

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Supporting Underserved and Strengthening Trans-
6 parency, Accountability, and Integrity Now and for the
7 Future of 340B Act” or the “SUSTAIN 340B Act”.

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

Sec. 1. Short title; table of contents.
Sec. 2. Sense of Congress.

2

- Sec. 3. Contract pharmacy.
- Sec. 4. Patient definition.
- Sec. 5. 340B Rebate Model Pilot Program sunset.
- Sec. 6. Child sites.
- Sec. 7. Transparency.
- Sec. 8. Enhancing program integrity.
- Sec. 9. Preventing duplicate discounts.
- Sec. 10. Patient financial assistance.
- Sec. 11. Ensuring the equitable treatment of covered entities and pharmacies participating in the 340B drug discount program.
- Sec. 12. User fee program.
- Sec. 13. Studies and reports.
- Sec. 14. Additional resources.
- Sec. 15. Definitions.
- Sec. 16. Effective date.

1 **SEC. 2. SENSE OF CONGRESS.**

2 It is the sense of Congress that the purpose of the
3 drug discount program under section 340B of the Public
4 Health Service Act (42 U.S.C. 256b) is to stretch scarce
5 Federal resources and help safety net providers maintain,
6 improve, and expand patient access to health care services
7 by requiring drug manufacturers, as a condition of partici-
8 pation in the Medicaid program under title XIX of the
9 Social Security Act (42 U.S.C. 1396 et seq.) and the
10 Medicare program under part B of title XVIII of the So-
11 cial Security Act (42 U.S.C. 1395j et seq.), to provide dis-
12 counts at the point of purchase to covered entities that
13 serve a disproportionate share of low-income and under-
14 served patients or medically vulnerable patients.

15 **SEC. 3. CONTRACT PHARMACY.**

16 (a) **USE OF CONTRACT PHARMACIES.**—Section
17 340B(a) of the Public Health Service Act (42 U.S.C.
18 256b(a)) is amended by adding at the end the following:

1 “(11) CONTRACT PHARMACIES.—

2 “(A) IN GENERAL.—A covered entity may
3 elect to use one or more wholly-owned phar-
4 macies, in addition to one or more contract
5 pharmacies, to acquire and dispense to patients
6 of the covered entity covered outpatient drugs
7 purchased by the covered entity pursuant to an
8 agreement described in paragraph (1).

9 “(B) LIMITS ON CERTAIN CONTRACT
10 PHARMACIES.—

11 “(i) IN GENERAL.—Subject to clause
12 (ii), each covered entity that elects to use
13 one or more contract pharmacies to dis-
14 pense covered outpatient drugs purchased
15 by the covered entity pursuant to an agree-
16 ment described in paragraph (1) to pa-
17 tients of the covered entity shall cancel the
18 contract with any such pharmacy that has
19 not dispensed any covered outpatient drugs
20 to such patients in the most recent 12-
21 month period.

22 “(ii) EXCEPTIONS.—A covered entity
23 is not required to cancel the contract of a
24 pharmacy that has not dispensed covered
25 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-

1 tract pharmacy arrangement, in accordance
2 with such registration requirements as the Sec-
3 retary may establish through regulations. Such
4 registration requirements shall include requiring
5 the covered entity to do each of the following:

6 “(i) Submit all contract pharmacy
7 agreements to the Secretary in a timely
8 manner, prior to implementing the con-
9 tract pharmacy agreement.

10 “(ii) Register each contract pharmacy
11 arrangement with the Secretary prior to
12 implementing the contract pharmacy
13 agreement.

14 “(iii) Attest to the covered entity’s
15 compliance with the requirements under
16 this section.

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

23 “(E) IMPROVEMENTS IN CONTRACT PHAR-
24 MACY ARRANGEMENT INTEGRITY.—To ensure
25 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).

1 “(ii) Develop standard contract provi-
2 sions that are required to be included in
3 each written agreement described in clause
4 (i), including provisions providing that—

5 “(I) the contract pharmacy is re-
6 quired to provide pharmacy services;

7 “(II) the contract pharmacy is
8 required to provide data to the cov-
9 ered entity to support the submission
10 by the covered entity of covered out-
11 patient data to a clearinghouse con-
12 tracted entity described in section
13 1150D(a) of the Social Security Act;

14 “(III) neither the contract phar-
15 macy nor the covered entity will re-
16 quire a patient to use a certain phar-
17 macy or to obtain a prescription from
18 the covered entity, or otherwise inter-
19 fere with patient choice of a pharmacy
20 provider, except in the case of a cov-
21 ered entity participating in the pro-
22 gram under section 2616;

23 “(IV) the contract pharmacy may
24 provide other services to the covered
25 entity or its patients at the option of

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

3 “(V) regardless of the services
4 provided by the contract pharmacy,
5 access to covered outpatient drugs
6 purchased under this section will be
7 restricted to patients of the covered
8 entity;

9 “(VI) the contract pharmacy will
10 provide the covered entity with any in-
11 formation requested consistent with
12 customary business practices, such as
13 quarterly billing statements, status re-
14 ports of collections, or receiving and
15 dispensing records;

16 “(VII) the covered entity and the
17 contract pharmacy will develop and
18 implement a system to verify eligi-
19 bility of patients, in accordance with
20 subsection (b)(3), and will establish
21 and maintain safeguards to prevent
22 diversion of covered outpatient drugs;

23 “(VIII) the contract pharmacy
24 may not use covered outpatient drugs
25 purchased under this section to dis-

1 pense prescriptions that are reim-
2 bursed under the Medicaid program
3 under title XIX of the Social Security
4 Act, unless the covered entity, the
5 contract pharmacy, and the State
6 Medicaid agency have established an
7 arrangement to prevent duplicate dis-
8 counts, consistent with paragraph
9 (5)(A), and such arrangement is re-
10 ported to the Secretary;

11 “(IX) the contract pharmacy
12 agrees to be subject to annual inde-
13 pendent audits commissioned by the
14 covered entity; and

15 “(X) both the covered entity and
16 the contract pharmacy shall be subject
17 to audits, by the Secretary and drug
18 manufacturers, of records that pertain
19 to the covered entity’s compliance
20 with paragraph (5), to prevent diver-
21 sion and violations of the duplicate
22 discount prohibition.

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

1 mines necessary, between covered entities
2 and contract pharmacies to ensure compli-
3 ance with the requirements under this sec-
4 tion, to analyze program operations, and to
5 provide program oversight.

6 “(iv) Provide specific guidance to cov-
7 ered entities regarding the practices and
8 procedures for contract pharmacy over-
9 sight, including the scope and frequency of
10 such oversight.

11 “(v) Establish a retention period of at
12 least 3 years during which covered entities
13 and contract pharmacies are required to
14 maintain all relevant auditable records in
15 relation to contract pharmacy arrange-
16 ments, including records relating to trans-
17 actions of drugs purchased pursuant to an
18 agreement under paragraph (1), sufficient
19 to demonstrate compliance with the re-
20 quirements described in paragraph (5).”.

21 (b) MANUFACTURER REQUIREMENTS.—Section
22 340B(a) of the Public Health Service Act (42 U.S.C.
23 256b(a)), as amended by subsection (a), is further amend-
24 ed by adding at the end the following:

1 “(12) MANUFACTURER REQUIREMENTS.—A
2 manufacturer of a covered outpatient drug that is
3 subject to an agreement with the Secretary under
4 paragraph (1) shall, as a condition of such agree-
5 ment, comply with the following requirements:

6 “(A) Offer the covered entity covered out-
7 patient drugs for purchase at or below the ap-
8 plicable ceiling price described in paragraph (1)
9 regardless of whether the drug is dispensed di-
10 rectly by the covered entity or through a con-
11 tract pharmacy of the covered entity.

12 “(B) Deliver or allow the delivery of cov-
13 ered outpatient drugs purchased by a covered
14 entity at or below the applicable ceiling price
15 described in paragraph (1) to locations, includ-
16 ing pharmacy locations as requested by a cov-
17 ered entity, in accordance with the covered enti-
18 ty’s contract pharmacy agreements.

19 “(C) Not, directly or indirectly, place any
20 of the following conditions on the offers made
21 to a covered entity to purchase a covered out-
22 patient drug at or below the applicable ceiling
23 price described in paragraph (1) for dispensing
24 according to the applicable written contract
25 pharmacy arrangements:

1 “(i) Restricting distribution options
2 only with respect to covered outpatient
3 drugs, covered entities, or contract phar-
4 macies.

5 “(ii) Requiring the submission of
6 claims data to the manufacturer, except
7 for submissions to the entity receiving the
8 contract to maintain the clearinghouse
9 under section 1150D of the Social Security
10 Act.

11 “(iii) Such other conditions as the
12 Secretary may prohibit through notice and
13 comment rulemaking.”.

14 (c) PROGRAM INTEGRITY.—Section
15 340B(d)(1)(B)(vi)(III) of the Public Health Service Act
16 (42 U.S.C. 256b(d)(1)(B)(vi)(III)) is amended—

17 (1) by striking “intentionally charges” and in-
18 serting the following: “intentionally—

19 “(aa) charges”;

20 (2) by striking the period and inserting a semi-
21 colon; and

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

23 “(bb) refuses to offer a cov-
24 ered outpatient drug for purchase
25 at or below the ceiling price;

1 “(cc) refuses to deliver a
2 covered outpatient drug pur-
3 chased by a covered entity at or
4 below the ceiling price; or

5 “(dd) places conditions on
6 the ability of a covered entity to
7 purchase a covered outpatient
8 drug at or below the ceiling
9 price.”.

10 (d) TRANSPARENCY.—Paragraph (11) of section
11 340B(a) of the Public Health Service Act (42 U.S.C.
12 256b(a)), as added by subsection (a), is amended by add-
13 ing at the end the following:

14 “(F) TRANSPARENCY.—Each covered enti-
15 ty that uses one or more contract pharmacies
16 as described in this paragraph shall make the
17 following information about each contract phar-
18 macy arrangement pursuant to this paragraph
19 and registered under subparagraph (C) avail-
20 able to the Secretary for publication on the
21 website of the Department of Health and
22 Human Services:

23 “(i) The name of the covered entity,
24 including each child site, that uses a con-
25 tract pharmacy.

1 “(ii) The name and address of each
2 contract pharmacy location to which the
3 contract pharmacy arrangement applies.

4 “(iii) The effective date of the con-
5 tract pharmacy arrangement.

6 “(iv) The last year a covered out-
7 patient drug was dispensed under the con-
8 tract pharmacy arrangement from each lo-
9 cation.

10 “(v) The number of covered out-
11 patient drugs dispensed annually from
12 each location under this section.

13 “(vi) Whether the contract pharmacy
14 is a mail-order or payer-mandated phar-
15 macy.”.

16 (e) AUDITING.—Section 340B(a)(5)(C) of the Public
17 Health Service Act (42 U.S.C. 256b(a)(5)(C)) is amend-
18 ed—

19 (1) by striking “A covered entity” and inserting
20 the following:

21 “(i) IN GENERAL.—A covered entity”;

22 and

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

24 “(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.

14 “(II) PROCESS.— In order to ini-
15 tiate an audit under subclause (I), a
16 manufacturer shall—

“(aa) demonstrate credible
allegations to the Secretary about
noncompliance under subpara-
graph (B) or (C) of paragraph
(11) and evidence of good faith
outreach to determine compli-
ance, including through—

24 “(AA) notification to
25 the covered entity in writing

1 when the manufacturer de-
2 termined that the covered
3 entity may have violated the
4 requirements under subpara-
5 graph (B) or (C) of para-
6 graph (11); and

7 “(BB) providing the
8 covered entity a 30-day pe-
9 riod, beginning on the date
10 of notification under subitem
11 (AA), to resolve the matter;
12 and

13 “(bb) submit to the Sec-
14 retary evidence of the credible al-
15 legations described in item (aa)
16 to request authorization to pro-
17 ceed with an audit of the covered
18 entity.

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

24 “(IV) AUTHORITY TO ESTABLISH
25 AUDIT PROCESS.—The Secretary shall

1 establish, through notice and com-
2 ment rulemaking, a process for mak-
3 ing a determination of a credible alle-
4 gation under this clause, a timeline
5 for making such a determination, and
6 the audit process relating to the num-
7 ber, scope, and duration of audits au-
8 thorized under this clause.”.

9 **SEC. 4. PATIENT DEFINITION.**

10 (a) PATIENT DEFINITION.—

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

14 “(3) PATIENT.—

15 “(A) IN GENERAL.—In this section, the
16 term ‘patient’, with respect to a covered entity,
17 means an individual who—

18 “(i) has received an outpatient health
19 care service from the covered entity at any
20 point within the preceding 2 years;

21 “(ii) has a relationship with the cov-
22 ered entity such that the covered entity
23 creates and maintains an auditable medical
24 record in a form and manner consistent
25 with State and Federal law, that dem-

1 onstrates the existence of a patient rela-
2 tionship in accordance with this paragraph
3 for each prescription or order for a covered
4 outpatient drug, and maintains such
5 record for a period of at least 3 years, or
6 longer if required by State or Federal law;
7 and

8 “(iii) received a prescription or order
9 for a covered outpatient drug—

10 “(I) from a practitioner as a re-
11 sult of an outpatient health care serv-
12 ice described in clause (i); or

13 “(II) as a result of a referral de-
14 scribed in subsection (a)(13).

15 “(B) AIDS DRUG PURCHASING ASSIST-
16 ANCE PROGRAM PATIENTS.—An individual reg-
17 istered in the program of a covered entity de-
18 scribed in subsection (a)(4)(E) is a patient of
19 the covered entity for purposes of this para-
20 graph.

21 “(C) STATE OR POLITICAL SUBDIVISION
22 OF A STATE RECEIVING FUNDING UNDER SEC-
23 TION 318.—An individual who receives a drug
24 purchased by a State or political subdivision of
25 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

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

7 “(4) OUTPATIENT HEALTH CARE SERVICE.—
8 The term ‘outpatient health care service’ means an
9 outpatient health care service—

10 “(A) that was furnished pursuant to a
11 valid, written order that is documented or a re-
12 ferral that is documented in the medical record
13 for the patient that is maintained by the cov-
14 ered entity; and

15 “(B)(i) for which reimbursement under
16 title XVIII or XIX of the Social Security Act
17 would be available when the services were fur-
18 nished;

19 “(ii) that can be identified by a CPT es-
20 tablished by the American Medical Association
21 or HCPCS code established by the Centers for
22 Medicare & Medicaid Services as of the date the
23 services were furnished; or

24 “(iii) in the case of covered entity de-
25 scribed in any of subparagraphs (A) through

1 (K) of subsection (a)(4), that is a service that
2 is consistent with the scope of the grant or des-
3 ignation described in the applicable such sub-
4 paragraph.

5 “(5) PRACTITIONER.—The term ‘practitioner’
6 means a health care practitioner who—

7 “(A)(i) is an employee or independent con-
8 tractor of a covered entity, and the covered en-
9 tity bills for such services and is responsible for
10 the care furnished by such practitioner; or

11 “(ii) furnishes health care services under
12 an ongoing contractual obligation to a covered
13 entity, cooperative arrangement pursuant to
14 section 330 with a covered entity described in
15 subsection (a)(4)(A), or, only in the case of a
16 covered entity that is prohibited to enter into
17 contractual obligations, pursuant to medical
18 staff membership with a covered entity, such
19 that the covered entity maintains clinical re-
20 sponsibility for the health care services that re-
21 sulted in the patient receiving a prescription or
22 order for the covered outpatient drug; and

23 “(B) is not excluded, pursuant to section
24 1128 of the Social Security Act, from participa-
25 tion in the Medicare program or a State health

1 care program (as defined in section 1128(h) of
2 the Social Security Act).”.

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

7 “(iii) AUDITS RELATING TO PATIENT
8 STATUS.—

9 “(I) IN GENERAL.—A covered
10 entity providing covered outpatient
11 drugs pursuant to an agreement
12 under paragraph (1) shall permit the
13 Secretary and the manufacturer to
14 audit, at the Secretary’s or manufac-
15 turer’s expense, the records of the en-
16 tity with respect to drugs of the man-
17 ufacturer that directly pertain to the
18 entity’s compliance with—

19 “(aa) treating individuals as
20 patients of the entity only as de-
21 scribed in subsection (b)(3); and

22 “(bb) the requirements for
23 providing such drugs to referred
24 patients pursuant to paragraph
25 (13).

1 “(II) AUDITING.—The Secretary
2 shall audit the records of covered enti-
3 ties with respect to records described
4 in this clause not less frequently than
5 every 3 years, and shall audit high-
6 risk and high-volume, as defined by
7 the Secretary, covered entities more
8 frequently, in a manner that is not
9 overly burdensome to the covered enti-
10 ty. The Secretary shall establish a
11 mechanism for manufacturers to re-
12 quest and authorize audits specific to
13 referral prescription eligibility under
14 paragraph (13) upon demonstration of
15 a credible allegation of non-compli-
16 ance.

17 “(III) AUTHORITY TO ESTABLISH
18 PROCESS.—The Secretary shall estab-
19 lish, through notice and comment
20 rulemaking, a process for manufactur-
21 ers and covered entities to make a
22 good faith attempt to resolve any con-
23 cerns identified by a manufacturer
24 prior to the initiation of an audit
25 under this clause. A manufacturer

1 shall provide to the covered entity the
2 same materials that the manufacturer
3 provided to the Secretary to support a
4 credible allegation under this clause,
5 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—

9 (A) by striking “subparagraphs (A)” and
10 inserting “subparagraph (A)”; and

11 (B) by striking “If the Secretary” and in-

12 serting the following:

13 “(i) IN GENERAL.—If the Secretary”;
14 and

15 (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)—

25

1 “(I) the covered entity shall de-
2 velop a corrective action plan, which
3 shall be subject to approval and moni-
4 toring by the Secretary; and

5 “(II) if the Secretary determines
6 that the covered entity has not ade-
7 quately corrected its noncompliance in
8 accordance with such plan—

9 “(aa) the covered entity
10 shall be ineligible to participate
11 in the drug discount program
12 under this section for a period
13 determined by the Secretary, not
14 to exceed 3 years; and

15 “(bb) the Secretary may
16 order the covered entity to pay
17 civil monetary penalties, pursu-
18 ant to subpart O of part 1003 of
19 title 42, Code of Federal Regula-
20 tions (or any successor regula-
21 tions), with respect to any cov-
22 ered outpatient drugs purchased
23 by the covered entity during the
24 period in which the covered entity
25 was found to be not in compli-

1 ance with the requirements of
2 treating an individual as a pa-
3 tient of the entity as described in
4 subsection (b)(3) or the require-
5 ments of paragraph (13).”.

6 (b) COVERED ENTITY REGISTRATION.—Section
7 340B(a)(5) of the Public Health Service Act (42 U.S.C.
8 256b(a)(5)) is amended by adding at the end the fol-
9 lowing:

10 “(E) COVERED ENTITY REGISTRATION.—
11 As a condition for participation in the drug dis-
12 count program under this section, a covered en-
13 tity shall register with the Secretary and be list-
14 ed on the 340B Office of Pharmacy Affairs In-
15 formation System (or a successor to such sys-
16 tem).”.

17 (c) TREATMENT OF CERTAIN PRESCRIPTIONS FOR
18 PATIENTS REFERRED TO NON-340B PROVIDERS.—Sec-
19 tion 340B(a) of the Public Health Service Act (42 U.S.C.
20 256b(a)), as amended by section 3(b), is further amended
21 by adding at the end the following:

22 “(13) REFERRAL PRESCRIPTIONS.—

23 “(A) IN GENERAL.—In the case of a pa-
24 tient of an eligible covered entity who is re-
25 ferred by such covered entity to a prescribing

1 provider who is not providing care on behalf of
2 a covered entity, and such prescribing provider
3 prescribes a drug within 12 months of the pa-
4 tient receiving such referral, the eligible covered
5 entity may provide such drug to such patient as
6 a covered outpatient drug pursuant to the pro-
7 gram under this section, in the same manner
8 and under the same conditions as the covered
9 entity would provide such drug to such patient
10 had the covered entity prescribed the drug, in
11 accordance with the requirements under sub-
12 paragraph (C).

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

16 “(i) an entity described in any of sub-
17 paragraphs (A) through (K) or (N) of
18 paragraph (4); or

19 “(ii) a sole community hospital de-
20 scribed in paragraph (4)(O).

21 “(C) REQUIREMENTS.—

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

1 “(I) the covered entity has a doc-
2 umented relationship with the patient,
3 as described in subsection (b)(3), and
4 has documentation of the provision of
5 care provided by the covered entity
6 and the prescribing provider and con-
7 sultation with the prescribing provider
8 regarding such patient, including doc-
9 umentation of the referral and the
10 prescription;

11 “(II) the patient was referred to
12 the prescribing provider who pre-
13 scribed the drug by the covered entity;

14 “(III) the prescription is filled at
15 the covered entity’s wholly-owned
16 pharmacy or contract pharmacy;

17 “(IV) the covered entity main-
18 tains, for a period of at least 3 years,
19 documentation of compliance with this
20 paragraph, including all documents
21 subject to audit under paragraph
22 (5)(C);

23 “(V) the covered entity does not
24 share the savings received from pur-

1 chasing the covered outpatient drug
2 with the prescribing provider; and

3 “(VI) the covered entity meets
4 such other requirements as the Sec-
5 retary may establish through notice
6 and comment rulemaking.

7 “(ii) EXCEPTED DRUGS.—

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

13 “(aa) is an infused drug;

14 “(bb) is a clinician-adminis-
15 tered drug; or

16 “(cc) otherwise requires ad-
17 ministration by a clinician.

18 “(II) EXCEPTIONS.—A covered
19 entity may provide a patient a covered
20 outpatient drug described in subclause
21 (I) pursuant to subparagraph (A) if—

22 “(aa) the eligible covered en-
23 tity is a covered entity described
24 in paragraph (4)(A) and was pro-
25 viding infusion services necessary

1 to deliver a required primary
2 health service or an additional
3 health service (as defined in sec-
4 tion 330(b)(1)) pursuant to fund-
5 ing received under section 330,
6 as of the date of enactment of
7 the SUSTAIN 340B Act; or

8 “(bb) the Secretary deter-
9 mines, through notice and com-
10 ment rulemaking, that low-in-
11 come, medically underserved resi-
12 dents of the service area of the
13 eligible covered entity lack access
14 to infusion services within a rea-
15 sonable distance and based on
16 this determination, the eligible
17 covered entity receives approval
18 from the Secretary to provide
19 these services pursuant to fund-
20 ing provided under section 330,
21 subject to all the requirements of
22 that section.

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

1 “(E) ADDRESSING SIGNIFICANT VOLUME
2 OF DRUGS PROVIDED TO REFERRED PA-
3 TIENTS.—

4 “(i) IN GENERAL.—The Secretary
5 shall audit any eligible covered entity that,
6 in any year, provides covered outpatient
7 drugs to patients who received a prescrip-
8 tion for such drug from a provider who is
9 not a covered entity in a volume that ex-
10 ceeds the lesser of—

11 “(I) 20 percent of the total num-
12 ber of covered outpatient drugs pur-
13 chased by the covered entity at or
14 below the applicable ceiling price and
15 dispensed by the covered entity for the
16 year; or

17 “(II) the average annual percent-
18 age over the most recent 3-year pe-
19 riod, of the total number of covered
20 outpatient drugs purchased by the
21 covered entity at or below the applica-
22 ble ceiling price for the year and dis-
23 pensed by the covered entity to pa-
24 tients, that were dispensed to patients
25 who received a prescription for such

1 drug from a provider who is not a
2 covered entity.

3 “(ii) HARDSHIP EXCEPTIONS.—The
4 Secretary shall develop specific criteria for
5 a hardship exceptions process, that is not
6 overly burdensome to a covered entity,
7 under which an eligible covered entity may
8 exceed the threshold established under
9 clause (i) without requiring an audit de-
10 scribed in such clause only if the eligible
11 covered entity provides required informa-
12 tion to the Secretary to demonstrate such
13 hardship, such as a medical need or work-
14 force shortage, in accordance with the cri-
15 teria established by the Secretary.

16 “(iii) REPORTING.—A covered entity
17 shall report annually to the Secretary—

18 “(I) the percentage of the cov-
19 ered entity’s revenue under the drug
20 discount program derived from drugs
21 prescribed by a prescribing provider
22 pursuant to this subsection; and

23 “(II) the percentage of the total
24 number of covered outpatient drugs
25 purchased by the covered entity that

1 were prescribed by a prescribing pro-
2 vider pursuant to this subsection.

3 “(iv) PUBLIC AVAILABILITY OF IN-
4 FORMATION.—The Secretary shall make
5 aggregate information on eligible covered
6 entities identified under clause (i) available
7 on the website of the Health Resources
8 and Services Administration, in such form
9 and manner that the Secretary determines
10 appropriate, and shall not identify any spe-
11 cific covered entity.

12 “(F) ENFORCEMENT.—

13 “(i) CORRECTIVE ACTION PLAN.—In
14 the case that the Secretary finds that a
15 covered entity has failed to comply with
16 any requirement under this paragraph,
17 such covered entity shall be required to
18 submit a corrective action plan to the Sec-
19 retary, which shall be subject to approval
20 and monitoring by the Secretary.

21 “(ii) LOSS OF REFERRAL AUTHORIZA-
22 TION.—A covered entity that fails to com-
23 ply with a corrective action plan within
24 180 days of approval of such plan by the
25 Secretary under clause (i) shall become in-

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

6 “(iii) MONETARY PENALTIES.—The
7 Secretary may impose civil monetary pen-
8 alties, pursuant to subpart O of part 1003
9 of title 42, Code of Federal Regulations (or
10 any successor regulations), on a covered
11 entity for any discounts received by such
12 entity on covered outpatient drugs pro-
13 vided to referred patients under this para-
14 graph, if the covered entity is found to be
15 noncompliant with the requirements of this
16 paragraph with respect to the relevant
17 drug.

18 “(G) DEFINITIONS.—For the purposes of
19 this paragraph—

20 “(i) the term ‘prescribing provider’
21 means a licensed health care provider who
22 prescribes a drug to a patient of a covered
23 entity based on the referral of the patient
24 by the covered entity to the provider; and

1 “(ii) the term ‘referral’ means a writ-
2 ten, electronic, or otherwise documented
3 order by a licensed health care provider or-
4 dering, or the recertifying of the need for,
5 a health service.”.

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

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

16 (2) not later than 2 years after the date of en-
17 actment of this Act, and for each of the next 10
18 years, submit to Congress a report on the study
19 under paragraph (1).

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

21 Not later than 1 year after the date of enactment
22 of this Act, the Secretary of Health and Human Services
23 (referred to in this section as the “Secretary”) shall con-
24 clude the 340B Rebate Model Pilot Program, or a sub-
25 stantially similar program established by the Department

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

9 **SEC. 6. CHILD SITES.**

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

14 “(14) CHILD SITES.—

15 “(A) IN GENERAL.—A covered entity de-
16 scribed in subparagraph (L), (M), (N), or (O)
17 of paragraph (4) that owns and operates a child
18 site that participates in the drug discount pro-
19 gram under this section shall maintain docu-
20 mentation of, and annually recertify to the Sec-
21 retary through such certification processes es-
22 tablished under title XVIII of the Social Secu-
23 rity Act, that each such child site is wholly-
24 owned by the entity and clinically and finan-
25 cially integrated with the covered entity and

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

3 “(i) registering each child site with
4 the Secretary, which, in the case of a child
5 site that is eligible for participation as de-
6 scribed in subparagraph (B)(ii), shall in-
7 clude submission of the attestation (absent
8 billing requirements) that the child site
9 meets the Medicare provider-based rules
10 under section 413.65 of title 42, Code of
11 Federal Regulations (or any successor reg-
12 ulations);

13 “(ii) applying the same financial as-
14 sistance policy for patients as applies with
15 respect to other sites operated by the cov-
16 ered entity; and

17 “(iii) ensuring that each child site
18 complies with the Medicare provider-based
19 rules under section 413.65 of title 42,
20 Code of Federal Regulations (or any suc-
21 cessor regulations) or meets the require-
22 ments of subparagraph (B)(i).

23 “(B) ELIGIBILITY FOR CHILD SITES.—

24 “(i) IN GENERAL.—A child site is eli-
25 gible for participation in the drug discount

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

6 “(I) The child site applies the
7 same financial assistance policy for
8 patients as the covered entity.

9 “(II) The child site ensures that
10 the providers who order or dispense
11 covered outpatient drugs purchased
12 under this section at the child site or
13 a contract pharmacy of the covered
14 entity have clinical responsibility for
15 health care services that result in the
16 receipt of a prescription or order of
17 the covered outpatient drug purchased
18 under this section that is dispensed.

19 “(III) The child site provides a
20 clinically meaningful range of services,
21 as determined by the services that
22 providers or suppliers employed by,
23 contracted with, or authorized to pro-
24 vide services at, the child site are
25 qualified to deliver.

1 “(IV) The child site is operated
2 under the same license as the covered
3 entity, except in areas where the State
4 requires a separate license for the
5 child site, or in States where State
6 law does not permit licensure of the
7 child site and the covered entity under
8 a single license. If a State health fa-
9 cilities cost review commission or
10 other agency that has authority to
11 regulate the rates charged by pro-
12 viders in a State finds that a child
13 site is not part of the covered entity,
14 the child site shall not be eligible for
15 the drug discount program under this
16 section.

17 “(V) The clinical services of the
18 child site and the covered entity are
19 integrated as evidenced by the fol-
20 lowing:

21 “(aa) Professional staff of
22 the child site have clinical privi-
23 leges at the covered entity.

24 “(bb) The covered entity
25 maintains the same monitoring

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

4 “(cc) The medical director
5 of the child site maintains a re-
6 porting relationship with the
7 chief medical officer or other
8 similar official of the covered en-
9 tity that has the same frequency,
10 intensity, and level of account-
11 ability that exists in the relation-
12 ship between the medical director
13 of a department of the covered
14 entity and the chief medical offi-
15 cer or other similar official of the
16 covered entity, and is under the
17 same type of supervision and ac-
18 countability as any other direc-
19 tor, medical or otherwise, of the
20 covered entity.

21 “(dd) Medical staff commit-
22 tees or other professional com-
23 mittees at the covered entity are
24 responsible for medical activities
25 in the child site, including quality

1 assurance, utilization review, and
2 the coordination and integration
3 of services, to the extent prac-
4 ticable, between the child site and
5 covered entity.

6 “(ee) Medical records for pa-
7 tients treated in the child site are
8 integrated into a unified retrieval
9 system, or have the ability to be
10 readily accessed by the covered
11 entity.

12 “(ff) Inpatient and out-
13 patient services of the child site
14 and the covered entity are inte-
15 grated, and patients treated at
16 the child site who require further
17 care have full access to all serv-
18 ices of the covered entity and are
19 referred where appropriate to the
20 corresponding inpatient or out-
21 patient department or service of
22 the covered entity.

23 “(VI) The financial operations of
24 the child site are fully integrated with-
25 in the financial system of the covered

1 entity, as evidenced by shared income
2 and expenses between the covered en-
3 tity and the child site. For purposes
4 of the Medicare program under title
5 XVIII of the Social Security Act, the
6 costs of a child site are reported in
7 the appropriate cost center or cost
8 centers of the covered entity, and the
9 financial status of any child site is in-
10 corporated and readily identified in
11 the covered entity's trial balance.

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

17 “(VIII) The child site is operated
18 under the ownership and control of
19 the covered entity, as evidenced by the
20 following:

21 “(aa) The business enter-
22 prise that constitutes the child
23 site is 100 percent owned by the
24 covered entity.

1 “(bb) The covered entity
2 and the child site have the same
3 governing body.

4 “(cc) The child site is oper-
5 ated under the same organiza-
6 tional documents as the covered
7 entity, and is subject to common
8 bylaws and operating decisions of
9 the governing body of the covered
10 entity.

11 “(dd) The covered entity has
12 final responsibility for adminis-
13 trative decisions, final approval
14 for contracts with outside parties,
15 final approval for personnel ac-
16 tions, final responsibility for per-
17 sonnel policies (such as fringe
18 benefits or code of conduct), and
19 final approval for medical staff
20 appointments at the child site.

21 “(IX) The reporting relationship
22 between the child site and the covered
23 entity have the same frequency, inten-
24 sity, and level of accountability that
25 exists in the relationship between the

1 covered entity and its other depart-
2 ments, as evidenced by compliance
3 with the following requirements:

4 “(aa) The child site is under
5 the direct supervision of the cov-
6 ered entity.

7 “(bb) The child site is oper-
8 ated under the same monitoring
9 and oversight by the covered enti-
10 ty as any other department of
11 the covered entity, and is oper-
12 ated as any other department of
13 the covered entity with regard to
14 supervision and accountability.
15 The director or individual respon-
16 sible for daily operations at the
17 child site—

18 “(AA) maintains a re-
19 porting relationship with a
20 manager at the covered enti-
21 ty that has the same fre-
22 quency, intensity, and level
23 of accountability that exists
24 in the relationship between

1 the covered entity and its
2 existing departments; and
3 “(BB) is accountable to
4 the governing body of the
5 covered entity, in the same
6 manner as any department
7 head of the covered entity.

8 “(X) The following administra-
9 tive functions of the child site are in-
10 tegrated with the functions of the cov-
11 ered entity: billing services, records,
12 human resources, payroll, employee
13 benefit package, salary structure, and
14 purchasing services. Either the same
15 employees or group of employees han-
16 dle such administrative functions for
17 the child site and the covered entity,
18 or the administrative functions for
19 both the child site and the covered en-
20 tity are—

21 “(aa) contracted out under
22 the same contract agreement; or
23 “(bb) handled under dif-
24 ferent contract agreements, with
25 the contract of the child site

1 being managed by the covered
2 entity.

3 “(XI)(aa) The child site is listed
4 on the covered entity’s most recently
5 filed Medicare cost report on a line
6 that is reimbursable under the Medi-
7 care program (or, if the covered entity
8 does not file a Medicare cost report,
9 the covered entity submits to the Sec-
10 retary a signed statement certifying
11 that the site would be correctly in-
12 cluded on a reimbursable line of a
13 Medicare cost report if the covered en-
14 tity filed a cost report).

15 “(bb) Such cost report dem-
16 onstrates that the services provided at
17 the child site have associated costs
18 and charges for covered entity out-
19 patient department services under
20 title XVIII of the Social Security Act
21 (or, if the covered entity does not file
22 a Medicare cost report, the covered
23 entity submits to the Secretary a
24 signed statement certifying that the
25 services provided at the child site in-

1 clude or consist solely of outpatient
2 services).

3 “(ii) HRSA DEEMING.—

4 “(I) IN GENERAL.—If the Ad-
5 ministrator of the Centers for Medi-
6 care & Medicaid Services has deter-
7 mined a site to be qualified as a pro-
8 vider-based entity and in compliance
9 with the provider-based requirements
10 under section 413.65 of title 42, Code
11 of Federal Regulations (or any suc-
12 cessor regulations), the Secretary
13 shall deem the site to have met the re-
14 quirements described in clause (i).

15 “(II) RULE OF CONSTRUC-
16 TION.—This clause shall authorize the
17 Secretary to establish a process to de-
18 termine whether a child site, as deter-
19 mined by the Administrator of the
20 Centers for Medicare & Medicaid
21 Services, complies with the Medicare
22 provider-based rules under section
23 413.65 of title 42, Code of Federal
24 Regulations (or any successor regula-
25 tions).

1 “(iii) PROCESS FOR REGISTRATION.—

2 The Secretary shall develop a process for
3 the registration of child sites that are eligi-
4 ble for participation under clause (i) or
5 (ii).

6 “(iv) ELIGIBILITY DELAY FOR CER-
7 TAIN CHILD SITES.—

8 “(I) NEWLY ACQUIRED SITES.—

9 “(aa) IN GENERAL.—Except
10 as provided in item (bb), a child
11 site acquired by a covered entity
12 after the date of enactment of
13 the SUSTAIN 340B Act that
14 was not eligible to participate in
15 the drug discount program prior
16 to such date shall not be eligible
17 to participate in the drug dis-
18 count program under this section
19 until the date that is 3 years
20 after the date of such acquisition.

21 “(bb) HARDSHIP EXEMP-
22 TION.—The Secretary may, on a
23 case-by-case basis, determine
24 that a newly acquired child site
25 will be eligible to participate in

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

5 “(II) NEWLY CONSTRUCTED
6 SITES.—A newly constructed child site
7 that began operations after the date
8 of enactment of the SUSTAIN 340B
9 Act shall not be eligible to participate
10 in the drug discount program as de-
11 scribed in clause (i) unless such site
12 meets all of the requirements under
13 this subparagraph.

14 “(C) INAPPROPRIATE TREATMENT OF A
15 PROVIDER AS A CHILD SITE.—Not later than
16 180 days after the first recertification of the
17 covered entity that occurs after the date of en-
18 actment of the SUSTAIN 340B Act, the Sec-
19 retary shall establish a process through notice
20 and comment rulemaking for determining the
21 status of a child site that, prior to such date of
22 enactment, was deemed qualified as a child site
23 but that does not meet the criteria set forth in
24 this subsection.

25 “(D) REPORTS.—

1 “(i) GAO REPORT ON PROGRAM IN-
2 TEGRITY.—Not later than 3 years after the
3 date of enactment of the SUSTAIN 340B
4 Act, the Comptroller General of the United
5 States shall submit to the appropriate
6 committees of Congress a report that ana-
7 lyzes relevant data, including data made
8 available pursuant to subsection (d)(5),
9 and makes recommendations with respect
10 to any policies needed to address program
11 integrity issues associated with child sites
12 in the drug discount program under this
13 section.

14 “(ii) HHS REPORTS TO CONGRESS.—
15 Not later than 2 years after the date of en-
16 actment of the SUSTAIN 340B Act, and
17 every 2 years thereafter, the Secretary
18 shall submit to the appropriate committees
19 of Congress a report that analyzes the use
20 of child sites in the drug discount program
21 under this section, and that—

22 “(I) characterizes the scope and
23 nature of child sites in the drug dis-
24 count program under this section, in-
25 cluding—

1 “(aa) the number of newly
2 acquired child sites;

3 “(bb) the number of newly
4 constructed child sites;

5 “(cc) the concentration of
6 the child sites across geographic
7 areas; and

8 “(dd) the payer-mix of the
9 child sites;

10 “(II) assesses the effect of eligi-
11 bility delays described in subpara-
12 graph (B)(iv); and

13 “(III) makes recommendations
14 with respect to policies needed to ad-
15 dress any issues identified in such re-
16 port.

17 “(iii) GAO REPORT ON BEST PRAC-
18 TICES.—Not later than 1 year after the
19 date of enactment of the SUSTAIN 340B
20 Act, the Comptroller General of the United
21 States shall submit a report to the appro-
22 priate committees of Congress that—

23 “(I) analyzes input solicited from
24 relevant stakeholders, including cov-
25 ered entities and manufacturers, re-

1 garding potential best practices for
2 ensuring savings received by child
3 sites through participation in the drug
4 discount program under this section
5 are used to meaningfully improve ac-
6 cess to care, including by expanding
7 access to health care services or
8 health-related benefits for patients
9 and communities served by the cov-
10 ered entity, including child sites of the
11 covered entity; and

12 “(II) makes recommendations to
13 the Secretary and appropriate com-
14 mittees of Congress with respect to
15 implementation of best practices iden-
16 tified and analyzed pursuant to sub-
17 clause (I).”.

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

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

1 for a period of at least 3 years and be subject
2 to audits by the Secretary of records that per-
3 tain to the compliance of the covered entity and
4 child site with the provisions of paragraph
5 (14).”.

6 **SEC. 7. TRANSPARENCY.**

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

10 “(5) REPORTING OF PROGRAM SAVINGS.—

11 “(A) IN GENERAL.—Not later than 1 year
12 after the date of enactment of the SUSTAIN
13 340B Act, and annually thereafter, each cov-
14 ered entity shall report to the Secretary the fol-
15 lowing information with respect to the covered
16 entity, including with respect to all child sites
17 and contract pharmacy arrangements, for the
18 preceding year:

19 “(i) The total number of individuals
20 who were dispensed or administered cov-
21 ered outpatient drugs during such pre-
22 ceding year that were subject to an agree-
23 ment under subsection (a)(1).

24 “(ii) The total number of prescrip-
25 tions dispensed or administered with cov-

1 ered outpatient drugs purchased under this
2 section and billed to insurance, organized
3 by type of health insurance coverage (as
4 specified by the Secretary, including by the
5 Medicare program under title XVIII of the
6 Social Security Act, the Medicaid program
7 under title XIX of such Act, the Children’s
8 Health Insurance Program under title XXI
9 of such Act, health insurance coverage of-
10 fered in the individual or group market or
11 a group health plan (as such terms are de-
12 fined in section 2791), and uninsured).

13 “(iii)(I) The cost incurred at each cov-
14 ered entity for charity care, reported as a
15 fraction, where the numerator is the
16 amount of charity care reported on work-
17 sheet S-10 of the Medicare cost report (or
18 any successor), and the denominator is the
19 total operating cost of the covered entity,
20 as reported for the most recent cost report-
21 ing period; or

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

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

7 “(iv) At the option of the covered en-
8 tity, information pertaining to under-reim-
9 bursed care provided by the covered entity.

10 “(v)(I) A description, submitted in a
11 standardized form and manner prescribed
12 by the Secretary, of the covered entity’s
13 use of the savings received through partici-
14 pation in the drug discount program under
15 this section, including a description of
16 health care services or health-related bene-
17 fits used to benefit the patients and com-
18 munities served by the covered entity, de-
19 lineated by categories of services and bene-
20 fits and populations served, including such
21 services and benefits provided to under-
22 served, uninsured, or medically vulnerable
23 patients and communities; and

24 “(II) an attestation by the chief exec-
25 utive officer, chief executive financial offi-

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

5 “(vi) The financial demographics of
6 patients of the covered entity, including—

7 “(I) the percentage of patients
8 eligible for financial assistance pro-
9 grams and sliding scale fees;

10 “(II) the percentage of patients
11 who reside in a health professional
12 shortage area (as defined in section
13 332) or a medically underserved com-
14 munity (as defined in section 799B);

15 “(III) the percentage of patients
16 who reside in or are part of a medi-
17 cally underserved population (as de-
18 fined in section 330(b)(3));

19 “(IV) the percentage of unin-
20 sured patients;

21 “(V) the percentage of patients
22 who are Medicaid beneficiaries; and

23 “(VI) the percentage of patients
24 who are Children’s Health Insurance
25 Program beneficiaries.

1 “(vii) Policies of the covered entity to
2 promote access and adherence to pre-
3 scribed medication.

4 “(viii) In the case of a nongovern-
5 mental hospital, any contracts between
6 such hospital and a State or local govern-
7 mental entity, and any modifications to
8 any such contract.

9 “(ix) Any third-party administrators
10 in contract with the covered entity for the
11 administration of the drug discount pro-
12 gram.

13 “(x) The funding shortfall for the cov-
14 ered entity attributable to services provided
15 to Medicare and Medicaid beneficiaries, as
16 reported on the Internal Revenue Service
17 Form 990.

18 “(xi) The number of patients using
19 the outpatient services of the covered enti-
20 ty.

21 “(xii) Operation costs to the covered
22 entity related to the drug discount pro-
23 gram under this section.

24 “(B) RECORDS RETENTION.—A covered
25 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

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

3 “(D) SUBMISSION PROCESS.—Not later
4 than 1 year after the date of enactment of the
5 SUSTAIN 340B Act, the Secretary shall estab-
6 lish a process by which the information required
7 to be submitted under subparagraph (A) may
8 be submitted directly to the 340B Office of
9 Pharmacy Affairs Information System (or a
10 successor to such system).

11 “(E) REPORTS TO CONGRESS.—Not later
12 than 1 year after the date of the enactment of
13 the SUSTAIN 340B Act, and annually there-
14 after, the Secretary shall submit a report to the
15 appropriate committees of Congress on the in-
16 formation collected under subparagraph (A).

17 “(F) REGULATIONS.—The Secretary may
18 promulgate regulations to carry out this para-
19 graph.”.

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

24 “(iv) AUDITS OF PROGRAM SAVINGS
25 RECORDS.—A covered entity shall permit

1 the Secretary to audit, at the Secretary's
2 expense, the records of the covered entity
3 used for purposes of reporting under sub-
4 section (d)(5)(A), including how the dis-
5 count from drugs subject to an agreement
6 under paragraph (1) is used by the covered
7 entity.”.

8 **SEC. 8. ENHANCING PROGRAM INTEGRITY.**

9 (a) AUDITS.—

10 (1) IN GENERAL.—Section 340B(a)(5)(C) of
11 the Public Health Service Act (42 U.S.C.
12 256b(a)(5)(C)), as amended by section 7(b), is fur-
13 ther amended by adding at the end the following:

14 “(v) ADDITIONAL AUDITS.—

15 “(I) IN GENERAL.—In addition
16 to the audits otherwise authorized
17 under this subparagraph, the Sec-
18 retary may audit, to assess compliance
19 with requirements under this sec-
20 tion—

21 “(aa) covered entities, in-
22 cluding the child sites of a cov-
23 ered entity and contract phar-
24 macies, to identify any violations
25 under this section, including vio-

1 lations related to improperly
2 claiming eligibility for the pro-
3 gram under this section, drug di-
4 version, duplicate discounts, use
5 of contract pharmacies, or claim-
6 ing a discount under this section
7 on a drug that is not a covered
8 outpatient drug purchased pursu-
9 ant to an agreement under para-
10 graph (1); and

11 “(bb) manufacturers, includ-
12 ing to identify any failure to pro-
13 vide an accurate ceiling price.

14 “(II) STANDARDS.—The Sec-
15 retary shall conduct audits described
16 in this clause in accordance with gen-
17 erally accepted standards that the
18 Secretary determines appropriate and
19 shall make the protocol for such au-
20 dits publicly available.

21 “(III) REQUIREMENTS.—The
22 Secretary may not close an audit de-
23 scribed in subclause (I) before a cor-
24 rective action plan required by the

1 Secretary has been fully implemented,
2 as applicable.

3 “(IV) 340B VENDOR INFORMA-
4 TION.—To meet the requirements for
5 submission of information for audits
6 under this clause, with respect to car-
7 rying out the program under this sec-
8 tion, a covered entity shall contract
9 only with vendors agreeing to—

10 “(aa) submit data to the
11 Secretary and independent out-
12 side auditors contracting with the
13 covered entity as necessary to de-
14 termine the covered entity’s com-
15 pliance with statutory and regu-
16 latory requirements under this
17 program, prohibitions on drug di-
18 version and duplicate discounts,
19 use of contract pharmacies, and
20 claims for discounts on covered
21 outpatient drugs purchased pur-
22 suant to agreements under para-
23 graph (1); and

24 “(bb) respond to requests
25 from auditors in a timely man-

1 ner, as determined by the Sec-
2 retary.

3 “(V) CONSEQUENCES OF
4 AUDIT.—The Secretary shall ensure
5 that, in the case of an audit finding
6 that—

7 “(aa) a covered entity did
8 not meet one or more of the eligi-
9 bility criteria for being a covered
10 entity, as defined in paragraph
11 (4), during the full period under
12 review in an audit, the audit re-
13 sults in consequences that are
14 consistent and appropriate with
15 the violation and that do not
16 treat the failure to meet eligi-
17 bility criteria as an issue that can
18 be corrected retroactively; or

19 “(bb) a manufacturer did
20 not meet its requirements pursu-
21 ant to an agreement under para-
22 graph (1) during the full period
23 under review in an audit, the
24 audit results in consequences
25 that are consistent and appro-

1 appropriate with the violation and that
2 do not treat the failure to meet
3 the criteria as an issue that can
4 be corrected retroactively.

5 “(VI) REGULATIONS.—Not later
6 than 1 year after the date of enact-
7 ment of the SUSTAIN 340B Act, the
8 Secretary shall establish, through no-
9 tice and comment rulemaking, the
10 audit and reporting procedures re-
11 quired by this clause.”.

12 (2) ADDITIONAL SANCTIONS AUTHORITY.—Sec-
13 tion 340B(d)(2)(B) of the Public Health Service Act
14 (42 U.S.C. 256b(d)(2)(B)) is amended—

15 (A) in clause (v)(II), by inserting “or
16 where the covered entity knowingly and inten-
17 tionally fails to implement a corrective action
18 plan relating to a violation involving improperly
19 claiming eligibility for the program under this
20 section, drug diversion, duplicate discounts,
21 compliance with contract pharmacy require-
22 ments, or claiming a discount on a drug that is
23 not a covered outpatient drug (or claiming a re-
24 bate on a drug in the case of an AIDS drug
25 purchasing assistance program, as determined

1 by the Secretary), within 180 days of the Sec-
2 retary notifying the entity of the requirement
3 for such plan, unless the Secretary determines
4 it is appropriate to allow additional time for
5 compliance,” after “knowing and intentional,”;
6 and

7 (B) by adding at the end the following:

8 “(vi) Increasing the frequency of au-
9 dits conducted for entities previously found
10 to be in violation of requirements of the
11 drug discount program that relate to eligi-
12 bility, drug diversion, duplicate discounts,
13 compliance with contract pharmacy re-
14 quirements, or claiming a discount on a
15 drug that is not a covered outpatient drug
16 (or claiming a rebate on a drug in the case
17 of an AIDS drug purchasing assistance
18 program described in subsection (a)(4)(E),
19 as determined by the Secretary), and as-
20 signing responsibility for making correc-
21 tions relating to such a violation to a cor-
22 porate officer of the covered entity.

23 “(vii)(I) Establishing a process for a
24 covered entity to develop and implement a
25 corrective action plan, and a process by

1 which the Secretary provides for proper
2 and timely notification of a potential viola-
3 tion by a covered entity.

4 “(II) Disenrolling from the program a
5 covered entity that fails to implement a
6 corrective action plan within 180 days of
7 issuance of a final audit report related to
8 a statutory violation involving improperly
9 claiming eligibility for the program under
10 this section, drug diversion, duplicate dis-
11 counts, compliance with contract pharmacy
12 requirements, claiming a discount on a
13 drug that is not a covered outpatient drug
14 (or claiming a rebate on a drug in the case
15 of an AIDS drug purchasing assistance
16 program described in subsection (a)(4)(E),
17 as determined by the Secretary), or failing
18 to comply with reporting of program sav-
19 ings and use of program savings as re-
20 quired.”.

21 (b) VERIFICATION OF PRIVATE NON-PROFIT HOS-
22 PITAL CONTRACTS WITH STATE OR LOCAL GOVERN-
23 MENTS.—Section 340B(a)(5) of the Public Health Service
24 Act (42 U.S.C. 256b(a)(5)), as amended by section 6(b),
25 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

1 that it is a mutually binding
2 agreement for the hospital to
3 provide health care services or
4 supplies in exchange for some-
5 thing of value;

6 “(bb) the contract clearly
7 lists the name of the hospital and
8 the unit of State or local govern-
9 ment that are parties to the con-
10 tract and is signed and appro-
11 priately dated by appropriate of-
12 ficials of the hospital and the
13 unit of State or local government;

14 “(cc) the contract specifies
15 an effective date;

16 “(dd) the contract clearly is
17 in effect and not expired at the
18 time of registration (or at the
19 time of recertification, in the case
20 of annual recertification, or for
21 the full period examined in an
22 audit, in the case of an audit);
23 and

24 “(ee) the contract explicitly
25 requires that the hospital provide

1 health care services, and that
2 such services must be provided to
3 individuals who are both low-in-
4 come and not eligible for either
5 the Medicaid program or the
6 Medicare program.

7 “(II) The Secretary shall verify
8 the contracts meeting the require-
9 ments of clause (i) for all covered en-
10 tities described in this subparagraph
11 and registered as of the date of enact-
12 ment of the SUSTAIN 340B Act by
13 no later than 1 year after the date of
14 enactment of the SUSTAIN 340B
15 Act.

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

22 “(ii) PROCESS.—The Secretary shall
23 develop a process to verify the contracts
24 meeting the requirement of clause (i)(I),
25 including specifying a timeline.”.

1 (c) VERIFICATION OF CERTAIN COVERED ENTI-
2 TIES.—Section 340B(a)(4)(L)(i) of the Public Health
3 Services Act (42 U.S.C. 256b(a)(4)(L)(i)) is amended by
4 inserting “(provided that such a private non-profit hos-
5 pital annually submits to the Secretary verification of such
6 an active contract with a State or local government and
7 verification of its non-profit status)” before the semicolon.

8 **SEC. 9. PREVENTING DUPLICATE DISCOUNTS.**

9 (a) 340B DRUG DISCOUNT PROGRAM DATA CLEAR-
10 INGHOUSE.—Part A of title XI of the Social Security Act
11 (42 U.S.C. 1301 et seq.) is amended by adding the fol-
12 lowing the following new section:

13 **“SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEAR-**
14 **INGHOUSE.**

15 “(a) CLEARINGHOUSE CONTRACTING ENTITY.—Not
16 later than 1 year after the date of enactment of this sec-
17 tion, the Secretary shall enter into a contract with an inde-
18 pendent, third-party entity (who shall be free of conflicts
19 of interest with covered entities, manufacturers, health
20 plans, third party administrators of health plans, entities
21 providing pharmacy benefit management services to health
22 plans, and of other conflicts of interest as specified by the
23 Secretary) for purposes of carrying out the clearinghouse
24 duties under subsection (b) with respect to the 340B drug
25 discount program to prevent duplicate discounts and en-

1 sure proper accounting. Such contract shall provide that
2 the third-party entity shall perform the duties described
3 in subsection (b) and shall be for a 4-year term that may
4 be renewed after a subsequent bidding process or using
5 competitive procedures, as defined in section 132 of title
6 41, United States Code.

7 “(b) DUTIES.—With respect to 340B drugs that are
8 dispensed to individuals who are entitled to or eligible for
9 benefits under the Medicare program under title XVIII,
10 the Medicaid program under title XIX (including benefits
11 provided under the Medicaid program through a managed
12 care arrangement), the Children’s Health Insurance Pro-
13 gram under title XXI (including benefits provided under
14 the Children’s Health Insurance Program through a man-
15 aged care arrangement), or a health plan, a third-party
16 entity with a contract in effect under subsection (a)
17 shall—

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

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

22 “(B) claims-level data from covered enti-
23 ties; and

1 “(C) any other data specified by the Sec-
2 retary as necessary for the entity to carry out
3 this section;

4 “(2) request, receive, and maintain data de-
5 scribed in paragraph (1) in a confidential manner;

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

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

14 “(5) provide the manufacturer of a 340B drug
15 with claims-level data submitted by a covered entity,
16 so that the manufacturer may identify units of a
17 340B drug that may generate a rebate or discount
18 under a voluntary rebate or discount arrangement,
19 such as those related to commercial plans;

20 “(6) where feasible, share with a covered entity,
21 the Secretary, a Medicaid State agency, or a manu-
22 facturer, data the third-party entity identifies in a
23 timely manner with the purpose of preventing any of
24 the violations described in section 2729A(b)(2) of
25 the Public Health Service Act;

1 “(7) determine total sales of 340B drugs to
2 such individuals for purposes of being used as the
3 basis for determining user fees under section
4 340B(a)(15) of such Act; and

5 “(8) allow covered entities described in subpara-
6 graphs (A) through (K) of section 340B(a)(4) of the
7 Public Health Service Act, which have the lowest
8 decile of patient volume, as calculated by the Sec-
9 retary, to make submissions required under this sec-
10 tion in an aggregated retrospective basis.

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

16 “(d) **RESTRICTIONS ON CONTRACTING ENTITY.**—
17 The entity receiving a contract under subsection (a)
18 shall—

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

24 “(2) not disclose confidential information ob-
25 tained through carrying out the clearinghouse duties

1 under this section other than as necessary to carry
2 out the purposes of this section, including for pro-
3 gram integrity functions;

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

7 “(4) not collect pricing information regarding
8 drugs that are not 340B drugs from covered enti-
9 ties.

10 “(e) DUTIES OF COVERED ENTITY.—Covered entities
11 shall facilitate and participate in data transmission with
12 the third-party entity with a contract in effect under sub-
13 section (a), including with respect to reporting on data
14 available through contract pharmacies.

15 “(f) RESTRICTIONS ON MANUFACTURER AND PBM
16 USE OF DATA.—

17 “(1) IN GENERAL.—A manufacturer who re-
18 ceives data under subsection (b)(5) may use such
19 data only for the purpose of preventing duplicate
20 discounts and diversion under this section.

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

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

3 “(3) ENFORCEMENT.—Any manufacturer or
4 other person found by the Secretary to have used
5 data received under subsection (b)(5) for uses other
6 than those described in paragraphs (1) and (2), such
7 as for pricing or marketing, shall be subject to civil
8 monetary penalties, pursuant to subpart O of part
9 1003 of title 42, Code of Federal Regulations (or
10 any successor regulations), subject to the discretion
11 of the Secretary.

12 “(g) PRIVACY REQUIREMENTS.—The information ex-
13 change required by subsection (b) shall occur in a manner
14 consistent with the privacy, security, and breach notifica-
15 tion regulations promulgated under section 264(c) of the
16 Health Insurance Portability and Accountability Act of
17 1996.

18 “(h) REPAYMENT TO MANUFACTURERS.—The Sec-
19 retary shall require a covered entity to work with affected
20 manufacturers regarding identified duplicate discounts for
21 340B drugs, regardless of the method used to dispense
22 the 340B drug, which shall include repayment—

23 “(1) by the covered entity as a result of the
24 covered entity’s noncompliance with section 340B of
25 the Public Health Service Act;

1 “(2) by a State Medicaid program of rebates
2 improperly requested by the State Medicaid pro-
3 gram; or

4 “(3) by a State Medicaid program where the fi-
5 nancial benefit of the duplicate discount accrues to
6 the State Medicaid program, regardless of whether
7 the duplicate discount occurred under the fee-for-
8 service or managed care payment arrangement.

9 “(i) DEFINITIONS.—In this section:

10 “(1) 340B DRUG.—The term ‘340B drug’
11 means a drug that is—

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

15 “(B) purchased under an agreement in ef-
16 fect under such section.

17 “(2) COVERED ENTITY.—The term ‘covered en-
18 tity’ means an entity described in section
19 340B(a)(4) of the Public Health Service Act.

20 “(3) DIVERSION.—The term ‘diversion’, with
21 respect to a covered entity and a 340B drug, means
22 the resale or otherwise transferring of the drug to
23 a person who is not a patient, as defined in section
24 340B(b)(3) of the Public Health Service Act, of the
25 covered entity.

1 “(4) DUPLICATE DISCOUNT.—The term ‘dupli-
2 cate discount’ means a payment under title XIX for
3 medical assistance described in section 1905(a)(12)
4 with respect to a 340B drug if the drug is subject
5 to the payment of a rebate to the State under sec-
6 tion 1927.

7 “(5) HEALTH PLANS.—The term ‘health plan’
8 has the meaning given to that term in section
9 1128C(c).

10 “(6) MANUFACTURER.—The term ‘manufac-
11 turer’ has the meaning given to that term in section
12 1927(k)(5).”.

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

15 (1) IN GENERAL.—A group health plan, a
16 health insurance issuer offering group or individual
17 coverage (as such terms are defined in section 2791
18 of the Public Health Service Act (42 U.S.C. 300gg–
19 91)), or an entity providing pharmacy benefit man-
20 agement services may not interfere with the ability
21 of covered entities, contract pharmacies (as such
22 terms are defined in section 340B of the Public
23 Health Service Act (42 U.S.C. 254b)), or manufac-
24 turers of drugs to prevent duplicate discounts or to
25 recoup the full amount of any identified duplicate

1 discounts pursuant to the drug discount program
2 under section 340B of the Public Health Service Act
3 (42 U.S.C. 254b).

4 (2) ENFORCEMENT.—The Secretary of Health
5 and Human Services shall impose civil monetary
6 penalties, pursuant to subpart O of part 1003 of
7 title 42, Code of Federal Regulations (or any suc-
8 cessor regulations), on any group health plan, health
9 insurance issuer, or entity providing pharmacy ben-
10 efit management services that violates paragraph
11 (1).

12 (c) OVERSIGHT.—Not later than 1 year after the date
13 of enactment of this Act, the Secretary of Health and
14 Human Services, acting through the Administrator of the
15 Centers for Medicare & Medicaid Services and the Admin-
16 istrator of the Health Resources and Services Administra-
17 tion, shall issue a report to the appropriate committees
18 of Congress detailing coordinated efforts, including
19 through the use of existing resources to address duplicate
20 discounts.

21 (d) REGULATIONS.—The Secretary of Health and
22 Human Services may promulgate such rules through no-
23 tice and comment rulemaking as the Secretary determines
24 appropriate to advance the purpose of the drug discount
25 program under section 340B of the Public Health Service

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

4 (e) DEFINITION.—In this section, the term “dupli-
5 cate discount” has the meaning given such term in section
6 1150D(h) of the Social Security Act, as added by sub-
7 section (a).

8 **SEC. 10. PATIENT FINANCIAL ASSISTANCE.**

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

12 “(H) PATIENT FINANCIAL ASSISTANCE.—

13 “(i) IN GENERAL.—Each covered enti-
14 ty shall—

15 “(I) ensure that its financial as-
16 sistance policy is transparent to pa-
17 tients at point of care and publicly re-
18 ported;

19 “(II) apply such financial assist-
20 ance policy to patients served by child
21 sites and contract pharmacies; and

22 “(III) upon request of the Sec-
23 retary, submit its financial assistance
24 policy to the Secretary.

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

6 “(iii) FINANCIAL ASSISTANCE POLICY
7 DEFINED.—In this subparagraph, a ‘finan-
8 cial assistance policy’ means—

9 “(I)(aa) a written financial as-
10 sistance policy described in section
11 501(r)(4)(A) of the Internal Revenue
12 Code of 1986, provided, at least, to
13 patients at 200 percent of the Federal
14 poverty level or less; and

15 “(bb) a sliding fee scale for cov-
16 ered outpatient drugs dispensed to pa-
17 tients under the drug discount pro-
18 gram under this section, as applicable;
19 or

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

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

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

4 “(v) LANGUAGE REQUIREMENTS.—A
5 covered entity shall make the financial as-
6 sistance policy described in clause (i) avail-
7 able to patients, including patients served
8 by child sites and contract pharmacies in
9 plain language (as defined in section
10 1311(e)(3)(B) of the Patient Protection
11 and Affordable Care Act).

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

17 “(vii) DELAYED EFFECTIVE DATE
18 FOR CERTAIN ENTITIES.—With respect to
19 a child site or contract pharmacy, the re-
20 quirements of this subparagraph shall
21 apply beginning on the date that is 3 years
22 after the date of enactment of the SUS-
23 TAIN 340B Act.”.

1 **SEC. 11. ENSURING THE EQUITABLE TREATMENT OF COV-**
2 **ERED ENTITIES AND PHARMACIES PARTICI-**
3 **PATING IN THE 340B DRUG DISCOUNT PRO-**
4 **GRAM.**

5 (a) GROUP HEALTH PLAN AND HEALTH INSURANCE
6 ISSUER REQUIREMENTS.—Subpart II of part A of title
7 XXVII of the Public Health Service Act (42 U.S.C.
8 300gg–11 et seq.) is amended by adding at the end the
9 following:

10 **“SEC. 2729A. REQUIREMENTS RELATING TO THE 340B DRUG**
11 **DISCOUNT PROGRAM.**

12 “(a) IN GENERAL.—A group health plan, a health
13 insurance issuer offering group or individual health insur-
14 ance coverage, or an entity providing pharmacy benefit
15 management services on behalf of such a plan or issuer
16 may not discriminate against a covered entity, a 340B
17 pharmacy, or a participant, beneficiary, or enrollee of such
18 plan or coverage by imposing requirements, exclusions, re-
19 imbursement terms, or other conditions on such entity or
20 340B pharmacy that differ from those applied to entities
21 or pharmacies that are not covered entities or 340B phar-
22 macies on the basis that the entity or pharmacy is a cov-
23 ered entity or 340B pharmacy or that the entity or 340B
24 pharmacy dispenses 340B drugs, including by taking any
25 action prohibited under subsection (b).

1 “(b) SPECIFIED PROHIBITED ACTIONS.—A group
2 health plan, a health insurance issuer offering group or
3 individual health insurance coverage, or an entity pro-
4 viding pharmacy benefit management services on behalf
5 of such a plan or issuer may not discriminate against a
6 covered entity, a 340B pharmacy, or a participant, bene-
7 ficiary, or enrollee of such plan or coverage by doing any
8 of the following:

9 “(1) Reimbursing a covered entity or 340B
10 pharmacy for a quantity of a 340B drug (as defined
11 in subsection (d)) in an amount less than such plan,
12 issuer, or entity providing pharmacy benefit manage-
13 ment services (as applicable) would pay to any other
14 similarly situated (as specified by the Secretary) en-
15 tity or pharmacy that is not a covered entity or a
16 340B pharmacy for such quantity of such drug on
17 the basis that the entity or pharmacy is a covered
18 entity or 340B pharmacy or that the entity or phar-
19 macy dispenses 340B drugs.

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

1 the basis that the entity or pharmacy is a covered
2 entity or 340B pharmacy or that the entity or phar-
3 macy dispenses 340B drugs:

4 “(A) Fees, chargebacks, clawbacks, adjust-
5 ments, or other assessments.

6 “(B) Professional dispensing fees.

7 “(C) Restrictions or requirements regard-
8 ing participation in standard or preferred phar-
9 macy networks.

10 “(D) Requirements relating to the fre-
11 quency or scope of audits or to inventory man-
12 agement systems using generally accepted ac-
13 counting principles.

14 “(E) Any other restrictions, conditions,
15 practices, or policies that, as specified by the
16 Secretary, interfere with the ability of a covered
17 entity to maximize the value of discounts pro-
18 vided under section 340B.

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

23 “(4) Requiring a covered entity or 340B phar-
24 macy to identify, either directly or through a third
25 party, 340B drugs.

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

6 “(A) the entity or pharmacy is a covered
7 entity or a 340B pharmacy; or

8 “(B) the entity or pharmacy is described in
9 any of subparagraphs (A) through (O) of sec-
10 tion 340B(a)(4).

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

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

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

20 “(B) is inconsistent with patient need and
21 access.

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

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

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

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

19 “(1) CONTRACT PHARMACY.—The term ‘con-
20 tract pharmacy’ has the meaning given such term in
21 section 340B(b).

22 “(2) COVERED ENTITY.—The term ‘covered en-
23 tity’ has the meaning given such term in section
24 340B(a)(4).

1 “(3) 340B DRUG.—The term ‘340B drug’
2 means a drug that is—

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

5 “(B) purchased under an agreement in ef-
6 fect under such section.

7 “(4) 340B PHARMACY.—The term ‘340B phar-
8 macy’ means a pharmacy that is wholly owned by a
9 covered entity or that is a contract pharmacy.”.

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

14 “(i) NONDISCRIMINATION.—

15 “(1) IN GENERAL.—A PDP sponsor offering a
16 prescription drug plan or an MA organization offer-
17 ing an MA–PD plan may not require a covered enti-
18 ty to make use of any 340B pharmacy in a manner
19 that—

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

23 “(B) is inconsistent with patient need and
24 access.

25 “(2) DEFINITIONS.—In this subsection—

1 “(A) the term ‘contract pharmacy’ has the
2 meaning given such term in section 340B(b) of
3 the Public Health Service Act;

4 “(B) the term ‘covered entity’ has the
5 meaning given such term in section 340B of the
6 Public Health Service Act; and

7 “(C) the term ‘340B pharmacy’ means a
8 pharmacy that is wholly-owned by a covered en-
9 tity or that is a contract pharmacy.”.

10 **SEC. 12. USER FEE PROGRAM.**

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

15 “(15) USER FEE PROGRAM.—

16 “(A) ESTABLISHMENT OF QUARTERLY
17 FEE.—Beginning in fiscal year 2031, the Sec-
18 retary shall in accordance with this section as-
19 sess user fees on, and collect such fees from,
20 each covered entity participating in the pro-
21 gram under this section. The fees shall be as-
22 sessed for a fiscal year and collected quarterly
23 during the last 3 quarters of such fiscal year
24 and the first quarter of the subsequent fiscal
25 year, and the total amount assessed and col-

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

4 “(B) ASSESSMENT OF USER FEES.—

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

9 “(I) \$50,000,000 for fiscal year
10 2031; and

11 “(II) for fiscal year 2032 and
12 each subsequent fiscal year, the
13 amount authorized to be assessed and
14 collected in the previous fiscal year
15 adjusted by the average annual per-
16 cent change that occurred in the Con-
17 sumer Price Index for all urban con-
18 sumers (Washington-Arlington-Alex-
19 andria, DC-VA-MD-WV; Not Sea-
20 sonally Adjusted; All items; Annual
21 Index) in the 12-month period ending
22 June 30 preceding the fiscal year for
23 which fees are being established.

24 “(ii) ALLOCATIONS OF ASSESSMENT
25 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.

11 “(II) APPLICABLE PERCENT-
12 AGE.—For purposes of subclause (I),
13 the applicable percentage of each cov-
14 ered entity for a fiscal year shall be
15 determined by—

16 “(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

1 by all covered entities in
2 such fiscal year; and

3 “(bb) multiplying the
4 amount determined under item
5 (aa) by 100.

6 “(iii) TIMING OF ASSESSMENT.—The
7 Secretary shall notify each covered entity
8 subject to this section of the amount of the
9 annual assessment imposed on such cov-
10 ered entity under this subsection not later
11 than December 31 of the fiscal year for
12 which such fees apply. Payments of such
13 assessments shall be made in 4 equal in-
14 stallments, which shall be made by the last
15 day of each quarter of the calendar year
16 immediately following the notification.

17 “(C) USE OF FEES.—Any fee collected
18 under this paragraph shall be used by the Sec-
19 retary for purposes of administering this section
20 and enhancing program integrity and oversight
21 activities under this section, including—

22 “(i) the development of a multi-func-
23 tional web-based system to collect fees
24 under this paragraph;

1 “(ii) the establishment, use, and
2 maintenance of the data clearinghouse
3 under section 1150D of the Social Security
4 Act;

5 “(iii) the improvement of the integ-
6 rity, transparency, security, searchability,
7 and reliability of the 340B Office of Phar-
8 macy Affairs Information System (or a
9 successor to such system);

10 “(iv) improvements to the compliance
11 tool used to integrate all information re-
12 lated to manufacturers that have entered
13 into agreements with the Secretary under
14 paragraph (1) and covered entities;

15 “(v) audits under this section of cov-
16 ered entities and such manufacturers; and

17 “(vi) any other uses for the purposes
18 of program integrity, as the Secretary de-
19 termines appropriate.

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

1 “(E) REGULATIONS.—The Secretary may
2 promulgate rules through notice and comment
3 rulemaking as necessary to carry out the user
4 fee program under this paragraph, which shall
5 include establishment of a process to provide
6 for exceptions to the fee amount under subpara-
7 graph (B), including the circumstances under
8 which such exceptions may apply to certain cov-
9 ered entities.

10 “(F) OVERSIGHT OF USER FEE PRO-
11 GRAM.—The Inspector General of the Depart-
12 ment of Health and Human Services shall—

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

16 “(ii) not later than September 30 of
17 each year for which a review is required
18 under clause (i), submit to Congress a re-
19 port on the review conducted under clause
20 (i), together with such recommendations as
21 the Inspector General determines appro-
22 priate.”.

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

1 by inserting “, has submitted user fees to the Secretary
2 in the amount assessed under paragraph (15) for the cur-
3 rent year,” after “paragraph (5)”.

4 **SEC. 13. STUDIES AND REPORTS.**

5 (a) GAO REPORT.—Not later than 2 years after the
6 date of enactment of this Act, the Comptroller General
7 of the United States shall submit to Congress a report
8 on the debt collection practices of hospitals, including hos-
9 pitals that participate in the drug discount program under
10 section 340B of the Public Health Service Act (42 U.S.C.
11 256b) as covered entities described in subparagraphs (L)
12 through (O) of subsection (a)(4) of such section 340B.

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

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

19 and

20 (2) not later than 2 years after the date of en-
21 actment of this Act, submit to Congress a report on
22 the study under paragraph (1).

23 (c) ASPE STUDY.—The Assistant Secretary for
24 Planning and Evaluation (referred to in this subsection
25 as the “Assistant Secretary”) shall conduct a study on the

1 interactions of the clearinghouse established under section
2 1150D of the Social Security Act (as added by section 9)
3 and any data collection system established by the Sec-
4 retary to carry out section 1193(d) of the Social Security
5 Act (42 U.S.C. 1320f–2(d)) or section 1860D–
6 14B(b)(1)(B) of such Act (42 U.S.C. 1395w–
7 114b(b)(1)(B)) to limit duplicative discounts for out-
8 patient prescription drugs. The Assistant Secretary shall
9 make recommendations to Congress on ways to streamline
10 and effectively operate such clearinghouse and data collec-
11 tion systems.

12 **SEC. 14. ADDITIONAL RESOURCES.**

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

16 “(f) AUTHORIZATIONS OF APPROPRIATIONS.—

17 “(1) AUTHORIZATION OF APPROPRIATIONS FOR
18 AUDITS, INVESTIGATIONS, AND OTHER OVERSIGHT
19 AND ENFORCEMENT ACTIVITIES.—In addition to
20 amounts made available under subsection (d)(4),
21 there are authorized to be appropriated, to the In-
22 spector General of the Department of Health and
23 Human Services, \$3,000,000 for each of fiscal years
24 2027 through 2031, for purposes of conducting au-
25 dits, investigations, and other oversight and enforce-

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

3 “(2) AUTHORIZATION OF APPROPRIATION FOR
4 GENERAL PURPOSES.—In addition to amounts made
5 available under paragraph (1) and subsection (d)(4),
6 there are authorized to be appropriated \$9,000,000
7 for each of fiscal years 2027 through 2030, for pur-
8 poses of implementing the activities under this sec-
9 tion, as added by the SUSTAIN 340B Act.”.

10 (b) HIRING AUTHORITY; REGULATIONS.—Section
11 340B of the Public Health Service Act (42 U.S.C. 256b),
12 as amended by subsection (a), is further amended by add-
13 ing at the end the following:

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

18 “(h) REGULATIONS.—The Secretary shall promul-
19 gate regulations through notice and comment rulemaking,
20 as appropriate to implement this section.”.

21 **SEC. 15. DEFINITIONS.**

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

1 “(6) CHILD SITE.—In this section, the term
2 ‘child site’ means a site that is wholly-owned and op-
3 erated by a covered entity.

4 “(7) CONTRACT PHARMACY.—In this section,
5 the term ‘contract pharmacy’ means a pharmacy
6 with which a covered entity has contracted to dis-
7 pense covered outpatient drugs on behalf of the cov-
8 ered entity whether distributed in person or via
9 mail.”.

10 **SEC. 16. EFFECTIVE DATE.**

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