

118TH CONGRESS
2D SESSION

S. _____

To _____ .

IN THE SENATE OF THE UNITED STATES

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

A BILL

To _____ .

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. Child sites.
- Sec. 6. Transparency.
- Sec. 7. Enhancing program integrity.
- Sec. 8. Preventing duplicate discounts.
- Sec. 9. Ensuring the equitable treatment of covered entities and pharmacies participating in the 340B drug discount program.
- Sec. 10. User fee program.
- Sec. 11. Studies and reports.
- Sec. 12. Additional resources for oversight.
- Sec. 13. Definitions.
- Sec. 14. 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 title XVIII of the Social Security
11 Act (42 U.S.C. 1395 et seq.), to provide discounts to cov-
12 ered entities that serve a disproportionate share of low-
13 income and underserved patients.

14 SEC. 3. CONTRACT PHARMACY.

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

18 “(11) CONTRACT PHARMACIES.—

19 “(A) IN GENERAL.—In the case of a cov-
20 ered entity that elects to contract with a phar-

1 macy or pharmacies to dispense covered out-
2 patient drugs purchased by a covered entity at
3 or below the applicable ceiling price described in
4 paragraph (1) to patients of the covered entity,
5 a manufacturer of a covered outpatient drug
6 that is subject to an agreement with the Sec-
7 retary under paragraph (1) shall comply with
8 the following requirements:

9 “(i) Offer each covered entity covered
10 outpatient drugs for purchase at or below
11 the applicable ceiling price described in
12 paragraph (1) regardless of whether the
13 drug is dispensed through a pharmacy
14 under contract with a covered entity or di-
15 rectly by the covered entity.

16 “(ii) Deliver or allow the delivery of
17 covered outpatient drugs purchased by a
18 covered entity and their associated sites at
19 or below the applicable ceiling price de-
20 scribed in paragraph (1) to pharmacy loca-
21 tions as requested by a covered entity, in
22 accordance with the covered entity’s con-
23 tract pharmacy agreements.

24 “(iii) Not place any of the following
25 conditions on the ability of a covered entity

1 to purchase a covered outpatient drug at
2 or below the applicable ceiling price de-
3 scribed in paragraph (1) for dispensing ac-
4 cording to the applicable written contract
5 pharmacy arrangements:

6 “(I) Restricting distribution op-
7 tions only with respect to covered out-
8 patient drugs, covered entities, or con-
9 tract pharmacies.

10 “(II) Requiring the submission of
11 claims data directly to the manufac-
12 turer out of submissions to the entity
13 receiving the contract to maintain the
14 clearinghouse under section 1150D of
15 the Social Security Act.

16 “(III) Such other conditions as
17 the Secretary may prohibit.

18 “(B) REGISTRATION OF CONTRACT.—Each
19 covered entity shall annually register with the
20 Secretary any contract described in subpara-
21 graph (A), in accordance with such registration
22 requirements as the Secretary may establish
23 through guidance. Such registration require-
24 ments shall include requiring covered entities
25 to—

1 “(i) submit all contract pharmacy
2 agreements to the Secretary in a timely
3 manner;

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

9 “(iii) attest to their compliance with
10 the requirements under this section.

11 “(C) CONTRACT REVIEW PROCESS.—The
12 Secretary shall establish a process to review all
13 written agreements between a covered entity
14 and each of its contract pharmacies, as de-
15 scribed in subparagraph (A), to ensure compli-
16 ance with the requirements under this sub-
17 section.

18 “(D) IMPROVEMENTS IN CONTRACT PHAR-
19 MACY ARRANGEMENT INTEGRITY.—To ensure
20 the integrity of contract pharmacy arrange-
21 ments described in subparagraph (A), including
22 to prevent diversion and duplicate discounts de-
23 scribed in paragraph (5)(A), the Secretary shall
24 promulgate rules to carry out the following:

1 “(i) Require a written agreement be-
2 tween a covered entity and any pharmacy
3 with which the covered entity has a con-
4 tract pharmacy arrangement. Each such
5 agreement shall—

6 “(I) list the address of each con-
7 tract pharmacy location that will dis-
8 pense drugs on behalf of the covered
9 entity, including all parent, child,
10 principal, or associated sites that plan
11 to use the contract pharmacy;

12 “(II) be signed and in effect not
13 later than the day before the contract
14 pharmacy begins dispensing covered
15 outpatient drugs purchased under this
16 section on behalf of the covered entity;
17 and

18 “(III) include the standard con-
19 tract provisions established under
20 clause (ii).

21 “(ii) Develop standard contract provi-
22 sions that are required be included in each
23 written agreement described in clause (i),
24 including provisions providing that—

1 “(I) the contract pharmacy is re-
2 sponsible for providing pharmacy serv-
3 ices and providing data to covered en-
4 tities to support the submission by the
5 covered entity of covered outpatient
6 data to a clearinghouse contracted en-
7 tity described in section 1150D(a) of
8 the Social Security Act;

9 “(II) the covered entity will not
10 interfere with patient choice of a
11 pharmacy provider, including by not
12 requiring a patient to use a certain
13 pharmacy or to obtain a prescription
14 from the covered entity;

15 “(III) the contract pharmacy
16 may provide other services to the cov-
17 ered entity or its patients at the op-
18 tion of the covered entity, such as
19 home care, delivery, and reimburse-
20 ment services;

21 “(IV) regardless of the services
22 provided by the contract pharmacy,
23 access to covered outpatient drugs
24 purchased under this section will be

1 restricted to patients of the covered
2 entity;

3 “(V) the covered entity and the
4 contract pharmacy will adhere to all
5 Federal, State, and local laws and re-
6 quirements;

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

14 “(VII) the covered entity and the
15 contract pharmacy will develop and
16 implement a system to verify eligi-
17 bility of patients, in accordance with
18 subsection (b)(3), and will establish
19 and maintain safeguards to prevent
20 diversion of covered outpatient drugs
21 purchased under this section to indi-
22 viduals who are not patients of the
23 covered entity;

24 “(VIII) the contract pharmacy
25 may not use covered outpatient drugs

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

11 “(IX) the contract pharmacy
12 agrees to be subject to periodic inde-
13 pendent audits, not less frequently
14 than annually, commissioned by the
15 covered entity; and

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

24 “(iii) Review written agreements, at
25 the time of registration or recertification,

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

7 “(iv) Provide specific guidance to cov-
8 ered entities regarding the needed prac-
9 tices and procedures for contract pharmacy
10 oversight, including the scope and fre-
11 quency of such oversight.

12 “(v) Establish a retention period of at
13 least **【10 years】** during which covered en-
14 tities and contract pharmacies are required
15 to maintain all relevant auditable records
16 in relation to contract pharmacy arrange-
17 ments, including records relating to trans-
18 actions of drugs purchased pursuant to an
19 agreement under paragraph (1), sufficient
20 to demonstrate compliance with the re-
21 quirements described in paragraph
22 (5)(A).”.

23 (b) PROGRAM INTEGRITY.—Section
24 340B(d)(1)(B)(vi)(III) of the Public Health Service Act
25 (42 U.S.C. 256b(d)(1)(B)(vi)(III)) is amended—

1 (1) by striking “intentionally charges a” and in-
2 sserting the following: “intentionally—

3 “(aa) charges a”;

4 (2) by striking the period and inserting a semi-
5 colon; and

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

7 “(bb) refuses to offer a cov-
8 ered outpatient drug for purchase
9 at or below the maximum appli-
10 cable price under subsection
11 (a)(1) or deliver a covered out-
12 patient drug purchased by a cov-
13 ered entity at or below such max-
14 imum applicable price; or

15 “(cc) places conditions on
16 the ability of a covered entity to
17 purchase a covered outpatient
18 drug at or below the maximum
19 applicable price under subsection
20 (a)(1).”.

21 **SEC. 4. PATIENT DEFINITION.**

22 **【TBD/refer to explanatory document.】**

1 **SEC. 5. CHILD SITES.**

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

5 “(12) CHILD SITES.—

6 “(A) IN GENERAL.—A covered entity de-
7 scribed in subparagraph (L), (M), (N), or (O)
8 of paragraph (4) that owns and operates a child
9 site that participates in the drug discount pro-
10 gram under this section shall ensure that each
11 child site is wholly-owned by the entity and
12 clinically and financially integrated with the
13 covered entity and providing care consistent
14 with the policies of the covered entity, including
15 by—

16 “(i) registering each child site with
17 the Secretary;

18 “(ii) applying the same financial as-
19 sistance policy and patient assistance pol-
20 icy as apply with respect to other sites op-
21 erated by the covered entity; and

22 “(iii) ensuring that each child site
23 meets the requirements of subparagraph
24 (B).

25 “(B) ELIGIBILITY FOR CHILD SITES.—

1 “(i) IN GENERAL.—A child site is eli-
2 gible for participation in the drug discount
3 program under this section, through the
4 eligibility of the covered entity that owns
5 and operates such child site, only if the
6 covered entity demonstrates that the child
7 site meets the following requirements:

8 “(I) The child site applies the
9 same patient financial assistance pol-
10 icy as the covered entity.

11 “(II) The child site participates
12 as a provider or supplier in both the
13 Medicare program under title XVIII
14 of the Social Security Act, and the
15 Medicaid program under title XIX of
16 such Act of the State in which the
17 child site is located, without discrimi-
18 nation against patients of such pro-
19 grams at such locations.

20 “(III) The child site ensures that
21 the providers who order or dispense
22 covered outpatient drugs purchased
23 under this section at the child site or
24 a contract pharmacy of the covered
25 entity have clinical responsibility for

1 health care services that are directly
2 related to the use of the covered out-
3 patient drug purchased under this
4 section that is dispensed.

5 “(IV) If the child site is owned
6 by a covered entity described in para-
7 graph (4)(L), the child site shall en-
8 sure that the provider who prescribes
9 a covered outpatient drug purchased
10 under this section is an employee or
11 bona fide contractor of the covered
12 entity and a member of the entity’s
13 medical staff.

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

19 “(VI) The child site and the cov-
20 ered entity are operated under the
21 same license, except in areas where
22 the State requires a separate license
23 for the child site, or in States where
24 State law does not permit licensure of
25 the child site and the covered entity

1 under a single license. If a State
2 health facilities' cost review commis-
3 sion or other agency that has author-
4 ity to regulate the rates charged by
5 providers in a State finds that a child
6 site is not part of the covered entity,
7 the child site shall not be eligible for
8 the drug discount program under this
9 section.

10 “(VII) The clinical services of the
11 child site and the covered entity are
12 integrated as evidenced by the fol-
13 lowing:

14 “(aa) Professional staff of
15 the child site have clinical privi-
16 leges at the covered entity.

17 “(bb) The covered entity
18 maintains the same monitoring
19 and oversight of the child site as
20 for any other owned entity or
21 subsidiary of the covered entity.

22 “(cc) The medical director
23 of the child site maintains a re-
24 porting relationship with the
25 chief medical officer or other

16

1 similar official of the covered en-
2 tity that has the same frequency,
3 intensity, and level of account-
4 ability that exists in the relation-
5 ship between the medical director
6 of a department of the covered
7 entity and the chief medical offi-
8 cer or other similar official of the
9 covered entity, and is under the
10 same type of supervision and ac-
11 countability as any other direc-
12 tor, medical or otherwise, of the
13 covered entity.

14 “(dd) Medical staff commit-
15 tees or other professional com-
16 mittees at the covered entity are
17 responsible for medical activities
18 in the child site, including quality
19 assurance, utilization review, and
20 the coordination and integration
21 of services, to the extent prac-
22 ticable, between the child site and
23 covered entity.

24 “(ee) Medical records for pa-
25 tients treated in the child site are

1 integrated into a unified retrieval
2 system, or have the ability to be
3 readily accessed by the covered
4 entity.

5 “(ff) Inpatient and out-
6 patient services of the child site
7 and the covered entity are inte-
8 grated, and patients treated at
9 the child site who require further
10 care have full access to all serv-
11 ices of the covered entity and are
12 referred where appropriate to the
13 corresponding inpatient or out-
14 patient department or service of
15 the covered entity.

16 “(VIII) The financial operations
17 of the child site are fully integrated
18 within the financial system of the cov-
19 ered entity, as evidenced by shared in-
20 come and expenses between the cov-
21 ered entity and the child site. For
22 purposes of the Medicare program
23 under title XVIII of the Social Secu-
24 rity Act, the costs of a child site are
25 reported in the appropriate cost cen-

1 ter or cost centers of the covered enti-
2 ty, and the financial status of any
3 child site is incorporated and readily
4 identified in the covered entity's trial
5 balance.

6 “(IX) The child site is held out
7 to the public as part of the covered
8 entity. When patients enter the child
9 site, they are aware that they are en-
10 tering the covered entity.

11 “(X) The child site is operated
12 under the ownership and control of
13 the covered entity, as evidenced by the
14 following:

15 “(aa) The business enter-
16 prise that constitutes the child
17 site is 100 percent owned by the
18 covered entity.

19 “(bb) The covered entity
20 and the child site have the same
21 governing body.

22 “(cc) The child site is oper-
23 ated under the same organiza-
24 tional documents as the covered
25 entity, and is subject to common

19

1 bylaws and operating decisions of
2 the governing body of the covered
3 entity.

4 “(dd) The covered entity has
5 final responsibility for adminis-
6 trative decisions, final approval
7 for contracts with outside parties,
8 final approval for personnel ac-
9 tions, final responsibility for per-
10 sonnel policies (such as fringe
11 benefits or code of conduct), and
12 final approval for medical staff
13 appointments at the child site.

14 “(XI) The reporting relationship
15 between the child site and the covered
16 entity have the same frequency, inten-
17 sity, and level of accountability that
18 exists in the relationship between the
19 covered entity and its other depart-
20 ments, as evidenced by compliance
21 with all of the following requirements:

22 “(aa) The child site is under
23 the direct supervision of the cov-
24 ered entity.

1 “(bb) The child site is oper-
2 ated under the same monitoring
3 and oversight by the covered enti-
4 ty as any other department of
5 the covered entity, and is oper-
6 ated just as any other depart-
7 ment of the covered entity with
8 regard to supervision and ac-
9 countability. The director or indi-
10 vidual responsible for daily oper-
11 ations at the child site—

12 “(AA) maintains a re-
13 porting relationship with a
14 manager at the covered enti-
15 ty that has the same fre-
16 quency, intensity, and level
17 of accountability that exists
18 in the relationship between
19 the covered entity and its
20 existing departments; and

21 “(BB) is accountable to
22 the governing body of the
23 covered entity, in the same
24 manner as any department
25 head of the covered entity.

1 “(XII) The following administra-
2 tive functions of the child site are in-
3 tegrated with the functions of the cov-
4 ered entity: billing services, records,
5 human resources, payroll, employee
6 benefit package, salary structure, and
7 purchasing services. Either the same
8 employees or group of employees han-
9 dle such administrative functions for
10 the child site and the covered entity,
11 or the administrative functions for
12 both the child site and the covered en-
13 tity are—

14 “(aa) contracted out under
15 the same contract agreement; or

16 “(bb) handled under dif-
17 ferent contract agreements, with
18 the contract of the child site
19 being managed by the covered
20 entity.

21 “(XIII) **【The location of the**
22 **child site.】**

23 “(C) INAPPROPRIATE TREATMENT OF A
24 PROVIDER AS A CHILD SITE.—Not later than
25 **【180 days】** after the date of enactment of the

1 SUSTAIN 340B Act, the Secretary shall pro-
2 mulgate **[final]** rules to establish a procedure
3 in the case of a child site that, prior to such
4 date of enactment, was deemed qualified as a
5 child site but that does not meet the criteria set
6 forth in this subsection.

7 “(D) AUDITS.—Both the covered entity
8 and the child site shall maintain auditable
9 records and be subject to audits by the Sec-
10 retary of records that pertain to the compliance
11 of the covered entity and child site with the
12 provisions of this paragraph.”.

13 **SEC. 6. TRANSPARENCY.**

14 Section 340B(d) of the Public Health Service Act (42
15 U.S.C. 256b(d)) is amended by adding at the end the fol-
16 lowing:

17 “(5) REPORTING OF PROGRAM SAVINGS.—

18 “(A) IN GENERAL.—Not later than 1 year
19 after the date of enactment of the SUSTAIN
20 340B Act, and annually thereafter, each cov-
21 ered entity shall report to the Secretary, as an
22 addendum to the Medicare cost report most re-
23 cently submitted by such entity, the following
24 information with respect to the entity, including

1 all sites and contract pharmacy arrangements
2 of the entity, for the 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 filled with covered outpatient drugs
10 purchased under this section and billed to
11 insurance, organized by type of health in-
12 surance coverage (as specified by the Sec-
13 retary, including by the Medicare program
14 under title XVIII of the Social Security
15 Act, the Medicaid program under title XIX
16 of such Act, the Children’s Health Insur-
17 ance Program under title XXI of such Act,
18 health insurance coverage offered in the in-
19 dividual or group market or a group health
20 plan (as such terms are defined in section
21 2791), and uninsured);

22 “(iii)(I) The cost incurred at each site
23 for charity care, based on the charity care
24 level of the covered entity, defined as a
25 fraction, the numerator of which is the

1 amount of charity care reported on work-
2 sheet S-10 of the Medicare cost report (or
3 any successor), and the denominator of
4 which is the total operating cost of the
5 hospital, as reported for the most recent
6 cost reporting period; or

7 “(II) in the case of a covered entity
8 that is not required to submit a Medicare
9 cost report that indicates charity care lev-
10 els, a qualitative description of the charity
11 care provided by such entity, in the aggre-
12 gate, in such manner that is not overly
13 burdensome to covered entities, as the Sec-
14 retary may require.

15 “(iv) A description of the covered en-
16 tity’s use of the savings received through
17 participation in the drug discount program
18 under this section, including a description
19 of health care services or health-related
20 benefits used to benefit the patients and
21 communities served by the covered entity,
22 delineated by categories of services and
23 benefits and populations served, including
24 such services and benefits provided to un-

1 derserved and uninsured patients and com-
2 munities.

3 “(v) The financial demographics of
4 patients of the covered entity, including—

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

8 “(II) the percentage of patients
9 who reside in a health professional
10 shortage area (as defined in section
11 332), a medically underserved commu-
12 nity (as defined in section 799B), or
13 who are part of a medically under-
14 served population (as defined in sec-
15 tion 330(b)(3)), and the percentage of
16 uninsured patients;

17 “(III) the percentage patients
18 who are Medicaid beneficiaries; and

19 “(IV) the percentage of patients
20 who are Children’s Health Insurance
21 Program beneficiaries.

22 “(vi) Policies of the covered entity to
23 promote access and adherence to pre-
24 scribed medication.

1 “(vii) In the case of a nongovern-
2 mental hospital, any contracts between
3 such hospital and a State or local govern-
4 mental entity, and any modifications to
5 any such contract.

6 “(viii) Any third-party administrators
7 in contract with the covered entity for the
8 administration of the drug discount pro-
9 gram.

10 “(ix) Any contract pharmacy loca-
11 tions.

12 “(x) The estimated discount realized
13 by the covered entity as a result of partici-
14 pation in the drug discount program under
15 this section, as calculated by comparing
16 the covered entity’s cost of acquiring drugs
17 at the discounted price under this section
18 with the wholesale acquisition cost of such
19 drugs.

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

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

1 “(B) RECORDS RETENTION.—Covered en-
2 tities shall retain such records and provide such
3 records and reports as the Secretary determines
4 necessary for purposes of carrying out this
5 paragraph.

6 “(C) AUDITS.—A covered entity shall per-
7 mit the Secretary to audit, at the Secretary’s
8 expense, the records of the entity used for pur-
9 poses of reporting under subparagraph (A), in-
10 cluding how the discount from drugs subject to
11 an agreement under subsection (a)(1) furnished
12 by such entity is used by such entity.

13 “(D) AVAILABILITY OF INFORMATION.—

14 “(i) IN GENERAL.—Not later than
15 **[30 days]** after receiving the information
16 reported by covered entities under para-
17 graph (1), the Secretary shall publish such
18 information on the public website of the
19 Department of Health and Human Serv-
20 ices, which may include the website of the
21 340B Office of Pharmacy Affairs Informa-
22 tion System or a successor to such system.

23 “(ii) FORMAT.—Data published under
24 clause (i) shall be published in an elec-
25 tronic and searchable format that shows

1 each category of data reported both in the
2 aggregate and identified by individual cov-
3 ered entities described in subsection (a)(4).
4 In carrying out this paragraph, with re-
5 spect to data reported pursuant to para-
6 graph (1), the Secretary shall ensure that
7 any proprietary information be redacted
8 from contracts submitted pursuant to
9 paragraph (1)(B)(vii) before posting such
10 contracts.

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

17 **SEC. 7. ENHANCING PROGRAM INTEGRITY.**

18 (a) AUDITS.—

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

22 “(f) AUDITS.—

23 “(1) AUDITS BY THE SECRETARY.—

24 “(A) IN GENERAL.—In addition to the au-
25 dits authorized under subsection (a)(5)(C), be-

1 ginning **[XXX]**, the Secretary may audit cov-
2 ered entities, including the contract pharmacies
3 and child sites of such entities, and manufac-
4 turers to assess compliance with requirements
5 under this section, including identifying any
6 statutory violations related to improperly claim-
7 ing eligibility for the program under this sec-
8 tion, drug diversion, duplicate discounts, use of
9 contract pharmacies or claiming a discount
10 under this section on a drug that is not a cov-
11 ered outpatient drug purchased under this sec-
12 tion.

13 “(B) STANDARDS.—The Secretary shall
14 conduct audits described in this subsection in
15 accordance with generally accepted standards,
16 as may be prescribed by the Comptroller Gen-
17 eral of the United States, and shall make the
18 protocol for such audits publicly available.

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

24 “(2) 340B VENDOR INFORMATION.—To meet
25 the requirements for submission of information for

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

3 “(A) submit data to the Secretary and
4 independent outside auditors contracting with
5 covered entities necessary to determine the cov-
6 ered entity’s compliance with statutory and reg-
7 ulatory requirements under this program, prohi-
8 bitions on drug diversion and duplicate dis-
9 counts, use of contract pharmacies, and claims
10 for discounts on covered outpatient drugs pur-
11 chased pursuant to agreements under sub-
12 section (a)(1); and

13 “(B) respond to requests from auditors in
14 a timely manner.

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

18 “(A) specifies how auditors shall determine
19 whether a covered entity’s contract with a State
20 or local government described in subsection
21 (a)(4)(L)(i) requires the provision of health
22 care services and requires the health care serv-
23 ices provided to individuals who are low-income
24 and are not eligible for participation in either
25 the Medicaid program under title XIX of the

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

3 “(B) describes how the auditors will review
4 eligibility for being a covered entity and assess
5 and document findings regarding each of the
6 specific eligibility-related criteria for each enti-
7 ty, including whether a private nonprofit hos-
8 pital’s contract with a State or local govern-
9 ment is appropriately signed, covers the time
10 periods under review in the audit, and requires
11 the hospital to provide health care services to
12 low-income individuals who are not eligible for
13 participation in the Medicaid program or the
14 Medicare program.

15 “(4) CONSEQUENCES OF AUDIT.—The Sec-
16 retary shall ensure that, in the case of an audit find-
17 ing that an entity did not meet one or more of the
18 eligibility criteria for being a covered entity, as de-
19 fined in subsection (a)(4), the full period under re-
20 view in an audit, the audit results in consequences
21 that are consistent and appropriate with the viola-
22 tion and that do not treat the failure to meet eligi-
23 bility criteria as an issue that can be corrected retro-
24 actively.

1 “(5) REGULATIONS.—Not later than 1 year
2 after the date of enactment of the SUSTAIN 340B
3 Act, the Secretary shall promulgate rules to estab-
4 lish the audit and reporting procedures required by
5 this subsection.”.

6 (2) CONFORMING AMENDMENTS.—

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

12 (B) ADDITIONAL SANCTIONS AUTHOR-
13 ITY.—Section 340B(d)(2)(B)(v) of the Public
14 Health Service Act (42 U.S.C.
15 256b(d)(2)(B)(v)) is amended—

16 (i) in subclause (II), by inserting “or
17 where the covered entity fails to implement
18 a corrective action plan relating to a viola-
19 tion involving improperly claiming eligi-
20 bility for the program under this section,
21 drug diversion, duplicate discounts, compli-
22 ance with contract pharmacy requirements,
23 or claiming a discount or rebate on a drug
24 that is not a covered outpatient drug, with-
25 in **[6 months]** of the Secretary notifying

1 the entity of the requirement for such
2 plan,” after “knowing and intentional,”

3 (ii) by adding at the end the fol-
4 lowing:

5 “(IV) Increasing the frequency of
6 audits conducted for entities pre-
7 viously found to be in violation of re-
8 quirements of the drug discount pro-
9 gram that relate to eligibility, drug di-
10 version, duplicate discounts, compli-
11 ance with contract pharmacy require-
12 ments, or claiming a discount or re-
13 bate on a drug that is not a covered
14 outpatient drug, and assigning re-
15 sponsibility for making corrections re-
16 lating to such a violation to a cor-
17 porate officer of the entity.

18 “(V) Disenrolling from the pro-
19 gram covered entities that fail to im-
20 plement a corrective action plan with-
21 in 6 months of issuance of a final
22 audit report related to a statutory vio-
23 lation involving improperly claiming
24 eligibility for the program under this
25 section, drug diversion, duplicate dis-

1 counts, compliance with contract
2 pharmacy requirements, or claiming a
3 discount or rebate on a drug that is
4 not a covered outpatient drug.”.

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

12 **SEC. 8. PREVENTING DUPLICATE DISCOUNTS.**

13 (a) 340B DRUG DISCOUNT PROGRAM DATA CLEAR-
14 INGHOUSE.—

15 (1) IN GENERAL.—Part A of title XI of the So-
16 cial Security Act (42 U.S.C. 1301 et seq.) is amend-
17 ed by adding the following the following new section:

18 **“SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEAR-
19 INGHOUSE.**

20 “(a) CLEARINGHOUSE CONTRACTING ENTITY.—Not
21 later than **[1 year]** after the date of enactment of this
22 section, the Secretary shall enter into a contract with an
23 independent, third-party entity (who shall be free of con-
24 flicts of interest with covered entities, manufacturers,
25 health plans, and of other conflicts of interest as specified

1 by the Secretary) for purposes of carrying out the clear-
2 inghouse duties under subsection (b) with respect to the
3 340B drug discount program to prevent duplicate dis-
4 counts and ensure proper accounting. Such contract shall
5 provide that the third-party entity shall perform the duties
6 described in subsection (b) and shall be for a **[4-year]**
7 term that may be renewed after a subsequent bidding
8 process or using competitive procedures, as defined in sec-
9 tion 132 of title 41, United States Code.

10 “(b) DUTIES.—With respect to 340B drugs that are
11 dispensed to individuals who are entitled to or eligible for
12 benefits under the Medicare program under title XVIII,
13 the Medicaid program under title XIX, the Children’s
14 Health Insurance Program under title XXI, or health in-
15 surance coverage offered in the individual or group market
16 or a group health plan (as such terms are defined in sec-
17 tion 2791 of the Public Health Service Act), a third-party
18 entity with a contract in effect under subsection (a)
19 shall—

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

22 “(A) claims level rebate file data under
23 section 1927, from State Medicaid agencies;

24 “(B) claims level data from covered enti-
25 ties; and

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

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

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

10 “(4) notify the covered entity, the Secretary,
11 the State Medicaid agency, and the manufacturer of
12 any violation described in paragraph (2) to allow for
13 remediation;

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

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

1 “(7) allow covered entities except those de-
2 scribed under subparagraph (L), (M), (N), or (O) of
3 section 340B(a)(4) of the Public Health Service Act
4 the option of submitting claims level data on an ag-
5 gregated retrospective basis that does not require
6 the application of modifiers on individual claims or
7 point-of-sale identification; and

8 “(8) determine total sales of 340B drugs to
9 such individuals for purposes of being used as the
10 basis for determining user fees under section
11 340B(a)(11) of such Act.

12 “(c) RESTRICTIONS ON CONTRACTING ENTITY.—The
13 entity receiving a contract under subsection (a) shall—

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

19 “(2) not disclose confidential information ob-
20 tained through carrying out the clearinghouse duties
21 under this section other than as necessary to carry
22 out the purposes of this section, including for pro-
23 gram integrity functions;

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

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

7 “(d) DUTIES OF COVERED ENTITY.—Covered enti-
8 ties shall facilitate and participate in data transmission
9 with a third-party entity with a contract in effect under
10 subsection (a), including with respect to reporting on data
11 available through external contract pharmacies.

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

18 “(f) REPAYMENT TO MANUFACTURERS.—The Sec-
19 retary shall require covered entities to work with affected
20 manufacturers regarding repayment of identified duplicate
21 discounts for 340B drugs that occur in a State Medicaid
22 fee-for-service and managed care program, regardless of
23 whether the duplicate discount occurred under the fee-for-
24 service or managed care payment arrangement, and re-
25 gardless of the method used to dispense the 340B drug.

1 “(g) DEFINITIONS.—In this section:

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

5 “(2) MANUFACTURER.—The term ‘manufac-
6 turer’ has the meaning given that term in section
7 1927(k)(5).

8 “(3) HEALTH PLANS.—The term ‘health plan’
9 has the meaning given that term in section
10 1128C(c).

11 “(4) 340B DRUG.—The term ‘340B drug’
12 means a drug that is—

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

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

18 (2) OVERSIGHT.—Not later than 1 year after
19 the date of enactment of this Act, the Secretary of
20 Health and Human Services, acting through the Ad-
21 ministrator of the Centers for Medicare & Medicaid
22 Services and the Administrator of the Health Re-
23 sources and Services Administration, shall issue a
24 report to Congress detailing coordinated efforts, in-
25 cluding through the use of existing resources to ad-

1 dress requests from covered entities (as defined in
2 section 340B(a)(4) of the Public Health Service Act
3 (42 U.S.C. 256b(a)(4))) for payment under title
4 XIX of the Social Security Act (42 U.S.C. 1396 et
5 seq.) for medical assistance for a drug that is sub-
6 ject to an agreement under section 340B(a) of the
7 Public Health Service Act (42 U.S.C. 256b(a)) if the
8 drug is subject to the payment of a rebate to the
9 State under section 1927 of the Social Security Act
10 (42 U.S.C. 1396r–8), as prohibited under section
11 340B(a)(5)(A) of the Public Health Service Act (42
12 U.S.C. 256b(a)(5)(A)).

13 (3) REGULATIONS.—The Secretary of Health
14 and Human Services may promulgate such rules as
15 the Secretary determines appropriate to advance the
16 purpose of the drug discount program under section
17 340B of the Public Health Service Act (42 U.S.C.
18 256b) and prevent duplicate discounts through the
19 clearinghouse established by the amendment made
20 by paragraph (1).

21 (b) PATIENT ASSISTANCE PROGRAMS.—Section
22 340B(a) of the Public Health Service Act (42 U.S.C.
23 256b(a)), as amended by section 5, is further amended
24 by adding at the end the following:

25 “(13) PATIENT ASSISTANCE PROGRAMS.—

1 “(A) IN GENERAL.—Covered entities shall
2 extend their patient financial assistance policy
3 to patients served by child sites and contract
4 pharmacies. The covered entity shall ensure
5 that its financial assistance policy is trans-
6 parent to patients at point of care and publicly
7 reported. The Secretary shall require covered
8 entities to maintain auditable records related to
9 the implementation and enforcement of this
10 paragraph.

11 “(B) FINANCIAL ASSISTANCE POLICY DE-
12 FINED.—In this paragraph, a ‘financial assist-
13 ance policy’ means—

14 “(i)(I) a written financial assistance
15 policy described in section 501(r)(4)(A) of
16 the Internal Revenue Code of 1986, pro-
17 vided patients up to at least 200 percent of
18 the Federal poverty level; and

19 “(II) a sliding fee scale for covered
20 outpatient drugs dispensed to patients
21 under the drug discount program under
22 this section, as applicable; or

23 “(ii) such other alternative policy as
24 the Secretary may determine with respect
25 to a specific covered entity.

1 “(C) OVERSIGHT.—The Comptroller Gen-
2 eral of the United States shall conduct a study
3 and report to Congress on the impact of re-
4 quirements of this paragraph on patient access
5 to covered outpatient drugs purchased under
6 this section.

7 “(D) RULE OF CONSTRUCTION.—Compli-
8 ance with this paragraph shall not be consid-
9 ered a prohibited act under section 1128A,
10 1128B(b), or 1877 of the Social Security Act.”.

11 **SEC. 9. ENSURING THE EQUITABLE TREATMENT OF COV-**
12 **ERED ENTITIES AND PHARMACIES PARTICI-**
13 **PATING IN THE 340B DRUG DISCOUNT PRO-**
14 **GRAM.**

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

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

22 “(a) IN GENERAL.—A group health plan, a health
23 insurance issuer offering group or individual health insur-
24 ance coverage, or a pharmacy benefit manager may not
25 discriminate against a covered entity (as defined in sub-

1 section (d)(1)), a contract pharmacy (as defined in sub-
2 section (d)(2)), or a participant, beneficiary, or enrollee
3 of such plan or coverage by imposing requirements, exclu-
4 sions, reimbursement terms, or other conditions on such
5 entity or pharmacy that differ from those applied to enti-
6 ties or pharmacies that are not covered entities or speci-
7 fied pharmacies on the basis that the entity or pharmacy
8 is a covered entity or contract pharmacy or that the entity
9 or pharmacy dispenses 340B drugs, including by taking
10 any action prohibited under subsection (b).

11 “(b) SPECIFIED PROHIBITED ACTIONS.—A group
12 health plan, a health insurance issuer offering group or
13 individual health insurance coverage, or a pharmacy ben-
14 efit manager may not discriminate against a covered enti-
15 ty, a contract pharmacy, or a participant, beneficiary, or
16 enrollee of such plan or coverage by doing any of the fol-
17 lowing:

18 “(1) Reimbursing a covered entity or contract
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 manager (as applicable) would pay to any
22 other similarly situated (as specified by the Sec-
23 retary) entity or pharmacy that is not a covered en-
24 tity or a contract pharmacy for such quantity of
25 such drug on the basis that the entity or pharmacy

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

3 “(2) Imposing any terms or conditions on cov-
4 ered entities or specified pharmacies with respect to
5 any of the following that differ from such terms or
6 conditions applied to other similarly situated entities
7 or pharmacies that are not covered entities or speci-
8 fied pharmacies on the basis that the entity or phar-
9 macy is a covered entity or contract pharmacy or
10 that the entity or pharmacy dispenses 340B drugs:

11 “(A) Fees, chargebacks, clawbacks, adjust-
12 ments, or other assessments.

13 “(B) Professional dispensing fees.

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

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

21 “(E) Any other restrictions, conditions,
22 practices, or policies that, as specified by the
23 Administrator of the Health Resources and
24 Services Administration, interfere with the abil-

1 ity of a covered entity to maximize the value of
2 discounts provided under section 340B.

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

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

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

15 “(A) the entity or pharmacy is a covered
16 entity or a contract 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 for health insurance cov-
22 erage, denying coverage of a drug on the basis that
23 such drug is a 340B drug.

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

1 monetary penalty on any pharmacy benefit manager that
2 violates the requirements of this section. Such penalty
3 shall not exceed \$5,000 per violation per day. The Sec-
4 retary shall issue proposed regulations to implement this
5 subsection not later than 60 days after the date of the
6 enactment of this subsection and shall finalize such regu-
7 lations not later than 180 days after such date of enact-
8 ment.

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

10 “(1) COVERED ENTITY.—The term ‘covered en-
11 tity’ has the meaning given such term in section
12 340B(a)(4).

13 “(2) CONTRACT PHARMACY.—The term ‘con-
14 tract pharmacy’ means a pharmacy with which a
15 covered entity has contracted to dispense 340B
16 drugs on behalf of the covered entity whether dis-
17 tributed in person or via mail.

18 “(3) 340B DRUG.—The term ‘340B drug’
19 means a drug that is—

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

22 “(B) purchased under an agreement in ef-
23 fect under such section.”.

1 **SEC. 10. USER FEE PROGRAM.**

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

6 “(14) USER FEE PROGRAM.—

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

12 “(B) FEE AMOUNTS.—The fees described
13 in subparagraph (A) shall be assessed and col-
14 lected from each covered entity on an [annual
15 basis], in amount equal to [.01 percent] of the
16 [average difference, over the most recent 5-year
17 period, between the price paid by the covered
18 entity pursuant to the drug discount program
19 under this section for outpatient drugs and the
20 wholesale acquisition cost of such covered out-
21 patient drugs].

22 “(C) USE OF FEES.—Any fee collected
23 under this paragraph shall be used for purposes
24 of administering this section and enhancing
25 program integrity and oversight activities under
26 this section, including—

1 “(i) the development of a multi-func-
2 tional web-based system to collect fees
3 under this paragraph;

4 “(ii) the establishment, use, and
5 maintenance of the data clearinghouse
6 under section 1150D of the Social Security
7 Act;

8 “(iii) the improvement of the integ-
9 rity, transparency, security, searchability,
10 and reliability of the 340B Office of Phar-
11 macy Affairs Information System (or a
12 successor system), including to ensure that
13 such system continues to meet the needs of
14 external stakeholders;

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

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

22 “(vi) any other uses for the purposes
23 of program integrity, as the Secretary de-
24 termines appropriate.

1 “(D) SUPPLEMENT NOT SUPPLANT.—Any
2 fee collected under this paragraph shall be used
3 to supplement and not supplant amounts other-
4 wise provided in appropriations Acts to carry
5 out this section.

6 “(E) REGULATIONS.—The Secretary may
7 promulgate rules as necessary to carry out the
8 user fee program under this paragraph.

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

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

15 “(ii) not later than **[xx]** of each year
16 for which a review is required under clause
17 (i), submit to Congress a report on the re-
18 view conducted under clause (i), together
19 with such recommendations as the Inspec-
20 tor General determines appropriate.”.

21 (b) CONFORMING AMENDMENT.—Section 340B(a)(4)
22 of the Public Health Service Act (42 U.S.C. 256b(a)(4))
23 is amended, in the matter preceding subparagraph (A),
24 by inserting “, has submitted user fees to the Secretary

1 in the amount assessed under paragraph (14) for the cur-
2 rent year,” after “paragraph (5)”.

3 **SEC. 11. STUDIES AND REPORTS.**

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

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

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

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

21 **SEC. 12. ADDITIONAL RESOURCES FOR OVERSIGHT.**

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

1 the Treasury not otherwise appropriated, **【\$3,000,000】**,
2 to remain available until expended, for purposes of con-
3 ducting audits, investigations, and other oversight and en-
4 forcement activities with respect to the drug discount pro-
5 gram under section 340B of the Public Health Service Act
6 (42 U.S.C. 256b).

7 **SEC. 13. DEFINITIONS.**

8 Section 340B(c) of the Public Health Service Act (42
9 U.S.C. 256b(c)) is amended by adding at the end the fol-
10 lowing:

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

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

20 **SEC. 14. EFFECTIVE DATE.**

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