23 sides within the service area of
24 the covered entity (as defined in
25 clause (x)(IV)); or

1 “(bb) the covered entity dis-
2 pensing such drug (or on whose
3 behalf such drug is dispensed)
4 through a mail order pharmacy
5 to such a patient is described in
6 subparagraph (N) of paragraph
7 (4) or is a sole community hos-
8 pital described in subparagraph
9 (O) of such paragraph, and the
10 patient dispensed such drug re-
11 sides in a county that is not part
12 of a Metropolitan Statistical
13 Area, as defined by the Office of
14 Management and Budget.

15 “(II) REQUIREMENTS FOR USE
16 OF MAIL ORDER CONTRACT PHAR-
17 MACIES.—Subject to the conditions
18 set forth in this subparagraph, a cov-
19 ered entity described in item (aa) or
20 (bb) of subclause (I) may enter into
21 written agreements with contract
22 pharmacies that are mail order phar-
23 macies to dispense to patients de-
24 scribed in such relevant clause covered
25 outpatient drugs purchased by such

1 covered entity in violation of subpara-
2 graph (B), that the patient afford-
3 ability requirements specified in sub-
4 paragraphs (G) and (H), as applica-
5 ble, are appropriately applied at the
6 point of drug dispense or administra-
7 tion, that data and other information
8 is submitted in accordance with sub-
9 paragraph (F), and that the non-
10 duplication requirement in section
11 1193(d) of the Social Security Act is
12 satisfied; and

13 “(II) written agreements between
14 covered entities and contract phar-
15 macies described in clause (vii).

16 “(vii) WRITTEN AGREEMENT RE-
17 QUIRED.—The written agreement between
18 a covered entity and a contract pharmacy
19 described in this subparagraph shall in-
20 clude binding and enforceable obligations
21 on the contract pharmacy to comply with
22 the covered entity’s compliance procedures
23 described in clause (ii)(II) with respect to
24 covered outpatient drugs dispensed to pa-
25 tients of such entity in accordance with

1 this subparagraph. Within 30 days of the
2 applicable effective date of such written
3 agreement, including any amendment or
4 addendum thereto, the covered entity shall
5 submit a copy of the agreement, together
6 with any amendments or addenda, to the
7 Secretary in a form and manner specified
8 by the Secretary. The Secretary shall re-
9 view all such agreements, including amend-
10 ments and addenda, for compliance with
11 the requirements set forth in this subpara-
12 graph and may require a covered entity
13 and contract pharmacy to modify an agree-
14 ment to conform to the requirements of
15 this subparagraph. Such agreements, in-
16 cluding amendments and addenda, shall be
17 considered records of the covered entity
18 subject to audit under subparagraph (C).

19 “(viii) CLARIFICATION FOR COVERED
20 OUTPATIENT DRUGS SUBJECT TO RE-
21 STRICTED DISTRIBUTION.—Notwith-
22 standing any other provision of this sec-
23 tion, a manufacturer of a covered out-
24 patient drug requiring exclusive use of a
25 specialty pharmacy or a restricted distribu-

1 tion network shall be deemed to have satis-
2 fied its obligations under this subpara-
3 graph with respect to a contract pharmacy
4 if such manufacturer offers each covered
5 entity such drug for purchase at or below
6 the applicable ceiling price described in
7 paragraph (1) through a wholesaler, dis-
8 tributor, or pharmacy included in the re-
9 stricted distribution network for such drug.

10 “(ix) PENALTIES FOR CONTRACT
11 PHARMACY COMPLIANCE VIOLATIONS.—

12 “(I) IN GENERAL.—A contract
13 pharmacy that is found to have vio-
14 lated the covered entity compliance
15 procedures described in clause (ii)(II),
16 violated subparagraph (A), or violated
17 subparagraph (B) shall—

18 “(aa) in the first instance of
19 such violation, be liable to a man-
20 ufacturer of a covered outpatient
21 drug that is the subject of such
22 violation in an amount equal to
23 the reduction in the price of such
24 drug (as described in subsection
25 (a)(1)), plus interest on such

1 amount, which shall be com-
2 pounded monthly and equal to
3 the current short-term interest
4 rate as determined by the Fed-
5 eral Reserve for the time period
6 for which the covered entity is
7 liable;

8 “(bb) in the second instance
9 of such violation—

10 “(AA) be liable to a
11 manufacturer of a covered
12 outpatient drug that is the
13 subject of such violation in
14 an amount equal to the re-
15 duction in the price of the
16 drug (as described in para-
17 graph (1)), plus interest on
18 such amount, which shall be
19 calculated in the manner
20 specified in item (aa); and

21 “(BB) be required to
22 pay a civil monetary penalty
23 equal to \$3,000 for each
24 claim for a covered out-
25 patient drug that is subject

1 to the violation, which
2 amount shall be adjusted for
3 inflation annually to reflect
4 the rate of change in the
5 Consumer Price Index for
6 all urban consumers pub-
7 lished by the Bureau of
8 Labor Statistics; and

9 “(cc) in the third instance of
10 such violation—

11 “(AA) be liable to a
12 manufacturer of a covered
13 outpatient drug that is the
14 subject of such violation in
15 an amount equal to the re-
16 duction in the price of the
17 drug (as described in para-
18 graph (1)), plus interest on
19 such amount, which shall be
20 calculated in the manner
21 specified in item (aa);

22 “(BB) be required to
23 pay a civil monetary penalty
24 equal to \$3,000 for each
25 claim for a covered out-

1 patient drug that is subject
2 to the violation, which
3 amount shall be adjusted for
4 inflation annually to reflect
5 the rate of change in the
6 Consumer Price Index for
7 all urban consumers pub-
8 lished by the Bureau of
9 Labor Statistics; and
10 “(CC) be removed from
11 the program under this sec-
12 tion and disqualified from
13 reentry into such program
14 for a period of not less than
15 2 years, or such longer pe-
16 riod as the Secretary may
17 determine based on the se-
18 verity of the violation (or
19 violations) and the risk such
20 pharmacy presents to the in-
21 tegrity of the program, with
22 no ability to reenter the pro-
23 gram unless and until the
24 Secretary determines such
25 pharmacy has resolved the

1 violation (or violations) and
2 taken reasonable steps to
3 prevent similar future viola-
4 tions.

5 “(II) CORRECTIVE ACTION
6 PLAN.—In the first instance of a vio-
7 lation described in subclause (I)(aa),
8 in the second instance of a violation
9 described in subclause (I)(bb), and
10 prior to reentry into the program fol-
11 lowing a violation described in sub-
12 clause (I)(cc)—

13 “(aa) the pharmacy shall
14 conduct an internal review to
15 identify the cause of the violation
16 (or violations) that is inclusive of
17 all calendar quarters within the
18 period in which such violation (or
19 violations) occurred and all cov-
20 ered outpatient drugs subject to
21 an agreement under this section
22 dispensed during such period;

23 “(bb) the pharmacy shall
24 prepare a written corrective ac-
25 tion plan, in a form specified by

1 the Secretary, which shall in-
2 clude, at a minimum, the results
3 of such internal review, the phar-
4 macy's methodology for identi-
5 fying the full scope of such viola-
6 tion (or violations), and the phar-
7 macy's proposed corrective ac-
8 tions, and submit such plan to
9 the Secretary in a form and man-
10 ner specified by the Secretary;
11 and

12 “(cc) the Secretary shall re-
13 view such plan, notify the phar-
14 macy of any revisions to such
15 plan, including additional correc-
16 tive actions, necessary for the
17 Secretary to approve such plan,
18 and publish the approved plan on
19 a public website of the Depart-
20 ment of Health and Human
21 Services (with redactions of any
22 confidential or proprietary infor-
23 mation).

24 “(III) CIVIL MONETARY PENALTY
25 FOR VIOLATIONS BY REMOVED PHAR-

1 MACY.—A contract pharmacy removed
2 from the program under this section
3 pursuant to subclause (I)(cc) that dis-
4 penses a covered outpatient drug sub-
5 ject to an agreement under this sec-
6 tion during a time period that such
7 pharmacy is removed from the pro-
8 gram and is not approved for reentry
9 shall be required to pay a civil mone-
10 tary penalty equal to \$3,000 for each
11 claim for each such drug dispensed
12 during such period, which amount
13 shall be adjusted for inflation annu-
14 ally to reflect the rate of change in
15 the Consumer Price Index for all
16 urban consumers published by the Bu-
17 reau of Labor Statistics.

18 “(IV) PROCEDURES AND DELE-
19 GATION.—The provisions of section
20 1128A of the Social Security Act
21 (other than subsections (a) and (b))
22 shall apply for purposes of any pay-
23 ment, civil monetary penalty, or re-
24 moval described in this clause in the
25 same manner as such provisions apply

1 to a penalty or proceeding under sec-
2 tion 1128A(a). The Office of Inspec-
3 tor General of the Department of
4 Health and Human Services shall
5 carry out the provisions of this clause.

6 “(x) DEFINITIONS.—In this subpara-
7 graph:

8 “(I) CONTRACT PHARMACY.—
9 The term ‘contract pharmacy’ means,
10 with respect to a covered entity de-
11 scribed in clause (ii), any individual
12 pharmacy (as determined by a na-
13 tional provider identifier unique to the
14 pharmacy address) that is—

15 “(aa) licensed as a phar-
16 macy by the relevant State (or
17 States);

18 “(bb) authorized to dispense
19 covered outpatient drugs subject
20 to an agreement under this sec-
21 tion to patients of such entity (as
22 defined in subsection (b)(3)) pur-
23 suant to a valid written agree-
24 ment with such entity (as de-

40

1 scribed in this subparagraph);

2 and

3 “(cc) not an entity phar-
4 macy.

5 “(II) ENTITY PHARMACY.—The
6 term ‘entity pharmacy’ means any in-
7 dividual pharmacy (as determined by
8 a national provider identifier unique
9 to the pharmacy address) that is—

10 “(aa)(AA) licensed as a
11 pharmacy by the relevant State
12 (or States); and

13 “(BB) the same legal entity
14 as a covered entity and located
15 within the covered entity’s service
16 area, if the covered entity is de-
17 scribed in one of subparagraphs
18 (A) through (K) of paragraph (4)
19 and is not a specified nonhospital
20 covered entity (as defined in sub-
21 section (b)(6)); or

22 “(bb) the same legal entity
23 as a covered entity and located
24 within the covered entity’s 4
25 walls, if the covered entity is de-

1 scribed in one of subparagraphs
2 (L) through (O) of paragraph (4)
3 or is a specified nonhospital cov-
4 ered entity (as defined in sub-
5 section (b)(6)).

6 “(III) MAIL ORDER PHAR-
7 MACY.—The term ‘mail order phar-
8 macy’ is a pharmacy that is licensed
9 as a pharmacy by the State (or
10 States) and that dispenses prescrip-
11 tion medications to individuals pri-
12 marily through the mail, as deter-
13 mined in accordance with guidance
14 issued by the Secretary in connection
15 with part 447, subpart I of title 42 of
16 the Code of Federal Regulations (or
17 any successor regulations).

18 “(IV) SERVICE AREA.—The term
19 ‘service area’ means, with respect to a
20 covered entity described in paragraph
21 (4), other than a covered entity de-
22 scribed in subparagraph (G) of such
23 paragraph, the Public Use Microdata
24 Area (as defined by the United States
25 Census Bureau) in which such entity

1 is located and all Public Use
2 Microdata Areas that are contiguous
3 with the Public Use Microdata Area
4 in which such entity is located, each
5 of which shall be listed in the identi-
6 fication system described in subsection
7 (d)(2)(B)(iv).

8 “(xi) RULES OF CONSTRUCTION.—

9 “(I) LOCATION.—For purposes
10 of this subparagraph, the location of a
11 covered entity shall be determined
12 based on the physical address of the
13 entity listed in the identification sys-
14 tem described in subsection
15 (d)(2)(B)(iv) without regard to any
16 off-campus outpatient facilities (pro-
17 vided that, for purposes of this sub-
18 clause, the term ‘campus’ has the
19 meaning given such term in section
20 413.65(a)(2) of title 42, Code of Fed-
21 eral Regulations (or any successor
22 regulations)).

23 “(II) SAME LEGAL ENTITY.—For
24 purposes of this subparagraph, a
25 pharmacy is the same legal entity as

1 the covered entity if the name, owner-
2 ship, and employer identification num-
3 ber of the pharmacy is identical to the
4 name, ownership, and employer identi-
5 fication number of the covered enti-
6 ty.”.

7 **SEC. 6. TRANSPARENCY.**

8 (a) IN GENERAL.—Section 340B(a)(5) of the Public
9 Health Service Act (42 U.S.C. 256b(a)(5)), as amended
10 by section 5, is further amended by adding at the end the
11 following:

12 “(F) REPORTING.—

13 “(i) IN GENERAL.—During the first
14 **[calendar]** year beginning on or after the
15 date that is 14 months after the date of
16 enactment of this subparagraph and dur-
17 ing each subsequent year the following re-
18 porting requirements shall apply:

19 “(I) DSH REPORTING.—Each
20 covered entity described in subpara-
21 graph (L) of paragraph (4) (and any
22 other covered entity specified by the
23 Secretary) shall report to the Sec-
24 retary (at a time and in a form and
25 manner specified by the Secretary)

1 the following information with respect
2 to the preceding year:

3 “(aa) Such entity shall re-
4 port, with respect to such a cov-
5 ered entity and each child site, as
6 applicable, of such entity, the
7 margin generated on covered out-
8 patient drugs subject to an
9 agreement under this section dis-
10 pensed or furnished by such enti-
11 ty or site (and any entity phar-
12 macy or contract pharmacy dis-
13 pensing such drugs on behalf of
14 such entity in accordance with
15 subparagraph (E)), as follows:

16 “(AA) Such a covered
17 entity (which shall include
18 child sites of the entity) with
19 net patient revenues (as de-
20 fined in line 3 of Worksheet
21 G3 of the Medicare cost re-
22 port or in any successor
23 form) for **[such]/[the pre-**
24 **ceding]** year that is less
25 than \$200,000,000 (which

45

1 amount shall be increased
2 for a subsequent year by the
3 percentage increase in the
4 Consumer Price Index for
5 all urban consumers for the
6 12-month period ending with
7 **【June】** of the previous
8 year) shall report the mar-
9 gin in the aggregate by sub-
10 tracting the aggregate net
11 costs to acquire such covered
12 outpatient drugs from ag-
13 gregate payments received
14 for such covered outpatient
15 drugs.

16 “(BB) Such a covered
17 entity (which shall include
18 child sites of the entity) with
19 net patient revenues (as de-
20 fined in line 3 of Worksheet
21 G3 of the Medicare cost re-
22 port or in any successor
23 form) for **【such】/【the pre-
24 ceding】** year that is equal to
25 or greater than

47

1 (which amount shall be increased
2 for a subsequent year by the per-
3 centage increase in the Consumer
4 Price Index for all Urban Con-
5 sumers for the 12-month period
6 ending with **【June】** of the pre-
7 vious year) that is a private non-
8 profit hospital shall submit a
9 copy of each contract (including
10 any appendices or addenda or
11 subsequent amendments) with a
12 State or local government to pro-
13 vide health care services to low-
14 income individuals who are unin-
15 sured to the Secretary.

16 “(cc) Each such covered en-
17 tity (which shall include child
18 sites of the entity) with net pa-
19 tient revenues (as defined in line
20 3 of Worksheet G3 of the Medi-
21 care cost report or in any suc-
22 cessor form) for **【such】/【the pre-
23 ceding】** year that is equal to or
24 greater than \$1,000,000,000
25 (which amount shall be increased

1 for a subsequent year by the per-
2 centage increase in the Consumer
3 Price Index for all Urban Con-
4 sumers for the 12-month period
5 ending with **【June】** of the pre-
6 vious year) shall report, with re-
7 spect to such covered entity and
8 each child site and contract phar-
9 macy, as applicable, of such enti-
10 ty, the following:

11 “(AA) The total num-
12 ber of individuals who were
13 dispensed or administered
14 covered outpatient drugs
15 during such preceding year
16 that were subject to an
17 agreement under this sec-
18 tion.

19 “(BB) The number of
20 such individuals described in
21 a category specified in
22 clause (iii), broken down by
23 each such category.

24 “(CC) The percentage
25 of the total number of indi-

1 viduals furnished items and
2 services during such pre-
3 ceding year who were dis-
4 pensed or administered cov-
5 ered outpatient drugs during
6 such preceding year that
7 were subject to an agree-
8 ment under this section.

9 “(DD) For each cat-
10 egory specified in clause
11 (iii), the percentage of the
12 total number of individuals
13 described in such category
14 furnished items and services
15 during such preceding year
16 who were dispensed or ad-
17 ministered covered out-
18 patient drugs during such
19 preceding year that were
20 subject to an agreement
21 under this section.

22 “(II) REPORTING ON CHARITY
23 CARE.—Each covered entity described
24 in one of subparagraphs (L) through
25 (O) of paragraph (4) with net patient

1 revenues (as defined in line 3 of
2 Worksheet G3 of the Medicare cost
3 report or in any successor form) for
4 **【such】/【the preceding】** year that is
5 equal to or greater than
6 \$1,000,000,000 (which amount shall
7 be increased for a subsequent year by
8 the percentage increase in the Con-
9 sumer Price Index for all Urban Con-
10 sumers for the 12-month period end-
11 ing with **【June】** of the previous year)
12 shall report, with respect to such cov-
13 ered entity and each child site, as ap-
14 plicable, of such entity, the total costs
15 incurred during the year at each such
16 site (as defined in line 200, column 3
17 of worksheet C, part 1 of the Medi-
18 care cost report, or in any successor
19 form) and the cost incurred at each
20 such site for charity care (as defined
21 in line 23 of worksheet S-10 to the
22 Medicare cost report, or in any suc-
23 cessor form).

24 “(III) REPORTING BY CAT-
25 EGORIES OF EXPENDITURE.—Each

1 covered entity described in one of sub-
2 paragraphs (A) through (K) of para-
3 graph (4) with net patient revenues
4 for **【such】/【the preceding】** year that
5 is equal to or greater than
6 \$200,000,000 (which amount shall be
7 increased for a subsequent year by the
8 percentage increase in the Consumer
9 Price Index for all Urban Consumers
10 for the 12-month period ending with
11 **【June】** of the previous year) shall re-
12 port use of margin generated on cov-
13 ered outpatient drugs subject to an
14 agreement under this section in the
15 following categories of expenditures, if
16 applicable, which the Secretary shall
17 define in interim final regulations in a
18 manner consistent with reporting
19 under the Health Resources and Serv-
20 ices Administration Uniform Data
21 System (referred to in this subclause
22 as ‘UDS’):

23 “(aa) Medical care.

24 “(bb) Dental care.

25 “(cc) Mental health.

1 “(dd) Pharmaceuticals.

2 “(ee) Sliding fee discounts.

3 “(ff) Case management.

4 “(gg) Transportation.

5 “(hh) Patient and commu-
6 nity education.

7 “(ii) Community health
8 workers.

9 “(jj) Outreach.

10 “(kk) Eligibility assistance.

11 “(ll) Nutritional assessment
12 and referral.

13 “(ii) PUBLICATION.—The Secretary
14 shall publish data reported under clause (i)
15 with respect to a year annually on the pub-
16 lic website of the Department of Health
17 and Human Services in an electronic and
18 searchable format, which may include the
19 340B Office of Pharmacy Affairs Informa-
20 tion System (or a successor to such sys-
21 tem), in a manner that shows each cat-
22 egory of data reported (excluding contracts
23 submitted under clause (i)(I)(bb)) in the
24 aggregate and identified by the specific
25 covered entity submitting such data, and

1 shall publish each contract submitted
2 under clause (i)(I)(bb). The Secretary shall
3 include in such publication the dispropor-
4 tionate patient percentage (as defined in
5 section 1886(d)(5)(F)(vi) of the Social Se-
6 curity Act) of each such covered entity (if
7 applicable) for each cost reporting period
8 occurring during such year.

9 “(iii) CATEGORIES SPECIFIED.—For
10 purposes of clause (i)(I), the categories
11 specified in this clause are the following:

12 “(I) Individuals covered under a
13 group health plan or group or indi-
14 vidual health insurance coverage (as
15 such terms are defined in section
16 2791).

17 “(II) Individuals entitled to bene-
18 fits under part A or enrolled under
19 part B of title XVIII of the Social Se-
20 curity Act.

21 “(III) Individuals enrolled under
22 a State plan under title XIX of such
23 Act (or a waiver of such plan).

24 “(IV) Individuals enrolled under
25 a State child health plan under title

1 XXI of such Act (or a waiver of such
2 plan).

3 “(V) Individuals not described in
4 any of subclauses (I) through (IV)
5 and not covered under any Federal
6 health care program (as defined in
7 section 1128B of such Act but includ-
8 ing the program established under
9 chapter 89 of title 5, United States
10 Code).

11 “(iv) DEFINITIONS.—In this subpara-
12 graph:

13 “(I) CHILD SITE.—The term
14 ‘child site’ has the meaning given such
15 term in subparagraph (I)(i).

16 “(II) ENTITY PHARMACY.—The
17 term ‘entity pharmacy’ has the mean-
18 ing given such term in subparagraph
19 (E).

20 “(III) MARGIN.—The term ‘mar-
21 gin’ means, with respect to covered
22 outpatient drugs purchased by a cov-
23 ered entity under an agreement under
24 this section, the following amount for
25 such drugs dispensed, furnished, or

1 administered to an individual by such
2 entity or a child site of such entity
3 (and any entity pharmacy or contract
4 pharmacy dispensing such drugs on
5 behalf of such entity in accordance
6 with subparagraph (E))—

7 “(aa) aggregate payments
8 received by the covered entity for
9 such drugs from individuals (in-
10 cluding cost-sharing amounts)
11 and third parties, including gov-
12 ernment and private payors;
13 minus

14 “(bb) the sum of—

15 “(AA) aggregate costs
16 to acquire such drugs at ei-
17 ther the ceiling price de-
18 scribed in paragraph (1) or
19 any voluntary subceiling
20 price at which the covered
21 entity purchased such drugs,
22 as applicable; and

23 “(BB) aggregate costs
24 incurred by the covered enti-
25 ty that are necessary for

1 such entity to participate in
2 the program under this sec-
3 tion and to comply with
4 such program’s require-
5 ments, including program-
6 related compliance, legal,
7 educational, and administra-
8 tive costs (such costs shall
9 be determined in accordance
10 with Generally Accepted Ac-
11 counting Principles), and
12 compensation paid to third-
13 party administrators or con-
14 tract pharmacies to carry
15 out program-related func-
16 tions.

17 “(v) CIVIL MONETARY PENALTY.—A
18 covered entity that violates a requirement
19 of this subparagraph shall be subject to a
20 civil monetary penalty of \$3,000 for each
21 such violation, which amount shall be ad-
22 justed for inflation annually to reflect the
23 rate of change in the Consumer Price
24 Index for all urban consumers published by
25 the Bureau of Labor Statistics for the 12-

1 month period ending with **【June】** of the
2 previous year. The provisions of section
3 1128A of the Social Security Act (other
4 than subsections (a) and (b)) shall apply to
5 a civil monetary penalty under this clause
6 in the same manner as such provisions
7 apply to a penalty or proceeding under sec-
8 tion 1128A(a). The Office of Inspector
9 General of the Department of Health and
10 Human Services shall carry out this
11 clause.”.

12 (b) REGULATIONS.—Not later than 180 days after
13 the date of enactment of this Act, the Secretary of Health
14 and Human Services shall issue an interim final rule to
15 carry out section 340B(a)(5)(F) of the Public Health
16 Service Act, as added by subsection (a).

17 **SEC. 7. ENSURING AFFORDABILITY.**

18 Section 340B(a)(5) of the Public Health Service Act
19 (42 U.S.C. 256b(a)(5)), as amended by section 6, is fur-
20 ther amended by adding at the end the following:

21 “(G) PATIENT AFFORDABILITY REQUIRE-
22 MENTS FOR HOSPITAL COVERED ENTITIES.—

23 “(i) IN GENERAL.—Notwithstanding
24 any other provision of law, a covered entity
25 described in one of subparagraphs (L)

1 through (O) of paragraph (4) shall estab-
2 lish a sliding fee scale that results in the
3 covered entity providing, on behalf of an
4 applicable patient, a discount that results
5 in such patient paying no more than the
6 maximum out-of-pocket obligation (as de-
7 fined in clause (ii)), with respect to each
8 covered outpatient drug subject to an
9 agreement under this section dispensed,
10 furnished, or administered to such patient
11 at such covered entity, any child site, or
12 any entity pharmacy. The sliding fee scale
13 and related policies shall be written and
14 posted prominently at each such covered
15 entity location, including any child site and
16 entity pharmacy, and shall be included in
17 any billing-related communications sent by
18 such covered entity to any patient dis-
19 pensed, furnished, or administered a cov-
20 ered outpatient drug at such covered entity
21 location, including any child site or entity
22 pharmacy. Eligibility for a reduced out-of-
23 pocket obligation pursuant to this clause
24 shall be based on insurance and income in-
25 formation provided by the applicable pa-

1 lesser of 30 percent of the otherwise
2 applicable out-of-pocket obligation or
3 \$50, which shall be adjusted for infla-
4 tion annually to reflect rate of the
5 change in the Consumer Price Index
6 for all urban consumers published by
7 the Bureau of Labor Statistics.

8 “(iii) CERTIFICATION OF SLIDING FEE
9 SCALE AVAILABILITY.—Each covered enti-
10 ty required under clause (i) to establish a
11 sliding fee scale shall submit such sliding
12 fee scale to the Secretary, at such time and
13 in such manner as the Secretary deter-
14 mines appropriate to certify compliance,
15 which may be published by the Secretary,
16 as appropriate.

17 “(iv) APPLICABILITY TO CONTRACT
18 PHARMACIES.—With respect to an applica-
19 ble patient of a covered entity described in
20 clause (i) dispensed a covered outpatient
21 drug subject to an agreement under this
22 section on behalf of such covered entity at
23 a contract pharmacy pursuant to subpara-
24 graph (E), such covered entity shall re-
25 quire such contract pharmacy to provide

1 discounts to applicable patients on behalf
2 of such covered entity and comply with all
3 other requirements described in clauses (i)
4 and (ii) as if such contract pharmacy were
5 a covered entity described in clause (i).

6 “(v) DEFINITIONS.—In this subpara-
7 graph:

8 “(I) APPLICABLE PATIENT.—The
9 term ‘applicable patient’ means a pa-
10 tient, as defined in subsection (b)(3),
11 who is not covered under minimum es-
12 sential coverage as defined under sec-
13 tion 5000A(f) of the Internal Revenue
14 Code of 1986 or has family income
15 below 200 percent of the Federal pov-
16 erty guidelines and is covered under a
17 group health plan, health insurance
18 coverage in the individual market or
19 group market (as such terms are de-
20 fined in section 2791 of the Public
21 Health Service Act) or coverage de-
22 scribed in section 156.602(a), title 45,
23 Code of Federal Regulations (or any
24 successor regulation).

1 “(II) CHILD SITE.—The term
2 ‘child site’ has the meaning given such
3 term in subparagraph (I)(i).

4 “(III) CONTRACT PHARMACY.—
5 The term ‘contract pharmacy’ shall
6 have the meaning given such term in
7 subparagraph (E).

8 “(IV) ENTITY PHARMACY.—The
9 term ‘entity pharmacy’ shall have the
10 meaning given such term in subpara-
11 graph (E).

12 “(V) FEDERAL POVERTY GUIDE-
13 LINES.—The term ‘Federal poverty
14 guidelines’ means the poverty guide-
15 lines updated periodically in the Fed-
16 eral Register by the Department of
17 Health and Human Services pursuant
18 to section 673 of the Community
19 Services Block Grant Act.

20 “(VI) OUT-OF-POCKET OBLIGA-
21 TION.—The term ‘out-of-pocket obli-
22 gation’ means any copayment, coin-
23 surance, deductible, or other cost-
24 sharing amount or payment required
25 from an applicable patient in connec-

1 the requirements described in this subpara-
2 graph and shall issue final regulations not
3 later than 90 days after the date of enact-
4 ment of this subparagraph. The authority
5 to promulgate regulations under this clause
6 is limited to specifying the obligations of
7 covered entities and contract pharmacies
8 under this subparagraph and other details
9 necessary to carry out the requirements of
10 this subparagraph efficiently, effectively,
11 and in conformity with this subparagraph.

12 “(viii) **OIG STUDIES.**—The Office of
13 Inspector General of the Department of
14 Health and Human Services shall conduct
15 and publish annual studies of covered enti-
16 ty (including child site and entity phar-
17 macy) and contract pharmacy practices
18 with respect to the requirements under this
19 subparagraph and evaluate whether appli-
20 cable patients are receiving assistance to
21 reduce their out-of-pocket obligations in
22 accordance with this subparagraph.

23 “(H) **PATIENT AFFORDABILITY REQUIRE-**
24 **MENTS FOR CERTAIN NONHOSPITAL COVERED**
25 **ENTITIES.**—

1 “(i) IN GENERAL.—Notwithstanding
2 any other provision of law, a covered entity
3 described in one of subparagraphs (A)
4 through (K) of paragraph (4) that is re-
5 quired by the Federal statute authorizing
6 the grant, project, or contract that is the
7 basis for such entity’s participation in the
8 program under this section to provide af-
9 fordability assistance to eligible individuals
10 receiving health care items or services from
11 such entity shall, with respect to an appli-
12 cable patient (as defined in clause (iii))
13 dispensed or administered a covered out-
14 patient drug subject to an agreement
15 under this section at a covered entity site,
16 including an entity pharmacy, establish a
17 policy that provides a discount to reduce
18 the out-of-pocket obligation of an applica-
19 ble patient with respect to such drug to an
20 amount sufficient to ensure such patient is
21 not denied access to such drug based on
22 such patient’s ability to pay for such drug.

23 “(ii) APPLICABILITY TO CONTRACT
24 PHARMACIES.—With respect to an applica-
25 ble patient of a covered entity described in

1 clause (i) dispensed a covered outpatient
2 drug subject to an agreement under this
3 section on behalf of such covered entity at
4 a contract pharmacy pursuant to subpara-
5 graph (E), such covered entity shall re-
6 quire such contract pharmacy to provide
7 discounts to applicable patients on behalf
8 of such covered entity in accordance with
9 the covered entity's policy described in
10 clause (i).

11 “(iii) DEFINITIONS.—In this subpara-
12 graph:

13 “(I) APPLICABLE PATIENT.—The
14 term ‘applicable patient’ has the
15 meaning given such term in subpara-
16 graph (G).

17 “(II) CONTRACT PHARMACY.—
18 The term ‘contract pharmacy’ has the
19 meaning given such term in subpara-
20 graph (E).

21 “(III) ENTITY PHARMACY.—The
22 term ‘entity pharmacy’ has the mean-
23 ing given such term in subparagraph
24 (E).

1 “(IV) FEDERAL POVERTY GUIDE-
2 LINES.—The term ‘Federal poverty
3 guidelines’ has the meaning given
4 such term in subparagraph (G).

5 “(V) OUT-OF-POCKET OBLIGA-
6 TION.—The term ‘out-of-pocket obli-
7 gation’ has the meaning given such
8 term in subparagraph (G).”.

9 **SEC. 8. HOSPITAL CHILD SITES.**

10 (a) HOSPITAL CHILD SITE REQUIREMENTS.—Sec-
11 tion 340B(a)(5) of the Public Health Service Act (42
12 U.S.C. 256b(a)(5)), as amended by section 7, is further
13 amended by adding at the end the following:

14 “(I) HOSPITAL CHILD SITE REQUIRE-
15 MENTS.—

16 “(i) IN GENERAL.—A covered entity
17 described in one of subparagraphs (L)
18 through (O) of paragraph (4) may register
19 an off-campus outpatient facility associated
20 with such covered entity for inclusion in
21 the identification system described in sub-
22 section (d)(2)(B)(iv) to participate in the
23 program under this section as an integral
24 part of such covered entity if such covered
25 entity demonstrates to the Secretary, in a

1 manner specified by the Secretary, that
2 such facility satisfies each of the require-
3 ments in this subparagraph. For purposes
4 of this section, each facility registered to
5 participate in the program under this sec-
6 tion and satisfying the requirements in this
7 subparagraph shall be referred to as a
8 ‘child site’.

9 “(I) The facility is listed on the
10 covered entity’s most recently filed
11 Medicare cost report on a line that is
12 reimbursable under the Medicare pro-
13 gram (or, if the covered entity is a
14 children’s hospital that does not file a
15 Medicare cost report, the covered enti-
16 ty submits to the Secretary a signed
17 statement certifying that the facility
18 would be correctly included on a reim-
19 bursable line of a Medicare cost report
20 if the covered entity filed a cost re-
21 port).

22 “(II) Such cost report dem-
23 onstrates that the services provided at
24 the facility have associated costs and
25 charges for hospital outpatient depart-

1 ment services under title XVIII of the
2 Social Security Act (or, if the covered
3 entity is a children’s hospital that
4 does not file a Medicare cost report,
5 the covered entity submits to the Sec-
6 retary a signed statement certifying
7 that the services provided at the facil-
8 ity include outpatient services).

9 “(III) The facility is wholly
10 owned by the covered entity.

11 “(IV) The Secretary has made a
12 determination, under the process de-
13 scribed in section 413.65(b) of title
14 42, Code of Federal Regulations (or
15 any successor regulations), that the
16 facility meets the Medicare provider-
17 based standards under section 413.65
18 of title 42, Code of Federal Regula-
19 tions (or any successor regulations)
20 for an off-campus outpatient depart-
21 ment of the covered entity.

22 “(V) The facility provides out-
23 patient health care services that are
24 not limited to only dispensing, admin-

1 istering, or otherwise furnishing cov-
2 ered outpatient drugs.

3 “(VI) The facility is subject to
4 and adheres to all charity care and
5 sliding fee scale policies of the covered
6 entity and makes such policies pub-
7 licly available in a manner consistent
8 with requirements established under
9 section 501(r) of the Internal Revenue
10 Code of 1986 applicable to hospital fi-
11 nancial assistance policies.

12 “(VII) The facility is located in
13 an area with a shortage of personal
14 health services that is—

15 “(aa) initially designated by
16 the Secretary pursuant to section
17 330(b)(3), on or before **【**Decem-
18 ber 1, 2025**】**; or

19 “(bb) designated by the Sec-
20 retary pursuant to subpara-
21 graphs (A) through (C) of section
22 330(b)(3), after **【**December 1,
23 2025**】**, using the scoring method-
24 ology and criteria specified by the

71

1 Secretary as of **December 1,**
2 **2025**].

3 “(VIII) In the case of a covered
4 entity described in one of subpara-
5 graphs (L) through (O) of paragraph
6 (4) that is a private nonprofit hospital
7 that has, as the basis for its participa-
8 tion in the program under this sec-
9 tion, a contract with a State or local
10 government to provide outpatient
11 health care services to low income in-
12 dividuals described in paragraphs
13 (4)(L)(i), the facility independently
14 complies with all requirements appli-
15 cable to such covered entity with re-
16 spect to such contract.

17 “(IX) For the most recent year,
18 the facility’s total cost incurred for
19 charity care (as such term is defined
20 in line 23 of worksheet S–10 to the
21 Medicare cost report, or in any suc-
22 cessor form) furnished at such facility
23 during such year, as a share of the fa-
24 cility’s total patient service revenue, is

1 greater than or equal to the greater
2 of—

3 “(aa) for such year, the
4 total cost incurred for charity
5 care, as a share of total patient
6 service revenue, furnished at the
7 covered entity’s on-campus loca-
8 tions; or

9 “(bb) the average cost in-
10 curred for charity care, as a
11 share of total patient service rev-
12 enue, calculated for the year
13 prior to the most recent year for
14 which data is available, across all
15 hospitals in the State where the
16 facility is located that receive
17 payments for inpatient hospital
18 services under the prospective
19 payment system established
20 under section 1886(d) of the So-
21 cial Security Act.

22 “(X) For the most recent year,
23 the facility’s share of total outpatient
24 services revenue derived from base re-
25 imbursement to such entity (excluding

1 supplemental and indirect reimburse-
2 ment) under title XIX of the Social
3 Security Act (including with respect
4 to individuals also entitled to benefits
5 under part A of title XVIII of such
6 Act or enrolled in part B of title
7 XVIII of such Act) and payments
8 under title XXI of such Act for items
9 and services furnished on an out-
10 patient basis at the facility (including
11 any cost-sharing for such items and
12 services) is greater than or equal to
13 the greater of—

14 “(aa) for such year, the
15 share of total outpatient services
16 revenue derived from base reim-
17 bursement to such entity (exclud-
18 ing supplemental and indirect re-
19 imbursement) under title XIX of
20 the Social Security Act (including
21 with respect to individuals also
22 entitled to benefits under part A
23 of title XVIII of such Act or en-
24 rolled in part B of title XVIII of
25 such Act) and payments under

1 title XXI of such Act for items
2 and services furnished on an out-
3 patient basis at the on-campus
4 locations of the covered entity
5 with which the facility is associ-
6 ated (including any cost-sharing
7 for such items and services) ; or
8 “(bb) the average share of
9 total outpatient services revenue
10 derived from base reimbursement
11 (excluding supplemental and indi-
12 rect reimbursement) under title
13 XIX of the Social Security Act
14 (including with respect to individ-
15 uals also entitled to benefits
16 under part A of title XVIII of
17 such Act or enrolled in part B of
18 title XVIII of such Act) and pay-
19 ments under title XXI of such
20 Act for items and services fur-
21 nished on an outpatient basis (in-
22 cluding any cost-sharing for such
23 items and services), calculated
24 for the year prior to the most re-
25 cent year for which data is avail-

1 able, across all hospitals in the
2 State where the facility is located
3 that receive payments for out-
4 patient hospital services under
5 the prospective payment system
6 for covered outpatient depart-
7 ment services established under
8 section 1833(t) of such Act.

9 “(XI) The covered entity cer-
10 tifies, at the time such facility is ini-
11 tially registered for inclusion in the
12 identification system described in sub-
13 section (d)(2)(B)(iv) to participate in
14 the drug pricing program under this
15 section and annually thereafter as
16 part of the recertification process,
17 that the facility satisfies all applicable
18 requirements under this subpara-
19 graph.

20 “(ii) LIMITATION.—Only an off-cam-
21 pus outpatient facility that meets each of
22 the requirements under this subparagraph
23 may purchase covered outpatient drugs
24 under the 340B program or use covered
25 outpatient drugs purchased under the

1 340B program by another part of the cov-
2 ered entity that is authorized to participate
3 in such program. Any transfer of 340B
4 drugs to another facility or another part of
5 a covered entity that is not authorized to
6 participate in the 340B program shall be
7 deemed a violation of subparagraph (B).

8 “(iii) DEREGISTRATION.—If at any
9 time following registration a requirement
10 described in clause (i) is no longer fully
11 satisfied with respect to a facility, the cov-
12 ered entity described in such clause shall
13 immediately notify the Secretary that such
14 facility no longer fully satisfies the relevant
15 requirement, deregister the facility from
16 the program under this section, remove the
17 facility from the identification system de-
18 scribed in subsection (d)(2)(B)(iv), and
19 take all necessary actions to prohibit such
20 facility from making any purchases under
21 the program under this section or rep-
22 resenting to third parties that such facility
23 may purchase covered outpatient drugs
24 under such program.

1 short-term interest rate as determined by
2 the Federal Reserve for the time period for
3 which the covered entity is liable.

4 “(v) CIVIL MONETARY PENALTY.—
5 Where a covered entity knowingly and in-
6 tentiously violates clause (ii) or otherwise
7 fails to satisfy a requirement in clause (iii)
8 or clause (iv), the covered entity shall be
9 required to pay a civil monetary penalty
10 equal to \$2,500 for each such violation,
11 which amount shall be adjusted for infla-
12 tion annually to reflect the rate of change
13 in the Consumer Price Index for all urban
14 consumers published by the Bureau of
15 Labor Statistics. The provisions of section
16 1128A of the Social Security Act (other
17 than subsections (a) and (b)) shall apply to
18 a civil monetary penalty under this clause
19 in the same manner as such provisions
20 apply to a penalty or proceeding under sec-
21 tion 1128A(a). The Office of Inspector
22 General of the Department of Health and
23 Human Services shall carry out the provi-
24 sions related to the imposition of civil mon-
25 etary penalties under this clause.

1 “(vi) SECRETARIAL PUBLICATION OF
2 REPORTS.—On an annual basis, the Sec-
3 retary shall prepare and make available to
4 the public in an electronic, machine read-
5 able format separate reports listing facili-
6 ties that satisfy the requirements in each
7 of subclauses (IX) and (X) of clause (i).

8 “(vii) DEFINITION.—For purposes of
9 this subparagraph, the term ‘campus’ has
10 the meaning given such term in section
11 413.65(a)(2) of title 42, Code of Federal
12 Regulations (or any successor regula-
13 tions).”.

14 (b) EFFECTIVE DATE.—Subparagraph (I) of section
15 340B(a)(5) of the Public Health Service Act, as added by
16 subsection (a), shall become effective 120 days after the
17 date of enactment of this Act.

18 (c) IMPLEMENTATION OF HOSPITAL CHILD SITE
19 STANDARDS.—Not later than 60 days prior to the effec-
20 tive date described in subsection (b), the Secretary shall
21 issue program instructions directing each covered entity
22 described in section 340B(a)(5)(I)(i) of the Public Health
23 Service Act, as added by subsection (a), to, before such
24 effective date, register in the identification system de-
25 scribed in section 340B(d)(2)(B)(iv) of the Public Health

1 Service Act, or update existing registrations in such sys-
2 tem for, off-campus outpatient (provided that, for pur-
3 poses of this subsection, the term “campus” has the mean-
4 ing given such term in section 413.65(a)(2) of title 42,
5 Code of Federal Regulations (or any successor regula-
6 tions)) facilities associated with such covered entity that
7 satisfy the requirements of such section. Such instructions
8 shall direct each such covered entity to, on or before such
9 effective date, remove from such system the existing reg-
10 istration of any off-campus outpatient facility associated
11 with such covered entity that does not satisfy the require-
12 ments of such section 340B(a)(5)(I)(i). Clauses (iii)
13 through (v) of section 340B(a)(5)(I) of the Public Health
14 Service Act shall apply with respect to any covered entity
15 described in one of subparagraphs (L) through (O) of sec-
16 tion 340B(a)(4) of such Act that fails to remove a facility
17 described in the immediately preceding sentence on or be-
18 fore the effective date described in subsection (b).

19 **SEC. 9. CONTRACTING REFORMS.**

20 Section 340B of the Public Health Service Act (42
21 U.S.C. 256b) is amended by adding at the end the fol-
22 lowing:

23 “(f) REQUIREMENTS FOR TPA AND CONTRACT
24 PHARMACY REMUNERATION.—

1 “(1) THIRD-PARTY ADMINISTRATOR FEES.—A
2 third-party administrator furnishing 340B program-
3 related services on behalf of a covered entity de-
4 scribed in subsection (a)(4), including reviewing or
5 processing claims or other information to identify
6 covered outpatient drugs dispensed to individuals
7 who are patients of the covered entity (as defined in
8 subsection (b)(3)) may receive remuneration from
9 such covered entity for the performance of such
10 services only if—

11 “(A) such remuneration is a flat dollar
12 amount not directly or indirectly based on any
13 price of, or discount or other remuneration pro-
14 vided with respect to, a covered outpatient
15 drug, paid for each unit of service furnished to
16 the covered entity, regardless of whether a pre-
17 scription was dispensed to an individual who is
18 a patient of the covered entity;

19 “(B) the amount of such remuneration is
20 consistent with fair market value in an arm’s-
21 length transaction for the bona fide, itemized
22 340B-related services actually performed on be-
23 half of the covered entity; and

1 “(C) such remuneration complies with ap-
2 plicable State and Federal law, including sec-
3 tion 1128B(b) of the Social Security Act.

4 “(2) CONTRACT PHARMACY FEES.—A contract
5 pharmacy that has entered into a written agreement
6 with a covered entity pursuant to and satisfies the
7 applicable requirements in subsection (a)(5)(E) may
8 receive remuneration from such covered entity for
9 the performance of services associated with dis-
10 pensing covered outpatient drugs subject to an
11 agreement under this section to individuals who are
12 patients of the covered entity (as defined in sub-
13 section (b)(3)) only if—

14 “(A) such remuneration is a flat dollar
15 amount not directly or indirectly based on any
16 price of, or discount or other remuneration pro-
17 vided with respect to, a covered outpatient
18 drug, paid for each dispense of such a drug to
19 a patient of the covered entity;

20 “(B) the amount of remuneration for each
21 dispense does not exceed 125 percent of the av-
22 erage per-prescription dispensing fee paid to
23 such pharmacy by all third-party payors, based
24 on data from the most recent full calendar year
25 for which such data is available;

1 “(C) the amount of such remuneration is
2 consistent with fair market value in an arm’s-
3 length transaction for the bona fide, itemized
4 340B-related services actually performed on be-
5 half of the covered entity; and

6 “(D) such remuneration complies with ap-
7 plicable State and Federal law, including sec-
8 tion 1128B(b) of the Social Security Act.

9 For purposes of subparagraph (B), if a covered enti-
10 ty has entered into an agreement for contract phar-
11 macy services pursuant to subsection (a)(5)(E) that
12 permits the contract pharmacy service provider to
13 dispense covered outpatient drugs on behalf of the
14 covered entity at more than one pharmacy location,
15 the average dispensing fee shall be calculated across
16 all pharmacy locations subject to such agreement.

17 “(3) AUDITABLE RECORDS.—A covered entity
18 shall retain copies of written agreements with third-
19 party administrators or contract pharmacies de-
20 scribed in this subsection for a period of time speci-
21 fied by the Secretary and shall make copies of such
22 agreements available to the Secretary or their des-
23 ignee upon request.

24 “(4) CIVIL MONETARY PENALTY.—A third-
25 party administrator or contract pharmacy described

1 in this subsection that fails to comply with the appli-
2 cable requirements specified in this subsection shall
3 be required to pay a civil monetary penalty equal to
4 10 times the amount such third-party administrator
5 or contract pharmacy received for the performance
6 of relevant services described in this subsection. The
7 provisions of section 1128A of the Social Security
8 Act (other than subsections (a) and (b)) shall apply
9 to a civil monetary penalty under this paragraph in
10 the same manner as such provisions apply to a pen-
11 alty or proceeding under section 1128A(a). The Of-
12 fice of Inspector General of the Department of
13 Health and Human Services shall carry out the pro-
14 visions related to the imposition of civil monetary
15 penalties under this paragraph.”.

16 **SEC. 10. PRIME VENDOR PROGRAM.**

17 Section 340B(a)(8) of the Public Health Service Act
18 (42 U.S.C. 256b(a)(8)) is amended to read as follows:

19 “(8) **PRIME VENDOR PROGRAM.**—

20 “(A) **IN GENERAL.**—The Secretary shall
21 establish a prime vendor program under which
22 the Secretary enters into contracts with at least
23 2 separate prime vendors (referred to in this
24 paragraph as ‘prime vendor contracts’), and
25 covered entities may enter into contracts with

1 such prime vendors for the distribution of cov-
2 ered outpatient drugs (referred to in this para-
3 graph as ‘distribution contracts’). The Sec-
4 retary shall begin solicitation of a second prime
5 vendor contract not later than 1 year after the
6 date of enactment of the 340B Drug Pricing
7 Integrity and Affordability for Patients Act.

8 “(B) REQUIREMENTS FOR CONTRACT
9 WITH THE SECRETARY.—To be eligible to enter
10 into, and maintain, a prime vendor contract
11 with the Secretary under subparagraph (A), a
12 prime vendor shall, at a minimum—

13 “(i) have no conflicts of interest with
14 respect to its financial, contractual, organi-
15 zational, or other interests that relate to
16 the work under the contract with the Sec-
17 retary; and

18 “(ii) not be owned wholly or as a sub-
19 sidiary of, operated by, have a revenue
20 sharing agreement with, or otherwise
21 maintain joint ownership with an entity de-
22 scribed in paragraph (4)(L)(iii).

23 “(C) PRIME VENDOR REQUIREMENTS.—A
24 prime vendor receiving a prime vendor contract
25 under this paragraph shall agree to the fol-

1 lowing terms as conditions for receiving such
2 contract:

3 “(i) The prime vendor may not charge
4 covered entities with which the vendor has
5 entered into a distribution contract a fee
6 for enrollment or participation in the prime
7 vendor program pursuant to such contract.

8 “(ii) The prime vendor may not par-
9 ticipate in the negotiation of contracts on
10 behalf of covered entities with which the
11 vendor has entered into a distribution con-
12 tract for procurement of products that are
13 not covered outpatient drugs, including
14 drugs (as defined in section 201(g) of the
15 Federal Food, Drug, and Cosmetic Act)
16 (including biological products), devices (as
17 defined in section 201(h) of such Act), and
18 other articles as the Secretary may pro-
19 hibit.

20 “(iii) If a prime vendor offers edu-
21 cational services to covered entities, such
22 services shall be provided at no cost to cov-
23 ered entities with which the vendor has en-
24 tered into a distribution contract.

1 “(iv) The Secretary shall have unlim-
2 ited rights in data (as such terms are de-
3 fined in the Federal Acquisition Regula-
4 tion) first produced in the performance of
5 a prime vendor contract and data delivered
6 under such contract. In addition to any
7 data to which the Secretary has access as
8 specified in a prime vendor contract, the
9 Secretary may, at any time during per-
10 formance of such contract or within a pe-
11 riod of **[5]** years after the term of this
12 contract ends, require delivery of, or pro-
13 vide public access to, any data first pro-
14 duced or specifically used in the perform-
15 ance of the contract.

16 “(D) DISTRIBUTION TO COVERED ENTI-
17 TIES OTHER THAN THROUGH PRIME VEN-
18 DORS.—If a covered entity obtains covered out-
19 patient drugs directly from a manufacturer, the
20 manufacturer shall be responsible for the costs
21 of distribution, even if the covered entity has a
22 distribution contract with a prime vendor.”.

1 **SEC. 11. TRANSFER OF CIVIL PENALTY AMOUNTS COL-**
2 **LECTED.**

3 Section 340B of the Public Health Service Act (42
4 U.S.C. 256b), as amended by section 10, is further
5 amended by adding at the end the following:

6 “(g) **TRANSFER OF AMOUNTS COLLECTED.**—Each
7 fiscal year, the Secretary of the Treasury shall transfer
8 to the Office of Pharmacy Affairs of the Health Resources
9 and Services Administration an amount equal to the total
10 amount collected in civil monetary penalties for violations
11 of this section in the previous fiscal year, for purposes of
12 administering this section.”.

13 **SEC. 12. APPLICATION; REGULATIONS AND GUIDANCE.**

14 (a) **APPLICATION.**—Except as otherwise provided, the
15 amendments made by this Act to section 340B of the Pub-
16 lic Health Service Act (42 U.S.C. 256b) shall apply begin-
17 ning on the date that is 1 year after the date of enactment
18 of this Act.

19 (b) **REGULATIONS AND GUIDANCE.**—The Secretary
20 of Health and Human Services may, from time to time,
21 promulgate regulations and guidance to implement section
22 340B of the Public Health Service Act (42 U.S.C. 256b),
23 as amended by this Act.