SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''340B Drug Pricing Integrity and Affordability for Patients Act''.

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

SEC. 2. REBATE CONDITIONS.

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

(1) in paragraph (1)—

(A) by striking ''(taking into account any rebate or discount, as provided by the Secretary)''; and

(B) by striking ''paragraph (2)'' and inserting ''paragraph (2)(A)'';

(2) in paragraph (2)—

(A) in the paragraph heading, by striking ''DEFINED'' and inserting ''; DISCOUNT AND REBATE CONDITIONS'';

(B) in subparagraph (A), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and adjusting the margins accordingly;

(C) in subparagraph (B)—

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

(ii) in subclause (I), as so redesignated, by striking ''subparagraph (A)'' and inserting ''clause (i)'';

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

(E) by inserting before clause (i), as so redesignated, the following:

''(A) REBATE PERCENTAGE DEFINED.—'';

and

(F) by adding at the end the following:

''(B) DISCOUNT AND REBATE CONDITIONS.—

"(i) IN GENERAL.—A manufacturer may elect to make the ceiling price available to a covered entity through either a discount or rebate, as follows:

"(I) REQUIREMENTS FOR DISCOUNTS.—A manufacturer may elect to make the ceiling price available through a discount offered at the time of sale, whereby the covered entity pays the ceiling price for a covered outpatient drug and—

"(aa) maintains a segregated inventory system in which covered outpatient drugs purchased at the ceiling price are physically distinguishable from such drugs not purchased at the ceiling price;

"(bb) establishes policies and procedures for identifying patients (as defined in subsection (b)(3)) at the time of dispensing to ensure that drugs purchased at the ceiling price are given only

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

"(cc) submits standardized claims documentation, as described in clause (iii), to the manufacturer or the delegated contractor of the manufacturer within 30 days of the date on which the covered outpatient drug is dispensed; and

"(dd) submits a signed attestation to, and documentation demonstrating, compliance with the requirements of items (aa) and (bb), by a qualified representative, to the Secretary and the manufacturer on an annual basis.

"(II) REQUIREMENTS FOR REBATES.—A manufacturer may elect to make the ceiling price available through a retrospective rebate, whereby the covered entity pays a non-ceiling price acquisition cost for the covered outpatient drug at the time of

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

"(aa) the covered entity shall submit a request for a rebate to the manufacturer or the delegated contractor of the manufacturer with the required standardized claims documentation, as described in clause (iii), within [90] days of the date on such the drug is dispensed or administered; and

"(bb) the manufacturer—

"(AA) pays all undisputed claims within 10 days (except as provided in clause (iii)(II)) of receiving a request under item (aa) by issuing a rebate (either in the form of a credit or cash value) equal to the difference between the actual

acquisition cost and the ceiling price; and

"(BB) with respect to disputed claims, provides the covered entity with the rationale and specific documentation for reasons the claim is denied within a minimum amount of time as determined by the Secretary, provides an opportunity for the covered entity to submit additional information to the manufacturer or request review of the disputed claim by the Secretary, and in the case that the covered entity submits such additional information or as the Secretary determines appropriate following secretarial review of the disputed claim, reconsiders the claim [within a minimum amount of

time as determined by the Secretary].

"(III) REQUIREMENTS FOR A CLAIMS REPOSITORY.—A manufacturer may elect to make the ceiling price available through a discount offered after the covered entity submits standardized claims data described in clause (iii) to a claims repository operated by the Secretary, which shall act to prevent diversion and duplication of discounts, and fulfill other requirements under this section, whereby—

"(aa) the covered entity pays the ceiling price for a covered outpatient drug and—

"(AA) maintains a segregated inventory system in which covered outpatient drugs purchased at the ceiling price are physically distinguishable from such drugs not purchased at the ceiling price;

"(BB) establishes policies and procedures for identifying patients (as defined in subsection (b)(3)) at the time of dispensing to ensure that drugs purchased at the ceiling price are given only to patients of the covered entity, consistent with paragraph (5)(B);

"(CC) submits standardized claims documentation, as described in clause (iii), to the Secretary within 30 days of the date on which the covered outpatient drug is dispensed; and

"(DD) submits an attestation signed by a qualified representative confirming compliance with the requirements of subitems (AA) and (BB), and documentation demonstrating such compliance, to the Sec-

retary and the manufacturer on an annual basis; and

"(bb) the Secretary, through operation of the claims repository—

"(AA) requests and receives, in the most efficient and least burdensome manner practicable, standardized claims data;

"(BB) requests, receives, and maintains data described in subitem (AA) in a confidential manner;

"(CC) ensures that claims-level data submissions by covered entities are complete and accurate, and if not, obtain complete and accurate data from the covered entity;

"(DD) notifies of any violation described in subitem (BB), and when necessary to allow for reme-

diation, shares such data with the purpose of preventing any violations of this section with, the covered entity, the State Medicaid agency, the manufacturer, the Veterans Health Administration, and the Department of Defense, as applicable;

''(EE) allows covered entities except those described under subparagraph (L), (M), (N), or (O) of paragraph (4) the option of submitting claims level data on an aggregated retrospective basis that does not require the application of modifiers on individual claims or point-of-sale identification.

''(ii) COVERED ENTITIES PASSING SAVINGS, DISCOUNTS, OR REBATES TO PATIENTS.—Covered entities that elect to

make all outpatient drugs available to patients at a cost of not more than the ceiling price (plus a nominal dispensing fee that shall not exceed an amount determined by the Secretary) may opt to—

"(I) participate in the program through a discount mechanism subject to clause (i)(I);

"(II) participate in the program through a rebate mechanism pursuant to clause (i)(II), under which all undisputed claims will be paid [within 7 days of receiving a claim/upon receipt of the claim]; or

"(III) participate in the program through a claims repository pursuant to clause (i)(III).

"(iii) STANDARDIZED CLAIMS DATA.—The following data fields shall constitute standardized claims data required to be submitted by a covered entity for purposes of claiming a discount or rebate as described in clause (i):

"(I) Healthcare Encounter Data, including the Billing Service Provider

ID, date of service, Rendering Physician ID, HCPCS Code, Diagnosis COD, and Place of Service Code.

"(II) As appropriate for the setting in which the drug is dispensed, one of the following:

"(aa) For retail claims, the Unique Transaction ID, RX Identifier (RXID), Fill Number, NDC11, Quantity, Unit of Measure, days supply, Ordering Physician NPI, CE Submitted (340B ID), Pharmacy ID (DEA, HIN or NPI), date of service, paid date, BIN, PCN, GRP, and Claims Modifiers.

"(bb) For medical claims, the Unique Transaction ID, NDC11, Quantity, Unit of Measure, days supply, Patient ID (Tokenized), Ordering Physician NPI, CE Submitter (340B ID or NPI), CE Administration Location (340B ID), CE Administration Location – Medical (NPI),

date of service, paid date, Insured's Plan Name or Program Name, Insured's Policy Group or FECA Number, and Claims Modifiers.

''(III) Additional data as required by the Secretary to prevent diversion, duplication of discounts, or fulfill other requirements under this section.

''(iv) RESPONSIBILITIES OF THE SECRETARY.—As part of the auditing of covered entities and manufacturers, the Secretary shall provide monitoring and oversight of each manufacturer's operation of discount or rebate systems and covered entities' participation in such systems, including by reviewing the discount or rebate conditions set by covered entities. Such oversight shall include review for alleged overcharges pursuant to subsection (d).'';

(3) by amending subparagraph (C) of paragraph (5) to read as follows:

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

covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating only to the number, duration, and scope of audits) to conduct routine audits and audits for cause, at the Secretary's or the manufacturer's expense, with the option to utilize the manufacturer's internal auditing staff at either the Secretary's or manufacturer's discretion, the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.'';

(4) in paragraph (7)—

(A) in the paragraph heading, by striking ''OF CERTAIN'' and inserting ''AND RECERTIFICATION OF'';

(B) in subparagraph (A)—

(i) by striking ''this section'' and inserting ''the 340B Drug Pricing Integrity and Affordability for Patients Act''; and

(ii) by striking ''subparagraphs (J) and (K) of'';

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

''(B) INCLUSION OF PURCHASE AND PROFIT INFORMATION.—The process developed under subparagraph (A) shall include a requirement that an entity described in subparagraph (J) or (K) of paragraph (4) applying for certification or recertification submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs, and, in the case of recertification, the total revenues generated for such covered outpatient drugs in the preceding year.'';

(D) in subparagraph (C), by striking ''make available to all manufacturers of covered outpatient drugs'' and inserting ''make publicly available'';

(E) in subparagraph (D), by striking ''subparagraphs (J) and (K) of'';

(F) in subparagraph (E), by striking ''a not more frequent basis than'' and inserting ''an''; and

(G) by adding at the end the following:

''(F) PENALTIES FOR MISREPRESENTATIONS AND MISSTATEMENTS.—Any covered en-

tity that knowingly misrepresents or misstates information under this section shall be subject to a civil monetary penalty for each covered outpatient drug that was unlawfully purchased by the entity through the program under this section as a result of an improper certification or recertification, in an amount not to exceed 2 times the total amount of the discounts or rebates provided to the entity under paragraph (2)(C) for any period during which the misrepresentations or misstatements applied.''; and

(5) in the heading of paragraph (10), by inserting ''OR REBATE'' after ''DISCOUNT''.

SEC. 3. AMENDMENTS TO THE ELIGIBILITY OF SUBGRANTEES.

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

(1) by redesignating subparagraph (E) as subparagraph (G); and

(2) by inserting after subparagraph (D) the following:

''(E) SUBGRANTEE DATA SUBMISSIONS.—The process developed under subparagraph (A) shall include a requirement that an entity ap-

plying for certification under this paragraph submit to the Secretary—

"(i) information on the grant received by the entity under title XXVI that establishes the entity's eligibility as a covered entity described in paragraph (4)(J) or under section 318 that establishes the entity's eligibility as a covered entity described in paragraph (4)(K);

"(ii) information regarding the entity's status as a public or nonprofit entity; and

"(iii) certification by the entity that—

"(I) revenues generated by participation in the program under this section are consistent with the scope of the grant described in clause (i); and

"(II) the patient population treated by the entity is primarily low income or uninsured.

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

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

SEC. 4. ADDITIONAL DEFINITIONS.

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

''(3) PATIENT.—In this section, the term 'patient' means an individual who—

''(A) with respect to a covered entity and each covered outpatient drug—

''(i) has received an outpatient health care service at the covered entity within the preceding 2 years;

''(ii) has a relationship with the covered entity such that the covered entity creates and maintains an auditable medical record in a form and manner consistent with Federal and State law, that demonstrates the existence of a patient relationship in accordance with this paragraph, and maintains such record for a period of at least 3 years, or longer if required by Federal and State law; and

''(iii) received the prescription or order for the covered outpatient drug from

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

"(B) is registered in a State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI.

"(4) OUTPATIENT HEALTH CARE SERVICE.—In this section, the term '*outpatient* health care service' means an outpatient health care service—

"(A) that is paid by the insurer or third-party payor as outpatient items and services (or where third-party reimbursement is not made, such items and services are deemed outpatient if less than 24 hours have elapsed between such individual's hospital registration and discharge); or

"(B) in the case of a covered entity described in any of subparagraphs (A) through (K) of subsection (a)(4), that is consistent with the scope of the grant or designation described in the applicable such subparagraph.

"(5) PRACTITIONER.—In this section, the term 'practitioner' means a health care provider who—

"(A)(i) is an employee or independent contractor of a covered entity, and the covered en-

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

"(ii) furnishes the outpatient health care service to the individual on behalf of the covered entity under an ongoing contractual obligation to the covered entity such that the covered entity maintains clinical responsibility for the health care provided to the individual that resulted in the individual receiving a prescription or order for the covered outpatient drug, if state law prohibits or substantially limits the ability of the covered entity to bill for services of the practitioner; and

"(B) is not excluded, pursuant to section 1128 of the Social Security Act, from participation in the Medicare Program or a State health care program as defined in section 1128(h) of the Social Security Act.

"(6) SPECIFIED NONHOSPITAL COVERED ENTITY.—

"(A) IN GENERAL.—In this section, the term 'specified nonhospital covered entity' means a covered entity that—

"(i) is described in one of subparagraphs (B) through (K) of subsection (a)(4), other than a covered entity described in subparagraph (G) of such subsection, and—

"(I) has average annual operating revenues exceeding $1,000,000,000 calculated over the most recent 3-year period for which data are available, which revenue threshold shall be adjusted for inflation annually to reflect rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics; or

"(II) is an affiliate of a hospital; or

"(ii) is described in subsection (a)(4)(A) and becomes affiliated with a hospital on or after [December 1, 2025].

"(B) AFFILIATE.—

"(i) IN GENERAL.—For purposes of subparagraph (A), the term 'affiliate' means an entity that, directly or indirectly, controls, is controlled by, or is under com-

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

''(ii) CONTROL.—For purposes of clause (i), the term 'control' means the power to direct the management and policies of an entity, directly or indirectly, whether through the ownership of voting securities, by contract, or otherwise.''.

SEC. 5. CONTRACT PHARMACIES.

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

''(E) CONTRACT PHARMACIES.—

''(i) IN GENERAL.—Subject to the conditions set forth in this subparagraph, a covered entity may enter into written agreements with contract pharmacies to dispense to patients of such entity covered outpatient drugs purchased by such entity under the 340B program. Subject to such conditions, a manufacturer of covered outpatient drugs shall ship or facilitate shipment of such drugs to contract pharmacies at the request of such covered entity. Ex-

cept with respect to covered outpatient drugs shipped to and dispensed by a contract pharmacy as provided in this subparagraph, and notwithstanding any other provision in this section, a manufacturer of covered outpatient drugs shall have no obligation to pay a discount or rebate under this section with respect to covered outpatient drugs delivered or otherwise transferred to any location other than a registered address of the covered entity (including an entity pharmacy or child site (as described in subparagraph (I)(i)), as applicable) listed in the identification system described in subsection (d)(2)(B)(iv).

''(ii) CONDITIONS FOR COVERED ENTITY USE OF CONTRACT PHARMACIES.—In order for a covered entity to enter into a written agreement with a contract pharmacy to dispense to patients of such entity covered outpatient drugs purchased by such entity under the program under this section, the entity shall—

''(I)(aa) be described in one of subparagraphs (A) through (K) of

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

''(bb) be described in one of subparagraphs (L) through (O) of paragraph (4);

''(II) establish and implement compliance procedures to satisfy the requirements described in subparagraphs (A), (B), (F), (G) (as applicable), and (H) (as applicable) of paragraph (5) and section 1193(d) of the Social Security Act with respect to covered outpatient drugs purchased by the covered entity under this section, including with respect to such drugs dispensed by a contract pharmacy, which compliance procedures shall be considered records of the covered entity subject to audit under subparagraph (C);

''(III) prior to purchasing covered outpatient drugs subject to an agreement under this section to be shipped to or dispensed by such pharmacy, register such pharmacy in the identification system described in subsection (d)(2)(B)(iv) as a contract pharmacy, to include such pharmacy's national provider identifier, and certify to the Secretary upon initial registration of such pharmacy in such system and annually thereafter that such pharmacy complies with all requirements under this subparagraph, including the covered entity compliance procedures described in subclause (II); and

''(IV) as applicable, comply with the requirements and limitations set forth in clauses (iii) through (vii) of this subparagraph.

''(iii) LIMITATION ON CONTRACT PHARMACIES FOR CERTAIN HOSPITAL COVERED ENTITIES.—Notwithstanding clause (ii), a covered entity described in para-

graph (4)(L), a free-standing cancer hospital described in paragraph (4)(M), and a rural referral center described in paragraph (4)(O) may not enter into written agreements with more than 5 contract pharmacies to dispense covered outpatient drugs purchased by the covered entity under this section to patients of such entity under this subparagraph. For purposes of this clause, a contract pharmacy shall not include a mail order pharmacy.

''(iv) SERVICE AREA REQUIREMENT FOR ELIGIBLE CONTRACT PHARMACIES.—A contract pharmacy with which a covered entity enters into a written agreement to dispense covered outpatient drugs to patients of such entity subject to the conditions in this subparagraph shall be located in the service area of the covered entity (as defined in clause (x)(IV)). Notwithstanding any other provision in this subparagraph, this clause (iv) shall not apply with respect to a covered entity described in paragraph (4)(G) or a contract pharmacy that is a mail order pharmacy.

"(v) REQUIREMENTS FOR USE OF MAIL ORDER PHARMACIES.—

"(I) IN GENERAL.—Notwithstanding any other provision of this section, a covered outpatient drug subject to an agreement under this section may be dispensed to a patient of a covered entity through a mail order pharmacy only if—

"(aa) the covered entity dispensing such drug (or on whose behalf such drug is dispensed) through a mail order pharmacy to such a patient is described in one of subparagraphs (A) through (K) of paragraph (4), such entity is not a specified non-hospital covered entity (as defined in subsection (b)(6)), and, except for a covered entity described in paragraph (4)(G), the patient dispensed such drug resides within the service area of the covered entity (as defined in clause (x)(IV)); or

"(bb) the covered entity dispensing such drug (or on whose behalf such drug is dispensed) through a mail order pharmacy to such a patient is described in subparagraph (N) of paragraph (4) or is a sole community hospital described in subparagraph (O) of such paragraph, and the patient dispensed such drug resides in a county that is not part of a Metropolitan Statistical Area, as defined by the Office of Management and Budget.

"(II) REQUIREMENTS FOR USE OF MAIL ORDER CONTRACT PHARMACIES.—Subject to the conditions set forth in this subparagraph, a covered entity described in item (aa) or (bb) of subclause (I) may enter into written agreements with contract pharmacies that are mail order pharmacies to dispense to patients described in such relevant clause covered outpatient drugs purchased by such

entity under the drug discount program.

''(vi) REQUIREMENTS FOR COVERED ENTITY COMPLIANCE PROCEDURES AND WRITTEN AGREEMENTS.—Not later than 180 days after the date of enactment of the 340B Drug Pricing Integrity and Affordability for Patients Act, the Secretary shall issue guidance to covered entities (which may be followed by regulations issued by the Secretary for such purposes, as appropriate) specifying requirements for—

''(I) covered entity compliance procedures described in clause (ii)(II) that the Secretary determines are sufficient to ensure that covered outpatient drugs are not subject to duplicate discounts in violation of subsection (a)(5)(A) (including with respect to such drugs used by Medicaid managed care enrollees), that such drugs cannot be resold or otherwise transferred to persons who do not meet the definition of a patient of the

covered entity in violation of subparagraph (B), that the patient affordability requirements specified in subparagraphs (G) and (H), as applicable, are appropriately applied at the point of drug dispense or administration, that data and other information is submitted in accordance with subparagraph (F), and that the nonduplication requirement in section 1193(d) of the Social Security Act is satisfied; and

''(II) written agreements between covered entities and contract pharmacies described in clause (vii).

''(vii) WRITTEN AGREEMENT REQUIRED.—The written agreement between a covered entity and a contract pharmacy described in this subparagraph shall include binding and enforceable obligations on the contract pharmacy to comply with the covered entity's compliance procedures described in clause (ii)(II) with respect to covered outpatient drugs dispensed to patients of such entity in accordance with

this subparagraph. Within 30 days of the applicable effective date of such written agreement, including any amendment or addendum thereto, the covered entity shall submit a copy of the agreement, together with any amendments or addenda, to the Secretary in a form and manner specified by the Secretary. The Secretary shall review all such agreements, including amendments and addenda, for compliance with the requirements set forth in this subparagraph and may require a covered entity and contract pharmacy to modify an agreement to conform to the requirements of this subparagraph. Such agreements, including amendments and addenda, shall be considered records of the covered entity subject to audit under subparagraph (C).

''(viii) CLARIFICATION FOR COVERED OUTPATIENT DRUGS SUBJECT TO RESTRICTED DISTRIBUTION.—Notwithstanding any other provision of this section, a manufacturer of a covered outpatient drug requiring exclusive use of a specialty pharmacy or a restricted distribu-

tion network shall be deemed to have satisfied its obligations under this subparagraph with respect to a contract pharmacy if such manufacturer offers each covered entity such drug for purchase at or below the applicable ceiling price described in paragraph (1) through a wholesaler, distributor, or pharmacy included in the restricted distribution network for such drug.

''(ix) PENALTIES FOR CONTRACT PHARMACY COMPLIANCE VIOLATIONS.—

''(I) IN GENERAL.—A contract pharmacy that is found to have violated the covered entity compliance procedures described in clause (ii)(II), violated subparagraph (A), or violated subparagraph (B) shall—

''(aa) in the first instance of such violation, be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of such drug (as described in subsection (a)(1)), plus interest on such

amount, which shall be compounded monthly and equal to the current short-term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable;

''(bb) in the second instance of such violation—

''(AA) be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of the drug (as described in paragraph (1)), plus interest on such amount, which shall be calculated in the manner specified in item (aa); and

''(BB) be required to pay a civil monetary penalty equal to $3,000 for each claim for a covered outpatient drug that is subject

to the violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics; and

''(cc) in the third instance of such violation—

''(AA) be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of the drug (as described in paragraph (1)), plus interest on such amount, which shall be calculated in the manner specified in item (aa);

''(BB) be required to pay a civil monetary penalty equal to $3,000 for each claim for a covered out-

patient drug that is subject to the violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics; and

''(CC) be removed from the program under this section and disqualified from reentry into such program for a period of not less than 2 years, or such longer period as the Secretary may determine based on the severity of the violation (or violations) and the risk such pharmacy presents to the integrity of the program, with no ability to reenter the program unless and until the Secretary determines such pharmacy has resolved the

violation (or violations) and taken reasonable steps to prevent similar future violations.

"(II) CORRECTIVE ACTION PLAN.—In the first instance of a violation described in subclause (I)(aa), in the second instance of a violation described in subclause (I)(bb), and prior to reentry into the program following a violation described in subclause (I)(cc)—

"(aa) the pharmacy shall conduct an internal review to identify the cause of the violation (or violations) that is inclusive of all calendar quarters within the period in which such violation (or violations) occurred and all covered outpatient drugs subject to an agreement under this section dispensed during such period;

"(bb) the pharmacy shall prepare a written corrective action plan, in a form specified by

the Secretary, which shall include, at a minimum, the results of such internal review, the pharmacy's methodology for identifying the full scope of such violation (or violations), and the pharmacy's proposed corrective actions, and submit such plan to the Secretary in a form and manner specified by the Secretary; and

''(cc) the Secretary shall review such plan, notify the pharmacy of any revisions to such plan, including additional corrective actions, necessary for the Secretary to approve such plan, and publish the approved plan on a public website of the Department of Health and Human Services (with redactions of any confidential or proprietary information).

''(III) CIVIL MONETARY PENALTY FOR VIOLATIONS BY REMOVED PHAR-

MACY.—A contract pharmacy removed from the program under this section pursuant to subclause (I)(cc) that dispenses a covered outpatient drug subject to an agreement under this section during a time period that such pharmacy is removed from the program and is not approved for reentry shall be required to pay a civil monetary penalty equal to $3,000 for each claim for each such drug dispensed during such period, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics.

''(IV) PROCEDURES AND DELEGATION.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply for purposes of any payment, civil monetary penalty, or removal described in this clause in the same manner as such provisions apply

to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions of this clause.

''(x) DEFINITIONS.—In this subparagraph:

''(I) CONTRACT PHARMACY.—The term 'contract pharmacy' means, with respect to a covered entity described in clause (ii), any individual pharmacy (as determined by a national provider identifier unique to the pharmacy address) that is—

''(aa) licensed as a pharmacy by the relevant State (or States);

''(bb) authorized to dispense covered outpatient drugs subject to an agreement under this section to patients of such entity (as defined in subsection (b)(3)) pursuant to a valid written agreement with such entity (as de-

scribed in this subparagraph); and

"(cc) not an entity pharmacy.

"(II) ENTITY PHARMACY.—The term 'entity pharmacy' means any individual pharmacy (as determined by a national provider identifier unique to the pharmacy address) that is—

"(aa)(AA) licensed as a pharmacy by the relevant State (or States); and

"(BB) the same legal entity as a covered entity and located within the covered entity's service area, if the covered entity is described in one of subparagraphs (A) through (K) of paragraph (4) and is not a specified nonhospital covered entity (as defined in subsection (b)(6)); or

"(bb) the same legal entity as a covered entity and located within the covered entity's 4 walls, if the covered entity is de-

scribed in one of subparagraphs (L) through (O) of paragraph (4) or is a specified nonhospital covered entity (as defined in subsection (b)(6)).

''(III) MAIL ORDER PHARMACY.—The term 'mail order pharmacy' is a pharmacy that is licensed as a pharmacy by the State (or States) and that dispenses prescription medications to individuals primarily through the mail, as determined in accordance with guidance issued by the Secretary in connection with part 447, subpart I of title 42 of the Code of Federal Regulations (or any successor regulations).

''(IV) SERVICE AREA.—The term 'service area' means, with respect to a covered entity described in paragraph (4), other than a covered entity described in subparagraph (G) of such paragraph, the Public Use Microdata Area (as defined by the United States Census Bureau) in which such entity

is located and all Public Use Microdata Areas that are contiguous with the Public Use Microdata Area in which such entity is located, each of which shall be listed in the identification system described in subsection (d)(2)(B)(iv).

''(xi) RULES OF CONSTRUCTION.—

''(I) LOCATION.—For purposes of this subparagraph, the location of a covered entity shall be determined based on the physical address of the entity listed in the identification system described in subsection (d)(2)(B)(iv) without regard to any off-campus outpatient facilities (provided that, for purposes of this subclause, the term 'campus' has the meaning given such term in section 413.65(a)(2) of title 42, Code of Federal Regulations (or any successor regulations)).

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

the covered entity if the name, ownership, and employer identification number of the pharmacy is identical to the name, ownership, and employer identification number of the covered entity.''.

SEC. 6. TRANSPARENCY.

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

''(F) REPORTING.—

''(i) IN GENERAL.—During the first [calendar] year beginning on or after the date that is 14 months after the date of enactment of this subparagraph and during each subsequent year the following reporting requirements shall apply:

''(I) DSH REPORTING.—Each covered entity described in subparagraph (L) of paragraph (4) (and any other covered entity specified by the Secretary) shall report to the Secretary (at a time and in a form and manner specified by the Secretary)

the following information with respect to the preceding year:

"(aa) Such entity shall report, with respect to such a covered entity and each child site, as applicable, of such entity, the margin generated on covered outpatient drugs subject to an agreement under this section dispensed or furnished by such entity or site (and any entity pharmacy or contract pharmacy dispensing such drugs on behalf of such entity in accordance with subparagraph (E)), as follows:

"(AA) Such a covered entity (which shall include child sites of the entity) with net patient revenues (as defined in line 3 of Worksheet G3 of the Medicare cost report or in any successor form) for **[**such**]**/**[**the preceding**]** year that is less than $200,000,000 (which

amount shall be increased for a subsequent year by the percentage increase in the Consumer Price Index for all urban consumers for the 12-month period ending with **[**June**]** of the previous year) shall report the margin in the aggregate by subtracting the aggregate net costs to acquire such covered outpatient drugs from aggregate payments received for such covered outpatient drugs.

''(BB) Such a covered entity (which shall include child sites of the entity) with net patient revenues (as defined in line 3 of Worksheet G3 of the Medicare cost report or in any successor form) for **[**such**]**/**[**the preceding**]** year that is equal to or greater than

$200,000,000 (which amount shall be increased for a subsequent year by the percentage increase in the Consumer Price Index for all urban consumers for the 12-month period ending with **[**June**]** of the previous year) shall report the margin with each component of the margin calculation described in item (aa) and subitem (AA) and (BB) of item (bb) of clause (iv)(III) listed as a separate line item.

''(bb) Each such covered entity (which shall include child sites of the entity) with net patient revenues (as defined in line 3 of Worksheet G3 of the Medicare cost report or in any successor form) for **[**such**]**/**[**the preceding**]** year that is equal to or greater than $200,000,000

(which amount shall be increased for a subsequent year by the percentage increase in the Consumer Price Index for all Urban Consumers for the 12-month period ending with [June] of the previous year) that is a private nonprofit hospital shall submit a copy of each contract (including any appendices or addenda or subsequent amendments) with a State or local government to provide health care services to low-income individuals who are uninsured to the Secretary.

''(cc) Each such covered entity (which shall include child sites of the entity) with net patient revenues (as defined in line 3 of Worksheet G3 of the Medicare cost report or in any successor form) for [such]/[the preceding] year that is equal to or greater than $1,000,000,000 (which amount shall be increased

for a subsequent year by the percentage increase in the Consumer Price Index for all Urban Consumers for the 12-month period ending with [June] of the previous year) shall report, with respect to such covered entity and each child site and contract pharmacy, as applicable, of such entity, the following:

"(AA) The total number of individuals who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section.

"(BB) The number of such individuals described in a category specified in clause (iii), broken down by each such category.

"(CC) The percentage of the total number of indi-

viduals furnished items and services during such preceding year who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section.

''(DD) For each category specified in clause (iii), the percentage of the total number of individuals described in such category furnished items and services during such preceding year who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section.

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

revenues (as defined in line 3 of Worksheet G3 of the Medicare cost report or in any successor form) for **[**such**]**/**[**the preceding**]** year that is equal to or greater than $1,000,000,000 (which amount shall be increased for a subsequent year by the percentage increase in the Consumer Price Index for all Urban Consumers for the 12-month period ending with **[**June**]** of the previous year) shall report, with respect to such covered entity and each child site, as applicable, of such entity, the total costs incurred during the year at each such site (as defined in line 200, column 3 of worksheet C, part 1 of the Medicare cost report, or in any successor form) and the cost incurred at each such site for charity care (as defined in line 23 of worksheet S–10 to the Medicare cost report, or in any successor form).

''(III) REPORTING BY CATEGORIES OF EXPENDITURE.—Each

covered entity described in one of subparagraphs (A) through (K) of paragraph (4) with net patient revenues for [such]/[the preceding] year that is equal to or greater than $200,000,000 (which amount shall be increased for a subsequent year by the percentage increase in the Consumer Price Index for all Urban Consumers for the 12-month period ending with [June] of the previous year) shall report use of margin generated on covered outpatient drugs subject to an agreement under this section in the following categories of expenditures, if applicable, which the Secretary shall define in interim final regulations in a manner consistent with reporting under the Health Resources and Services Administration Uniform Data System (referred to in this subclause as 'UDS'):

"(aa) Medical care.

"(bb) Dental care.

"(cc) Mental health.

"(dd) Pharmaceuticals.

"(ee) Sliding fee discounts.

"(ff) Case management.

"(gg) Transportation.

"(hh) Patient and community education.

"(ii) Community health workers.

"(jj) Outreach.

"(kk) Eligibility assistance.

"(ll) Nutritional assessment and referral.

"(ii) PUBLICATION.—The Secretary shall publish data reported under clause (i) with respect to a year annually on the public website of the Department of Health and Human Services in an electronic and searchable format, which may include the 340B Office of Pharmacy Affairs Information System (or a successor to such system), in a manner that shows each category of data reported (excluding contracts submitted under clause (i)(I)(bb)) in the aggregate and identified by the specific covered entity submitting such data, and

shall publish each contract submitted under clause (i)(I)(bb). The Secretary shall include in such publication the disproportionate patient percentage (as defined in section 1886(d)(5)(F)(vi) of the Social Security Act) of each such covered entity (if applicable) for each cost reporting period occurring during such year.

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

''(I) Individuals covered under a group health plan or group or individual health insurance coverage (as such terms are defined in section 2791).

''(II) Individuals entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act.

''(III) Individuals enrolled under a State plan under title XIX of such Act (or a waiver of such plan).

''(IV) Individuals enrolled under a State child health plan under title

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

''(V) Individuals not described in any of subclauses (I) through (IV) and not covered under any Federal health care program (as defined in section 1128B of such Act but including the program established under chapter 89 of title 5, United States Code).

''(iv) DEFINITIONS.—In this subparagraph:

''(I) CHILD SITE.—The term 'child site' has the meaning given such term in subparagraph (I)(i).

''(II) ENTITY PHARMACY.—The term 'entity pharmacy' has the meaning given such term in subparagraph (E).

''(III) MARGIN.—The term 'margin' means, with respect to covered outpatient drugs purchased by a covered entity under an agreement under this section, the following amount for such drugs dispensed, furnished, or

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

"(aa) aggregate payments received by the covered entity for such drugs from individuals (including cost-sharing amounts) and third parties, including government and private payors; minus

"(bb) the sum of—

"(AA) aggregate costs to acquire such drugs at either the ceiling price described in paragraph (1) or any voluntary subceiling price at which the covered entity purchased such drugs, as applicable; and

"(BB) aggregate costs incurred by the covered entity that are necessary for

such entity to participate in the program under this section and to comply with such program's requirements, including program-related compliance, legal, educational, and administrative costs (such costs shall be determined in accordance with Generally Accepted Accounting Principles), and compensation paid to third-party administrators or contract pharmacies to carry out program-related functions.

''(v) CIVIL MONETARY PENALTY.—A covered entity that violates a requirement of this subparagraph shall be subject to a civil monetary penalty of $3,000 for each such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics for the 12-

month period ending with [June] of the previous year. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out this clause.''.

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

SEC. 7. ENSURING AFFORDABILITY.

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

''(G) PATIENT AFFORDABILITY REQUIREMENTS FOR HOSPITAL COVERED ENTITIES.—

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

through (O) of paragraph (4) shall establish a sliding fee scale that results in the covered entity providing, on behalf of an applicable patient, a discount that results in such patient paying no more than the maximum out-of-pocket obligation (as defined in clause (ii)), with respect to each covered outpatient drug subject to an agreement under this section dispensed, furnished, or administered to such patient at such covered entity, any child site, or any entity pharmacy. The sliding fee scale and related policies shall be written and posted prominently at each such covered entity location, including any child site and entity pharmacy, and shall be included in any billing-related communications sent by such covered entity to any patient dispensed, furnished, or administered a covered outpatient drug at such covered entity location, including any child site or entity pharmacy. Eligibility for a reduced out-of-pocket obligation pursuant to this clause shall be based on insurance and income information provided by the applicable pa-

tient. With respect to covered outpatient drugs that are self-administered by an applicable patient, the out-of-pocket reductions described in this clause shall apply at the point of sale.

''(ii) MAXIMUM OUT-OF-POCKET OBLIGATION.—For each dispense or administration of a covered outpatient drug, the maximum out-of-pocket obligation for an applicable patient with family income—

''(I) below the Federal poverty guidelines is $0;

''(II) at or above the Federal poverty guidelines but below 200 percent of the Federal poverty guidelines is the lesser of 20 percent of the otherwise applicable out-of-pocket obligation or $35, which shall be adjusted for inflation annually to reflect rate of the change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics; and

''(III) at or above 200 percent of the Federal poverty guidelines is the

lesser of 30 percent of the otherwise applicable out-of-pocket obligation or $50, which shall be adjusted for inflation annually to reflect rate of the change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics.

''(iii) CERTIFICATION OF SLIDING FEE SCALE AVAILABILITY.—Each covered entity required under clause (i) to establish a sliding fee scale shall submit such sliding fee scale to the Secretary, at such time and in such manner as the Secretary determines appropriate to certify compliance, which may be published by the Secretary, as appropriate.

''(iv) APPLICABILITY TO CONTRACT PHARMACIES.—With respect to an applicable patient of a covered entity described in clause (i) dispensed a covered outpatient drug subject to an agreement under this section on behalf of such covered entity at a contract pharmacy pursuant to subparagraph (E), such covered entity shall require such contract pharmacy to provide

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

''(v) DEFINITIONS.—In this subparagraph:

''(I) APPLICABLE PATIENT.—The term 'applicable patient' means a patient, as defined in subsection (b)(3), who is not covered under minimum essential coverage as defined under section 5000A(f) of the Internal Revenue Code of 1986 or has family income below 200 percent of the Federal poverty guidelines and is covered under a group health plan, health insurance coverage in the individual market or group market (as such terms are defined in section 2791 of the Public Health Service Act) or coverage described in section 156.602(a), title 45, Code of Federal Regulations (or any successor regulation).

"(II) CHILD SITE.—The term 'child site' has the meaning given such term in subparagraph (I)(i).

"(III) CONTRACT PHARMACY.—The term 'contract pharmacy' shall have the meaning given such term in subparagraph (E).

"(IV) ENTITY PHARMACY.—The term 'entity pharmacy' shall have the meaning given such term in subparagraph (E).

"(V) FEDERAL POVERTY GUIDELINES.—The term 'Federal poverty guidelines' means the poverty guidelines updated periodically in the Federal Register by the Department of Health and Human Services pursuant to section 673 of the Community Services Block Grant Act.

"(VI) OUT-OF-POCKET OBLIGATION.—The term 'out-of-pocket obligation' means any copayment, coinsurance, deductible, or other cost-sharing amount or payment required from an applicable patient in connec-

tion with such patient's receipt of a specific health care item or service, including a covered outpatient drug.

"(vi) CIVIL MONETARY PENALTY.—A covered entity or contract pharmacy that violates a requirement of this subparagraph shall be subject to a civil monetary penalty of $2,500 for each such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions of this clause.

"(vii) REGULATIONS.—The Secretary shall promulgate regulations through notice and comment rulemaking to implement

the requirements described in this subparagraph and shall issue final regulations not later than 90 days after the date of enactment of this subparagraph. The authority to promulgate regulations under this clause is limited to specifying the obligations of covered entities and contract pharmacies under this subparagraph and other details necessary to carry out the requirements of this subparagraph efficiently, effectively, and in conformity with this subparagraph.

''(viii) OIG STUDIES.—The Office of Inspector General of the Department of Health and Human Services shall conduct and publish annual studies of covered entity (including child site and entity pharmacy) and contract pharmacy practices with respect to the requirements under this subparagraph and evaluate whether applicable patients are receiving assistance to reduce their out-of-pocket obligations in accordance with this subparagraph.

''(H) PATIENT AFFORDABILITY REQUIREMENTS FOR CERTAIN NONHOSPITAL COVERED ENTITIES.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) that is required by the Federal statute authorizing the grant, project, or contract that is the basis for such entity's participation in the program under this section to provide affordability assistance to eligible individuals receiving health care items or services from such entity shall, with respect to an applicable patient (as defined in clause (iii)) dispensed or administered a covered outpatient drug subject to an agreement under this section at a covered entity site, including an entity pharmacy, establish a policy that provides a discount to reduce the out-of-pocket obligation of an applicable patient with respect to such drug to an amount sufficient to ensure such patient is not denied access to such drug based on such patient's ability to pay for such drug.

"(ii) APPLICABILITY TO CONTRACT PHARMACIES.—With respect to an applicable patient of a covered entity described in

clause (i) dispensed a covered outpatient drug subject to an agreement under this section on behalf of such covered entity at a contract pharmacy pursuant to subparagraph (E), such covered entity shall require such contract pharmacy to provide discounts to applicable patients on behalf of such covered entity in accordance with the covered entity's policy described in clause (i).

''(iii) DEFINITIONS.—In this subparagraph:

''(I) APPLICABLE PATIENT.—The term 'applicable patient' has the meaning given such term in subparagraph (G).

''(II) CONTRACT PHARMACY.—The term 'contract pharmacy' has the meaning given such term in subparagraph (E).

''(III) ENTITY PHARMACY.—The term 'entity pharmacy' has the meaning given such term in subparagraph (E).

"(IV) FEDERAL POVERTY GUIDELINES.—The term 'Federal poverty guidelines' has the meaning given such term in subparagraph (G).

"(V) OUT-OF-POCKET OBLIGATION.—The term 'out-of-pocket obligation' has the meaning given such term in subparagraph (G).".

SEC. 8. HOSPITAL CHILD SITES.

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

"(I) HOSPITAL CHILD SITE REQUIREMENTS.—

"(i) IN GENERAL.—A covered entity described in one of subparagraphs (L) through (O) of paragraph (4) may register an off-campus outpatient facility associated with such covered entity for inclusion in the identification system described in subsection (d)(2)(B)(iv) to participate in the program under this section as an integral part of such covered entity if such covered entity demonstrates to the Secretary, in a

manner specified by the Secretary, that such facility satisfies each of the requirements in this subparagraph. For purposes of this section, each facility registered to participate in the program under this section and satisfying the requirements in this subparagraph shall be referred to as a 'child site'.

"(I) The facility is listed on the covered entity's most recently filed Medicare cost report on a line that is reimbursable under the Medicare program (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the facility would be correctly included on a reimbursable line of a Medicare cost report if the covered entity filed a cost report).

"(II) Such cost report demonstrates that the services provided at the facility have associated costs and charges for hospital outpatient depart-

ment services under title XVIII of the Social Security Act (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the services provided at the facility include outpatient services).

''(III) The facility is wholly owned by the covered entity.

''(IV) The Secretary has made a determination, under the process described in section 413.65(b) of title 42, Code of Federal Regulations (or any successor regulations), that the facility meets the Medicare provider-based standards under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations) for an off-campus outpatient department of the covered entity.

''(V) The facility provides outpatient health care services that are not limited to only dispensing, admin-

istering, or otherwise furnishing covered outpatient drugs.

''(VI) The facility is subject to and adheres to all charity care and sliding fee scale policies of the covered entity and makes such policies publicly available in a manner consistent with requirements established under section 501(r) of the Internal Revenue Code of 1986 applicable to hospital financial assistance policies.

''(VII) The facility is located in an area with a shortage of personal health services that is—

''(aa) initially designated by the Secretary pursuant to section 330(b)(3), on or before [December 1, 2025]; or

''(bb) designated by the Secretary pursuant to subparagraphs (A) through (C) of section 330(b)(3), after [December 1, 2025], using the scoring methodology and criteria specified by the

Secretary as of [December 1, 2025].

''(VIII) In the case of a covered entity described in one of subparagraphs (L) through (O) of paragraph (4) that is a private nonprofit hospital that has, as the basis for its participation in the program under this section, a contract with a State or local government to provide outpatient health care services to low income individuals described in paragraphs (4)(L)(i), the facility independently complies with all requirements applicable to such covered entity with respect to such contract.

''(IX) For the most recent year, the facility's total cost incurred for charity care (as such term is defined in line 23 of worksheet S–10 to the Medicare cost report, or in any successor form) furnished at such facility during such year, as a share of the facility's total patient service revenue, is

greater than or equal to the greater of—

"(aa) for such year, the total cost incurred for charity care, as a share of total patient service revenue, furnished at the covered entity's on-campus locations; or

"(bb) the average cost incurred for charity care, as a share of total patient service revenue, calculated for the year prior to the most recent year for which data is available, across all hospitals in the State where the facility is located that receive payments for inpatient hospital services under the prospective payment system established under section 1886(d) of the Social Security Act.

"(X) For the most recent year, the facility's share of total outpatient services revenue derived from base reimbursement to such entity (excluding

supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis at the facility (including any cost-sharing for such items and services) is greater than or equal to the greater of—

"(aa) for such year, the share of total outpatient services revenue derived from base reimbursement to such entity (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under

title XXI of such Act for items and services furnished on an outpatient basis at the on-campus locations of the covered entity with which the facility is associated (including any cost-sharing for such items and services) ; or

''(bb) the average share of total outpatient services revenue derived from base reimbursement (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis (including any cost-sharing for such items and services), calculated for the year prior to the most recent year for which data is avail-

able, across all hospitals in the State where the facility is located that receive payments for outpatient hospital services under the prospective payment system for covered outpatient department services established under section 1833(t) of such Act.

''(XI) The covered entity certifies, at the time such facility is initially registered for inclusion in the identification system described in subsection (d)(2)(B)(iv) to participate in the drug pricing program under this section and annually thereafter as part of the recertification process, that the facility satisfies all applicable requirements under this subparagraph.

''(ii) LIMITATION.—Only an off-campus outpatient facility that meets each of the requirements under this subparagraph may purchase covered outpatient drugs under the 340B program or use covered outpatient drugs purchased under the

340B program by another part of the covered entity that is authorized to participate in such program. Any transfer of 340B drugs to another facility or another part of a covered entity that is not authorized to participate in the 340B program shall be deemed a violation of subparagraph (B).

''(iii) DEREGISTRATION.—If at any time following registration a requirement described in clause (i) is no longer fully satisfied with respect to a facility, the covered entity described in such clause shall immediately notify the Secretary that such facility no longer fully satisfies the relevant requirement, deregister the facility from the program under this section, remove the facility from the identification system described in subsection (d)(2)(B)(iv), and take all necessary actions to prohibit such facility from making any purchases under the program under this section or representing to third parties that such facility may purchase covered outpatient drugs under such program.

"(iv) OBLIGATION TO SELF-DISCLOSE.—A covered entity described in clause (i) shall immediately disclose to the Secretary and the manufacturer of the affected covered outpatient drug any purchase made under the program under this section by or on behalf of the covered entity with respect to a facility that, at the time of the purchase of such drug, did not fully satisfy the requirements in such clause. Any such purchase shall require the covered entity to promptly conduct an audit supervised by the Secretary to identify the full scope of noncompliance with such requirements and to provide the written results of such audit to the Secretary and the manufacturer of the affected covered outpatient drug. The covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the noncompliance in an amount equal to the reduction in the price of the drugs provided under paragraph (1), plus interest on such amount, which shall be compounded monthly and equal to the current

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

''(v) CIVIL MONETARY PENALTY.—Where a covered entity knowingly and intentionally violates clause (ii) or otherwise fails to satisfy a requirement in clause (iii) or clause (iv), the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for all urban consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this clause.

"(vi) SECRETARIAL PUBLICATION OF REPORTS.—On an annual basis, the Secretary shall prepare and make available to the public in an electronic, machine readable format separate reports listing facilities that satisfy the requirements in each of subclauses (IX) and (X) of clause (i).

"(vii) DEFINITION.—For purposes of this subparagraph, the term 'campus' has the meaning given such term in section 413.65(a)(2) of title 42, Code of Federal Regulations (or any successor regulations).".

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

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

Service Act, or update existing registrations in such system for, off-campus outpatient (provided that, for purposes of this subsection, the term ''campus'' has the meaning given such term in section 413.65(a)(2) of title 42, Code of Federal Regulations (or any successor regulations)) facilities associated with such covered entity that satisfy the requirements of such section. Such instructions shall direct each such covered entity to, on or before such effective date, remove from such system the existing registration of any off-campus outpatient facility associated with such covered entity that does not satisfy the requirements of such section 340B(a)(5)(I)(i). Clauses (iii) through (v) of section 340B(a)(5)(I) of the Public Health Service Act shall apply with respect to any covered entity described in one of subparagraphs (L) through (O) of section 340B(a)(4) of such Act that fails to remove a facility described in the immediately preceding sentence on or before the effective date described in subsection (b).

SEC. 9. CONTRACTING REFORMS.

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

''(f) REQUIREMENTS FOR TPA AND CONTRACT PHARMACY REMUNERATION.—

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

"(A) such remuneration is a flat dollar amount not directly or indirectly based on any price of, or discount or other remuneration provided with respect to, a covered outpatient drug, paid for each unit of service furnished to the covered entity, regardless of whether a prescription was dispensed to an individual who is a patient of the covered entity;

"(B) the amount of such remuneration is consistent with fair market value in an arm's-length transaction for the bona fide, itemized 340B-related services actually performed on behalf of the covered entity; and

"(C) such remuneration complies with applicable State and Federal law, including section 1128B(b) of the Social Security Act.

"(2) CONTRACT PHARMACY FEES.—A contract pharmacy that has entered into a written agreement with a covered entity pursuant to and satisfies the applicable requirements in subsection (a)(5)(E) may receive remuneration from such covered entity for the performance of services associated with dispensing covered outpatient drugs subject to an agreement under this section to individuals who are patients of the covered entity (as defined in subsection (b)(3)) only if—

"(A) such remuneration is a flat dollar amount not directly or indirectly based on any price of, or discount or other remuneration provided with respect to, a covered outpatient drug, paid for each dispense of such a drug to a patient of the covered entity;

"(B) the amount of remuneration for each dispense does not exceed 125 percent of the average per-prescription dispensing fee paid to such pharmacy by all third-party payors, based on data from the most recent full calendar year for which such data is available;

"(C) the amount of such remuneration is consistent with fair market value in an arm's-length transaction for the bona fide, itemized 340B-related services actually performed on behalf of the covered entity; and

"(D) such remuneration complies with applicable State and Federal law, including section 1128B(b) of the Social Security Act.

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

"(3) AUDITABLE RECORDS.—A covered entity shall retain copies of written agreements with third-party administrators or contract pharmacies described in this subsection for a period of time specified by the Secretary and shall make copies of such agreements available to the Secretary or their designee upon request.

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

in this subsection that fails to comply with the applicable requirements specified in this subsection shall be required to pay a civil monetary penalty equal to 10 times the amount such third-party administrator or contract pharmacy received for the performance of relevant services described in this subsection. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this paragraph.''.

SEC. 10. PRIME VENDOR PROGRAM.

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

''(8) PRIME VENDOR PROGRAM.—

''(A) IN GENERAL.—The Secretary shall establish a prime vendor program under which the Secretary enters into contracts with at least 2 separate prime vendors (referred to in this paragraph as 'prime vendor contracts'), and covered entities may enter into contracts with

such prime vendors for the distribution of covered outpatient drugs (referred to in this paragraph as 'distribution contracts'). The Secretary shall begin solicitation of a second prime vendor contract not later than 1 year after the date of enactment of the 340B Drug Pricing Integrity and Affordability for Patients Act.

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

''(i) have no conflicts of interest with respect to its financial, contractual, organizational, or other interests that relate to the work under the contract with the Secretary; and

''(ii) not be owned wholly or as a subsidiary of, operated by, have a revenue sharing agreement with, or otherwise maintain joint ownership with an entity described in paragraph (4)(L)(iii).

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

lowing terms as conditions for receiving such contract:

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

"(ii) The prime vendor may not participate in the negotiation of contracts on behalf of covered entities with which the vendor has entered into a distribution contract for procurement of products that are not covered outpatient drugs, including drugs (as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act) (including biological products), devices (as defined in section 201(h) of such Act), and other articles as the Secretary may prohibit.

"(iii) If a prime vendor offers educational services to covered entities, such services shall be provided at no cost to covered entities with which the vendor has entered into a distribution contract.

"(iv) The Secretary shall have unlimited rights in data (as such terms are defined in the Federal Acquisition Regulation) first produced in the performance of a prime vendor contract and data delivered under such contract. In addition to any data to which the Secretary has access as specified in a prime vendor contract, the Secretary may, at any time during performance of such contract or within a period of **[**5**]** years after the term of this contract ends, require delivery of, or provide public access to, any data first produced or specifically used in the performance of the contract.

"(D) DISTRIBUTION TO COVERED ENTITIES OTHER THAN THROUGH PRIME VENDORS.—If a covered entity obtains covered outpatient drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution, even if the covered entity has a distribution contract with a prime vendor.".

SEC. 11. TRANSFER OF CIVIL PENALTY AMOUNTS COLLECTED.

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

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

SEC. 12. APPLICATION; REGULATIONS AND GUIDANCE.

(a) APPLICATION.—Except as otherwise provided, the amendments made by this Act to section 340B of the Public Health Service Act (42 U.S.C. 256b) shall apply beginning on the date that is 1 year after the date of enactment of this Act.

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