118TH CONGRESS
2D SESSION

S. _____

To _____ .

IN THE SENATE OF THE UNITED STATES

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

A BILL

To _____ .

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 scare 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 title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), to provide discounts to covered entities that serve a disproportionate share of low-income and underserved 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.—In the case of a covered entity that elects to contract with a phar-

macy or pharmacies to dispense covered outpatient drugs purchased by a covered entity at or below the applicable ceiling price described in paragraph (1) to patients of the covered entity, a manufacturer of a covered outpatient drug that is subject to an agreement with the Secretary under paragraph (1) shall comply with the following requirements:

''(i) Offer each 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 through a pharmacy under contract with a covered entity or directly by the covered entity.

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

''(iii) Not place any of the following conditions on the ability of 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 directly to the manufacturer out of 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.

"(B) REGISTRATION OF CONTRACT.—Each covered entity shall annually register with the Secretary any contract described in subparagraph (A), in accordance with such registration requirements as the Secretary may establish through guidance. Such registration requirements shall include requiring covered entities to—

"(i) submit all contract pharmacy agreements to the Secretary in a timely manner;

"(ii) register each contract pharmacy arrangement with the Secretary, in relation to both the parent and child or associated sites, as applicable, prior to implementing the contract pharmacy agreement; and

"(iii) attest to their compliance with the requirements under this section.

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

"(D) IMPROVEMENTS IN CONTRACT PHARMACY ARRANGEMENT INTEGRITY.—To ensure the integrity of contract pharmacy arrangements described in subparagraph (A), 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 any pharmacy with which the covered entity has a contract pharmacy arrangement. Each such agreement shall—

"(I) list the address of each contract pharmacy location that will dispense drugs on behalf of the covered entity, including all parent, child, principal, or associated sites that plan to use the contract pharmacy;

"(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 be included in each written agreement described in clause (i), including provisions providing that—

''(I) the contract pharmacy is responsible for providing pharmacy services and providing data to covered entities 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;

''(II) the covered entity will not interfere with patient choice of a pharmacy provider, including by not requiring a patient to use a certain pharmacy or to obtain a prescription from the covered entity;

''(III) 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, and reimbursement services;

''(IV) 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;

''(V) the covered entity and the contract pharmacy will adhere to all Federal, State, and local laws and requirements;

''(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, and 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 purchased under this section to individuals who are not patients of the covered entity;

''(VIII) the contract pharmacy may not use covered outpatient drugs

purchased under this section to dispense 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);

''(IX) the contract pharmacy agrees to be subject to periodic independent audits, not less frequently than annually, 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 determines 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 needed practices and procedures for contract pharmacy oversight, including the scope and frequency of such oversight.

''(v) Establish a retention period of at least [10 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)(A).''.

(b) 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 a'' and inserting the following: ''intentionally—

''(aa) charges a'';

(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 maximum applicable price under subsection (a)(1) or deliver a covered outpatient drug purchased by a covered entity at or below such maximum applicable price; or

''(cc) places conditions on the ability of a covered entity to purchase a covered outpatient drug at or below the maximum applicable price under subsection (a)(1).''.

SEC. 4. PATIENT DEFINITION.

[TBD/refer to explanatory document.**]**

SEC. 5. CHILD SITES.

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

''(12) 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 ensure that each 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;

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

''(iii) ensuring that each child site meets the requirements of subparagraph (B).

''(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 patient financial assistance policy as the covered entity.

"(II) The child site participates as a provider or supplier in both the Medicare program under title XVIII of the Social Security Act, and the Medicaid program under title XIX of such Act of the State in which the child site is located, without discrimination against patients of such programs at such locations.

"(III) 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 are directly related to the use of the covered outpatient drug purchased under this section that is dispensed.

''(IV) If the child site is owned by a covered entity described in paragraph (4)(L), the child site shall ensure that the provider who prescribes a covered outpatient drug purchased under this section is an employee or bona fide contractor of the covered entity and a member of the entity's medical staff.

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

''(VI) The child site and the covered entity are operated under the same license, 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.

''(VII) 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.

''(VIII) 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 cen-

ter 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.

"(IX) The child site is held out to the public as part of the covered entity. When patients enter the child site, they are aware that they are entering the covered entity.

"(X) 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.

''(XI) 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 all of 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 just 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.

"(XII) 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.

"(XIII) [The location of the child site.]

"(C) INAPPROPRIATE TREATMENT OF A PROVIDER AS A CHILD SITE.—Not later than [180 days] after the date of enactment of the

SUSTAIN 340B Act, the Secretary shall promulgate [final] rules to establish a procedure in the case 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) AUDITS.—Both the covered entity and the child site shall maintain auditable records 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 this paragraph.''.

SEC. 6. TRANSPARENCY.

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, as an addendum to the Medicare cost report most recently submitted by such entity, the following information with respect to the entity, including

all sites and contract pharmacy arrangements of the entity, 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 filled with covered 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 site for charity care, based on the charity care level of the covered entity, defined as a fraction, the numerator of which is the

amount of charity care reported on worksheet S–10 of the Medicare cost report (or any successor), and the denominator of which is the total operating cost of the hospital, 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 that indicates charity care levels, a qualitative description of the charity care provided by such entity, in the aggregate, in such manner that is not overly burdensome to covered entities, as the Secretary may require.

''(iv) A description 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 un-

derserved and uninsured patients and communities.

''(v) 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), a medically underserved community (as defined in section 799B), or who are part of a medically underserved population (as defined in section 330(b)(3)), and the percentage of uninsured patients;

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

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

''(vi) Policies of the covered entity to promote access and adherence to prescribed medication.

"(vii) 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.

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

"(ix) Any contract pharmacy locations.

"(x) The estimated discount realized by the covered entity as a result of participation in the drug discount program under this section, as calculated by comparing the covered entity's cost of acquiring drugs at the discounted price under this section with the wholesale acquisition cost of such drugs.

"(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.—Covered entities shall retain such records and provide such records and reports as the Secretary determines necessary for purposes of carrying out this paragraph.

"(C) AUDITS.—A covered entity shall permit the Secretary to audit, at the Secretary's expense, the records of the entity used for purposes of reporting under subparagraph (A), including how the discount from drugs subject to an agreement under subsection (a)(1) furnished by such entity is used by such entity.

"(D) AVAILABILITY OF INFORMATION.—

"(i) IN GENERAL.—Not later than [30 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 individual covered entities 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 paragraph (1)(B)(vii) before posting such contracts.

''(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 Congress on the information collected under subparagraph (A).''.

SEC. 7. ENHANCING PROGRAM INTEGRITY.

(a) AUDITS.—

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

''(f) AUDITS.—

''(1) AUDITS BY THE SECRETARY.—

''(A) IN GENERAL.—In addition to the audits authorized under subsection (a)(5)(C), be-

ginning **[**XXX**]**, the Secretary may audit covered entities, including the contract pharmacies and child sites of such entities, and manufacturers to assess compliance with requirements under this section, including identifying any statutory violations 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 under this section.

''(B) STANDARDS.—The Secretary shall conduct audits described in this subsection in accordance with generally accepted standards, as may be prescribed by the Comptroller General of the United States, and shall make the protocol for such audits publicly available.

''(C) REQUIREMENTS.—The Secretary may not close an audit described in subparagraph (A) before a corrective action plan required by the Secretary has been fully implemented, as applicable.

''(2) 340B VENDOR INFORMATION.—To meet the requirements for submission of information for

audits under paragraph (1), covered entities shall contract only with vendors agreeing to—

"(A) submit data to the Secretary and independent outside auditors contracting with covered entities 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 subsection (a)(1); and

"(B) respond to requests from auditors in a timely manner.

"(3) AUDIT GUIDANCE.—Not later than **[**x**]**, the Secretary shall issue guidance for drug discount program auditors that—

"(A) specifies how auditors shall determine whether a covered entity's contract with a State or local government described in subsection (a)(4)(L)(i) requires the provision of health care services and requires the health care services provided to individuals who are low-income and are not eligible for participation in either the Medicaid program under title XIX of the

Social Security Act or the Medicare program under title XVIII of such Act; and

''(B) describes how the auditors will review eligibility for being a covered entity and assess and document findings regarding each of the specific eligibility-related criteria for each entity, including whether a private nonprofit hospital's contract with a State or local government is appropriately signed, covers the time periods under review in the audit, and requires the hospital to provide health care services to low-income individuals who are not eligible for participation in the Medicaid program or the Medicare program.

''(4) CONSEQUENCES OF AUDIT.—The Secretary shall ensure that, in the case of an audit finding that an entity did not meet one or more of the eligibility criteria for being a covered entity, as defined in subsection (a)(4), 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.

''(5) REGULATIONS.—Not later than 1 year after the date of enactment of the SUSTAIN 340B Act, the Secretary shall promulgate rules to establish the audit and reporting procedures required by this subsection.''.

(2) CONFORMING AMENDMENTS.—

(A) GENERAL SANCTIONS AUTHORITY.—Section 340B(a)(5)(D) of the Public Health Service Act (42 U.S.C. 256b(a)(5)(D)) is amended by inserting ''or subsection (f)'' after ''subparagraph (C)''.

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

(i) in subclause (II), by inserting ''or where the covered entity 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 or rebate on a drug that is not a covered outpatient drug, within [6 months] of the Secretary notifying

the entity of the requirement for such plan,'' after ''knowing and intentional,''

(ii) by adding at the end the following:

''(IV) 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 or rebate on a drug that is not a covered outpatient drug, and assigning responsibility for making corrections relating to such a violation to a corporate officer of the entity.

''(V) Disenrolling from the program covered entities that fail to implement a corrective action plan within 6 months 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 dis-

counts, compliance with contract pharmacy requirements, or claiming a discount or rebate on a drug that is not a covered outpatient drug.''.

(b) 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)'' before the semicolon.

SEC. 8. PREVENTING DUPLICATE DISCOUNTS.

(a) 340B DRUG DISCOUNT PROGRAM DATA CLEARINGHOUSE.—

(1) IN GENERAL.—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, 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 ensure 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, the Children's Health Insurance Program under title XXI, or health insurance coverage offered in the individual or group market or a group health plan (as such terms are defined in section 2791 of the Public Health Service Act), 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 paragraph (2) 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) allow covered entities except those described under subparagraph (L), (M), (N), or (O) of section 340B(a)(4) of the Public Health Service Act 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; and

''(8) 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)(11) of such Act.

''(c) 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.

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

''(e) 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.

''(f) REPAYMENT TO MANUFACTURERS.—The Secretary shall require covered entities to work with affected manufacturers regarding repayment of identified duplicate discounts for 340B drugs that occur in a State Medicaid fee-for-service and managed care program, regardless of whether the duplicate discount occurred under the fee-for-service or managed care payment arrangement, and regardless of the method used to dispense the 340B drug.

''(g) DEFINITIONS.—In this section:

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

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

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

''(4) 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) 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 Congress detailing coordinated efforts, including through the use of existing resources to ad-

dress requests from covered entities (as defined in section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4))) for payment under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) for medical assistance for a drug that is subject to an agreement under section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) if the drug is subject to the payment of a rebate to the State under section 1927 of the Social Security Act (42 U.S.C. 1396r–8), as prohibited under section 340B(a)(5)(A) of the Public Health Service Act (42 U.S.C. 256b(a)(5)(A)).

(3) REGULATIONS.—The Secretary of Health and Human Services may promulgate such rules 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 paragraph (1).

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

"(13) PATIENT ASSISTANCE PROGRAMS.—

"(A) IN GENERAL.—Covered entities shall extend their patient financial assistance policy to patients served by child sites and contract pharmacies. The covered entity shall ensure that its financial assistance policy is transparent to patients at point of care and publicly reported. The Secretary shall require covered entities to maintain auditable records related to the implementation and enforcement of this paragraph.

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

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

"(II) 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.

''(C) OVERSIGHT.—The Comptroller General of the United States shall conduct a study and report to Congress on the impact of requirements of this paragraph on patient access to covered outpatient drugs purchased under this section.

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

SEC. 9. 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 new section:

''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 a pharmacy benefit manager may not discriminate against a covered entity (as defined in sub-

section (d)(1)), a contract pharmacy (as defined in subsection (d)(2)), or a participant, beneficiary, or enrollee of such plan or coverage by imposing requirements, exclusions, reimbursement terms, or other conditions on such entity or pharmacy that differ from those applied to entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or 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 a pharmacy benefit manager may not discriminate against a covered entity, a contract pharmacy, or a participant, beneficiary, or enrollee of such plan or coverage by doing any of the following:

''(1) Reimbursing a covered entity or contract pharmacy for a quantity of a 340B drug (as defined in subsection (d)) in an amount less than such plan, issuer, or manager (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 contract pharmacy for such quantity of such drug on the basis that the entity or pharmacy

is a covered entity or contract pharmacy or that the entity or pharmacy dispenses 340B drugs.

''(2) Imposing any terms or conditions on covered entities or specified pharmacies with respect to any of the following that differ from such terms or conditions applied to other similarly situated entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or contract 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 Administrator of the Health Resources and Services Administration, interfere with the abil-

ity 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 contract pharmacy, whether in person or via direct delivery, mail, or other form of shipment.

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

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

"(A) the entity or pharmacy is a covered entity or a contract 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 for health insurance coverage, denying coverage of a drug on the basis that such drug is a 340B drug.

"(c) ENFORCEMENT MECHANISM FOR PHARMACY BENEFIT MANAGERS.—The Secretary shall impose a civil

monetary penalty on any pharmacy benefit manager 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 60 days after the date of the enactment of this subsection and shall finalize such regulations not later than 180 days after such date of enactment.

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

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

''(2) CONTRACT PHARMACY.—The term 'contract pharmacy' means a pharmacy with which a covered entity has contracted to dispense 340B drugs on behalf of the covered entity whether distributed in person or via mail.

''(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.''.

SEC. 10. 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 8(b), is further amended by adding at the end the following:

"(14) USER FEE PROGRAM.—

"(A) IN GENERAL.—Beginning in fiscal year [xx,] the Secretary shall assess and collect fees from covered entities participating in the program under this section, in accordance with this paragraph.

"(B) FEE AMOUNTS.—The fees described in subparagraph (A) shall be assessed and collected from each covered entity on an [annual basis], in amount equal to [.01 percent] of the [average difference, over the most recent 5-year period, between the price paid by the covered entity pursuant to the drug discount program under this section for outpatient drugs and the wholesale acquisition cost of such covered outpatient drugs].

"(C) USE OF FEES.—Any fee collected under this paragraph shall be used 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 system), including to ensure that such system continues to meet the needs of external stakeholders;

"(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 fee 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 as necessary to carry out the user fee program under this paragraph.

"(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 [xx] 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 (14) for the current year,'' after ''paragraph (5)''.

SEC. 11. STUDIES AND REPORTS.

(a) MACPAC REPORT.—Not later than 1 year after the data of enactment of this Act, the Medicaid and CHIP Payment and Access Commission shall submit a report to Congress on the efforts that State Medicaid agencies have taken to prevent duplicate discounts under the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b).

(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).

SEC. 12. ADDITIONAL RESOURCES FOR OVERSIGHT.

In addition to amounts otherwise available, there are authorized to be appropriated to the Inspector General of the Department of Health and Human Services for each of fiscal years 2025 through 2029, out of any money in

the Treasury not otherwise appropriated, [$3,000,000], to remain available until expended, for purposes of conducting audits, investigations, and other oversight and enforcement activities with respect to the drug discount program under section 340B of the Public Health Service Act (42 U.S.C. 256b).

SEC. 13. DEFINITIONS.

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

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

''(4) 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. 14. EFFECTIVE DATE.

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