

119TH CONGRESS
2D SESSION

S. 5244

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

AUGUST 5, 2026

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 Health, Education, Labor, and Pensions

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.
- 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.

1 **SEC. 3. CONTRACT PHARMACY.**

2 (a) USE OF CONTRACT PHARMACIES.—Section
3 340B(a) of the Public Health Service Act (42 U.S.C.
4 256b(a)) is amended by adding at the end the following:

5 “(11) CONTRACT PHARMACIES.—

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

13 “(B) LIMITS ON CERTAIN CONTRACT
14 PHARMACIES.—

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

“(ii) EXCEPTIONS.—A covered entity is not required to cancel the contract of a pharmacy that has not dispensed covered outpatient drugs in the most recent 12-month period, as described in clause (i), if—

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

“(II) there is a change to the covered entity’s service area;

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

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

“(iii) THRESHOLD FOR HIGH NUMBER OF CONTRACT PHARMACIES.—The Secretary may develop a process that is not overly burdensome to the covered entities to increase audits on covered entities that

1 use a high number of contract pharmacies,
2 as determined by the Secretary.

3 “(C) REGISTRATION OF CONTRACT.—A
4 covered entity shall register with the Secretary,
5 and annually recertify, any contract for a con-
6 tract pharmacy arrangement, in accordance
7 with such registration requirements as the Sec-
8 retary may establish through regulations. Such
9 registration requirements shall include requiring
10 the covered entity to do each of the following:

11 “(i) Submit all contract pharmacy
12 agreements to the Secretary in a timely
13 manner, prior to implementing the con-
14 tract pharmacy agreement.

15 “(ii) Register each contract pharmacy
16 arrangement with the Secretary prior to
17 implementing the contract pharmacy
18 agreement.

19 “(iii) Attest to the covered entity’s
20 compliance with the requirements under
21 this section.

22 “(D) CONTRACT REVIEW PROCESS.—The
23 Secretary shall establish a process to review
24 written agreements between a covered entity
25 and each of its contract pharmacies described

in subparagraph (E)(i), to ensure compliance with the requirements under this subsection.

“(E) IMPROVEMENTS IN CONTRACT PHARMACY ARRANGEMENT INTEGRITY.—To ensure the integrity of contract pharmacy arrangements 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

1 section on behalf of the covered entity;
2 and

3 “(III) include the standard con-
4 tract provisions established under
5 clause (ii).

6 “(ii) Develop standard contract provi-
7 sions that are required to be included in
8 each written agreement described in clause
9 (i), including provisions providing that—

10 “(I) the contract pharmacy is re-
11 quired to provide pharmacy services;

12 “(II) the contract pharmacy is
13 required to provide data to the cov-
14 ered entity to support the submission
15 by the covered entity of covered out-
16 patient data to a clearinghouse con-
17 tracted entity described in section
18 1150D(a) of the Social Security Act;

19 “(III) neither the contract phar-
20 macy nor the covered entity will re-
21 quire a patient to use a certain phar-
22 macy or to obtain a prescription from
23 the covered entity, or otherwise inter-
24 fere with patient choice of a pharmacy
25 provider, except in the case of a cov-

1 ered entity participating in the pro-
2 gram under section 2616;

3 “(IV) the contract pharmacy may
4 provide other services to the covered
5 entity or its patients at the option of
6 the covered entity, such as home care,
7 delivery, or reimbursement services;

8 “(V) regardless of the services
9 provided by the contract pharmacy,
10 access to covered outpatient drugs
11 purchased under this section will be
12 restricted to patients of the covered
13 entity;

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

21 “(VII) the covered entity and the
22 contract pharmacy will develop and
23 implement a system to verify eligi-
24 bility of patients, in accordance with
25 subsection (b)(3), and will establish

1 and maintain safeguards to prevent
2 diversion of covered outpatient drugs;

3 “(VIII) the contract pharmacy
4 may not use covered outpatient drugs
5 purchased under this section to dis-
6 pense prescriptions that are reim-
7 bursed under the Medicaid program
8 under title XIX of the Social Security
9 Act, unless the covered entity, the
10 contract pharmacy, and the State
11 Medicaid agency have established an
12 arrangement to prevent duplicate dis-
13 counts, consistent with paragraph
14 (5)(A), and such arrangement is re-
15 ported to the Secretary;

16 “(IX) the contract pharmacy
17 agrees to be subject to annual inde-
18 pendent audits commissioned by the
19 covered entity; and

20 “(X) both the covered entity and
21 the contract pharmacy shall be subject
22 to audits, by the Secretary and drug
23 manufacturers, of records that pertain
24 to the covered entity’s compliance
25 with paragraph (5), to prevent diver-

1 sion and violations of the duplicate
2 discount prohibition.

3 “(iii) Review written agreements, at
4 the time of registration or recertification,
5 or more frequently if the Secretary deter-
6 mines necessary, between covered entities
7 and contract pharmacies to ensure compli-
8 ance with the requirements under this sec-
9 tion, to analyze program operations, and to
10 provide program oversight.

11 “(iv) Provide specific guidance to cov-
12 ered entities regarding the practices and
13 procedures for contract pharmacy over-
14 sight, including the scope and frequency of
15 such oversight.

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

1 (b) MANUFACTURER REQUIREMENTS.—Section
 2 340B(a) of the Public Health Service Act (42 U.S.C.
 3 256b(a)), as amended by subsection (a), is further amend-
 4 ed by adding at the end the following:

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

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

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

23 “(C) Not, directly or indirectly, place any
 24 of the following conditions on the offers made
 25 to a covered entity to purchase a covered out-

1 patient drug at or below the applicable ceiling
 2 price described in paragraph (1) for dispensing
 3 according to the applicable written contract
 4 pharmacy arrangements:

5 “(i) Restricting distribution options
 6 only with respect to covered outpatient
 7 drugs, covered entities, or contract phar-
 8 macies.

9 “(ii) Requiring the submission of
 10 claims data to the manufacturer, except
 11 for submissions to the entity receiving the
 12 contract to maintain the clearinghouse
 13 under section 1150D of the Social Security
 14 Act.

15 “(iii) Such other conditions as the
 16 Secretary may prohibit through notice and
 17 comment rulemaking.”.

18 (c) PROGRAM INTEGRITY.—Section

19 340B(d)(1)(B)(vi)(III) of the Public Health Service Act
 20 (42 U.S.C. 256b(d)(1)(B)(vi)(III)) is amended—

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

23 “(aa) charges”;

24 (2) by striking the period and inserting a semi-
 25 colon; and

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

2 “(bb) refuses to offer a cov-
3 ered outpatient drug for purchase
4 at or below the ceiling price;

5 “(cc) refuses to deliver a
6 covered outpatient drug pur-
7 chased by a covered entity at or
8 below the ceiling price; or

9 “(dd) places conditions on
10 the ability of a covered entity to
11 purchase a covered outpatient
12 drug at or below the ceiling
13 price.”.

14 (d) TRANSPARENCY.—Paragraph (11) of section
15 340B(a) of the Public Health Service Act (42 U.S.C.
16 256b(a)), as added by subsection (a), is amended by add-
17 ing at the end the following:

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

1 website of the Department of Health and
 2 Human Services:

3 “(i) The name of the covered entity,
 4 including each child site, that uses a con-
 5 tract pharmacy.

6 “(ii) The name and address of each
 7 contract pharmacy location to which the
 8 contract pharmacy arrangement applies.

9 “(iii) The effective date of the con-
 10 tract pharmacy arrangement.

11 “(iv) The last year a covered out-
 12 patient drug was dispensed under the con-
 13 tract pharmacy arrangement from each lo-
 14 cation.

15 “(v) The number of covered out-
 16 patient drugs dispensed annually from
 17 each location under this section.

18 “(vi) Whether the contract pharmacy
 19 is a mail-order or payer-mandated phar-
 20 macy.”.

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

24 (1) by striking “A covered entity” and inserting
 25 the following:

1 “(i) IN GENERAL.—A covered entity”;

2 and

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

4 “(ii) CONTRACT PHARMACY AUDITS.—

5 “(I) IN GENERAL.—A covered
6 entity that uses one or more contract
7 pharmacies shall permit the Secretary
8 or the manufacturer of a covered out-
9 patient drug that the covered entity or
10 pharmacy purchased under this sec-
11 tion to audit at the Secretary’s or the
12 manufacturer’s expense the records of
13 the covered entity and contract phar-
14 macy to assess compliance with the
15 contract pharmacy requirements
16 under paragraph (11) with respect to
17 drugs of the manufacturer.

18 “(II) PROCESS.— In order to ini-
19 tiate an audit under subclause (I), a
20 manufacturer shall—

21 “(aa) demonstrate credible
22 allegations to the Secretary about
23 noncompliance under subpara-
24 graph (B) or (C) of paragraph
25 (11) and evidence of good faith

1 outreach to determine compli-
2 ance, including through—

3 “(AA) notification to
4 the covered entity in writing
5 when the manufacturer de-
6 termined that the covered
7 entity may have violated the
8 requirements under subpara-
9 graph (B) or (C) of para-
10 graph (11); and

11 “(BB) providing the
12 covered entity a 30-day pe-
13 riod, beginning on the date
14 of notification under subitem
15 (AA), to resolve the matter;
16 and

17 “(bb) submit to the Sec-
18 retary evidence of the credible al-
19 legations described in item (aa)
20 to request authorization to pro-
21 ceed with an audit of the covered
22 entity.

23 “(III) CORPORATE OFFICERS.—A
24 corporate officer of the covered entity
25 shall be responsible for corrections of

1 noncompliance identified in an audit
 2 conducted under this clause.

3 “(IV) AUTHORITY TO ESTABLISH
 4 AUDIT PROCESS.—The Secretary shall
 5 establish, through notice and com-
 6 ment rulemaking, a process for mak-
 7 ing a determination of a credible alle-
 8 gation under this clause, a timeline
 9 for making such a determination, and
 10 the audit process relating to the num-
 11 ber, scope, and duration of audits au-
 12 thorized under this clause.”.

13 **SEC. 4. PATIENT DEFINITION.**

14 (a) PATIENT DEFINITION.—

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

18 “(3) PATIENT.—

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

22 “(i) has received an outpatient health
 23 care service from the covered entity at any
 24 point within the preceding 2 years;

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

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

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

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

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

1 “(C) STATE OR POLITICAL SUBDIVISION
2 OF A STATE RECEIVING FUNDING UNDER SEC-
3 TION 318.—An individual who receives a drug
4 purchased by a State or political subdivision of
5 a State, for the treatment of a disease or condi-
6 tion for which the State or political subdivision
7 of a State has received such award under sec-
8 tion 318, is a patient exclusively of the State or
9 political subdivision of the State for the purpose
10 of qualifying that prescription for 340B pricing
11 under this section.

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

17 “(i) the administration of a drug, or
18 the dispensing of a drug for subsequent
19 self-administration or administration in the
20 home setting; or

21 “(ii) an infusion of a drug.

22 “(E) EXCEPTION FOR DISCHARGE PRE-
23 SCRIPTIONS.—In the case of a patient dis-
24 charged from an emergency department or in-
25 patient hospital stay from a covered entity de-

scribed in any of subparagraph (A) through (O) of subsection (a)(4) that results in an outpatient prescription, a covered entity may provide such drug to the individual as a covered outpatient drug pursuant to the program under this section, and shall be deemed to meet the requirements for establishment of a patient under subparagraph (A) in the same manner and under the same conditions as the covered entity would provide such drug to such patient had the covered entity prescribed the drug.

“(4) OUTPATIENT HEALTH CARE SERVICE.—

The term ‘outpatient health care service’ means an outpatient health care service—

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

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

“(ii) that can be identified by a CPT established by the American Medical Association

1 or HCPCS code established by the Centers for
2 Medicare & Medicaid Services as of the date the
3 services were furnished; or

4 “(iii) in the case of covered entity de-
5 scribed in any of subparagraphs (A) through
6 (K) of subsection (a)(4), that is a service that
7 is consistent with the scope of the grant or des-
8 ignation described in the applicable such sub-
9 paragraph.

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

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

16 “(ii) furnishes health care services under
17 an ongoing contractual obligation to a covered
18 entity, cooperative arrangement pursuant to
19 section 330 with a covered entity described in
20 subsection (a)(4)(A), or, only in the case of a
21 covered entity that is prohibited to enter into
22 contractual obligations, pursuant to medical
23 staff membership with a covered entity, such
24 that the covered entity maintains clinical re-
25 sponsibility for the health care services that re-

1 sulted in the patient receiving a prescription or
2 order for the covered outpatient drug; and

3 “(B) is not excluded, pursuant to section
4 1128 of the Social Security Act, from participa-
5 tion in the Medicare program or a State health
6 care program (as defined in section 1128(h) of
7 the Social Security Act).”.

8 (2) AUDITS.—Section 340B(a)(5)(C) of the
9 Public Health Service Act (42 U.S.C.
10 256b(a)(5)(C)), as amended by section 3(e), is fur-
11 ther amended by adding at the end the following:

12 “(iii) AUDITS RELATING TO PATIENT
13 STATUS.—

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

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

4 “(bb) the requirements for
5 providing such drugs to referred
6 patients pursuant to paragraph
7 (13).

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

24 “(III) AUTHORITY TO ESTABLISH
25 PROCESS.—The Secretary shall estab-

1 lish, through notice and comment
 2 rulemaking, a process for manufactur-
 3 ers and covered entities to make a
 4 good faith attempt to resolve any con-
 5 cerns identified by a manufacturer
 6 prior to the initiation of an audit
 7 under this clause. A manufacturer
 8 shall provide to the covered entity the
 9 same materials that the manufacturer
 10 provided to the Secretary to support a
 11 credible allegation under this clause,
 12 as determined by the Secretary.”.

13 (3) ENFORCEMENT.—Section 340B(a)(5)(D) of
 14 the Public Health Service Act (42 U.S.C.
 15 256b(a)(5)(D)) is amended—

16 (A) by striking “subparagraphs (A)” and
 17 inserting “subparagraph (A)”;

18 (B) by striking “If the Secretary” and in-
 19 serting the following:

20 “(i) IN GENERAL.—If the Secretary”;

21 and

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

23 “(ii) SANCTIONS FOR NONCOMPLI-
 24 ANCE WITH PATIENT STATUS REQUIRE-
 25 MENTS.—If the Secretary determines, after

1 an audit described in subparagraph
2 (C)(iii), a covered entity to not be in com-
3 pliance with the requirements of treating
4 an individual as a patient of the covered
5 entity as described in subsection (b)(3) or
6 the requirements of paragraph (13)—

7 “(I) the covered entity shall de-
8 velop a corrective action plan, which
9 shall be subject to approval and moni-
10 toring by the Secretary; and

11 “(II) if the Secretary determines
12 that the covered entity has not ade-
13 quately corrected its noncompliance in
14 accordance with such plan—

15 “(aa) the covered entity
16 shall be ineligible to participate
17 in the drug discount program
18 under this section for a period
19 determined by the Secretary, not
20 to exceed 3 years; and

21 “(bb) the Secretary may
22 order the covered entity to pay
23 civil monetary penalties, pursu-
24 ant to subpart O of part 1003 of
25 title 42, Code of Federal Regula-

1 tions (or any successor regula-
 2 tions), with respect to any cov-
 3 ered outpatient drugs purchased
 4 by the covered entity during the
 5 period in which the covered entity
 6 was found to be not in compli-
 7 ance with the requirements of
 8 treating an individual as a pa-
 9 tient of the entity as described in
 10 subsection (b)(3) or the require-
 11 ments of paragraph (13).”.

12 (b) COVERED ENTITY REGISTRATION.—Section
 13 340B(a)(5) of the Public Health Service Act (42 U.S.C.
 14 256b(a)(5)) is amended by adding at the end the fol-
 15 lowing:

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

23 (c) TREATMENT OF CERTAIN PRESCRIPTIONS FOR
 24 PATIENTS REFERRED TO NON-340B PROVIDERS.—Sec-
 25 tion 340B(a) of the Public Health Service Act (42 U.S.C.

1 256b(a)), as amended by section 3(b), is further amended
 2 by adding at the end the following:

3 “(13) REFERRAL PRESCRIPTIONS.—

4 “(A) IN GENERAL.—In the case of a pa-
 5 tient of an eligible covered entity who is re-
 6 ferred by such covered entity to a prescribing
 7 provider who is not providing care on behalf of
 8 a covered entity, and such prescribing provider
 9 prescribes a drug within 12 months of the pa-
 10 tient receiving such referral, the eligible covered
 11 entity may provide such drug to such patient as
 12 a covered outpatient drug pursuant to the pro-
 13 gram under this section, in the same manner
 14 and under the same conditions as the covered
 15 entity would provide such drug to such patient
 16 had the covered entity prescribed the drug, in
 17 accordance with the requirements under sub-
 18 paragraph (C).

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

22 “(i) an entity described in any of sub-
 23 paragraphs (A) through (K) or (N) of
 24 paragraph (4); or

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

3 “(C) REQUIREMENTS.—

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

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

17 “(II) the patient was referred to
18 the prescribing provider who pre-
19 scribed the drug by the covered entity;

20 “(III) the prescription is filled at
21 the covered entity’s wholly-owned
22 pharmacy or contract pharmacy;

23 “(IV) the covered entity main-
24 tains, for a period of at least 3 years,
25 documentation of compliance with this

1 paragraph, including all documents
2 subject to audit under paragraph
3 (5)(C);

4 “(V) the covered entity does not
5 share the savings received from pur-
6 chasing the covered outpatient drug
7 with the prescribing provider; and

8 “(VI) the covered entity meets
9 such other requirements as the Sec-
10 retary may establish through notice
11 and comment rulemaking.

12 “(ii) EXCEPTED DRUGS.—

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

18 “(aa) is an infused drug;

19 “(bb) is a clinician-adminis-
20 tered drug; or

21 “(cc) otherwise requires ad-
22 ministration by a clinician.

23 “(II) EXCEPTIONS.—A covered
24 entity may provide a patient a covered

1 outpatient drug described in subclause
2 (I) pursuant to subparagraph (A) if—

3 “(aa) the eligible covered en-
4 tity is a covered entity described
5 in paragraph (4)(A) and was pro-
6 viding infusion services necessary
7 to deliver a required primary
8 health service or an additional
9 health service (as defined in sec-
10 tion 330(b)(1)) pursuant to fund-
11 ing received under section 330,
12 as of the date of enactment of
13 the SUSTAIN 340B Act; or

14 “(bb) the Secretary deter-
15 mines, through notice and com-
16 ment rulemaking, that low-in-
17 come, medically underserved resi-
18 dents of the service area of the
19 eligible covered entity lack access
20 to infusion services within a rea-
21 sonable distance and based on
22 this determination, the eligible
23 covered entity receives approval
24 from the Secretary to provide
25 these services pursuant to fund-

1 ing provided under section 330,
 2 subject to all the requirements of
 3 that section.

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

7 “(E) ADDRESSING SIGNIFICANT VOLUME
 8 OF DRUGS PROVIDED TO REFERRED PA-
 9 TIENTS.—

10 “(i) IN GENERAL.—The Secretary
 11 shall audit any eligible covered entity that,
 12 in any year, provides covered outpatient
 13 drugs to patients who received a prescrip-
 14 tion for such drug from a provider who is
 15 not a covered entity in a volume that ex-
 16 ceeds the lesser of—

17 “(I) 20 percent of the total num-
 18 ber of covered outpatient drugs pur-
 19 chased by the covered entity at or
 20 below the applicable ceiling price and
 21 dispensed by the covered entity for the
 22 year; or

23 “(II) the average annual percent-
 24 age over the most recent 3-year pe-
 25 riod, of the total number of covered

1 outpatient drugs purchased by the
2 covered entity at or below the applica-
3 ble ceiling price for the year and dis-
4 pensed by the covered entity to pa-
5 tients, that were dispensed to patients
6 who received a prescription for such
7 drug from a provider who is not a
8 covered entity.

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

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

24 “(I) the percentage of the cov-
25 ered entity’s revenue under the drug

1 discount program derived from drugs
 2 prescribed by a prescribing provider
 3 pursuant to this subsection; and

4 “(II) the percentage of the total
 5 number of covered outpatient drugs
 6 purchased by the covered entity that
 7 were prescribed by a prescribing pro-
 8 vider pursuant to this subsection.

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

18 “(F) ENFORCEMENT.—

19 “(i) CORRECTIVE ACTION PLAN.—In
 20 the case that the Secretary finds that a
 21 covered entity has failed to comply with
 22 any requirement under this paragraph,
 23 such covered entity shall be required to
 24 submit a corrective action plan to the Sec-

1 retary, which shall be subject to approval
2 and monitoring by the Secretary.

3 “(ii) LOSS OF REFERRAL AUTHORIZA-
4 TION.—A covered entity that fails to com-
5 ply with a corrective action plan within
6 180 days of approval of such plan by the
7 Secretary under clause (i) shall become in-
8 eligible to provide covered outpatient drugs
9 to referred patients under subparagraph
10 (A) for such period of time determined by
11 the Secretary under the corrective action
12 plan, not to exceed 3 years.

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

1 “(G) DEFINITIONS.—For the purposes of
2 this paragraph—

3 “(i) the term ‘prescribing provider’
4 means a licensed health care provider who
5 prescribes a drug to a patient of a covered
6 entity based on the referral of the patient
7 by the covered entity to the provider; and

8 “(ii) the term ‘referral’ means a writ-
9 ten, electronic, or otherwise documented
10 order by a licensed health care provider or-
11 dering, or the recertifying of the need for,
12 a health service.”.

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

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

23 (2) not later than 2 years after the date of en-
24 actment of this Act, and for each of the next 10

1 years, submit to Congress a report on the study
2 under paragraph (1).

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

4 Not later than 1 year after the date of enactment
5 of this Act, the Secretary of Health and Human Services
6 (referred to in this section as the “Secretary”) shall con-
7 clude the 340B Rebate Model Pilot Program, or a sub-
8 stantially similar program established by the Department
9 of Health and Human Services. The 340B Rebate Model
10 Pilot Program, or a substantially similar program, shall
11 not be expanded. One year after the date of enactment
12 of this Act, the Secretary shall discontinue the 340B Re-
13 bate Model Pilot Program, or a substantially similar pro-
14 gram, and transition to the 340B Drug Discount Program
15 Data Clearinghouse established under section 1150D of
16 the Social Security Act, as added by section 9(a).

17 **SEC. 6. CHILD SITES.**

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

22 “(14) CHILD SITES.—

23 “(A) IN GENERAL.—A covered entity de-
24 scribed in subparagraph (L), (M), (N), or (O)
25 of paragraph (4) that owns and operates a child

1 site that participates in the drug discount pro-
2 gram under this section shall maintain docu-
3 mentation of, and annually recertify to the Sec-
4 retary through such certification processes es-
5 tablished under title XVIII of the Social Secu-
6 rity Act, that each such child site is wholly-
7 owned by the entity and clinically and finan-
8 cially integrated with the covered entity and
9 providing care consistent with the policies of the
10 covered entity, including by—

11 “(i) registering each child site with
12 the Secretary, which, in the case of a child
13 site that is eligible for participation as de-
14 scribed in subparagraph (B)(ii), shall in-
15 clude submission of the attestation (absent
16 billing requirements) that the child site
17 meets the Medicare provider-based rules
18 under section 413.65 of title 42, Code of
19 Federal Regulations (or any successor reg-
20 ulations);

21 “(ii) applying the same financial as-
22 sistance policy for patients as applies with
23 respect to other sites operated by the cov-
24 ered entity; and

1 “(iii) ensuring that each child site
2 complies with the Medicare provider-based
3 rules under section 413.65 of title 42,
4 Code of Federal Regulations (or any suc-
5 cessor regulations), or meets the require-
6 ments of subparagraph (B)(i).

7 “(B) ELIGIBILITY FOR CHILD SITES.—

8 “(i) IN GENERAL.—A child site is eli-
9 gible for participation in the drug discount
10 program under this section, through the
11 eligibility of the covered entity that owns
12 and operates such child site, only if the
13 covered entity demonstrates that the child
14 site meets the following requirements:

15 “(I) The child site applies the
16 same financial assistance policy for
17 patients as the covered entity.

18 “(II) The child site ensures that
19 the providers who order or dispense
20 covered outpatient drugs purchased
21 under this section at the child site or
22 a contract pharmacy of the covered
23 entity have clinical responsibility for
24 health care services that result in the
25 receipt of a prescription or order of

1 the covered outpatient drug purchased
2 under this section that is dispensed.

3 “(III) The child site provides a
4 clinically meaningful range of services,
5 as determined by the services that
6 providers or suppliers employed by,
7 contracted with, or authorized to pro-
8 vide services at, the child site are
9 qualified to deliver.

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

1 “(V) The clinical services of the
2 child site and the covered entity are
3 integrated as evidenced by the fol-
4 lowing:

5 “(aa) Professional staff of
6 the child site have clinical privi-
7 leges at the covered entity.

8 “(bb) The covered entity
9 maintains the same monitoring
10 and oversight of the child site as
11 for any other owned entity or
12 subsidiary of the covered entity.

13 “(cc) The medical director
14 of the child site maintains a re-
15 porting relationship with the
16 chief medical officer or other
17 similar official of the covered en-
18 tity that has the same frequency,
19 intensity, and level of account-
20 ability that exists in the relation-
21 ship between the medical director
22 of a department of the covered
23 entity and the chief medical offi-
24 cer or other similar official of the
25 covered entity, and is under the

1 same type of supervision and ac-
2 countability as any other direc-
3 tor, medical or otherwise, of the
4 covered entity.

5 “(dd) Medical staff commit-
6 tees or other professional com-
7 mittees at the covered entity are
8 responsible for medical activities
9 in the child site, including quality
10 assurance, utilization review, and
11 the coordination and integration
12 of services, to the extent prac-
13 ticable, between the child site and
14 covered entity.

15 “(ee) Medical records for pa-
16 tients treated in the child site are
17 integrated into a unified retrieval
18 system, or have the ability to be
19 readily accessed by the covered
20 entity.

21 “(ff) Inpatient and out-
22 patient services of the child site
23 and the covered entity are inte-
24 grated, and patients treated at
25 the child site who require further

1 care have full access to all serv-
2 ices of the covered entity and are
3 referred where appropriate to the
4 corresponding inpatient or out-
5 patient department or service of
6 the covered entity.

7 “(VI) The financial operations of
8 the child site are fully integrated with-
9 in the financial system of the covered
10 entity, as evidenced by shared income
11 and expenses between the covered en-
12 tity and the child site. For purposes
13 of the Medicare program under title
14 XVIII of the Social Security Act, the
15 costs of a child site are reported in
16 the appropriate cost center or cost
17 centers of the covered entity, and the
18 financial status of any child site is in-
19 corporated and readily identified in
20 the covered entity’s trial balance.

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

1 “(VIII) The child site is operated
2 under the ownership and control of
3 the covered entity, as evidenced by the
4 following:

5 “(aa) The business enter-
6 prise that constitutes the child
7 site is 100 percent owned by the
8 covered entity.

9 “(bb) The covered entity
10 and the child site have the same
11 governing body.

12 “(cc) The child site is oper-
13 ated under the same organiza-
14 tional documents as the covered
15 entity, and is subject to common
16 bylaws and operating decisions of
17 the governing body of the covered
18 entity.

19 “(dd) The covered entity has
20 final responsibility for adminis-
21 trative decisions, final approval
22 for contracts with outside parties,
23 final approval for personnel ac-
24 tions, final responsibility for per-
25 sonnel policies (such as fringe

1 benefits or code of conduct), and
2 final approval for medical staff
3 appointments at the child site.

4 “(IX) The reporting relationship
5 between the child site and the covered
6 entity have the same frequency, inten-
7 sity, and level of accountability that
8 exists in the relationship between the
9 covered entity and its other depart-
10 ments, as evidenced by compliance
11 with the following requirements:

12 “(aa) The child site is under
13 the direct supervision of the cov-
14 ered entity.

15 “(bb) The child site is oper-
16 ated under the same monitoring
17 and oversight by the covered enti-
18 ty as any other department of
19 the covered entity, and is oper-
20 ated as any other department of
21 the covered entity with regard to
22 supervision and accountability.
23 The director or individual respon-
24 sible for daily operations at the
25 child site—

1 “(AA) maintains a re-
2 porting relationship with a
3 manager at the covered enti-
4 ty that has the same fre-
5 quency, intensity, and level
6 of accountability that exists
7 in the relationship between
8 the covered entity and its
9 existing departments; and

10 “(BB) is accountable to
11 the governing body of the
12 covered entity, in the same
13 manner as any department
14 head of the covered entity.

15 “(X) The following administra-
16 tive functions of the child site are in-
17 tegrated with the functions of the cov-
18 ered entity: billing services, records,
19 human resources, payroll, employee
20 benefit package, salary structure, and
21 purchasing services. Either the same
22 employees or group of employees han-
23 dle such administrative functions for
24 the child site and the covered entity,
25 or the administrative functions for

1 both the child site and the covered en-
2 tity are—

3 “(aa) contracted out under
4 the same contract agreement; or

5 “(bb) handled under dif-
6 ferent contract agreements, with
7 the contract of the child site
8 being managed by the covered
9 entity.

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

22 “(bb) Such cost report dem-
23 onstrates that the services provided at
24 the child site have associated costs
25 and charges for covered entity out-

1 patient department services under
2 title XVIII of the Social Security Act
3 (or, if the covered entity does not file
4 a Medicare cost report, the covered
5 entity submits to the Secretary a
6 signed statement certifying that the
7 services provided at the child site in-
8 clude or consist solely of outpatient
9 services).

10 “(ii) HRSA DEEMING.—

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

22 “(II) RULE OF CONSTRUC-
23 TION.—This clause shall authorize the
24 Secretary to establish a process to de-
25 termine whether a child site, as deter-

1 mined by the Administrator of the
 2 Centers for Medicare & Medicaid
 3 Services, complies with the Medicare
 4 provider-based rules under section
 5 413.65 of title 42, Code of Federal
 6 Regulations (or any successor regula-
 7 tions).

8 “(iii) PROCESS FOR REGISTRATION.—

9 The Secretary shall develop a process for
 10 the registration of child sites that are eligi-
 11 ble for participation under clause (i) or
 12 (ii).

13 “(iv) ELIGIBILITY DELAY FOR CER-

14 TAIN CHILD SITES.—

15 “(I) NEWLY ACQUIRED SITES.—

16 “(aa) IN GENERAL.—Except

17 as provided in item (bb), a child
 18 site acquired by a covered entity
 19 after the date of enactment of
 20 the SUSTAIN 340B Act that
 21 was not eligible to participate in
 22 the drug discount program prior
 23 to such date shall not be eligible
 24 to participate in the drug dis-
 25 count program under this section

1 until the date that is 3 years
2 after the date of such acquisition.

3 “(bb) HARDSHIP EXEMP-
4 TION.—The Secretary may, on a
5 case-by-case basis, determine
6 that a newly acquired child site
7 will be eligible to participate in
8 the drug discount program under
9 this section on a specified date
10 within 180 days after the date of
11 acquisition by the covered entity.

12 “(II) NEWLY CONSTRUCTED
13 SITES.—A newly constructed child site
14 that began operations after the date
15 of enactment of the SUSTAIN 340B
16 Act shall not be eligible to participate
17 in the drug discount program as de-
18 scribed in clause (i) unless such site
19 meets all of the requirements under
20 this subparagraph.

21 “(C) INAPPROPRIATE TREATMENT OF A
22 PROVIDER AS A CHILD SITE.—Not later than
23 180 days after the first recertification of the
24 covered entity that occurs after the date of en-
25 actment of the SUSTAIN 340B Act, the Sec-

1 retary shall establish a process through notice
2 and comment rulemaking for determining the
3 status of a child site that, prior to such date of
4 enactment, was deemed qualified as a child site
5 but that does not meet the criteria set forth in
6 this subsection.

7 “(D) REPORTS.—

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

21 “(ii) HHS REPORTS TO CONGRESS.—

22 Not later than 2 years after the date of en-
23 actment of the SUSTAIN 340B Act, and
24 every 2 years thereafter, the Secretary
25 shall submit to the appropriate committees

1 of Congress a report that analyzes the use
2 of child sites in the drug discount program
3 under this section, and that—

4 “(I) characterizes the scope and
5 nature of child sites in the drug dis-
6 count program under this section, in-
7 cluding—

8 “(aa) the number of newly
9 acquired child sites;

10 “(bb) the number of newly
11 constructed child sites;

12 “(cc) the concentration of
13 the child sites across geographic
14 areas; and

15 “(dd) the payer-mix of the
16 child sites;

17 “(II) assesses the effect of eligi-
18 bility delays described in subpara-
19 graph (B)(iv); and

20 “(III) makes recommendations
21 with respect to policies needed to ad-
22 dress any issues identified in such re-
23 port.

24 “(iii) GAO REPORT ON BEST PRAC-
25 TICES.—Not later than 1 year after the

1 date of enactment of the SUSTAIN 340B
2 Act, the Comptroller General of the United
3 States shall submit a report to the appro-
4 priate committees of Congress that—

5 “(I) analyzes input solicited from
6 relevant stakeholders, including cov-
7 ered entities and manufacturers, re-
8 garding potential best practices for
9 ensuring savings received by child
10 sites through participation in the drug
11 discount program under this section
12 are used to meaningfully improve ac-
13 cess to care, including by expanding
14 access to health care services or
15 health-related benefits for patients
16 and communities served by the cov-
17 ered entity, including child sites of the
18 covered entity; and

19 “(II) makes recommendations to
20 the Secretary and appropriate com-
21 mittees of Congress with respect to
22 implementation of best practices iden-
23 tified and analyzed pursuant to sub-
24 clause (I).”.

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

5 “(F) CHILD SITE RECORDKEEPING.—In
 6 the case of a covered entity that has registered
 7 a child site pursuant to paragraph (14), the
 8 covered entity shall maintain auditable records
 9 for a period of at least 3 years and be subject
 10 to audits by the Secretary of records that per-
 11 tain to the compliance of the covered entity and
 12 child site with the provisions of paragraph
 13 (14).”.

14 **SEC. 7. TRANSPARENCY.**

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

18 “(5) REPORTING OF PROGRAM SAVINGS.—
 19 “(A) IN GENERAL.—Not later than 1 year
 20 after the date of enactment of the SUSTAIN
 21 340B Act, and annually thereafter, each cov-
 22 ered entity shall report to the Secretary the fol-
 23 lowing information with respect to the covered
 24 entity, including with respect to all child sites

1 and contract pharmacy arrangements, for the
2 preceding year:

3 “(i) The total number of individuals
4 who were dispensed or administered cov-
5 ered outpatient drugs during such pre-
6 ceding year that were subject to an agree-
7 ment under subsection (a)(1).

8 “(ii) The total number of prescrip-
9 tions dispensed or administered with cov-
10 ered outpatient drugs purchased under this
11 section and billed to insurance, organized
12 by type of health insurance coverage (as
13 specified by the Secretary, including by the
14 Medicare program under title XVIII of the
15 Social Security Act, the Medicaid program
16 under title XIX of such Act, the Children’s
17 Health Insurance Program under title XXI
18 of such Act, health insurance coverage of-
19 fered in the individual or group market or
20 a group health plan (as such terms are de-
21 fined in section 2791), and uninsured).

22 “(iii)(I) The cost incurred at each cov-
23 ered entity for charity care, reported as a
24 fraction, where the numerator is the
25 amount of charity care reported on work-

1 sheet S–10 of the Medicare cost report (or
2 any successor), and the denominator is the
3 total operating cost of the covered entity,
4 as reported for the most recent cost report-
5 ing period; or

6 “(II) in the case of a covered entity
7 that is not required to submit a Medicare
8 cost report, a qualitative description of the
9 charity care provided by the covered entity,
10 to the extent applicable under the scope of
11 the grant for a covered entity described in
12 any of subparagraphs (A) through (O) of
13 subsection (a)(4), in such manner that is
14 not overly burdensome to covered entities,
15 as the Secretary may require.

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

19 “(v)(I) A description, submitted in a
20 standardized form and manner prescribed
21 by the Secretary, of the covered entity’s
22 use of the savings received through partici-
23 pation in the drug discount program under
24 this section, including a description of
25 health care services or health-related bene-

1 fits used to benefit the patients and com-
2 munities served by the covered entity, de-
3 lineated by categories of services and bene-
4 fits and populations served, including such
5 services and benefits provided to under-
6 served, uninsured, or medically vulnerable
7 patients and communities; and

8 “(II) an attestation by the chief exec-
9 utive officer, chief executive financial offi-
10 cer, or chief operating officer certifying
11 that such savings have been used to benefit
12 the patients and communities served by the
13 covered entity.

14 “(vi) The financial demographics of
15 patients of the covered entity, including—

16 “(I) the percentage of patients
17 eligible for financial assistance pro-
18 grams and sliding scale fees;

19 “(II) the percentage of patients
20 who reside in a health professional
21 shortage area (as defined in section
22 332) or a medically underserved com-
23 munity (as defined in section 799B);

24 “(III) the percentage of patients
25 who reside in or are part of a medi-

1 cally underserved population (as de-
2 fined in section 330(b)(3));

3 “(IV) the percentage of unin-
4 sured patients;

5 “(V) the percentage of patients
6 who are Medicaid beneficiaries; and

7 “(VI) the percentage of patients
8 who are Children’s Health Insurance
9 Program beneficiaries.

10 “(vii) Policies of the covered entity to
11 promote access and adherence to pre-
12 scribed medication.

13 “(viii) In the case of a nongovern-
14 mental hospital, any contracts between
15 such hospital and a State or local govern-
16 mental entity, and any modifications to
17 any such contract.

18 “(ix) Any third-party administrators
19 in contract with the covered entity for the
20 administration of the drug discount pro-
21 gram.

22 “(x) The funding shortfall for the cov-
23 ered entity attributable to services provided
24 to Medicare and Medicaid beneficiaries, as

1 reported on the Internal Revenue Service
2 Form 990.

3 “(xi) The number of patients using
4 the outpatient services of the covered enti-
5 ty.

6 “(xii) Operation costs to the covered
7 entity related to the drug discount pro-
8 gram under this section.

9 “(B) RECORDS RETENTION.—A covered
10 entity shall retain records described in subpara-
11 graph (A) for a period of at least 3 years and
12 provide such records and reports as the Sec-
13 retary determines necessary for purposes of car-
14 rying out this paragraph.

15 “(C) AVAILABILITY OF INFORMATION.—

16 “(i) IN GENERAL.—Not later than 90
17 days after receiving the information re-
18 ported by covered entities under paragraph
19 (1), the Secretary shall publish such infor-
20 mation on the public website of the De-
21 partment of Health and Human Services,
22 which may include the website of the 340B
23 Office of Pharmacy Affairs Information
24 System (or a successor to such system).

1 “(ii) FORMAT.—Data published under
2 clause (i) shall be published in an elec-
3 tronic and searchable format that shows
4 each category of data reported both in the
5 aggregate and identified by each type of
6 covered entity described in subsection
7 (a)(4). In carrying out this paragraph,
8 with respect to data reported pursuant to
9 paragraph (1), the Secretary shall ensure
10 that any proprietary information be re-
11 dacted from contracts submitted pursuant
12 to subparagraph (A)(viii) before posting
13 such contracts.

14 “(D) SUBMISSION PROCESS.—Not later
15 than 1 year after the date of enactment of the
16 SUSTAIN 340B Act, the Secretary shall estab-
17 lish a process by which the information required
18 to be submitted under subparagraph (A) may
19 be submitted directly to the 340B Office of
20 Pharmacy Affairs Information System (or a
21 successor to such system).

22 “(E) REPORTS TO CONGRESS.—Not later
23 than 1 year after the date of the enactment of
24 the SUSTAIN 340B Act, and annually there-
25 after, the Secretary shall submit a report to the

1 appropriate committees of Congress on the in-
 2 formation collected under subparagraph (A).

3 “(F) REGULATIONS.—The Secretary may
 4 promulgate regulations to carry out this para-
 5 graph.”.

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

10 “(iv) AUDITS OF PROGRAM SAVINGS
 11 RECORDS.—A covered entity shall permit
 12 the Secretary to audit, at the Secretary’s
 13 expense, the records of the covered entity
 14 used for purposes of reporting under sub-
 15 section (d)(5)(A), including how the dis-
 16 count from drugs subject to an agreement
 17 under paragraph (1) is used by the covered
 18 entity.”.

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

20 (a) AUDITS.—

21 (1) IN GENERAL.—Section 340B(a)(5)(C) of
 22 the Public Health Service Act (42 U.S.C.
 23 256b(a)(5)(C)), as amended by section 7(b), is fur-
 24 ther amended by adding at the end the following:

25 “(v) ADDITIONAL AUDITS.—

1 “(I) IN GENERAL.—In addition
2 to the audits otherwise authorized
3 under this subparagraph, the Sec-
4 retary may audit, to assess compliance
5 with requirements under this sec-
6 tion—

7 “(aa) covered entities, in-
8 cluding the child sites of a cov-
9 ered entity and contract phar-
10 macies, to identify any violations
11 under this section, including vio-
12 lations related to improperly
13 claiming eligibility for the pro-
14 gram under this section, drug di-
15 version, duplicate discounts, use
16 of contract pharmacies, or claim-
17 ing a discount under this section
18 on a drug that is not a covered
19 outpatient drug purchased pursu-
20 ant to an agreement under para-
21 graph (1); and

22 “(bb) manufacturers, includ-
23 ing to identify any failure to pro-
24 vide an accurate ceiling price.

1 “(II) STANDARDS.—The Sec-
2 retary shall conduct audits described
3 in this clause in accordance with gen-
4 erally accepted standards that the
5 Secretary determines appropriate and
6 shall make the protocol for such au-
7 dits publicly available.

8 “(III) REQUIREMENTS.—The
9 Secretary may not close an audit de-
10 scribed in subclause (I) before a cor-
11 rective action plan required by the
12 Secretary has been fully implemented,
13 as applicable.

14 “(IV) 340B VENDOR INFORMA-
15 TION.—To meet the requirements for
16 submission of information for audits
17 under this clause, with respect to car-
18 rying out the program under this sec-
19 tion, a covered entity shall contract
20 only with vendors agreeing to—

21 “(aa) submit data to the
22 Secretary and independent out-
23 side auditors contracting with the
24 covered entity as necessary to de-
25 termine the covered entity’s com-

1 pliance with statutory and regu-
2 latory requirements under this
3 program, prohibitions on drug di-
4 version and duplicate discounts,
5 use of contract pharmacies, and
6 claims for discounts on covered
7 outpatient drugs purchased pur-
8 suant to agreements under para-
9 graph (1); and

10 “(bb) respond to requests
11 from auditors in a timely man-
12 ner, as determined by the Sec-
13 retary.

14 “(V) CONSEQUENCES OF
15 AUDIT.—The Secretary shall ensure
16 that, in the case of an audit finding
17 that—

18 “(aa) a covered entity did
19 not meet one or more of the eligi-
20 bility criteria for being a covered
21 entity, as defined in paragraph
22 (4), during the full period under
23 review in an audit, the audit re-
24 sults in consequences that are
25 consistent and appropriate with

1 the violation and that do not
2 treat the failure to meet eligi-
3 bility criteria as an issue that can
4 be corrected retroactively; or

5 “(bb) a manufacturer did
6 not meet its requirements pursu-
7 ant to an agreement under para-
8 graph (1) during the full period
9 under review in an audit, the
10 audit results in consequences
11 that are consistent and appro-
12 priate with the violation and that
13 do not treat the failure to meet
14 the criteria as an issue that can
15 be corrected retroactively.

16 “(VI) REGULATIONS.—Not later
17 than 1 year after the date of enact-
18 ment of the SUSTAIN 340B Act, the
19 Secretary shall establish, through no-
20 tice and comment rulemaking, the
21 audit and reporting procedures re-
22 quired by this clause.”.

23 (2) ADDITIONAL SANCTIONS AUTHORITY.—Sec-
24 tion 340B(d)(2)(B) of the Public Health Service Act
25 (42 U.S.C. 256b(d)(2)(B)) is amended—

1 (A) in clause (v)(II), by inserting “or
2 where the covered entity knowingly and inten-
3 tionally fails to implement a corrective action
4 plan relating to a violation involving improperly
5 claiming eligibility for the program under this
6 section, drug diversion, duplicate discounts,
7 compliance with contract pharmacy require-
8 ments, or claiming a discount on a drug that is
9 not a covered outpatient drug (or claiming a re-
10 bate on a drug in the case of an AIDS drug
11 purchasing assistance program, as determined
12 by the Secretary), within 180 days of the Sec-
13 retary notifying the entity of the requirement
14 for such plan, unless the Secretary determines
15 it is appropriate to allow additional time for
16 compliance,” after “knowing and intentional,”;
17 and

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

19 “(vi) Increasing the frequency of au-
20 dits conducted for entities previously found
21 to be in violation of requirements of the
22 drug discount program that relate to eligi-
23 bility, drug diversion, duplicate discounts,
24 compliance with contract pharmacy re-
25 quirements, or claiming a discount on a

1 drug that is not a covered outpatient drug
2 (or claiming a rebate on a drug in the case
3 of an AIDS drug purchasing assistance
4 program described in subsection (a)(4)(E),
5 as determined by the Secretary), and as-
6 signing responsibility for making correc-
7 tions relating to such a violation to a cor-
8 porate officer of the covered entity.

9 “(vii)(I) Establishing a process for a
10 covered entity to develop and implement a
11 corrective action plan, and a process by
12 which the Secretary provides for proper
13 and timely notification of a potential viola-
14 tion by a covered entity.

15 “(II) Disenrolling from the program a
16 covered entity that fails to implement a
17 corrective action plan within 180 days of
18 issuance of a final audit report related to
19 a statutory violation involving improperly
20 claiming eligibility for the program under
21 this section, drug diversion, duplicate dis-
22 counts, compliance with contract pharmacy
23 requirements, claiming a discount on a
24 drug that is not a covered outpatient drug
25 (or claiming a rebate on a drug in the case

1 of an AIDS drug purchasing assistance
 2 program described in subsection (a)(4)(E),
 3 as determined by the Secretary), or failing
 4 to comply with reporting of program sav-
 5 ings and use of program savings as re-
 6 quired.”.

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

12 “(G) VERIFICATION OF PRIVATE NON-
 13 PROFIT HOSPITAL CONTRACTS WITH STATE OR
 14 LOCAL GOVERNMENTS.—

15 “(i) IN GENERAL.—In the case of a
 16 private non-profit hospital that has a con-
 17 tract with a State or local government to
 18 provide health care services to low-income
 19 individuals who are not eligible for Med-
 20 icaid or Medicare, whether the hospital is
 21 registered or seeking to register for the
 22 drug discount program as a covered entity
 23 described under subparagraph (L), (M),
 24 (N), or (O) of paragraph (4), the Secretary

1 shall take all of the following steps, each of
2 which shall be documented:

3 “(I) Prior to registering or ap-
4 proving annual recertification of such
5 a hospital (or while carrying out any
6 program audit of such a hospital), the
7 Secretary shall obtain and review the
8 hospital’s contract with a State or
9 local government and shall verify and
10 document that—

11 “(aa) the document provided
12 by the hospital is a contract, in
13 that it is a mutually binding
14 agreement for the hospital to
15 provide health care services or
16 supplies in exchange for some-
17 thing of value;

18 “(bb) the contract clearly
19 lists the name of the hospital and
20 the unit of State or local govern-
21 ment that are parties to the con-
22 tract and is signed and appro-
23 priately dated by appropriate of-
24 ficials of the hospital and the
25 unit of State or local government;

1 “(cc) the contract specifies
2 an effective date;

3 “(dd) the contract clearly is
4 in effect and not expired at the
5 time of registration (or at the
6 time of recertification, in the case
7 of annual recertification, or for
8 the full period examined in an
9 audit, in the case of an audit);
10 and

11 “(ee) the contract explicitly
12 requires that the hospital provide
13 health care services, and that
14 such services must be provided to
15 individuals who are both low-in-
16 come and not eligible for either
17 the Medicaid program or the
18 Medicare program.

19 “(II) The Secretary shall verify
20 the contracts meeting the require-
21 ments of clause (i) for all covered en-
22 tities described in this subparagraph
23 and registered as of the date of enact-
24 ment of the SUSTAIN 340B Act by
25 no later than 1 year after the date of

1 enactment of the SUSTAIN 340B
2 Act.

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

9 “(ii) PROCESS.—The Secretary shall
10 develop a process to verify the contracts
11 meeting the requirement of clause (i)(I),
12 including specifying a timeline.”.

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

20 **SEC. 9. PREVENTING DUPLICATE DISCOUNTS.**

21 (a) 340B DRUG DISCOUNT PROGRAM DATA CLEAR-
22 INGHOUSE.—Part A of title XI of the Social Security Act
23 (42 U.S.C. 1301 et seq.) is amended by adding the fol-
24 lowing the following new section:

1 **“SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEAR-**
2 **INGHOUSE.**

3 “(a) CLEARINGHOUSE CONTRACTING ENTITY.—Not
4 later than 1 year after the date of enactment of this sec-
5 tion, the Secretary shall enter into a contract with an inde-
6 pendent, third-party entity (who shall be free of conflicts
7 of interest with covered entities, manufacturers, health
8 plans, third-party administrators of health plans, entities
9 providing pharmacy benefit management services to health
10 plans, and of other conflicts of interest as specified by the
11 Secretary) for purposes of carrying out the clearinghouse
12 duties under subsection (b) with respect to the 340B drug
13 discount program to prevent duplicate discounts and en-
14 sure proper accounting. Such contract shall provide that
15 the third-party entity shall perform the duties described
16 in subsection (b) and shall be for a 4-year term that may
17 be renewed after a subsequent bidding process or using
18 competitive procedures, as defined in section 132 of title
19 41, United States Code.

20 “(b) DUTIES.—With respect to 340B drugs that are
21 dispensed to individuals who are entitled to or eligible for
22 benefits under the Medicare program under title XVIII,
23 the Medicaid program under title XIX (including benefits
24 provided under the Medicaid program through a managed
25 care arrangement), the Children’s Health Insurance Pro-
26 gram under title XXI (including benefits provided under

1 the Children’s Health Insurance Program through a man-
2 aged care arrangement), or a health plan, a third-party
3 entity with a contract in effect under subsection (a)
4 shall—

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

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

9 “(B) claims-level data from covered enti-
10 ties; and

11 “(C) any other data specified by the Sec-
12 retary as necessary for the entity to carry out
13 this section;

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

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

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

24 “(5) provide the manufacturer of a 340B drug
25 with claims-level data submitted by a covered entity,

1 so that the manufacturer may identify units of a
2 340B drug that may generate a rebate or discount
3 under a voluntary rebate or discount arrangement,
4 such as those related to commercial plans;

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

11 “(7) determine total sales of 340B drugs to
12 such individuals for purposes of being used as the
13 basis for determining user fees under section
14 340B(a)(15) of such Act; and

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

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

1 “(d) RESTRICTIONS ON CONTRACTING ENTITY.—

2 The entity receiving a contract under subsection (a)
3 shall—

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

9 “(2) not disclose confidential information ob-
10 tained through carrying out the clearinghouse duties
11 under this section other than as necessary to carry
12 out the purposes of this section, including for pro-
13 gram integrity functions;

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

17 “(4) not collect pricing information regarding
18 drugs that are not 340B drugs from covered enti-
19 ties.

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

1 “(f) RESTRICTIONS ON MANUFACTURER AND PBM
2 USE OF DATA.—

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

7 “(2) RESTRICTIONS ON PLANS, ISSUERS, AND
8 PBMS.—A health plan, third-party administrator of
9 a health plan, or entity providing pharmacy benefit
10 management services may use data received from
11 the clearinghouse only for the purpose of preventing
12 duplicate discounts and diversion under this section.

13 “(3) ENFORCEMENT.—Any manufacturer or
14 other person found by the Secretary to have used
15 data received under subsection (b)(5) for uses other
16 than those described in paragraphs (1) and (2), such
17 as for pricing or marketing, shall be subject to civil
18 monetary penalties, pursuant to subpart O of part
19 1003 of title 42, Code of Federal Regulations (or
20 any successor regulations), subject to the discretion
21 of the Secretary.

22 “(g) PRIVACY REQUIREMENTS.—The information ex-
23 change required by subsection (b) shall occur in a manner
24 consistent with the privacy, security, and breach notifica-
25 tion regulations promulgated under section 264(c) of the

1 Health Insurance Portability and Accountability Act of
2 1996.

3 “(h) REPAYMENT TO MANUFACTURERS.—The Sec-
4 retary shall require a covered entity to work with affected
5 manufacturers regarding identified duplicate discounts for
6 340B drugs, regardless of the method used to dispense
7 the 340B drug, which shall include repayment—

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

11 “(2) by a State Medicaid program of rebates
12 improperly requested by the State Medicaid pro-
13 gram; or

14 “(3) by a State Medicaid program where the fi-
15 nancial benefit of the duplicate discount accrues to
16 the State Medicaid program, regardless of whether
17 the duplicate discount occurred under the fee-for-
18 service or managed care payment arrangement.

19 “(i) DEFINITIONS.—In this section:

20 “(1) 340B DRUG.—The term ‘340B drug’
21 means a drug that is—

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

1 “(B) purchased under an agreement in ef-
2 fect under such section.

3 “(2) COVERED ENTITY.—The term ‘covered en-
4 tity’ means an entity described in section
5 340B(a)(4) of the Public Health Service Act.

6 “(3) DIVERSION.—The term ‘diversion’, with
7 respect to a covered entity and a 340B drug, means
8 the resale or otherwise transferring of the drug to
9 a person who is not a patient, as defined in section
10 340B(b)(3) of the Public Health Service Act, of the
11 covered entity.

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

18 “(5) HEALTH PLANS.—The term ‘health plan’
19 has the meaning given to that term in section
20 1128C(c).

21 “(6) MANUFACTURER.—The term ‘manufac-
22 turer’ has the meaning given to that term in section
23 1927(k)(5).”.

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

1 (1) IN GENERAL.—A group health plan, a
2 health insurance issuer offering group or individual
3 coverage (as such terms are defined in section 2791
4 of the Public Health Service Act (42 U.S.C. 300gg–
5 91)), or an entity providing pharmacy benefit man-
6 agement services may not interfere with the ability
7 of covered entities, contract pharmacies (as such
8 terms are defined in section 340B of the Public
9 Health Service Act (42 U.S.C. 254b)), or manufac-
10 turers of drugs to prevent duplicate discounts or to
11 recoup the full amount of any identified duplicate
12 discounts pursuant to the drug discount program
13 under section 340B of the Public Health Service Act
14 (42 U.S.C. 254b).

15 (2) ENFORCEMENT.—The Secretary of Health
16 and Human Services shall impose civil monetary
17 penalties, pursuant to subpart O of part 1003 of
18 title 42, Code of Federal Regulations (or any suc-
19 cessor regulations), on any group health plan, health
20 insurance issuer, or entity providing pharmacy ben-
21 efit management services that violates paragraph
22 (1).

23 (c) OVERSIGHT.—Not later than 1 year after the date
24 of enactment of this Act, the Secretary of Health and
25 Human Services, acting through the Administrator of the

1 Centers for Medicare & Medicaid Services and the Admin-
 2 istrator of the Health Resources and Services Administra-
 3 tion, shall issue a report to the appropriate committees
 4 of Congress detailing coordinated efforts, including
 5 through the use of existing resources to address duplicate
 6 discounts.

7 (d) REGULATIONS.—The Secretary of Health and
 8 Human Services may promulgate such rules through no-
 9 tice and comment rulemaking as the Secretary determines
 10 appropriate to advance the purpose of the drug discount
 11 program under section 340B of the Public Health Service
 12 Act (42 U.S.C. 256b) and prevent duplicate discounts
 13 through the clearinghouse established by the amendment
 14 made by subsection (a).

15 (e) DEFINITION.—In this section, the term “dupli-
 16 cate discount” has the meaning given such term in section
 17 1150D(h) of the Social Security Act, as added by sub-
 18 section (a).

19 **SEC. 10. PATIENT FINANCIAL ASSISTANCE.**

20 Section 340B(a)(5) of the Public Health Service Act
 21 (42 U.S.C. 256b(a)(5)), as amended by section 8(b), is
 22 further amended by adding at the end the following:

23 “(H) PATIENT FINANCIAL ASSISTANCE.—

24 “(i) IN GENERAL.—Each covered enti-
 25 ty shall—

1 “(I) ensure that its financial as-
2 sistance policy is transparent to pa-
3 tients at point of care and publicly re-
4 ported;

5 “(II) apply such financial assist-
6 ance policy to patients served by child
7 sites and contract pharmacies; and

8 “(III) upon request of the Sec-
9 retary, submit its financial assistance
10 policy to the Secretary.

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

16 “(iii) FINANCIAL ASSISTANCE POLICY
17 DEFINED.—In this subparagraph, a ‘finan-
18 cial assistance policy’ means—

19 “(I)(aa) a written financial as-
20 sistance policy described in section
21 501(r)(4)(A) of the Internal Revenue
22 Code of 1986, provided, at least, to
23 patients at 200 percent of the Federal
24 poverty level or less; and

1 “(bb) a sliding fee scale for cov-
2 ered outpatient drugs dispensed to pa-
3 tients under the drug discount pro-
4 gram under this section, as applicable;
5 or

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

9 “(iv) OVERSIGHT.—The Comptroller
10 General of the United States shall conduct
11 a study and report to Congress on the im-
12 pact of requirements of this subparagraph
13 on patient access to covered outpatient
14 drugs purchased under this section.

15 “(v) LANGUAGE REQUIREMENTS.—A
16 covered entity shall make the financial as-
17 sistance policy described in clause (i) avail-
18 able to patients, including patients served
19 by child sites and contract pharmacies in
20 plain language (as defined in section
21 1311(e)(3)(B) of the Patient Protection
22 and Affordable Care Act).

23 “(vi) RULE OF CONSTRUCTION.—
24 Compliance with this subparagraph shall
25 not be considered a prohibited act under

1 section 1128A, 1128B(b), or 1877 of the
2 Social Security Act.

3 “(vii) DELAYED EFFECTIVE DATE
4 FOR CERTAIN ENTITIES.—With respect to
5 a child site or contract pharmacy, the re-
6 quirements of this subparagraph shall
7 apply beginning on the date that is 3 years
8 after the date of enactment of the SUS-
9 TAIN 340B Act.”.

10 **SEC. 11. ENSURING THE EQUITABLE TREATMENT OF COV-**
11 **ERED ENTITIES AND PHARMACIES PARTICI-**
12 **PATING IN THE 340B DRUG DISCOUNT PRO-**
13 **GRAM.**

14 (a) GROUP HEALTH PLAN AND HEALTH INSURANCE
15 ISSUER REQUIREMENTS.—Subpart II of part A of title
16 XXVII of the Public Health Service Act (42 U.S.C.
17 300gg–11 et seq.) is amended by adding at the end the
18 following:

19 **“SEC. 2729A. REQUIREMENTS RELATING TO THE 340B DRUG**
20 **DISCOUNT PROGRAM.**

21 “(a) IN GENERAL.—A group health plan, a health
22 insurance issuer offering group or individual health insur-
23 ance coverage, or an entity providing pharmacy benefit
24 management services on behalf of such a plan or issuer
25 may not discriminate against a covered entity, a 340B

1 pharmacy, or a participant, beneficiary, or enrollee of such
 2 plan or coverage by imposing requirements, exclusions, re-
 3 imbursement terms, or other conditions on such entity or
 4 340B pharmacy that differ from those applied to entities
 5 or pharmacies that are not covered entities or 340B phar-
 6 macies on the basis that the entity or pharmacy is a cov-
 7 ered entity or 340B pharmacy or that the entity or 340B
 8 pharmacy dispenses 340B drugs, including by taking any
 9 action prohibited under subsection (b).

10 “(b) SPECIFIED PROHIBITED ACTIONS.—A group
 11 health plan, a health insurance issuer offering group or
 12 individual health insurance coverage, or an entity pro-
 13 viding pharmacy benefit management services on behalf
 14 of such a plan or issuer may not discriminate against a
 15 covered entity, a 340B pharmacy, or a participant, bene-
 16 ficiary, or enrollee of such plan or coverage by doing any
 17 of the following:

18 “(1) Reimbursing a covered entity or 340B
 19 pharmacy for a quantity of a 340B drug (as defined
 20 in subsection (d)) in an amount less than such plan,
 21 issuer, or entity providing pharmacy benefit manage-
 22 ment services (as applicable) would pay to any other
 23 similarly situated (as specified by the Secretary) en-
 24 tity or pharmacy that is not a covered entity or a
 25 340B pharmacy for such quantity of such drug 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 “(2) Imposing any terms or conditions on any
5 covered entity or 340B pharmacy, with respect to
6 any of the following that differ from such terms or
7 conditions applied to other similarly situated (as
8 specified by the Secretary) entities or pharmacies
9 that are not covered entities or 340B pharmacies on
10 the basis that the entity or pharmacy is a covered
11 entity or 340B pharmacy or that the entity or phar-
12 macy dispenses 340B drugs:

13 “(A) Fees, chargebacks, clawbacks, adjust-
14 ments, or other assessments.

15 “(B) Professional dispensing fees.

16 “(C) Restrictions or requirements regard-
17 ing participation in standard or preferred phar-
18 macy networks.

19 “(D) Requirements relating to the fre-
20 quency or scope of audits or to inventory man-
21 agement systems using generally accepted ac-
22 counting principles.

23 “(E) Any other restrictions, conditions,
24 practices, or policies that, as specified by the
25 Secretary, interfere with the ability of a covered

1 entity to maximize the value of discounts pro-
2 vided under section 340B.

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

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

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

15 “(A) the entity or pharmacy is a covered
16 entity or a 340B pharmacy; or

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

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

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

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

4 “(B) is inconsistent with patient need and
5 access.

6 “(8) Failing to enable pharmacies to distinguish
7 at the point-of-sale between private health plans and
8 State Medicaid plans sponsored by the same payer,
9 through methods such as using the same bank iden-
10 tification number and processor control number to
11 identify individual enrolled in both types of plans.

12 “(c) CIVIL MONETARY PENALTIES.—The Secretary
13 shall impose monetary penalties, pursuant to subpart O
14 of part 1003 of title 42, Code of Federal Regulations (or
15 any successor regulations), on any group health plan,
16 health insurance issuer offering group or individual health
17 insurance coverage, or entity providing pharmacy benefit
18 management services on behalf of such a plan or issuer
19 that violates the requirements of this section. Such penalty
20 shall not exceed \$5,000 per violation per day. The Sec-
21 retary shall issue proposed regulations to implement this
22 subsection not later than 180 days after the date of the
23 enactment of this section and shall finalize such regula-
24 tions not later than 1 year after such date of enactment.

1 The penalties under this subsection may be in addition
 2 to other enforcement actions available under this title.

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

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

7 “(2) COVERED ENTITY.—The term ‘covered en-
 8 tity’ has the meaning given such term in section
 9 340B(a)(4).

10 “(3) 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); and

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

16 “(4) 340B PHARMACY.—The term ‘340B phar-
 17 macy’ means a pharmacy that is wholly-owned by a
 18 covered entity or that is a contract pharmacy.”.

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

23 “(i) NONDISCRIMINATION.—

24 “(1) IN GENERAL.—A PDP sponsor offering a
 25 prescription drug plan or an MA organization offer-

1 ing an MA–PD plan may not require a covered enti-
 2 ty to make use of any 340B pharmacy in a manner
 3 that—

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

7 “(B) is inconsistent with patient need and
 8 access.

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

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

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

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

19 **SEC. 12. USER FEE PROGRAM.**

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

24 “(15) USER FEE PROGRAM.—

1 “(A) ESTABLISHMENT OF QUARTERLY
2 FEE.—Beginning in fiscal year 2031, the Sec-
3 retary shall in accordance with this section as-
4 sess user fees on, and collect such fees from,
5 each covered entity participating in the pro-
6 gram under this section. The fees shall be as-
7 sessed for a fiscal year and collected quarterly
8 during the last 3 quarters of such fiscal year
9 and the first quarter of the subsequent fiscal
10 year, and the total amount assessed and col-
11 lected for a fiscal year shall be the amount
12 specified in subparagraph (B)(i) for such year,
13 subject to subparagraph (C).

14 “(B) ASSESSMENT OF USER FEES.—

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

19 “(I) \$50,000,000 for fiscal year
20 2031; and

21 “(II) for fiscal year 2032 and
22 each subsequent fiscal year, the
23 amount authorized to be assessed and
24 collected in the previous fiscal year
25 adjusted by the average annual per-

cent change that occurred in the Consumer Price Index for all urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index) in the 12-month period ending June 30 preceding the fiscal year for which fees are being established.

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

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

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

1 “(aa) dividing—

2 “(AA) the number of
3 prescriptions for covered
4 outpatient drugs dispensed
5 by the covered entity in the
6 previous fiscal year; by

7 “(BB) the total number
8 of prescriptions for covered
9 outpatient drugs dispensed
10 by all covered entities in
11 such fiscal year; and

12 “(bb) multiplying the
13 amount determined under item
14 (aa) by 100.

15 “(iii) TIMING OF ASSESSMENT.—The
16 Secretary shall notify each covered entity
17 subject to this section of the amount of the
18 annual assessment imposed on such cov-
19 ered entity under this subsection not later
20 than December 31 of the fiscal year for
21 which such fees apply. Payments of such
22 assessments shall be made in 4 equal in-
23 stallments, which shall be made by the last
24 day of each quarter of the calendar year
25 immediately following the notification.

1 “(C) USE OF FEES.—Any fee collected
2 under this paragraph shall be used by the Sec-
3 retary for purposes of administering this section
4 and enhancing program integrity and oversight
5 activities under this section, including—

6 “(i) the development of a multi-func-
7 tional web-based system to collect fees
8 under this paragraph;

9 “(ii) the establishment, use, and
10 maintenance of the data clearinghouse
11 under section 1150D of the Social Security
12 Act;

13 “(iii) the improvement of the integ-
14 rity, transparency, security, searchability,
15 and reliability of the 340B Office of Phar-
16 macy Affairs Information System (or a
17 successor to such system);

18 “(iv) improvements to the compliance
19 tool used to integrate all information re-
20 lated to manufacturers that have entered
21 into agreements with the Secretary under
22 paragraph (1) and covered entities;

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

1 “(vi) any other uses for the purposes
2 of program integrity, as the Secretary de-
3 termines appropriate.

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

9 “(E) REGULATIONS.—The Secretary may
10 promulgate rules through notice and comment
11 rulemaking as necessary to carry out the user
12 fee program under this paragraph, which shall
13 include establishment of a process to provide
14 for exceptions to the fee amount under subpara-
15 graph (B), including the circumstances under
16 which such exceptions may apply to certain cov-
17 ered entities.

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

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

24 “(ii) not later than September 30 of
25 each year for which a review is required

1 under clause (i), submit to Congress a re-
2 port on the review conducted under clause
3 (i), together with such recommendations as
4 the Inspector General determines appro-
5 priate.”.

6 (b) CONFORMING AMENDMENT.—Section 340B(a)(4)
7 of the Public Health Service Act (42 U.S.C. 256b(a)(4))
8 is amended, in the matter preceding subparagraph (A),
9 by inserting “, has submitted user fees to the Secretary
10 in the amount assessed under paragraph (15) for the cur-
11 rent year,” after “paragraph (5)”.

12 **SEC. 13. STUDIES AND REPORTS.**

13 (a) GAO REPORT.—Not later than 2 years after the
14 date of enactment of this Act, the Comptroller General
15 of the United States shall submit to Congress a report
16 on the debt collection practices of hospitals, including hos-
17 pitals that participate in the drug discount program under
18 section 340B of the Public Health Service Act (42 U.S.C.
19 256b) as covered entities described in subparagraphs (L)
20 through (O) of subsection (a)(4) of such section 340B.

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

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

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

6 (c) ASPE STUDY.—The Assistant Secretary for
7 Planning and Evaluation (referred to in this subsection
8 as the “Assistant Secretary”) shall conduct a study on the
9 interactions of the clearinghouse established under section
10 1150D of the Social Security Act (as added by section 9)
11 and any data collection system established by the Sec-
12 retary to carry out section 1193(d) of the Social Security
13 Act (42 U.S.C. 1320f–2(d)) or section 1860D–
14 14B(b)(1)(B) of such Act (42 U.S.C. 1395w–
15 114b(b)(1)(B)) to limit duplicative discounts for out-
16 patient prescription drugs. The Assistant Secretary shall
17 make recommendations to Congress on ways to streamline
18 and effectively operate such clearinghouse and data collec-
19 tion systems.

20 **SEC. 14. ADDITIONAL RESOURCES.**

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

24 “(f) AUTHORIZATION OF APPROPRIATIONS.—

1 “(1) AUTHORIZATION OF APPROPRIATIONS FOR
 2 AUDITS, INVESTIGATIONS, AND OTHER OVERSIGHT
 3 AND ENFORCEMENT ACTIVITIES.—In addition to
 4 amounts made available under subsection (d)(4),
 5 there are authorized to be appropriated, to the In-
 6 specter General of the Department of Health and
 7 Human Services, \$3,000,000 for each of fiscal years
 8 2027 through 2031, for purposes of conducting au-
 9 dits, investigations, and other oversight and enforce-
 10 ment activities with respect to the drug discount
 11 program under this section.

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

19 (b) HIRING AUTHORITY; REGULATIONS.—Section
 20 340B of the Public Health Service Act (42 U.S.C. 256b),
 21 as amended by subsection (a), is further amended by add-
 22 ing at the end the following:

23 “(g) HIRING AUTHORITY.—The Administrator of the
 24 Health Resources and Services Administration may hire

1 such additional staff as may be necessary for purposes of
2 carrying out this section.

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

6 **SEC. 15. DEFINITIONS.**

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

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

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

19 **SEC. 16. EFFECTIVE DATE.**

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

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