119TH CONGRESS
2D SESSION

S. _____

To amend the Public Health Service Act with respect to the drug discount program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. MORAN (for himself, Ms. BALDWIN, Mrs. CAPITO, Mr. KAINE, Mr. BOOZMAN, and Mr. HICKENLOOPER) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act with respect to the drug discount program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Supporting Underserved and Strengthening Transparency, Accountability, and Integrity Now and for the Future of 340B Act'' or the ''SUSTAIN 340B Act''.

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

SEC. 2. SENSE OF CONGRESS.

It is the sense of Congress that the purpose of the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) is to stretch scarce Federal resources and help safety net providers maintain, improve, and expand patient access to health care services by requiring drug manufacturers, as a condition of participation in the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) and the Medicare program under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.), to provide discounts at the point of purchase to covered entities that serve a disproportionate share of low-income and underserved patients or medically vulnerable patients.

SEC. 3. CONTRACT PHARMACY.

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

"(11) CONTRACT PHARMACIES.—

"(A) IN GENERAL.—A covered entity may elect to use one or more wholly-owned pharmacies, in addition to one or more contract pharmacies, to acquire and dispense to patients of the covered entity covered outpatient drugs purchased by the covered entity pursuant to an agreement described in paragraph (1).

"(B) LIMITS ON CERTAIN CONTRACT PHARMACIES.—

"(i) IN GENERAL.—Subject to clause (ii), each covered entity that elects to use one or more contract pharmacies to dispense covered outpatient drugs purchased by the covered entity pursuant to an agreement described in paragraph (1) to patients of the covered entity shall cancel the contract with any such pharmacy that has not dispensed any covered outpatient drugs to such patients in the most recent 12-month period.

"(ii) EXCEPTIONS.—A covered entity is not required to cancel the contract of a pharmacy that has not dispensed covered outpatient drugs in the most recent 12-

month period, as described in clause (i), if—

"(I) there is a change of ownership of the covered entity or pharmacy requiring a new contract to continue an established arrangement;

"(II) there is a change to the covered entity's service area;

"(III) the contract pharmacy is necessary for the covered entity to preserve access for emergency or contingency use; or

"(IV) other circumstances exist, as the Secretary may determine appropriate.

"(iii) THRESHOLD FOR HIGH NUMBER OF CONTRACT PHARMACIES.—The Secretary may develop a process that is not overly burdensome to the covered entities to increase audits on covered entities that use a high number of contract pharmacies, as determined by the Secretary.

"(C) REGISTRATION OF CONTRACT.—A covered entity shall register with the Secretary, and annually recertify, any contract for a con-

tract pharmacy arrangement, in accordance with such registration requirements as the Secretary may establish through regulations. Such registration requirements shall include requiring the covered entity to do each of the following:

''(i) Submit all contract pharmacy agreements to the Secretary in a timely manner, prior to implementing the contract pharmacy agreement.

''(ii) Register each contract pharmacy arrangement with the Secretary prior to implementing the contract pharmacy agreement.

''(iii) Attest to the covered entity's compliance with the requirements under this section.

''(D) CONTRACT REVIEW PROCESS.—The Secretary shall establish a process to review written agreements between a covered entity and each of its contract pharmacies described in subparagraph (E)(i), to ensure compliance with the requirements under this subsection.

''(E) IMPROVEMENTS IN CONTRACT PHARMACY ARRANGEMENT INTEGRITY.—To ensure the integrity of contract pharmacy arrange-

ments described in this paragraph, including to prevent diversion and duplicate discounts described in paragraph (5)(A), the Secretary shall promulgate rules to carry out the following:

"(i) Require a written agreement between a covered entity and one or more contract pharmacies of the covered entity. Each such agreement shall—

"(I) list the address of each contract pharmacy location that will dispense drugs on behalf of the covered entity or reference the list of such covered entity sites that are active sites in the 340B Office of Pharmacy Affairs Information System (or a successor to such system);

"(II) be signed and in effect not later than the day before the contract pharmacy begins dispensing covered outpatient drugs purchased under this section on behalf of the covered entity; and

"(III) include the standard contract provisions established under clause (ii).

"(ii) Develop standard contract provisions that are required to be included in each written agreement described in clause (i), including provisions providing that—

"(I) the contract pharmacy is required to provide pharmacy services;

"(II) the contract pharmacy is required to provide data to the covered entity to support the submission by the covered entity of covered outpatient data to a clearinghouse contracted entity described in section 1150D(a) of the Social Security Act;

"(III) neither the contract pharmacy nor the covered entity will require a patient to use a certain pharmacy or to obtain a prescription from the covered entity, or otherwise interfere with patient choice of a pharmacy provider, except in the case of a covered entity participating in the program under section 2616;

"(IV) the contract pharmacy may provide other services to the covered entity or its patients at the option of

the covered entity, such as home care, delivery, or reimbursement services;

''(V) regardless of the services provided by the contract pharmacy, access to covered outpatient drugs purchased under this section will be restricted to patients of the covered entity;

''(VI) the contract pharmacy will provide the covered entity with any information requested consistent with customary business practices, such as quarterly billing statements, status reports of collections, or receiving and dispensing records;

''(VII) the covered entity and the contract pharmacy will develop and implement a system to verify eligibility of patients, in accordance with subsection (b)(3), and will establish and maintain safeguards to prevent diversion of covered outpatient drugs;

''(VIII) the contract pharmacy may not use covered outpatient drugs purchased under this section to dis-

pense prescriptions that are reimbursed under the Medicaid program under title XIX of the Social Security Act, unless the covered entity, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts, consistent with paragraph (5)(A), and such arrangement is reported to the Secretary;

''(IX) the contract pharmacy agrees to be subject to annual independent audits commissioned by the covered entity; and

''(X) both the covered entity and the contract pharmacy shall be subject to audits, by the Secretary and drug manufacturers, of records that pertain to the covered entity's compliance with paragraph (5), to prevent diversion and violations of the duplicate discount prohibition.

''(iii) Review written agreements, at the time of registration or recertification, or more frequently if the Secretary deter-

mines necessary, between covered entities and contract pharmacies to ensure compliance with the requirements under this section, to analyze program operations, and to provide program oversight.

''(iv) Provide specific guidance to covered entities regarding the practices and procedures for contract pharmacy oversight, including the scope and frequency of such oversight.

''(v) Establish a retention period of at least 3 years during which covered entities and contract pharmacies are required to maintain all relevant auditable records in relation to contract pharmacy arrangements, including records relating to transactions of drugs purchased pursuant to an agreement under paragraph (1), sufficient to demonstrate compliance with the requirements described in paragraph (5).''.

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

"(12) MANUFACTURER REQUIREMENTS.—A manufacturer of a covered outpatient drug that is subject to an agreement with the Secretary under paragraph (1) shall, as a condition of such agreement, comply with the following requirements:

"(A) Offer the covered entity covered outpatient drugs for purchase at or below the applicable ceiling price described in paragraph (1) regardless of whether the drug is dispensed directly by the covered entity or through a contract pharmacy of the covered entity.

"(B) Deliver or allow the delivery of covered outpatient drugs purchased by a covered entity at or below the applicable ceiling price described in paragraph (1) to locations, including pharmacy locations as requested by a covered entity, in accordance with the covered entity's contract pharmacy agreements.

"(C) Not, directly or indirectly, place any of the following conditions on the offers made to a covered entity to purchase a covered outpatient drug at or below the applicable ceiling price described in paragraph (1) for dispensing according to the applicable written contract pharmacy arrangements:

"(i) Restricting distribution options only with respect to covered outpatient drugs, covered entities, or contract pharmacies.

"(ii) Requiring the submission of claims data to the manufacturer, except for submissions to the entity receiving the contract to maintain the clearinghouse under section 1150D of the Social Security Act.

"(iii) Such other conditions as the Secretary may prohibit through notice and comment rulemaking.".

(c) PROGRAM INTEGRITY.—Section 340B(d)(1)(B)(vi)(III) of the Public Health Service Act (42 U.S.C. 256b(d)(1)(B)(vi)(III)) is amended—

(1) by striking "intentionally charges" and inserting the following: "intentionally—

"(aa) charges";

(2) by striking the period and inserting a semicolon; and

(3) by adding at the end the following:

"(bb) refuses to offer a covered outpatient drug for purchase at or below the ceiling price;

"(cc) refuses to deliver a covered outpatient drug purchased by a covered entity at or below the ceiling price; or

"(dd) places conditions on the ability of a covered entity to purchase a covered outpatient drug at or below the ceiling price.".

(d) TRANSPARENCY.—Paragraph (11) of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), as added by subsection (a), is amended by adding at the end the following:

"(F) TRANSPARENCY.—Each covered entity that uses one or more contract pharmacies as described in this paragraph shall make the following information about each contract pharmacy arrangement pursuant to this paragraph and registered under subparagraph (C) available to the Secretary for publication on the website of the Department of Health and Human Services:

"(i) The name of the covered entity, including each child site, that uses a contract pharmacy.

''(ii) The name and address of each contract pharmacy location to which the contract pharmacy arrangement applies.

''(iii) The effective date of the contract pharmacy arrangement.

''(iv) The last year a covered outpatient drug was dispensed under the contract pharmacy arrangement from each location.

''(v) The number of covered outpatient drugs dispensed annually from each location under this section.

''(vi) Whether the contract pharmacy is a mail-order or payer-mandated pharmacy.''.

(e) AUDITING.—Section 340B(a)(5)(C) of the Public Health Service Act (42 U.S.C. 256b(a)(5)(C)) is amended—

(1) by striking ''A covered entity'' and inserting the following:

''(i) IN GENERAL.—A covered entity''; and

(2) by adding at the end the following:

''(ii) CONTRACT PHARMACY AUDITS.—

"(I) IN GENERAL.—A covered entity that uses one or more contract pharmacies shall permit the Secretary or the manufacturer of a covered outpatient drug that the covered entity or pharmacy purchased under this section to audit at the Secretary's or the manufacturer's expense the records of the covered entity and contract pharmacy to assess compliance with the contract pharmacy requirements under paragraph (11) with respect to drugs of the manufacturer.

"(II) PROCESS.— In order to initiate an audit under subclause (I), a manufacturer shall—

"(aa) demonstrate credible allegations to the Secretary about noncompliance under subparagraph (B) or (C) of paragraph (11) and evidence of good faith outreach to determine compliance, including through—

"(AA) notification to the covered entity in writing

when the manufacturer determined that the covered entity may have violated the requirements under subparagraph (B) or (C) of paragraph (11); and

''(BB) providing the covered entity a 30-day period, beginning on the date of notification under subitem (AA), to resolve the matter; and

''(bb) submit to the Secretary evidence of the credible allegations described in item (aa) to request authorization to proceed with an audit of the covered entity.

''(III) CORPORATE OFFICERS.—A corporate officer of the covered entity shall be responsible for corrections of noncompliance identified in an audit conducted under this clause.

''(IV) AUTHORITY TO ESTABLISH AUDIT PROCESS.—The Secretary shall

establish, through notice and comment rulemaking, a process for making a determination of a credible allegation under this clause, a timeline for making such a determination, and the audit process relating to the number, scope, and duration of audits authorized under this clause.''.

SEC. 4. PATIENT DEFINITION.

(a) PATIENT DEFINITION.—

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

''(3) PATIENT.—

''(A) IN GENERAL.—In this section, the term 'patient', with respect to a covered entity, means an individual who—

''(i) has received an outpatient health care service from the covered entity at any point 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 State and Federal law, that dem-

onstrates the existence of a patient relationship in accordance with this paragraph for each prescription or order for a covered outpatient drug, and maintains such record for a period of at least 3 years, or longer if required by State or Federal law; and

''(iii) received a prescription or order for a covered outpatient drug—

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

''(II) as a result of a referral described in subsection (a)(13).

''(B) AIDS DRUG PURCHASING ASSISTANCE PROGRAM PATIENTS.—An individual registered in the program of a covered entity described in subsection (a)(4)(E) is a patient of the covered entity for purposes of this paragraph.

''(C) STATE OR POLITICAL SUBDIVISION OF A STATE RECEIVING FUNDING UNDER SECTION 318.—An individual who receives a drug purchased by a State or political subdivision of a State, for the treatment of a disease or condi-

tion for which the State or political subdivision of a State has received such award under section 318, is a patient exclusively of the State or political subdivision of the State for the purpose of qualifying that prescription for 340B pricing under this section.

''(D) EXCLUSIONS.—For purposes of this section, an individual shall not be considered a patient of a covered entity if the outpatient health care services received by the individual consist only of—

''(i) the administration of a drug, or the dispensing of a drug for subsequent self-administration or administration in the home setting; or

''(ii) an infusion of a drug.

''(E) EXCEPTION FOR DISCHARGE PRESCRIPTIONS.—In the case of a patient discharged from an emergency department or inpatient hospital stay from a covered entity described in any of subparagraph (A) through (O) of subsection (a)(4) that results in an outpatient prescription, a covered entity may provide such drug to the individual as a covered outpatient drug pursuant to the program under

this section, and shall be deemed to meet the requirements for establishment of a patient under subparagraph (A) in the same manner and under the same conditions as the covered entity would provide such drug to such patient had the covered entity prescribed the drug.

''(4) OUTPATIENT HEALTH CARE SERVICE.—The term 'outpatient health care service' means an outpatient health care service—

''(A) that was furnished pursuant to a valid, written order that is documented or a referral that is documented in the medical record for the patient that is maintained by the covered entity; and

''(B)(i) for which reimbursement under title XVIII or XIX of the Social Security Act would be available when the services were furnished;

''(ii) that can be identified by a CPT established by the American Medical Association or HCPCS code established by the Centers for Medicare & Medicaid Services as of the date the services were furnished; or

''(iii) in the case of covered entity described in any of subparagraphs (A) through

(K) of subsection (a)(4), that is a service that is consistent with the scope of the grant or designation described in the applicable such subparagraph.

''(5) PRACTITIONER.—The term 'practitioner' means a health care practitioner who—

''(A)(i) is an employee or independent contractor of a covered entity, and the covered entity bills for such services and is responsible for the care furnished by such practitioner; or

''(ii) furnishes health care services under an ongoing contractual obligation to a covered entity, cooperative arrangement pursuant to section 330 with a covered entity described in subsection (a)(4)(A), or, only in the case of a covered entity that is prohibited to enter into contractual obligations, pursuant to medical staff membership with a covered entity, such that the covered entity maintains clinical responsibility for the health care services that resulted in the patient receiving a prescription or order for the covered outpatient drug; 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).''.

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

''(iii) AUDITS RELATING TO PATIENT STATUS.—

''(I) IN GENERAL.—A covered entity providing covered outpatient drugs pursuant to an agreement under paragraph (1) shall permit the Secretary and the manufacturer to audit, at the Secretary's or manufacturer's expense, the records of the entity with respect to drugs of the manufacturer that directly pertain to the entity's compliance with—

''(aa) treating individuals as patients of the entity only as described in subsection (b)(3); and

''(bb) the requirements for providing such drugs to referred patients pursuant to paragraph (13).

"(II) AUDITING.—The Secretary shall audit the records of covered entities with respect to records described in this clause not less frequently than every 3 years, and shall audit high-risk and high-volume, as defined by the Secretary, covered entities more frequently, in a manner that is not overly burdensome to the covered entity. The Secretary shall establish a mechanism for manufacturers to request and authorize audits specific to referral prescription eligibility under paragraph (13) upon demonstration of a credible allegation of non-compliance.

"(III) AUTHORITY TO ESTABLISH PROCESS.—The Secretary shall establish, through notice and comment rulemaking, a process for manufacturers and covered entities to make a good faith attempt to resolve any concerns identified by a manufacturer prior to the initiation of an audit under this clause. A manufacturer

shall provide to the covered entity the same materials that the manufacturer provided to the Secretary to support a credible allegation under this clause, as determined by the Secretary.''.

(3) ENFORCEMENT.—Section 340B(a)(5)(D) of the Public Health Service Act (42 U.S.C. 256b(a)(5)(D)) is amended—

(A) by striking ''subparagraphs (A)'' and inserting ''subparagraph (A)''; and

(B) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary''; and

(C) by adding at the end the following:

''(ii) SANCTIONS FOR NONCOMPLIANCE WITH PATIENT STATUS REQUIREMENTS.—If the Secretary determines, after an audit described in subparagraph (C)(iii), a covered entity to not be in compliance with the requirements of treating an individual as a patient of the covered entity as described in subsection (b)(3) or the requirements of paragraph (13)—

"(I) the covered entity shall develop a corrective action plan, which shall be subject to approval and monitoring by the Secretary; and

"(II) if the Secretary determines that the covered entity has not adequately corrected its noncompliance in accordance with such plan—

"(aa) the covered entity shall be ineligible to participate in the drug discount program under this section for a period determined by the Secretary, not to exceed 3 years; and

"(bb) the Secretary may order the covered entity to pay civil monetary penalties, pursuant to subpart O of part 1003 of title 42, Code of Federal Regulations (or any successor regulations), with respect to any covered outpatient drugs purchased by the covered entity during the period in which the covered entity was found to be not in compli-

ance with the requirements of treating an individual as a patient of the entity as described in subsection (b)(3) or the requirements of paragraph (13).''.

(b) COVERED ENTITY REGISTRATION.—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) COVERED ENTITY REGISTRATION.—As a condition for participation in the drug discount program under this section, a covered entity shall register with the Secretary and be listed on the 340B Office of Pharmacy Affairs Information System (or a successor to such system).''.

(c) TREATMENT OF CERTAIN PRESCRIPTIONS FOR PATIENTS REFERRED TO NON-340B PROVIDERS.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), as amended by section 3(b), is further amended by adding at the end the following:

''(13) REFERRAL PRESCRIPTIONS.—

''(A) IN GENERAL.—In the case of a patient of an eligible covered entity who is referred by such covered entity to a prescribing

provider who is not providing care on behalf of a covered entity, and such prescribing provider prescribes a drug within 12 months of the patient receiving such referral, the eligible covered entity may provide such drug to such patient as a covered outpatient drug pursuant to the program under this section, in the same manner and under the same conditions as the covered entity would provide such drug to such patient had the covered entity prescribed the drug, in accordance with the requirements under subparagraph (C).

''(B) ELIGIBLE COVERED ENTITY.—For purposes of this paragraph, a covered entity is an eligible covered entity if such entity is—

''(i) an entity described in any of subparagraphs (A) through (K) or (N) of paragraph (4); or

''(ii) a sole community hospital described in paragraph (4)(O).

''(C) REQUIREMENTS.—

''(i) IN GENERAL.—An eligible covered entity may provide a drug to a patient as described in subparagraph (A) only if—

''(I) the covered entity has a documented relationship with the patient, as described in subsection (b)(3), and has documentation of the provision of care provided by the covered entity and the prescribing provider and consultation with the prescribing provider regarding such patient, including documentation of the referral and the prescription;

''(II) the patient was referred to the prescribing provider who prescribed the drug by the covered entity;

''(III) the prescription is filled at the covered entity's wholly-owned pharmacy or contract pharmacy;

''(IV) the covered entity maintains, for a period of at least 3 years, documentation of compliance with this paragraph, including all documents subject to audit under paragraph (5)(C);

''(V) the covered entity does not share the savings received from pur-

chasing the covered outpatient drug with the prescribing provider; and

''(VI) the covered entity meets such other requirements as the Secretary may establish through notice and comment rulemaking.

''(ii) EXCEPTED DRUGS.—

''(I) IN GENERAL.—Except as provided in subclause (II), a covered entity may not provide a patient a covered outpatient drug pursuant to subparagraph (A) if such drug—

''(aa) is an infused drug;

''(bb) is a clinician-administered drug; or

''(cc) otherwise requires administration by a clinician.

''(II) EXCEPTIONS.—A covered entity may provide a patient a covered outpatient drug described in subclause (I) pursuant to subparagraph (A) if—

''(aa) the eligible covered entity is a covered entity described in paragraph (4)(A) and was providing infusion services necessary

to deliver a required primary health service or an additional health service (as defined in section 330(b)(1)) pursuant to funding received under section 330, as of the date of enactment of the SUSTAIN 340B Act; or

''(bb) the Secretary determines, through notice and comment rulemaking, that low-income, medically underserved residents of the service area of the eligible covered entity lack access to infusion services within a reasonable distance and based on this determination, the eligible covered entity receives approval from the Secretary to provide these services pursuant to funding provided under section 330, subject to all the requirements of that section.

''(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to affect the application of subsection (e).

"(E) ADDRESSING SIGNIFICANT VOLUME OF DRUGS PROVIDED TO REFERRED PATIENTS.—

"(i) IN GENERAL.—The Secretary shall audit any eligible covered entity that, in any year, provides covered outpatient drugs to patients who received a prescription for such drug from a provider who is not a covered entity in a volume that exceeds the lesser of—

"(I) 20 percent of the total number of covered outpatient drugs purchased by the covered entity at or below the applicable ceiling price and dispensed by the covered entity for the year; or

"(II) the average annual percentage over the most recent 3-year period, of the total number of covered outpatient drugs purchased by the covered entity at or below the applicable ceiling price for the year and dispensed by the covered entity to patients, that were dispensed to patients who received a prescription for such

drug from a provider who is not a covered entity.

''(ii) HARDSHIP EXCEPTIONS.—The Secretary shall develop specific criteria for a hardship exceptions process, that is not overly burdensome to a covered entity, under which an eligible covered entity may exceed the threshold established under clause (i) without requiring an audit described in such clause only if the eligible covered entity provides required information to the Secretary to demonstrate such hardship, such as a medical need or workforce shortage, in accordance with the criteria established by the Secretary.

''(iii) REPORTING.—A covered entity shall report annually to the Secretary—

''(I) the percentage of the covered entity's revenue under the drug discount program derived from drugs prescribed by a prescribing provider pursuant to this subsection; and

''(II) the percentage of the total number of covered outpatient drugs purchased by the covered entity that

were prescribed by a prescribing provider pursuant to this subsection.

''(iv) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make aggregate information on eligible covered entities identified under clause (i) available on the website of the Health Resources and Services Administration, in such form and manner that the Secretary determines appropriate, and shall not identify any specific covered entity.

''(F) ENFORCEMENT.—

''(i) CORRECTIVE ACTION PLAN.—In the case that the Secretary finds that a covered entity has failed to comply with any requirement under this paragraph, such covered entity shall be required to submit a corrective action plan to the Secretary, which shall be subject to approval and monitoring by the Secretary.

''(ii) LOSS OF REFERRAL AUTHORIZATION.—A covered entity that fails to comply with a corrective action plan within 180 days of approval of such plan by the Secretary under clause (i) shall become in-

eligible to provide covered outpatient drugs to referred patients under subparagraph (A) for such period of time determined by the Secretary under the corrective action plan, not to exceed 3 years.

''(iii) MONETARY PENALTIES.—The Secretary may impose civil monetary penalties, pursuant to subpart O of part 1003 of title 42, Code of Federal Regulations (or any successor regulations), on a covered entity for any discounts received by such entity on covered outpatient drugs provided to referred patients under this paragraph, if the covered entity is found to be noncompliant with the requirements of this paragraph with respect to the relevant drug.

''(G) DEFINITIONS.—For the purposes of this paragraph—

''(i) the term 'prescribing provider' means a licensed health care provider who prescribes a drug to a patient of a covered entity based on the referral of the patient by the covered entity to the provider; and

"(ii) the term 'referral' means a written, electronic, or otherwise documented order by a licensed health care provider ordering, or the recertifying of the need for, a health service.".

(d) OIG REPORT ON REFERRAL PRESCRIPTIONS.—The Inspector General of the Department of Health and Human Services shall—

(1) during the 12-year period beginning on the date of enactment of this Act, conduct an annual study on covered outpatient drugs provided pursuant to prescriptions for referred patients under paragraph (13) of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), as added by subsection (c); and

(2) not later than 2 years after the date of enactment of this Act, and for each of the next 10 years, submit to Congress a report on the study under paragraph (1).

SEC. 5. 340B REBATE MODEL PILOT PROGRAM SUNSET.

Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall conclude the 340B Rebate Model Pilot Program, or a substantially similar program established by the Department

of Health and Human Services. The 340B Rebate Model Pilot Program, or a substantially similar program, shall not be expanded. One year after the date of enactment of this Act, the Secretary shall discontinue the 340B Rebate Model Pilot Program, or a substantially similar program, and transition to the 340B Drug Discount Program Data Clearinghouse established under section 1150D of the Social Security Act, as added by section 9(a).

SEC. 6. CHILD SITES.

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

"(14) CHILD SITES.—

"(A) IN GENERAL.—A covered entity described in subparagraph (L), (M), (N), or (O) of paragraph (4) that owns and operates a child site that participates in the drug discount program under this section shall maintain documentation of, and annually recertify to the Secretary through such certification processes established under title XVIII of the Social Security Act, that each such child site is wholly-owned by the entity and clinically and financially integrated with the covered entity and

providing care consistent with the policies of the covered entity, including by—

''(i) registering each child site with the Secretary, which, in the case of a child site that is eligible for participation as described in subparagraph (B)(ii), shall include submission of the attestation (absent billing requirements) that the child site meets the Medicare provider-based rules under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations);

''(ii) applying the same financial assistance policy for patients as applies with respect to other sites operated by the covered entity; and

''(iii) ensuring that each child site complies with the Medicare provider-based rules under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations) or meets the requirements of subparagraph (B)(i).

''(B) ELIGIBILITY FOR CHILD SITES.—

''(i) IN GENERAL.—A child site is eligible for participation in the drug discount

program under this section, through the eligibility of the covered entity that owns and operates such child site, only if the covered entity demonstrates that the child site meets the following requirements:

''(I) The child site applies the same financial assistance policy for patients as the covered entity.

''(II) The child site ensures that the providers who order or dispense covered outpatient drugs purchased under this section at the child site or a contract pharmacy of the covered entity have clinical responsibility for health care services that result in the receipt of a prescription or order of the covered outpatient drug purchased under this section that is dispensed.

''(III) The child site provides a clinically meaningful range of services, as determined by the services that providers or suppliers employed by, contracted with, or authorized to provide services at, the child site are qualified to deliver.

''(IV) The child site is operated under the same license as the covered entity, except in areas where the State requires a separate license for the child site, or in States where State law does not permit licensure of the child site and the covered entity under a single license. If a State health facilities cost review commission or other agency that has authority to regulate the rates charged by providers in a State finds that a child site is not part of the covered entity, the child site shall not be eligible for the drug discount program under this section.

''(V) The clinical services of the child site and the covered entity are integrated as evidenced by the following:

''(aa) Professional staff of the child site have clinical privileges at the covered entity.

''(bb) The covered entity maintains the same monitoring

and oversight of the child site as for any other owned entity or subsidiary of the covered entity.

''(cc) The medical director of the child site maintains a reporting relationship with the chief medical officer or other similar official of the covered entity that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the covered entity and the chief medical officer or other similar official of the covered entity, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the covered entity.

''(dd) Medical staff committees or other professional committees at the covered entity are responsible for medical activities in the child site, including quality

assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the child site and covered entity.

"(ee) Medical records for patients treated in the child site are integrated into a unified retrieval system, or have the ability to be readily accessed by the covered entity.

"(ff) Inpatient and outpatient services of the child site and the covered entity are integrated, and patients treated at the child site who require further care have full access to all services of the covered entity and are referred where appropriate to the corresponding inpatient or outpatient department or service of the covered entity.

"(VI) The financial operations of the child site are fully integrated within the financial system of the covered

entity, as evidenced by shared income and expenses between the covered entity and the child site. For purposes of the Medicare program under title XVIII of the Social Security Act, the costs of a child site are reported in the appropriate cost center or cost centers of the covered entity, and the financial status of any child site is incorporated and readily identified in the covered entity's trial balance.

''(VII) The child site is held out to the public as part of the covered entity, such that, when patients enter the child site, they are aware that they are entering the covered entity.

''(VIII) The child site is operated under the ownership and control of the covered entity, as evidenced by the following:

''(aa) The business enterprise that constitutes the child site is 100 percent owned by the covered entity.

"(bb) The covered entity and the child site have the same governing body.

"(cc) The child site is operated under the same organizational documents as the covered entity, and is subject to common bylaws and operating decisions of the governing body of the covered entity.

"(dd) The covered entity has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments at the child site.

"(IX) The reporting relationship between the child site and the covered entity have the same frequency, intensity, and level of accountability that exists in the relationship between the

covered entity and its other departments, as evidenced by compliance with the following requirements:

"(aa) The child site is under the direct supervision of the covered entity.

"(bb) The child site is operated under the same monitoring and oversight by the covered entity as any other department of the covered entity, and is operated as any other department of the covered entity with regard to supervision and accountability. The director or individual responsible for daily operations at the child site—

"(AA) maintains a reporting relationship with a manager at the covered entity that has the same frequency, intensity, and level of accountability that exists in the relationship between

the covered entity and its existing departments; and

''(BB) is accountable to the governing body of the covered entity, in the same manner as any department head of the covered entity.

''(X) The following administrative functions of the child site are integrated with the functions of the covered entity: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle such administrative functions for the child site and the covered entity, or the administrative functions for both the child site and the covered entity are—

''(aa) contracted out under the same contract agreement; or

''(bb) handled under different contract agreements, with the contract of the child site

being managed by the covered entity.

''(XI)(aa) The child site 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 does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the site would be correctly included on a reimbursable line of a Medicare cost report if the covered entity filed a cost report).

''(bb) Such cost report demonstrates that the services provided at the child site have associated costs and charges for covered entity outpatient department services under title XVIII of the Social Security Act (or, if the covered entity does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the services provided at the child site in-

clude or consist solely of outpatient services).

"(ii) HRSA DEEMING.—

"(I) IN GENERAL.—If the Administrator of the Centers for Medicare & Medicaid Services has determined a site to be qualified as a provider-based entity and in compliance with the provider-based requirements under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations), the Secretary shall deem the site to have met the requirements described in clause (i).

"(II) RULE OF CONSTRUCTION.—This clause shall authorize the Secretary to establish a process to determine whether a child site, as determined by the Administrator of the Centers for Medicare & Medicaid Services, complies with the Medicare provider-based rules under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations).

"(iii) PROCESS FOR REGISTRATION.—The Secretary shall develop a process for the registration of child sites that are eligible for participation under clause (i) or (ii).

"(iv) ELIGIBILITY DELAY FOR CERTAIN CHILD SITES.—

"(I) NEWLY ACQUIRED SITES.—

"(aa) IN GENERAL.—Except as provided in item (bb), a child site acquired by a covered entity after the date of enactment of the SUSTAIN 340B Act that was not eligible to participate in the drug discount program prior to such date shall not be eligible to participate in the drug discount program under this section until the date that is 3 years after the date of such acquisition.

"(bb) HARDSHIP EXEMPTION.—The Secretary may, on a case-by-case basis, determine that a newly acquired child site will be eligible to participate in

the drug discount program under this section on a specified date within 180 days after the date of acquisition by the covered entity.

"(II) NEWLY CONSTRUCTED SITES.—A newly constructed child site that began operations after the date of enactment of the SUSTAIN 340B Act shall not be eligible to participate in the drug discount program as described in clause (i) unless such site meets all of the requirements under this subparagraph.

"(C) INAPPROPRIATE TREATMENT OF A PROVIDER AS A CHILD SITE.—Not later than 180 days after the first recertification of the covered entity that occurs after the date of enactment of the SUSTAIN 340B Act, the Secretary shall establish a process through notice and comment rulemaking for determining the status of a child site that, prior to such date of enactment, was deemed qualified as a child site but that does not meet the criteria set forth in this subsection.

"(D) REPORTS.—

"(i) GAO REPORT ON PROGRAM INTEGRITY.—Not later than 3 years after the date of enactment of the SUSTAIN 340B Act, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report that analyzes relevant data, including data made available pursuant to subsection (d)(5), and makes recommendations with respect to any policies needed to address program integrity issues associated with child sites in the drug discount program under this section.

"(ii) HHS REPORTS TO CONGRESS.—Not later than 2 years after the date of enactment of the SUSTAIN 340B Act, and every 2 years thereafter, the Secretary shall submit to the appropriate committees of Congress a report that analyzes the use of child sites in the drug discount program under this section, and that—

"(I) characterizes the scope and nature of child sites in the drug discount program under this section, including—

"(aa) the number of newly acquired child sites;

"(bb) the number of newly constructed child sites;

"(cc) the concentration of the child sites across geographic areas; and

"(dd) the payer-mix of the child sites;

"(II) assesses the effect of eligibility delays described in subparagraph (B)(iv); and

"(III) makes recommendations with respect to policies needed to address any issues identified in such report.

"(iii) GAO REPORT ON BEST PRACTICES.—Not later than 1 year after the date of enactment of the SUSTAIN 340B Act, the Comptroller General of the United States shall submit a report to the appropriate committees of Congress that—

"(I) analyzes input solicited from relevant stakeholders, including covered entities and manufacturers, re-

garding potential best practices for ensuring savings received by child sites through participation in the drug discount program under this section are used to meaningfully improve access to care, including by expanding access to health care services or health-related benefits for patients and communities served by the covered entity, including child sites of the covered entity; and

''(II) makes recommendations to the Secretary and appropriate committees of Congress with respect to implementation of best practices identified and analyzed pursuant to subclause (I).''.

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

''(F) CHILD SITE RECORDKEEPING.—In the case of a covered entity that has registered a child site pursuant to paragraph (14), the covered entity shall maintain auditable records

for a period of at least 3 years and be subject to audits by the Secretary of records that pertain to the compliance of the covered entity and child site with the provisions of paragraph (14).''.

SEC. 7. TRANSPARENCY.

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

''(5) REPORTING OF PROGRAM SAVINGS.—

''(A) IN GENERAL.—Not later than 1 year after the date of enactment of the SUSTAIN 340B Act, and annually thereafter, each covered entity shall report to the Secretary the following information with respect to the covered entity, including with respect to all child sites and contract pharmacy arrangements, for the preceding year:

''(i) The total number of individuals who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under subsection (a)(1).

''(ii) The total number of prescriptions dispensed or administered with cov-

ered outpatient drugs purchased under this section and billed to insurance, organized by type of health insurance coverage (as specified by the Secretary, including by the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Children's Health Insurance Program under title XXI of such Act, health insurance coverage offered in the individual or group market or a group health plan (as such terms are defined in section 2791), and uninsured).

''(iii)(I) The cost incurred at each covered entity for charity care, reported as a fraction, where the numerator is the amount of charity care reported on worksheet S–10 of the Medicare cost report (or any successor), and the denominator is the total operating cost of the covered entity, as reported for the most recent cost reporting period; or

''(II) in the case of a covered entity that is not required to submit a Medicare cost report, a qualitative description of the charity care provided by the covered entity,

to the extent applicable under the scope of the grant for a covered entity described in any of subparagraphs (A) through (O) of subsection (a)(4), in such manner that is not overly burdensome to covered entities, as the Secretary may require.

''(iv) At the option of the covered entity, information pertaining to under-reimbursed care provided by the covered entity.

''(v)(I) A description, submitted in a standardized form and manner prescribed by the Secretary, of the covered entity's use of the savings received through participation in the drug discount program under this section, including a description of health care services or health-related benefits used to benefit the patients and communities served by the covered entity, delineated by categories of services and benefits and populations served, including such services and benefits provided to underserved, uninsured, or medically vulnerable patients and communities; and

''(II) an attestation by the chief executive officer, chief executive financial offi-

cer, or chief operating officer certifying that such savings have been used to benefit the patients and communities served by the covered entity.

''(vi) The financial demographics of patients of the covered entity, including—

''(I) the percentage of patients eligible for financial assistance programs and sliding scale fees;

''(II) the percentage of patients who reside in a health professional shortage area (as defined in section 332) or a medically underserved community (as defined in section 799B);

''(III) the percentage of patients who reside in or are part of a medically underserved population (as defined in section 330(b)(3));

''(IV) the percentage of uninsured patients;

''(V) the percentage of patients who are Medicaid beneficiaries; and

''(VI) the percentage of patients who are Children's Health Insurance Program beneficiaries.

"(vii) Policies of the covered entity to promote access and adherence to prescribed medication.

"(viii) In the case of a nongovernmental hospital, any contracts between such hospital and a State or local governmental entity, and any modifications to any such contract.

"(ix) Any third-party administrators in contract with the covered entity for the administration of the drug discount program.

"(x) The funding shortfall for the covered entity attributable to services provided to Medicare and Medicaid beneficiaries, as reported on the Internal Revenue Service Form 990.

"(xi) The number of patients using the outpatient services of the covered entity.

"(xii) Operation costs to the covered entity related to the drug discount program under this section.

"(B) RECORDS RETENTION.—A covered entity shall retain records described in subpara-

graph (A) for a period of at least 3 years and provide such records and reports as the Secretary determines necessary for purposes of carrying out this paragraph.

''(C) AVAILABILITY OF INFORMATION.—

''(i) IN GENERAL.—Not later than 90 days after receiving the information reported by covered entities under paragraph (1), the Secretary shall publish such information on the public website of the Department of Health and Human Services, which may include the website of the 340B Office of Pharmacy Affairs Information System (or a successor to such system).

''(ii) FORMAT.—Data published under clause (i) shall be published in an electronic and searchable format that shows each category of data reported both in the aggregate and identified by each type of covered entity described in subsection (a)(4). In carrying out this paragraph, with respect to data reported pursuant to paragraph (1), the Secretary shall ensure that any proprietary information be redacted from contracts submitted pursuant

to subparagraph (A)(viii) before posting such contracts.

''(D) SUBMISSION PROCESS.—Not later than 1 year after the date of enactment of the SUSTAIN 340B Act, the Secretary shall establish a process by which the information required to be submitted under subparagraph (A) may be submitted directly to the 340B Office of Pharmacy Affairs Information System (or a successor to such system).

''(E) REPORTS TO CONGRESS.—Not later than 1 year after the date of the enactment of the SUSTAIN 340B Act, and annually thereafter, the Secretary shall submit a report to the appropriate committees of Congress on the information collected under subparagraph (A).

''(F) REGULATIONS.—The Secretary may promulgate regulations to carry out this paragraph.''.

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

''(iv) AUDITS OF PROGRAM SAVINGS RECORDS.—A covered entity shall permit

the Secretary to audit, at the Secretary's expense, the records of the covered entity used for purposes of reporting under subsection (d)(5)(A), including how the discount from drugs subject to an agreement under paragraph (1) is used by the covered entity.''.

SEC. 8. ENHANCING PROGRAM INTEGRITY.

(a) AUDITS.—

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

''(v) ADDITIONAL AUDITS.—

''(I) IN GENERAL.—In addition to the audits otherwise authorized under this subparagraph, the Secretary may audit, to assess compliance with requirements under this section—

''(aa) covered entities, including the child sites of a covered entity and contract pharmacies, to identify any violations under this section, including vio-

lations related to improperly claiming eligibility for the program under this section, drug diversion, duplicate discounts, use of contract pharmacies, or claiming a discount under this section on a drug that is not a covered outpatient drug purchased pursuant to an agreement under paragraph (1); and

''(bb) manufacturers, including to identify any failure to provide an accurate ceiling price.

''(II) STANDARDS.—The Secretary shall conduct audits described in this clause in accordance with generally accepted standards that the Secretary determines appropriate and shall make the protocol for such audits publicly available.

''(III) REQUIREMENTS.—The Secretary may not close an audit described in subclause (I) before a corrective action plan required by the

Secretary has been fully implemented, as applicable.

''(IV) 340B VENDOR INFORMATION.—To meet the requirements for submission of information for audits under this clause, with respect to carrying out the program under this section, a covered entity shall contract only with vendors agreeing to—

''(aa) submit data to the Secretary and independent outside auditors contracting with the covered entity as necessary to determine the covered entity's compliance with statutory and regulatory requirements under this program, prohibitions on drug diversion and duplicate discounts, use of contract pharmacies, and claims for discounts on covered outpatient drugs purchased pursuant to agreements under paragraph (1); and

''(bb) respond to requests from auditors in a timely man-

ner, as determined by the Secretary.

''(V) CONSEQUENCES OF AUDIT.—The Secretary shall ensure that, in the case of an audit finding that—

''(aa) a covered entity did not meet one or more of the eligibility criteria for being a covered entity, as defined in paragraph (4), during the full period under review in an audit, the audit results in consequences that are consistent and appropriate with the violation and that do not treat the failure to meet eligibility criteria as an issue that can be corrected retroactively; or

''(bb) a manufacturer did not meet its requirements pursuant to an agreement under paragraph (1) during the full period under review in an audit, the audit results in consequences that are consistent and appro-

priate with the violation and that do not treat the failure to meet the criteria as an issue that can be corrected retroactively.

''(VI) REGULATIONS.—Not later than 1 year after the date of enactment of the SUSTAIN 340B Act, the Secretary shall establish, through notice and comment rulemaking, the audit and reporting procedures required by this clause.''.

(2) ADDITIONAL SANCTIONS AUTHORITY.—Section 340B(d)(2)(B) of the Public Health Service Act (42 U.S.C. 256b(d)(2)(B)) is amended—

(A) in clause (v)(II), by inserting ''or where the covered entity knowingly and intentionally fails to implement a corrective action plan relating to a violation involving improperly claiming eligibility for the program under this section, drug diversion, duplicate discounts, compliance with contract pharmacy requirements, or claiming a discount on a drug that is not a covered outpatient drug (or claiming a rebate on a drug in the case of an AIDS drug purchasing assistance program, as determined

by the Secretary), within 180 days of the Secretary notifying the entity of the requirement for such plan, unless the Secretary determines it is appropriate to allow additional time for compliance,'' after ''knowing and intentional,''; and

(B) by adding at the end the following:

''(vi) Increasing the frequency of audits conducted for entities previously found to be in violation of requirements of the drug discount program that relate to eligibility, drug diversion, duplicate discounts, compliance with contract pharmacy requirements, or claiming a discount on a drug that is not a covered outpatient drug (or claiming a rebate on a drug in the case of an AIDS drug purchasing assistance program described in subsection (a)(4)(E), as determined by the Secretary), and assigning responsibility for making corrections relating to such a violation to a corporate officer of the covered entity.

''(vii)(I) Establishing a process for a covered entity to develop and implement a corrective action plan, and a process by

which the Secretary provides for proper and timely notification of a potential violation by a covered entity.

''(II) Disenrolling from the program a covered entity that fails to implement a corrective action plan within 180 days of issuance of a final audit report related to a statutory violation involving improperly claiming eligibility for the program under this section, drug diversion, duplicate discounts, compliance with contract pharmacy requirements, claiming a discount on a drug that is not a covered outpatient drug (or claiming a rebate on a drug in the case of an AIDS drug purchasing assistance program described in subsection (a)(4)(E), as determined by the Secretary), or failing to comply with reporting of program savings and use of program savings as required.''.

(b) VERIFICATION OF PRIVATE NON-PROFIT HOSPITAL CONTRACTS WITH STATE OR LOCAL GOVERNMENTS.—Section 340B(a)(5) of the Public Health Service Act (42 U.S.C. 256b(a)(5)), as amended by section 6(b), is further amended by adding at the end the following:

"(G) VERIFICATION OF PRIVATE NON-PROFIT HOSPITAL CONTRACTS WITH STATE OR LOCAL GOVERNMENTS.—

"(i) IN GENERAL.—In the case of a private non-profit hospital that has a contract with a State or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare, whether the hospital is registered or seeking to register for the drug discount program as a covered entity described under subparagraph (L), (M), (N), or (O) of paragraph (4), the Secretary shall take all of the following steps, each of which shall be documented:

"(I) Prior to registering or approving annual recertification of such a hospital (or while carrying out any program audit of such a hospital), the Secretary shall obtain and review the hospital's contract with a State or local government and shall verify and document that—

"(aa) the document provided by the hospital is a contract, in

that it is a mutually binding agreement for the hospital to provide health care services or supplies in exchange for something of value;

"(bb) the contract clearly lists the name of the hospital and the unit of State or local government that are parties to the contract and is signed and appropriately dated by appropriate officials of the hospital and the unit of State or local government;

"(cc) the contract specifies an effective date;

"(dd) the contract clearly is in effect and not expired at the time of registration (or at the time of recertification, in the case of annual recertification, or for the full period examined in an audit, in the case of an audit); and

"(ee) the contract explicitly requires that the hospital provide

health care services, and that such services must be provided to individuals who are both low-income and not eligible for either the Medicaid program or the Medicare program.

''(II) The Secretary shall verify the contracts meeting the requirements of clause (i) for all covered entities described in this subparagraph and registered as of the date of enactment of the SUSTAIN 340B Act by no later than 1 year after the date of enactment of the SUSTAIN 340B Act.

''(III) The Secretary shall not register or recertify any covered entity described in this subparagraph if the entity's contract with a State or local government does not satisfy items (aa) through (ee) of subclause (I).

''(ii) PROCESS.—The Secretary shall develop a process to verify the contracts meeting the requirement of clause (i)(I), including specifying a timeline.''.

(c) VERIFICATION OF CERTAIN COVERED ENTITIES.—Section 340B(a)(4)(L)(i) of the Public Health Services Act (42 U.S.C. 256b(a)(4)(L)(i)) is amended by inserting ''(provided that such a private non-profit hospital annually submits to the Secretary verification of such an active contract with a State or local government and verification of its non-profit status)'' before the semicolon.

SEC. 9. PREVENTING DUPLICATE DISCOUNTS.

(a) 340B DRUG DISCOUNT PROGRAM DATA CLEARINGHOUSE.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding the following the following new section:

''SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEARINGHOUSE.

''(a) CLEARINGHOUSE CONTRACTING ENTITY.—Not later than 1 year after the date of enactment of this section, the Secretary shall enter into a contract with an independent, third-party entity (who shall be free of conflicts of interest with covered entities, manufacturers, health plans, third party administrators of health plans, entities providing pharmacy benefit management services to health plans, and of other conflicts of interest as specified by the Secretary) for purposes of carrying out the clearinghouse duties under subsection (b) with respect to the 340B drug discount program to prevent duplicate discounts and en-

sure proper accounting. Such contract shall provide that the third-party entity shall perform the duties described in subsection (b) and shall be for a 4-year term that may be renewed after a subsequent bidding process or using competitive procedures, as defined in section 132 of title 41, United States Code.

''(b) DUTIES.—With respect to 340B drugs that are dispensed to individuals who are entitled to or eligible for benefits under the Medicare program under title XVIII, the Medicaid program under title XIX (including benefits provided under the Medicaid program through a managed care arrangement), the Children's Health Insurance Program under title XXI (including benefits provided under the Children's Health Insurance Program through a managed care arrangement), or a health plan, a third-party entity with a contract in effect under subsection (a) shall—

''(1) request and receive, in the most efficient and least burdensome manner practicable—

''(A) claims-level rebate file data under section 1927, from State Medicaid agencies;

''(B) claims-level data from covered entities; and

''(C) any other data specified by the Secretary as necessary for the entity to carry out this section;

''(2) request, receive, and maintain data described in paragraph (1) in a confidential manner;

''(3) ensure that claims-level data submissions by covered entities are complete and accurate, and if not, obtain complete and accurate data from the covered entity;

''(4) notify the covered entity, the Secretary, the State Medicaid agency, and the manufacturer of any violation described in subsection (c) to allow for remediation;

''(5) provide the manufacturer of a 340B drug with claims-level data submitted by a covered entity, so that the manufacturer may identify units of a 340B drug that may generate a rebate or discount under a voluntary rebate or discount arrangement, such as those related to commercial plans;

''(6) where feasible, share with a covered entity, the Secretary, a Medicaid State agency, or a manufacturer, data the third-party entity identifies in a timely manner with the purpose of preventing any of the violations described in section 2729A(b)(2) of the Public Health Service Act;

"(7) determine total sales of 340B drugs to such individuals for purposes of being used as the basis for determining user fees under section 340B(a)(15) of such Act; and

"(8) allow covered entities described in subparagraphs (A) through (K) of section 340B(a)(4) of the Public Health Service Act, which have the lowest decile of patient volume, as calculated by the Secretary, to make submissions required under this section in an aggregated retrospective basis.

"(c) HARDSHIP EXEMPTION.—The Secretary may, on a case-by-case basis, determine that a covered entity may submit aggregate data if the Secretary determines that it is not feasible for the entity to submit claims-level data, as required under this section.

"(d) RESTRICTIONS ON CONTRACTING ENTITY.—The entity receiving a contract under subsection (a) shall—

"(1) ensure that it has no conflicts of interest, including no direct contractual involvement with any covered entity, payer, or manufacturer participating in the drug discount program under section 340B of the Public Health Service Act;

"(2) not disclose confidential information obtained through carrying out the clearinghouse duties

under this section other than as necessary to carry out the purposes of this section, including for program integrity functions;

''(3) not sell or otherwise generate revenue by licensing or making available the data described in subsection (b)(1); and

''(4) not collect pricing information regarding drugs that are not 340B drugs from covered entities.

''(e) DUTIES OF COVERED ENTITY.—Covered entities shall facilitate and participate in data transmission with the third-party entity with a contract in effect under subsection (a), including with respect to reporting on data available through contract pharmacies.

''(f) RESTRICTIONS ON MANUFACTURER AND PBM USE OF DATA.—

''(1) IN GENERAL.—A manufacturer who receives data under subsection (b)(5) may use such data only for the purpose of preventing duplicate discounts and diversion under this section.

''(2) RESTRICTIONS ON PLANS, ISSUERS, AND PBMS.—A health plan, third party administrator of a health plan, or entity providing pharmacy benefit management services may use data received from

the clearinghouse only for the purpose of preventing duplicate discounts and diversion under this section.

''(3) ENFORCEMENT.—Any manufacturer or other person found by the Secretary to have used data received under subsection (b)(5) for uses other than those described in paragraphs (1) and (2), such as for pricing or marketing, shall be subject to civil monetary penalties, pursuant to subpart O of part 1003 of title 42, Code of Federal Regulations (or any successor regulations), subject to the discretion of the Secretary.

''(g) PRIVACY REQUIREMENTS.—The information exchange required by subsection (b) shall occur in a manner consistent with the privacy, security, and breach notification regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(h) REPAYMENT TO MANUFACTURERS.—The Secretary shall require a covered entity to work with affected manufacturers regarding identified duplicate discounts for 340B drugs, regardless of the method used to dispense the 340B drug, which shall include repayment—

''(1) by the covered entity as a result of the covered entity's noncompliance with section 340B of the Public Health Service Act;

''(2) by a State Medicaid program of rebates improperly requested by the State Medicaid program; or

''(3) by a State Medicaid program where the financial benefit of the duplicate discount accrues to the State Medicaid program, regardless of whether the duplicate discount occurred under the fee-for-service or managed care payment arrangement.

''(i) DEFINITIONS.—In this section:

''(1) 340B DRUG.—The term '340B drug' means a drug that is—

''(A) a covered outpatient drug (as defined for purposes of section 340B of the Public Health Service Act); and

''(B) purchased under an agreement in effect under such section.

''(2) COVERED ENTITY.—The term 'covered entity' means an entity described in section 340B(a)(4) of the Public Health Service Act.

''(3) DIVERSION.—The term 'diversion', with respect to a covered entity and a 340B drug, means the resale or otherwise transferring of the drug to a person who is not a patient, as defined in section 340B(b)(3) of the Public Health Service Act, of the covered entity.

''(4) DUPLICATE DISCOUNT.—The term 'duplicate discount' means a payment under title XIX for medical assistance described in section 1905(a)(12) with respect to a 340B drug if the drug is subject to the payment of a rebate to the State under section 1927.

''(5) HEALTH PLANS.—The term 'health plan' has the meaning given to that term in section 1128C(c).

''(6) MANUFACTURER.—The term 'manufacturer' has the meaning given to that term in section 1927(k)(5).''.

(b) PROHIBITED ACTIONS OF GROUP HEALTH PLANS AND PBMS.—

(1) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual coverage (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)), or an entity providing pharmacy benefit management services may not interfere with the ability of covered entities, contract pharmacies (as such terms are defined in section 340B of the Public Health Service Act (42 U.S.C. 254b)), or manufacturers of drugs to prevent duplicate discounts or to recoup the full amount of any identified duplicate

discounts pursuant to the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 254b).

(2) ENFORCEMENT.—The Secretary of Health and Human Services shall impose civil monetary penalties, pursuant to subpart O of part 1003 of title 42, Code of Federal Regulations (or any successor regulations), on any group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates paragraph (1).

(c) OVERSIGHT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration, shall issue a report to the appropriate committees of Congress detailing coordinated efforts, including through the use of existing resources to address duplicate discounts.

(d) REGULATIONS.—The Secretary of Health and Human Services may promulgate such rules through notice and comment rulemaking as the Secretary determines appropriate to advance the purpose of the drug discount program under section 340B of the Public Health Service

Act (42 U.S.C. 256b) and prevent duplicate discounts through the clearinghouse established by the amendment made by subsection (a).

(e) DEFINITION.—In this section, the term ''duplicate discount'' has the meaning given such term in section 1150D(h) of the Social Security Act, as added by subsection (a).

SEC. 10. PATIENT FINANCIAL ASSISTANCE.

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

''(H) PATIENT FINANCIAL ASSISTANCE.—

''(i) IN GENERAL.—Each covered entity shall—

''(I) ensure that its financial assistance policy is transparent to patients at point of care and publicly reported;

''(II) apply such financial assistance policy to patients served by child sites and contract pharmacies; and

''(III) upon request of the Secretary, submit its financial assistance policy to the Secretary.

"(ii) RECORDS.—The Secretary shall require covered entities to maintain, for a period of at least 3 years, auditable records related to the implementation and enforcement of this subparagraph.

"(iii) FINANCIAL ASSISTANCE POLICY DEFINED.—In this subparagraph, a 'financial assistance policy' means—

"(I)(aa) a written financial assistance policy described in section 501(r)(4)(A) of the Internal Revenue Code of 1986, provided, at least, to patients at 200 percent of the Federal poverty level or less; and

"(bb) a sliding fee scale for covered outpatient drugs dispensed to patients under the drug discount program under this section, as applicable; or

"(II) such other alternative policy as the Secretary may determine with respect to a specific covered entity.

"(iv) OVERSIGHT.—The Comptroller General of the United States shall conduct a study and report to Congress on the im-

pact of requirements of this subparagraph on patient access to covered outpatient drugs purchased under this section.

''(v) LANGUAGE REQUIREMENTS.—A covered entity shall make the financial assistance policy described in clause (i) available to patients, including patients served by child sites and contract pharmacies in plain language (as defined in section 1311(e)(3)(B)of the Patient Protection and Affordable Care Act).

''(vi) RULE OF CONSTRUCTION.—Compliance with this subparagraph shall not be considered a prohibited act under section 1128A, 1128B(b), or 1877 of the Social Security Act.

''(vii) DELAYED EFFECTIVE DATE FOR CERTAIN ENTITIES.—With respect to a child site or contract pharmacy, the requirements of this subparagraph shall apply beginning on the date that is 3 years after the date of enactment of the SUSTAIN 340B Act.''.

SEC. 11. ENSURING THE EQUITABLE TREATMENT OF COVERED ENTITIES AND PHARMACIES PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM.

(a) GROUP HEALTH PLAN AND HEALTH INSURANCE ISSUER REQUIREMENTS.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

"SEC. 2729A. REQUIREMENTS RELATING TO THE 340B DRUG DISCOUNT PROGRAM.

''(a) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer may not discriminate against a covered entity, a 340B pharmacy, or a participant, beneficiary, or enrollee of such plan or coverage by imposing requirements, exclusions, reimbursement terms, or other conditions on such entity or 340B pharmacy that differ from those applied to entities or pharmacies that are not covered entities or 340B pharmacies on the basis that the entity or pharmacy is a covered entity or 340B pharmacy or that the entity or 340B pharmacy dispenses 340B drugs, including by taking any action prohibited under subsection (b).

''(b) SPECIFIED PROHIBITED ACTIONS.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer may not discriminate against a covered entity, a 340B pharmacy, or a participant, beneficiary, or enrollee of such plan or coverage by doing any of the following:

''(1) Reimbursing a covered entity or 340B pharmacy for a quantity of a 340B drug (as defined in subsection (d)) in an amount less than such plan, issuer, or entity providing pharmacy benefit management services (as applicable) would pay to any other similarly situated (as specified by the Secretary) entity or pharmacy that is not a covered entity or a 340B pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or 340B pharmacy or that the entity or pharmacy dispenses 340B drugs.

''(2) Imposing any terms or conditions on any covered entity or 340B pharmacy, with respect to any of the following that differ from such terms or conditions applied to other similarly situated (as specified by the Secretary) entities or pharmacies that are not covered entities or 340B pharmacies on

the basis that the entity or pharmacy is a covered entity or 340B pharmacy or that the entity or pharmacy dispenses 340B drugs:

"(A) Fees, chargebacks, clawbacks, adjustments, or other assessments.

"(B) Professional dispensing fees.

"(C) Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

"(D) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles.

"(E) Any other restrictions, conditions, practices, or policies that, as specified by the Secretary, interfere with the ability of a covered entity to maximize the value of discounts provided under section 340B.

"(3) Interfering with an individual's choice to receive a 340B drug from a covered entity or 340B pharmacy, whether in person or via direct delivery, mail, or other form of shipment.

"(4) Requiring a covered entity or 340B pharmacy to identify, either directly or through a third party, 340B drugs.

''(5) Refusing to contract with a covered entity or 340B pharmacy for reasons other than those that apply equally to entities or pharmacies that are not covered entities or 340B pharmacies, or on the basis that—

''(A) the entity or pharmacy is a covered entity or a 340B pharmacy; or

''(B) the entity or pharmacy is described in any of subparagraphs (A) through (O) of section 340B(a)(4).

''(6) With respect to a group health plan or health insurance issuer offering group or individual health insurance coverage, denying coverage of a drug on the basis that such drug is a 340B drug.

''(7) Requiring a covered entity to make use of any 340B pharmacy in a manner that—

''(A) does not meet the requirements set forth in section 340B for the use of contract pharmacies; or

''(B) is inconsistent with patient need and access.

''(8) Failing to enable pharmacies to distinguish at the point-of-sale between private health plans and State Medicaid plans sponsored by the same payer, through methods such as using the same bank iden-

tification number and processor control number to identify individual enrolled in both types of plans.

''(c) CIVIL MONETARY PENALTIES.—The Secretary shall impose monetary penalties, pursuant to subpart O of part 1003 of title 42, Code of Federal Regulations (or any successor regulations), on any group health plan, health insurance issuer offering group or individual health insurance coverage, or entity providing pharmacy benefit management services on behalf of such a plan or issuer that violates the requirements of this section. Such penalty shall not exceed $5,000 per violation per day. The Secretary shall issue proposed regulations to implement this subsection not later than 180 days after the date of the enactment of this section and shall finalize such regulations not later than 1 year after such date of enactment. The penalties under this subsection may be in addition to other enforcement actions available under this title.

''(d) DEFINITIONS.—For purposes of this section:

''(1) CONTRACT PHARMACY.—The term 'contract pharmacy' has the meaning given such term in section 340B(b).

''(2) COVERED ENTITY.—The term 'covered entity' has the meaning given such term in section 340B(a)(4).

''(3) 340B DRUG.—The term '340B drug' means a drug that is—

''(A) a covered outpatient drug (as defined for purposes of section 340B); and

''(B) purchased under an agreement in effect under such section.

''(4) 340B PHARMACY.—The term '340B pharmacy' means a pharmacy that is wholly owned by a covered entity or that is a contract pharmacy.''.

(b) MEDICARE PRESCRIPTION DRUG PLAN AND MA–PD PLAN REQUIREMENTS.—Section 1860D–12 of the Social Security Act (42 U.S.C. 1395w–112) is amended by adding at the end the following new subsection:

''(i) NONDISCRIMINATION.—

''(1) IN GENERAL.—A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan may not require a covered entity to make use of any 340B pharmacy in a manner that—

''(A) does not meet the requirements set forth in section 340B of the Public Health Service Act for the use of 340B pharmacies; or

''(B) is inconsistent with patient need and access.

''(2) DEFINITIONS.—In this subsection—

"(A) the term 'contract pharmacy' has the meaning given such term in section 340B(b) of the Public Health Service Act;

"(B) the term 'covered entity' has the meaning given such term in section 340B of the Public Health Service Act; and

"(C) the term '340B pharmacy' means a pharmacy that is wholly-owned by a covered entity or that is a contract pharmacy.".

SEC. 12. USER FEE PROGRAM.

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

"(15) USER FEE PROGRAM.—

"(A) ESTABLISHMENT OF QUARTERLY FEE.—Beginning in fiscal year 2031, the Secretary shall in accordance with this section assess user fees on, and collect such fees from, each covered entity participating in the program under this section. The fees shall be assessed for a fiscal year and collected quarterly during the last 3 quarters of such fiscal year and the first quarter of the subsequent fiscal year, and the total amount assessed and col-

lected for a fiscal year shall be the amount specified in subparagraph (B)(i) for such year, subject to subparagraph (C).

"(B) ASSESSMENT OF USER FEES.—

"(i) AMOUNT OF ASSESSMENT.—The total amount of user fees authorized to be assessed and collected under subsection (a) for a fiscal year is—

"(I) $50,000,000 for fiscal year 2031; and

"(II) for fiscal year 2032 and each subsequent fiscal year, the amount authorized to be assessed and collected in the previous fiscal year adjusted by the average annual percent change that occurred in the Consumer Price Index for all urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; Not Seasonally Adjusted; All items; Annual Index) in the 12-month period ending June 30 preceding the fiscal year for which fees are being established.

"(ii) ALLOCATIONS OF ASSESSMENT BY COVERED ENTITY.—

"(I) IN GENERAL.—The total user fees assessed and collected under subparagraph (A) each fiscal year with respect to each covered entity shall be an amount that is equal to the applicable percentage of covered outpatient drugs dispensed by such covered entity for the fiscal year multiplied by the amount specified in clause (i) for the fiscal year.

"(II) APPLICABLE PERCENTAGE.—For purposes of subclause (I), the applicable percentage of each covered entity for a fiscal year shall be determined by—

"(aa) dividing—

"(AA) the number of prescriptions for covered outpatient drugs dispensed by the covered entity in the previous fiscal year; by

"(BB) the total number of prescriptions for covered outpatient drugs dispensed

by all covered entities in such fiscal year; and

''(bb) multiplying the amount determined under item (aa) by 100.

''(iii) TIMING OF ASSESSMENT.—The Secretary shall notify each covered entity subject to this section of the amount of the annual assessment imposed on such covered entity under this subsection not later than December 31 of the fiscal year for which such fees apply. Payments of such assessments shall be made in 4 equal installments, which shall be made by the last day of each quarter of the calendar year immediately following the notification.

''(C) USE OF FEES.—Any fee collected under this paragraph shall be used by the Secretary for purposes of administering this section and enhancing program integrity and oversight activities under this section, including—

''(i) the development of a multi-functional web-based system to collect fees under this paragraph;

"(ii) the establishment, use, and maintenance of the data clearinghouse under section 1150D of the Social Security Act;

"(iii) the improvement of the integrity, transparency, security, searchability, and reliability of the 340B Office of Pharmacy Affairs Information System (or a successor to such system);

"(iv) improvements to the compliance tool used to integrate all information related to manufacturers that have entered into agreements with the Secretary under paragraph (1) and covered entities;

"(v) audits under this section of covered entities and such manufacturers; and

"(vi) any other uses for the purposes of program integrity, as the Secretary determines appropriate.

"(D) SUPPLEMENT NOT SUPPLANT.—Any fees collected under this paragraph shall be used to supplement and not supplant amounts otherwise provided in appropriations Acts to carry out this section.

"(E) REGULATIONS.—The Secretary may promulgate rules through notice and comment rulemaking as necessary to carry out the user fee program under this paragraph, which shall include establishment of a process to provide for exceptions to the fee amount under subparagraph (B), including the circumstances under which such exceptions may apply to certain covered entities.

"(F) OVERSIGHT OF USER FEE PROGRAM.—The Inspector General of the Department of Health and Human Services shall—

"(i) conduct an annual review of the user fee program under this paragraph for the first 5 years of such program; and

"(ii) not later than September 30 of each year for which a review is required under clause (i), submit to Congress a report on the review conducted under clause (i), together with such recommendations as the Inspector General determines appropriate.".

(b) CONFORMING AMENDMENT.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended, in the matter preceding subparagraph (A),

by inserting ‘‘, has submitted user fees to the Secretary in the amount assessed under paragraph (15) for the current year,’’ after ‘‘paragraph (5)’’.

SEC. 13. STUDIES AND REPORTS.

(a) GAO REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the debt collection practices of hospitals, including hospitals that participate in the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b) as covered entities described in subparagraphs (L) through (O) of subsection (a)(4)of such section 340B.

(b) HHS STUDY AND REPORT.—For the purpose of establishing reasonable dispensing fees for purposes of the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b), the Secretary of Health and Human Services shall—

(1) conduct a study on such dispensing fees; and

(2) not later than 2 years after the date of enactment of this Act, submit to Congress a report on the study under paragraph (1).

(c) ASPE STUDY.—The Assistant Secretary for Planning and Evaluation (referred to in this subsection as the ‘‘Assistant Secretary’’) shall conduct a study on the

interactions of the clearinghouse established under section 1150D of the Social Security Act (as added by section 9) and any data collection system established by the Secretary to carry out section 1193(d) of the Social Security Act (42 U.S.C. 1320f–2(d)) or section 1860D–14B(b)(1)(B) of such Act (42 U.S.C. 1395w–114b(b)(1)(B)) to limit duplicative discounts for outpatient prescription drugs. The Assistant Secretary shall make recommendations to Congress on ways to streamline and effectively operate such clearinghouse and data collection systems.

SEC. 14. ADDITIONAL RESOURCES.

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

''(f) AUTHORIZATIONS OF APPROPRIATIONS.—

''(1) AUTHORIZATION OF APPROPRIATIONS FOR AUDITS, INVESTIGATIONS, AND OTHER OVERSIGHT AND ENFORCEMENT ACTIVITIES.—In addition to amounts made available under subsection (d)(4), there are authorized to be appropriated, to the Inspector General of the Department of Health and Human Services, $3,000,000 for each of fiscal years 2027 through 2031, for purposes of conducting audits, investigations, and other oversight and enforce-

ment activities with respect to the drug discount program under this section.

''(2) AUTHORIZATION OF APPROPRIATION FOR GENERAL PURPOSES.—In addition to amounts made available under paragraph (1) and subsection (d)(4), there are authorized to be appropriated $9,000,000 for each of fiscal years 2027 through 2030, for purposes of implementing the activities under this section, as added by the SUSTAIN 340B Act.''.

(b) HIRING AUTHORITY; REGULATIONS.—Section 340B of the Public Health Service Act (42 U.S.C. 256b), as amended by subsection (a), is further amended by adding at the end the following:

''(g) HIRING AUTHORITY.—The Administrator of the Health Resources and Services Administration may hire such additional staff as may be necessary for purposes of carrying out this section.

''(h) REGULATIONS.—The Secretary shall promulgate regulations through notice and comment rulemaking, as appropriate to implement this section.''.

SEC. 15. DEFINITIONS.

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

''(6) CHILD SITE.—In this section, the term 'child site' means a site that is wholly-owned and operated by a covered entity.

''(7) CONTRACT PHARMACY.—In this section, the term 'contract pharmacy' means a pharmacy with which a covered entity has contracted to dispense covered outpatient drugs on behalf of the covered entity whether distributed in person or via mail.''.

SEC. 16. EFFECTIVE DATE.

This Act, including the amendments made by this Act, shall take effect on the date of enactment of this Act.