

118TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

To \_\_\_\_\_ .

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IN THE SENATE OF THE UNITED STATES

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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 \_\_\_\_\_

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**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 inhouse 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.