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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To strengthen the 340B drug discount program.

IN THE HOUSE OF REPRESENTATIVES

Mr. PETERS introduced the following bill; which was referred to the
Committee on _____

A BILL

To strengthen the 340B drug discount program.

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 “Strengthening the Exercise of Controls and Upgrading
6 Requirements for Efficiency in 340B Act” or the “SE-
7 CURE 340B Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Establishing a clear patient definition.

- Sec. 3. Allowable use and robust oversight of contract pharmacies.
- Sec. 4. Eligibility for child sites.
- Sec. 5. Improving patient affordability and protections.
- Sec. 6. Data reporting for transparency.
- Sec. 7. Enhancing program integrity.
- Sec. 8. Facilitating data exchange to improve program integrity.
- Sec. 9. Prohibition on discriminatory practices and contracting.
- Sec. 10. Ensuring HRSA has adequate resources to oversee the program.
- Sec. 11. Studies and reports.
- Sec. 12. Meanings.
- Sec. 13. Requirements for nonhospital covered entities and subgrantees.
- Sec. 14. Effective date.

1 **SEC. 2. ESTABLISHING A CLEAR PATIENT DEFINITION.**

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

5 “(11) PATIENT DEFINED.—

6 “(A) IN GENERAL.—In this section, the
7 term ‘patient’ means an individual who—

8 “(i) has received an outpatient health
9 care service from a prescribing provider at
10 a covered entity within the preceding 24
11 months, and such health care service—

12 “(I) is a service that was reim-
13 bursable under title XVIII of the So-
14 cial Security Act when furnished by a
15 prescribing provider or, in the case of
16 an individual who is not eligible for
17 benefits under such title, would have
18 been so reimbursable had the indi-
19 vidual been so eligible; a service shall
20 be considered reimbursable if it is of

1 a type eligible for reimbursement
2 under title XVIII; and

3 “(II) in the case of a covered en-
4 tity described in subparagraphs (A)
5 through (K) of subsection (a)(4), is a
6 service that is within the scope of the
7 grant or designation described in such
8 subparagraph.

9 “(ii) received the prescription or order
10 for the covered outpatient drug related to
11 the service described in clause (i); and

12 “(iii) has a relationship with the cov-
13 ered entity such that the covered entity
14 creates and maintains auditable health
15 care records which demonstrate that—

16 “(I) the covered entity maintains
17 a provider-to-patient relationship with
18 the individual for the healthcare serv-
19 ice related to the covered outpatient
20 prescription or order;

21 “(II) the prescribing provider has
22 clinical responsibility and oversight for
23 the individual’s health care service re-
24 lated to the prescription or order for

1 the covered outpatient drug with the
2 covered entity; and

3 “(III) any other information
4 specified by the Secretary through no-
5 tice and comment rulemaking.

6 “(B) APPLICATION.—For each prescription
7 or order for a covered outpatient drug, an indi-
8 vidual shall qualify as a patient under subpara-
9 graph (A) only if the requirements of such sub-
10 paragraph are independently satisfied with re-
11 spect to that prescription or order.

12 “(C) RECORD RETENTION AND AUDIT-
13 ING.—A covered entity shall—

14 “(i) retain auditable health care
15 records in a form and manner specified by
16 the Secretary through notice and comment
17 rulemaking which demonstrate the exist-
18 ence of a patient relationship in accordance
19 with this paragraph for each prescription
20 or order for a covered outpatient drug for
21 a period of the greater of 5 years or such
22 period as required under applicable state
23 and federal laws governing medical or
24 pharmacy records; and

1 “(ii) no more than one time annually,
2 in accordance with subsection (a)(5)(C),
3 permit the Secretary and the manufacturer
4 of a covered outpatient drug that is subject
5 to an agreement under this subsection, to
6 audit, at the Secretary’s or the manufac-
7 turer’s expense, the records of the entity
8 which demonstrate the existence of a pa-
9 tient relationship in accordance with this
10 paragraph and which directly pertain to
11 the entity’s compliance with the require-
12 ments of subsection (a)(5)(B).”.

13 (b) ADDITIONAL AMENDMENTS.—Section 340B of
14 the Public Health Service Act (42 U.S.C. 256b) is amend-
15 ed—

16 (1) in subsection (a), by adding at the end the
17 following:

18 “(12) PRESCRIBING PROVIDER.—In this sec-
19 tion, the term ‘prescribing provider’ means a health
20 care provider who, at the time the health care pro-
21 vider orders or prescribes a covered outpatient
22 drug—

23 “(A)(i) is an employee or independent con-
24 tractor of the covered entity such that the cov-
25 ered entity bills for services furnished by the

1 health care provider and is responsible for the
2 care furnished by such provider; or

3 “(ii) is an employee or independent con-
4 tractor of a physician organization affiliate of
5 the covered entity, has assigned their right to
6 bill and collect for professional services to such
7 physician organization affiliate, and furnishes
8 outpatient health care services to patients of
9 the covered entity.

10 “(B) has clinical responsibility over the
11 care related to the order or prescription for the
12 covered outpatient drug, as demonstrated by
13 the provider’s signature on the relevant order or
14 prescription for the covered outpatient drug;

15 “(C) is enrolled as a provider in the Medi-
16 care program under title XVIII of the Social
17 Security Act, or the Medicaid program under
18 title XIX of the Social Security Act; and

19 “(D) is not excluded by the Secretary from
20 participation in Medicare and State health care
21 programs pursuant to section 1128 of the So-
22 cial Security Act (42 U.S.C. 1320a-7).”; and

23 (2) in subsection (b), by adding at the end the
24 following:

1 “(3) PHYSICIAN ORGANIZATION AFFILIATE DE-
2 FINED.—For purposes of subparagraph (A)(ii), the
3 term ‘physician organization affiliate’ means an enti-
4 ty that—

5 “(A) is lawfully organized for the purpose
6 of employing or contracting with licensed pro-
7 fessionals to furnish clinical services;

8 “(B) has an ongoing, legally binding agree-
9 ment with the covered entity to provide health
10 care services to patients of the covered entity at
11 the covered entity’s locations; and

12 “(C) the outpatient healthcare services are
13 provided such that responsibility for the care
14 provided remains with the covered entity and
15 meets the other requirements in this para-
16 graph.”.

17 (c) REFERRAL REQUIREMENTS.—Section 340B of
18 the Public Health Service Act (42 U.S.C. 256b), as
19 amended, is amended by adding at the end the following
20 new subsection:

21 “(f) REFERRAL QUALIFICATIONS.—

22 “(1) IN GENERAL.—Subject to the require-
23 ments of this subsection, in the case of a patient of
24 an eligible covered entity who is referred by such
25 covered entity to a provider outside such covered en-

1 tity, and such non-covered entity provider prescribes
2 a covered outpatient drug within 24 months of the
3 date of such referral, the eligible covered entity may
4 provide such drug to such patient as a covered out-
5 patient drug pursuant to the drug discount program
6 under this section, in the same manner and under
7 the same conditions as the covered entity would pro-
8 vide such drug had such drug been prescribed by a
9 prescribing provider of such covered entity.

10 “(2) COVERED ENTITY ELIGIBILITY.—For pur-
11 poses of this subsection the covered entity that dis-
12 penses or administers the covered outpatient drug
13 must be—

14 “(A) a federally qualified health center, as
15 described in subsection (a)(4)(A), that is also a
16 comprehensive primary care medical home, cer-
17 tified as a Patient-Centered Medical Home by a
18 national accrediting organization;

19 “(B) a critical access hospital, as described
20 in subsection (a)(4)(N); or

21 “(C) a sole community hospital, as de-
22 scribed in subsection (a)(4)(O).

23 “(3) PATIENT ELIGIBILITY.—For purposes of
24 this subsection—

1 “(A) the individual to whom a covered out-
2 patient drug is dispensed or administered must
3 be a patient of the covered entity meeting the
4 requirements under (a)(11);

5 “(B) the individual must have received di-
6 rect care from the covered entity within 24
7 months prior to the date on which the indi-
8 vidual was referred to receive care by the pre-
9 scribing entity;

10 “(C) the care furnished to the individual
11 by the covered entity that resulted in the refer-
12 ral must be—

13 “(i) in the case of a federally qualified
14 health center described in paragraph
15 (2)(A), within the scope of the grant appli-
16 cation made to the Secretary under section
17 330(k)(1);

18 “(ii) in the case of a critical access
19 hospital described in paragraph (2)(B),
20 within the scope of the agreement with the
21 state under section 1820(c)(2) of the So-
22 cial Security Act; and

23 “(iii) in the case of a sole community
24 hospital described in paragraph (2)(C),
25 within the scope of the request made to the

1 Secretary for such classification under sec-
2 tion 1886(d)(5)(C)(iii) of the Social Secu-
3 rity Act;

4 “(D) the covered entity must have—

5 “(i) Referred the individual to the
6 prescribing entity;

7 “(ii) Consulted with a clinician at the
8 prescribing entity regarding the individ-
9 ual’s care; and

10 “(iii) Provided care to the individual
11 after dispensing or administering the pre-
12 scription, as appropriate; and

13 “(E) in the case of a federally qualified
14 health center described in paragraph (2)(A), a
15 prescription generated as a direct result of an
16 emergency department visit or hospital dis-
17 charge.

18 “(4) EXCLUSIONS.—The following categories of
19 drugs shall not be eligible for discounts under this
20 subsection—

21 “(A) orphan-designated drugs; or

22 “(B) in the case of a prescription written
23 by a federally-qualified health center described
24 in paragraph (2)(A), a drug that is infused or
25 that requires a clinician to administer, except

1 for those entities providing infusions as of the
2 date of enactment of this Act and subject to the
3 limitation described in paragraph (5).

4 “(5) DOCUMENTATION REQUIREMENTS.—

5 “(A) IN GENERAL.—In association with
6 any covered outpatient drug receiving a dis-
7 count under this subsection, the individual’s
8 medical record must include documentation to
9 demonstrate compliance with the requirements
10 of paragraph (3), including—

11 “(i) documentation of the direct care
12 provided to the individual by the covered
13 entity prior to the referral to the pre-
14 scribing entity;

15 “(ii) documentation of the referral
16 from the covered entity to the prescribing
17 entity;

18 “(iii) documentation of direct care re-
19 ceived by the individual from the covered
20 entity that resulted in the referral and that
21 occurred within 24 months prior to the ini-
22 tial referral;

23 “(iv) documentation of care received
24 by the individual from the prescribing enti-
25 ty within 24 months of the covered entity

1 referral, which may take the form of re-
2 ceipt of consult notes or documentation of
3 a discussion between the covered entity
4 and prescribing entity regarding the care
5 furnished by the prescribing entity;

6 “(v) documentation of ongoing con-
7 sultation between the covered entity and
8 the prescribing entity as appropriate for
9 the covered entity’s ongoing responsibility
10 of the individual’s care, consistent with the
11 scope of care described in paragraph
12 (3)(C); and

13 “(vi) documentation of the prescribing
14 entity’s prescription to be dispensed or ad-
15 ministered by the covered entity and up-
16 dated through the qualified entity’s medi-
17 cation list for the patient.

18 “(B) DOCUMENT RETENTION.—All docu-
19 mentation described under this paragraph shall
20 be maintained for a period of the greater of 5
21 years or such period as required under applica-
22 ble state and federal laws governing medical or
23 pharmacy records as auditable records that
24 demonstrate compliance with the requirements
25 of this subsection.

1 “(6) REFERRAL AUDITS BASED ON VOLUME.—

2 “(A) IN GENERAL.—The Secretary shall
3 conduct audits of any eligible covered entity
4 that meets the following conditions in a given
5 year—

6 “(i) referral prescriptions described in
7 paragraph (1) exceed 25 percent of the
8 total number of covered outpatient drugs
9 purchased and dispensed by the covered
10 entity for the year;

11 “(ii) referral prescriptions described
12 in paragraph (1) are in the 75th percentile
13 of all reporting covered entities by covered
14 entity classification; or

15 “(iii) referral prescriptions exceeding
16 the average annual percentage for that
17 covered entity classification over the most
18 recent 3-year period, of the total number
19 of covered outpatient drugs purchased and
20 dispensed by the qualified referral covered
21 entity.

22 “(B) TRANSPARENCY OF INFORMATION.—
23 The Secretary shall make public aggregate in-
24 formation on eligible covered entities audited
25 under subparagraph (A) available on a website

1 of the Health Resources and Services Adminis-
2 tration, in such form and manner that the Sec-
3 retary determines appropriate.

4 “(7) ADDITIONAL AUDITS.—

5 “(A) In addition to audits conducted under
6 paragraph (6), the Secretary shall audit any
7 covered entity receiving discounts under this
8 subsection for compliance with requirements of
9 this subsection every four years and, in the case
10 of covered entities receiving abnormal volumes
11 of discounts as compared to such covered enti-
12 ty’s discounts over the previous three year pe-
13 riod, more frequently (but no more than one
14 time annually).

15 “(B) The Secretary shall through notice
16 and comment rulemaking establish a process for
17 manufacturers to request audits of discounts
18 provided under this subsection at any time the
19 manufacturer provides documentation to the
20 Secretary of suspected non-compliance with the
21 requirements of this subsection, with informa-
22 tion received by the manufacturer from the
23 clearinghouse established under section 1150D
24 of the Social Security Act that provides credible

1 evidence of non-compliance serving as accept-
2 able documentation for this purpose.

3 “(8) ENFORCEMENT.—

4 “(A) LOSS OF REFERRAL AUTHORIZA-
5 TION.—

6 “(i) A covered entity for which the
7 Secretary determines through an audit
8 conducted pursuant to or otherwise author-
9 ized under this section that the share of
10 referral prescriptions during the previous
11 calendar year exceeds 35 percent of the
12 covered entity’s total number of covered
13 outpatient drugs purchased and dispensed
14 by the covered entity in the applicable
15 year, may be subject to a Corrective Action
16 Plan in accordance with the corrective ac-
17 tion plan process established under sub-
18 section (d)(2)(B)(vii).

19 “(ii) A covered entity that fails to im-
20 plement a Corrective Action Plan required
21 under clause (i) and comply with the
22 timeline for correction set forth in such
23 Corrective Action Plan shall immediately
24 lose eligibility under this subsection for a
25 period determined by the Secretary

1 through notice and comment rulemaking,
2 but no more than 1 year.

3 “(iii) The Secretary and the Adminis-
4 trator of the Health Resources and Serv-
5 ices Administration shall develop a process
6 through notice and comment rulemaking
7 for covered entities that lose eligibility for
8 discounts under this section pursuant to
9 clause (ii) to complete the Corrective Ac-
10 tion Plan and resume referrals under the
11 program.

12 “(B) MONETARY PENALTIES.—The Sec-
13 retary may impose civil monetary penalties on
14 covered entities for any discounts under this
15 section later deemed ineligible on the grounds
16 the covered entity is found to be noncompliant
17 with the requirements of this subsection with
18 respect to the relevant prescription. The
19 amount of such civil monetary penalties shall be
20 paid to the affected manufacturer.”.

21 **SEC. 3. ALLOWABLE USE AND ROBUST OVERSIGHT OF CON-**
22 **TRACT PHARMACIES.**

23 (a) USE OF CONTRACT PHARMACIES.—Section
24 340B(a) of the Public Health Service Act (42 U.S.C.

1 256b(a)) is further amended by adding at the end the fol-
2 lowing:

3 “(13) CONTRACT PHARMACIES.—

4 “(A) IN GENERAL.—In the case of a cov-
5 ered entity that elects to contract with a phar-
6 macy or pharmacies to dispense covered out-
7 patient drugs purchased by a covered entity at
8 or below the applicable ceiling price described in
9 paragraph (1) to patients of the covered entity,
10 a manufacturer of a covered outpatient drug
11 that is subject to an agreement with the Sec-
12 retary under paragraph (1) shall—

13 “(i) offer each covered entity covered
14 outpatient drugs for purchase at or below
15 the applicable ceiling price described in
16 paragraph (1) regardless of whether the
17 drug is dispensed directly by the covered
18 entity or via a contract pharmacy arrange-
19 ment;

20 “(ii) deliver or allow the delivery of
21 covered outpatient drugs purchased by cov-
22 ered entity sites to pharmacy locations as
23 requested by a covered entity, in accord-
24 ance with the covered entity’s contract
25 pharmacy agreements;

1 “(iii) not place any of the following
2 conditions on the ability of a covered entity
3 to purchase a covered outpatient drug at
4 or below the applicable ceiling price de-
5 scribed in paragraph (1) for dispensing ac-
6 cording to its written contract pharmacy
7 arrangements:

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

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

18 “(III) Conditioning, restricting,
19 or refusing participation in such an
20 arrangement solely on the basis that
21 the covered entity elected to use a
22 contract pharmacy.

23 “(IV) Any such other conditions
24 specified by the Secretary through no-
25 tice and comment rulemaking.

1 “(B) REGISTRATION OF CONTRACT.—Each
2 covered entity shall register with the Secretary
3 any contract described in subparagraph (A), in
4 accordance with such registration requirements
5 established by the Secretary through notice and
6 comment rulemaking. Such registration require-
7 ments shall include requiring covered entities
8 to—

9 “(i) submit all contract pharmacy
10 agreements to the Secretary in a timely
11 manner;

12 “(ii) register each contract pharmacy
13 arrangement with the Secretary, as appli-
14 cable, prior to implementing the contract
15 pharmacy agreement; and

16 “(iii) attest to their compliance with
17 the requirements under this subsection at
18 the time of contract pharmacy registration
19 and annually thereafter.

20 “(C) CONTRACT REVIEW PROCESS.—The
21 Secretary shall establish through notice and
22 comment rulemaking a process to review all
23 written agreements between a covered entity
24 and each of its contract pharmacies, as de-
25 scribed in subparagraph (A), to ensure compli-

1 ance with the requirements under this sub-
2 section. In connection with such review process,
3 there shall be no limitation on the number of
4 contract pharmacies a covered entity may con-
5 tract with nor any geographic limitation on the
6 location of such contract pharmacies.

7 “(D) TRANSPARENCY.—The Secretary
8 shall make the following information about con-
9 tract pharmacy arrangements that have been
10 approved under subparagraphs (A) and (B)
11 available on the public Internet website of the
12 Department of Health and Human Services:

13 “(i) Name(s) of each covered entity,
14 including the name of its child site(s) that
15 uses contract pharmacy(ies).

16 “(ii) Name(s) and address(es) of each
17 contract pharmacy location to which the
18 contract pharmacy arrangement applies.

19 “(iii) Effective date(s) of the contract
20 pharmacy arrangement(s).

21 “(iv) The last year a drug was dis-
22 pensed under the contract pharmacy ar-
23 rangement(s) from each location.

24 “(v) The volume of dispensed drugs
25 under this section per reporting period.

1 “(vi) The geographic distance between
2 the covered entity reported under (i) and
3 each contract pharmacy reported under
4 (ii).

5 “(vii) Information on the contract
6 pharmacy’s status as a mail-order or spe-
7 cialty pharmacy.

8 “(viii) Details on the location of the
9 contract pharmacy, including whether the
10 contract pharmacy is located in—

11 “(I) an urban area (under Cen-
12 sus definition);

13 “(II) a rural area (under Census
14 definition);

15 “(III) a frontier county or fron-
16 tier state (as defined in Section
17 1886(d)(3)(E)(iii)(II) of the Social
18 Security Act);

19 “(IV) a medically underserved
20 area (MUA) as defined in section
21 295p(6);

22 “(V) a Healthcare Provider
23 Shortage Area (HPSA) as defined in
24 section 254e; or

1 “(VI) an area classified as one
2 for a medically underserved popu-
3 lation (MUP) as defined in section
4 254b(b)(3).

5 “(E) IMPROVEMENTS IN CONTRACT PHAR-
6 MACY ARRANGEMENT INTEGRITY.—To ensure
7 the integrity of contract pharmacy arrange-
8 ments described in subparagraph (A), including
9 to prevent diversion and duplicate discounts de-
10 scribed in paragraph (5)(A), the Secretary shall
11 promulgate rules to carry out the following:

12 “(i) Require a written agreement be-
13 tween a covered entity and any pharmacy
14 with which the covered entity has a con-
15 tract pharmacy arrangement. Each such
16 agreement shall—

17 “(I) list the address of each con-
18 tract pharmacy location that will dis-
19 pense drugs on behalf of the covered
20 entity, including all covered entity
21 sites that plan to use the contract
22 pharmacy;

23 “(II) be signed and in effect not
24 later than the day before the contract
25 pharmacy begins dispensing covered

1 outpatient drugs purchased under this
2 section on behalf of the covered entity;
3 and

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

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

11 “(I) the covered entity will pur-
12 chase the drug and maintain title to
13 the drug pursuant to the terms of the
14 award or designation from the De-
15 partment of Health and Human Serv-
16 ices that qualifies such entity as a
17 covered entity and any applicable Fed-
18 eral, State, or local law;

19 “(II) the contract pharmacy is
20 responsible for providing pharmacy
21 services and providing data to covered
22 entities to support their submission of
23 covered outpatient drug data to a
24 clearinghouse contracted entity de-

1 scribed in section 1150D of the Social
2 Security Act;

3 “(III) the covered entity will not
4 interfere with patient choice of their
5 pharmacy provider nor require pa-
6 tients to use a certain pharmacy, in-
7 cluding to obtain a prescription from
8 the covered entity and obtain the drug
9 from the pharmacy provider of his or
10 her choice;

11 “(IV) the contract pharmacy may
12 provide other services to the covered
13 entity or its patients at the option of
14 the covered entity, such as home care,
15 delivery, and reimbursement services;

16 “(V) regardless of the services
17 provided by the contract pharmacy,
18 access to covered outpatient drugs
19 purchased under this section will be
20 restricted to patients of the covered
21 entity;

22 “(VI) the covered entity and the
23 contract pharmacy will adhere to all
24 Federal, State, and local laws and re-
25 quirements;

1 “(VII) the contract pharmacy
2 will provide the covered entity with
3 any information requested consistent
4 with customary business practices,
5 such as quarterly billing statements,
6 status reports of collections, receiving
7 and dispensing records, and informa-
8 tion required for audits under sub-
9 section (a)(5)(C);

10 “(VIII) the covered entity and
11 the contract pharmacy will utilize the
12 clearinghouse to verify patient eligi-
13 bility, as defined by the Secretary,
14 and will establish and maintain safe-
15 guards to prevent diversion of covered
16 outpatient drugs purchased under this
17 section;

18 “(IX) the contract pharmacy
19 may not use covered outpatient drugs
20 purchased under this section to dis-
21 pense prescriptions that are reim-
22 bursed under the Medicaid program
23 under title XIX of the Social Security
24 Act, unless the covered entity, the
25 contract pharmacy, and the State

1 Medicaid agency have established, in
2 writing and made available to phar-
3 maceutical manufacturers upon re-
4 quest, an arrangement to prevent du-
5 plicate discounts, consistent with
6 paragraph (5)(A);

7 “(X) both the covered entity and
8 the contract pharmacy shall be subject
9 to audits, by the Secretary and drug
10 manufacturers, of records that pertain
11 to the covered entity’s compliance
12 with paragraph (5), to prevent diver-
13 sion and violations of the duplicate
14 discount prohibition; and

15 “(XI) the contract pharmacy is
16 required to submit to the covered enti-
17 ty all data elements the covered entity
18 is required to report to the clearing-
19 house pursuant to section 1150D of
20 the Social Security Act.

21 “(iii) Review written agreements, at
22 the time of registration or recertification,
23 or more frequently if the Secretary deter-
24 mines necessary, between covered entities
25 and contract pharmacies to ensure compli-

1 ance with the requirements under this sec-
2 tion, to analyze program operations, and to
3 provide program oversight.

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

9 “(v) Establish a retention period of
10 the greater of 5 years or such period as re-
11 quired under applicable state and federal
12 laws governing medical or pharmacy
13 records during which covered entities and
14 contract pharmacies are required to main-
15 tain all relevant auditable records in rela-
16 tion to contract pharmacy arrangements,
17 including records relating to transactions
18 of drugs purchased pursuant to an agree-
19 ment under paragraph (1), sufficient to
20 demonstrate compliance with the require-
21 ments to prevent diversion and violations
22 of the duplicate discount prohibition.”.

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 serting the following: “intentionally—

3 “(aa) charges a covered enti-
4 ty a price for purchase of a cov-
5 ered outpatient drug that exceeds
6 the maximum applicable price
7 under subsection (a)(1);”;

8 (2) by striking the period and inserting a semi-
9 colon; and

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

11 “(bb) refuses to offer a cov-
12 ered outpatient drug for purchase
13 at or below the maximum appli-
14 cable price under subsection
15 (a)(1) or deliver or allow to be
16 delivered a covered outpatient
17 drug purchased by a covered en-
18 tity at or below such maximum
19 applicable price; and

20 “(cc) places conditions on
21 the ability of a covered entity to
22 purchase a covered outpatient
23 drug at or below the maximum
24 applicable price under subsection
25 (a)(1).”.

1 **SEC. 4. ELIGIBILITY FOR CHILD SITES.**

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

5 “(14) 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 maintain docu-
11 mentation of, and annually certify to the Sec-
12 retary through such certification processes es-
13 tablished under the Medicare enrollment and
14 cost reporting rules, that each such child site is
15 wholly-owned by the entity and clinically and fi-
16 nancially integrated with the covered entity and
17 providing care consistent with the policies of the
18 covered entity, including by—

19 “(i) registering each child site with
20 the Secretary;

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

25 “(iii) ensuring that each child site
26 complies with the Medicare provider-based

1 rules under section 413.65 of title 42,
2 Code of Federal Regulations (or any suc-
3 cessor regulations) or meets the require-
4 ments of subparagraph (B)(i).

5 “(B) ELIGIBILITY FOR CHILD SITES.—

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

13 “(I) The child site applies the
14 same patient financial assistance pol-
15 icy as the covered entity.

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

1 “(III) The child site ensures that
2 the providers who order or dispense
3 covered outpatient drugs purchased
4 under this section at the child site
5 have clinical responsibility for health
6 care services that are related to the
7 use of the covered outpatient drug
8 purchased under this section that is
9 dispensed.

10 “(IV) The child site provides a
11 clinically meaningful range of services
12 within the scope of the services that
13 prescribing providers employed by or
14 contracted with the child site, covered
15 entity, or a physician organization af-
16 filiate of the covered entity are quali-
17 fied to deliver.

18 “(V) If the child site is owned by
19 a covered entity described in para-
20 graph (4)(L), the child site shall en-
21 sure that the provider who prescribes
22 a covered outpatient drug purchased
23 under this section meets the require-
24 ments in paragraph (12).

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

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

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

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

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

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

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

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

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

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

23 “(VIII) The financial operations
24 of the child site are fully integrated
25 within the financial system of the cov-

1 ered entity, as evidenced by shared in-
2 come and expenses between the cov-
3 ered entity and the child site. For
4 purposes of the Medicare program
5 under title XVIII of the Social Secu-
6 rity Act, the costs of a child site are
7 reported in the appropriate cost cen-
8 ter or cost centers of the covered enti-
9 ty, and the financial status of any
10 child site is incorporated and readily
11 identified in the covered entity's trial
12 balance.

13 “(IX) The child site is held out
14 to the public as part of the covered
15 entity. When patients enter the child
16 site, they are aware that they are en-
17 tering the covered entity.

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

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

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covered entity; except that a child site may be jointly owned if:

“(AA) the covered entity holds a majority ownership interest of not less than 51 percent;

“(BB) each co-owner is either: (i) an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Code, or (ii) a State or local governmental entity, including a public university or academic medical center;

“(CC) each co-owner that is not a covered entity has, independent of the joint venture, a bona fide charitable, public health, or governmental mission that includes the direct provision of health care services to low-

1 income, uninsured, or medi-
2 cally underserved individ-
3 uals;

4 “(DD) no co-owner is a
5 for-profit entity;

6 “(EE) no co-owner that
7 is not a covered entity was
8 formed, reorganized, con-
9 verted, or materially restruc-
10 tured for the purpose of
11 qualifying as an eligible co-
12 owner under this subpara-
13 graph; and

14 “(FF) the Adminis-
15 trator of the Health Re-
16 sources and Services Admin-
17 istration has not determined,
18 after notice and an oppor-
19 tunity to respond, that the
20 joint venture structure was
21 constituted for the purpose
22 of obtaining eligibility under
23 the drug discount program
24 under this section or ex-
25 panding claims for discounts

1 under such program, rather
2 than to further the health
3 care mission of the covered
4 entity and the health care
5 needs of the patient popu-
6 lation served by the child
7 site.

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

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

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

1 final approval for medical staff
2 appointments at the child site.

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

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

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

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

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

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

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

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

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

10 “(XIII) The child site is listed on
11 the covered entity’s most recently filed
12 Medicare cost report on a line that is
13 reimbursable under the Medicare pro-
14 gram (or, if the covered entity is a
15 children’s hospital that does not file a
16 Medicare cost report, the covered enti-
17 ty submits to the Secretary a signed
18 statement certifying that the site
19 would be correctly included on a reim-
20 bursable line of a Medicare cost report
21 if the covered entity filed a cost re-
22 port). Such cost report demonstrates
23 that the services provided at the child
24 site have associated costs and charges
25 for covered entity outpatient depart-

1 ment services under title XVIII of the
2 Social Security Act (or, if the covered
3 entity is a children’s hospital that
4 does not file a Medicare cost report,
5 the covered entity submits to the Sec-
6 retary a signed statement certifying
7 that the services provided at the child
8 site include or consist solely of out-
9 patient services).

10 “(ii) HRSA DEEMING.—

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

22 “(II) RULE OF CONSTRUC-
23 TION.—This clause shall authorize the
24 Secretary to establish a process
25 through notice and comment rule-

1 making to determine whether a child
2 site, as determined by the Adminis-
3 trator of the Center for Medicare &
4 Medicaid Services, complies with the
5 Medicare provider-based rules.

6 “(iii) CHILD SITE REGISTRATION:
7 COMMUNITY NEED STANDARD.—

8 “(I) DEFINITIONS.—For pur-
9 poses of this subsection:

10 “(aa) The term ‘child site’
11 has the definition set forth in
12 Section 340B(b)(4).

13 “(bb) The term ‘Community
14 Vulnerability Score’ means the
15 percentile ranking assigned to a
16 ZIP Code Tabulation Area under
17 the Social Vulnerability Index
18 maintained by the Centers for
19 Disease Control and Prevention
20 and the Agency for Toxic Sub-
21 stances and Disease Registry
22 (CDC/ATSDR SVI), or such suc-
23 cessor or supplementary validated
24 index as the Secretary may des-
25 ignate by regulation, on a scale

1 of 0 to 1 in which a score of 1
2 represents maximum social vul-
3 nerability. The Secretary shall,
4 through notice and comment
5 rulemaking, establish a method
6 for mapping or aggregating the
7 underlying index to the ZIP Code
8 Tabulation Area level. Where the
9 Secretary designates a supple-
10 mentary or successor index, the
11 Secretary shall ensure that such
12 index is based on publicly avail-
13 able Zip Code Tabulation Area-
14 level or equivalent data, updated
15 at least biennially, and validated
16 for use in identifying medically
17 underserved or socially vulnerable
18 communities.

19 “(cc) The term ‘parent enti-
20 ty’ means the covered entity
21 whose eligibility status under
22 subsection (a)(4) forms the basis
23 for a child site’s registration.

24 “(dd) The term ‘qualifying
25 ZIP code’ means a ZIP Code

1 Tabulation Area with a Commu-
2 nity Vulnerability Score at or
3 above the 50th percentile thresh-
4 old when ranked nationally —
5 meaning the ZIP Code Tabula-
6 tion Area falls within the more
7 vulnerable half of all ZIP Code
8 Tabulation Areas in the United
9 States — or at or above the 40th
10 percentile threshold when ranked
11 against all ZIP Code Tabulation
12 Areas within the same State,
13 whichever threshold the covered
14 entity elects to apply. If the ZIP
15 Code Tabulation Area in which a
16 child site’s street address is lo-
17 cated has not been assigned a
18 Community Vulnerability Score,
19 including because the area is un-
20 populated, non-residential, or
21 otherwise lacks the underlying
22 data necessary to compute such a
23 score, the qualifying status of
24 such area shall be determined
25 based on the Community Vulner-

1 ability Score of the census tract
2 in which the street address is lo-
3 cated, or if no such score is avail-
4 able for that census tract, the
5 county in which the street ad-
6 dress is located, applying the
7 same national and State-relative
8 percentile thresholds described in
9 this subparagraph. The Secretary
10 shall, through notice and com-
11 ment rulemaking, define the cir-
12 cumstances under which a Zip
13 Code Tabulation Area is treated
14 as unscored and establish an-
15 other method for assigning a
16 Community Vulnerability Score.

17 “(ee) The term ‘ZIP Code
18 Tabulation Area’ means the geo-
19 graphic unit designated by the
20 United States Census Bureau
21 corresponding to a 5-digit ZIP
22 code, consistent with the geo-
23 graphic units used by the Sec-
24 retary under this subsection. For
25 purposes of this subsection, a

1 child site's ZIP Code Tabulation
2 Area shall be determined based
3 on the first five digits of the child
4 site's street address ZIP code as
5 registered with the Secretary.

6 “(II) COMMUNITY NEED STAND-
7 ARD FOR CHILD SITES.—

8 “(aa) GENERAL REQUIRE-
9 MENT.—A child site shall meet
10 the community need standard es-
11 tablished under this paragraph as
12 a condition of initial registration
13 and continued participation
14 under this section. A child site
15 meets such standard if the cov-
16 ered entity demonstrates that the
17 child site is physically located in
18 a qualifying ZIP Code Tabulation
19 Area, as determined using the
20 street address of the child site in
21 a manner specified by the Sec-
22 retary through notice and com-
23 ment rulemaking.

24 “(bb) APPLICATION TO NEW
25 CHILD SITES.—For a child site

1 seeking registration on or after
2 the date of enactment of this
3 subsection, compliance with item
4 (aa) shall be determined by the
5 Secretary at the time of initial
6 registration based on the Zip
7 Code Tabulation Area in which
8 the child site's street address is
9 situated, as submitted by the cov-
10 ered entity.

11 “(cc) APPLICATION TO EX-
12 ISTING CHILD SITES.—For a
13 child site registered as of the
14 date of enactment of this sub-
15 section, compliance with item
16 (aa) shall be evaluated at the
17 time of the next applicable recer-
18 tification of the covered entity.
19 For the purposes of applying the
20 community need standard to a
21 child site registered as of the
22 date of enactment of this sub-
23 section, the Secretary shall deter-
24 mine eligibility based on the Zip
25 Code Tabulation Area in which

1 the child site's street address is
2 situated at the time of such re-
3 certification.

4 “(dd) ONGOING VALIDA-
5 TION.—Compliance with the com-
6 munity need standard under item
7 (aa) shall be verified for all child
8 sites on an ongoing basis through
9 the annual recertification process,
10 or such other periodic review as
11 the Secretary may establish.

12 “(ee) FAILURE TO MEET
13 STANDARD.—A child site that
14 does not satisfy the community
15 need standard under item (aa),
16 as determined by the Secretary,
17 shall be subject to removal from
18 the covered entity's registration
19 in accordance with procedures es-
20 tablished by the Secretary, in-
21 cluding notice and an opportunity
22 to respond. Removal of a child
23 site from registration under this
24 paragraph shall not affect the
25 continued eligibility of the parent

1 entity or any other child site of
2 the parent entity that satisfies
3 the applicable standard.

4 “(ff) PAYOR-MIX EXCEP-
5 TION.—Notwithstanding item
6 (aa), a child site that does not
7 independently meet the commu-
8 nity need standard described in
9 item (aa) shall nonetheless be
10 deemed to meet such standard if
11 the covered entity demonstrates,
12 to the satisfaction of the Sec-
13 retary, that not less than 40 per-
14 cent of patients served by the
15 child site are enrolled in Med-
16 icaid, are uninsured, or have in-
17 comes at or below 200 percent of
18 the Federal poverty level, as de-
19 termined using patient data for
20 the most recent 12-month period.

21 “(gg) SAFETY-NET EXCEP-
22 TION.—The Secretary may grant
23 a temporary exception from the
24 community need standard under
25 item (aa) for a child site that

1 does not otherwise qualify under
2 item (aa) or (ff), if the covered
3 entity demonstrates that—

4 “(AA) the child site
5 provides primary care, be-
6 havioral health, substance
7 use treatment services or
8 other services specifically di-
9 rected at individuals who are
10 low income, uninsured, or
11 otherwise medically under-
12 served and for which there is
13 no adequate alternative pro-
14 vider within a reasonable ge-
15 ographic proximity — to a
16 patient population that in-
17 cludes a significant propor-
18 tion of low-income, unin-
19 sured, or otherwise medically
20 underserved individuals; and

21 “(BB) removal of the
22 child site from registration
23 under this section would ma-
24 terially reduce access to
25 such services for such pa-

1 tient population. Any excep-
2 tion granted under this sub-
3 paragraph shall be for a pe-
4 riod not to exceed 2 years,
5 subject to renewal upon re-
6 demonstration. The Sec-
7 retary shall promulgate reg-
8 ulations specifying the cri-
9 teria and application process
10 for exceptions under this
11 subparagraph.

12 “(hh) RULE OF CONSTRUC-
13 TION.—A child site shall not fail
14 to satisfy the community need
15 standard solely because the par-
16 ent entity is located in a different
17 ZIP Code Tabulation Area, pro-
18 vided the child site independently
19 satisfies the requirements of this
20 paragraph.

21 “(III) RULEMAKING.—Not later
22 than 6 months after the date of enact-
23 ment of this subsection, the Secretary
24 shall promulgate regulations to imple-
25 ment this subsection, including the

1 method for determining the Zip Code
2 Tabulation Area in which a child site
3 is located under item (aa) and, where
4 such area is unscored, the method for
5 assigning a Community Vulnerability
6 Score. In promulgating such regula-
7 tions, the Secretary shall account for
8 geographic disparities in national SVI
9 rankings by providing for a state-rel-
10 ative eligibility determination, con-
11 sistent with the state-relative thresh-
12 old established in subparagraph
13 (I)(dd), ensuring that child sites serv-
14 ing communities with relatively high
15 social vulnerability within their State
16 are not disadvantaged solely by lower
17 absolute national percentile rankings.

18 “(iv) LIMITATION.—Only a child site
19 that meets each of the requirements under
20 this subparagraph may purchase covered
21 outpatient drugs under the 340B program
22 or use covered outpatient drugs purchased
23 under the 340B program by another part
24 of the covered entity that is authorized to
25 participate in such program. Any transfer

1 of 340B drugs to another facility or an-
2 other part of a covered entity that is not
3 authorized to participate in the 340B pro-
4 gram shall be deemed a violation of para-
5 graph (5)(B).”.

6 **SEC. 5. IMPROVING PATIENT AFFORDABILITY AND PRO-**
7 **TECTIONS.**

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

11 “(15) PATIENT ASSISTANCE PROGRAMS.—

12 “(A) IN GENERAL.—Covered entities shall
13 maintain and extend their patient financial as-
14 sistance policy to patients served by their child
15 sites and contract pharmacies. The covered en-
16 tity shall ensure that its financial assistance
17 policy is transparent to patients at point of
18 care, satisfies the notice requirements in para-
19 graph (C), and publicly reported. The Secretary
20 shall establish a process, through notice and
21 comment rulemaking, to require covered entities
22 to maintain auditable records related to the im-
23 plementation and enforcement of this para-
24 graph. Nothing in this section shall be con-
25 strued to require a covered entity to waive or

1 eliminate all patient cost-sharing or other out-
2 of-pocket obligations, or to provide covered out-
3 patient drugs or related services at no cost, ex-
4 cept to the extent required under the covered
5 entity’s generally applicable financial assistance
6 policy.

7 “(B) FINANCIAL ASSISTANCE POLICY DE-
8 FINED.—In this paragraph, a ‘financial assist-
9 ance policy’ means a written financial assist-
10 ance policy described in section 501(r)(4)(A) of
11 the Internal Revenue Code of 1986, provided to
12 patients—

13 “(i) up to at least 400 percent of the
14 Federal poverty level, for covered entities
15 described under subparagraph (L), (M),
16 (N), and (O) of subsection (a)(4);

17 “(ii) up to at least 200 percent of the
18 Federal poverty level, for all covered enti-
19 ties not described in paragraph 14(b)(i)
20 that are not otherwise subject to sliding fee
21 schedule or grant requirements by law; and

22 “(iii) a sliding fee scale for covered
23 outpatient drugs dispensed to patients
24 under the drug discount program under
25 this section, as applicable, provided that—

1 “(I) for covered entities described
2 under subparagraph (L), (M), (N),
3 and (O) of subsection (a)(4)—

4 “(aa) such sliding fee sched-
5 ule must be made available for
6 all patients up to at least 400
7 percent of the Federal poverty
8 level; and

9 “(bb) copayment require-
10 ments under such sliding fee
11 schedule must be nominal in
12 amount; or

13 “(II) such other alternative policy
14 as the Secretary may determine
15 through notice and comment rule-
16 making with respect to a specific cov-
17 ered entity.

18 “(C) NOTICE.—

19 “(i) Covered entities shall provide ade-
20 quate notice and application of any finan-
21 cial assistance policy described in subpara-
22 graph (A).

23 “(ii) In order to ensure meaningful
24 understanding of eligibility of a patient for
25 a financial assistance policy, any notice de-

1 scribed in clause (i) must be made avail-
2 able to patients of the covered entity—

3 “(I) in a plain-language summary
4 (as defined in 42 U.S. Code
5 18031(e)(3)(B)) in English; and

6 “(II) if English is not the pri-
7 mary language in the community
8 served by the covered entity, in the
9 primary language served by such com-
10 munity.

11 “(D) IMPLEMENTATION FOR CONTRACT
12 PHARMACIES.—The financial assistance policies
13 under this section shall apply to contract phar-
14 macies by the following timeline:

15 “(i) prospectively to all newly reg-
16 istered contract pharmacy locations after
17 the enactment of this clause; or

18 “(ii) Not later than 3 years after the
19 date of enactment of this clause for all
20 other contract pharmacy locations.

21 “(E) OVERSIGHT.—The Comptroller Gen-
22 eral of the United States shall conduct a study
23 and report to Congress on the impact of re-
24 quirements of this paragraph on patient access

1 to covered outpatient drugs purchased under
2 this section.

3 “(F) RULE OF CONSTRUCTION.—Compli-
4 ance with this paragraph shall not be consid-
5 ered a prohibited act under section 1128A,
6 1128B(b), or 1877 of the Social Security Act.

7 “(16) MEDICAL DEBT.—

8 “(A) PROHIBITIONS.—

9 “(i) IN GENERAL.—Covered entities
10 described under subparagraph (L), (M),
11 (N), and (O) of subsection (a)(4) shall
12 not—

13 “(I) sell a patient’s debt to an-
14 other party;

15 “(II) report adverse information
16 about an individual to consumer credit
17 reporting agencies or credit bureaus;
18 and

19 “(III) defer or deny, or require a
20 payment before providing, medically
21 necessary care, because of an individ-
22 ual’s non-payment of one or more
23 bills.

24 “(ii) EXCEPTION.—A covered entity
25 described under subparagraph (L), (M),

1 (N), and (O) of subsection (a)(4) may sell
2 an individual's debt to another party if the
3 party's sole purpose is to pay for the indi-
4 vidual's debt in full.

5 “(B) DEBT COLLECTION.—

6 “(i) IN GENERAL.—Except as pro-
7 vided in clause (ii), covered entities de-
8 scribed under subparagraph (L), (M), (N),
9 and (O) of subsection (a)(4) shall not take
10 any legal action to collect debt from a pa-
11 tient at such covered entity.

12 “(ii) EXCEPTION.—A covered entity
13 described under subparagraph (L), (M),
14 (N), and (O) of subsection (a)(4) may col-
15 lect debt only from patients with a clear
16 ability to pay, as demonstrated by the
17 greater of—

18 “(I) income at or above 600 per-
19 cent of the Federal poverty level; or

20 “(II) assets valued at more than
21 400 percent of the patient's out-
22 standing balance of debt owed to the
23 covered entity.

24 “(iii) INTEREST.—A covered entity
25 described under subparagraph (L), (M),

1 (N), and (O) of subsection (a)(4) shall be
2 prohibited from charging interest on any
3 outstanding balance of debt owed by a pa-
4 tient to such covered entity that is more
5 than the allowable percentage specified in
6 the applicable usury laws or regulations of
7 the state in which the covered entity is lo-
8 cated.

9 “(C) MONITORING COMPLIANCE.—

10 “(i) IN GENERAL.—The Secretary
11 shall conduct an annual review, in a form
12 and manner established in regulations to
13 be promulgated by the Secretary not later
14 than 180 days after the date of enactment
15 of this subparagraph, to monitor covered
16 entity compliance with the requirements of
17 this paragraph.

18 “(ii) ENFORCEMENT.—If the Sec-
19 retary finds that, as a result of a review
20 described in clause (i), a covered entity is
21 not in compliance with the requirements of
22 this paragraph, the Secretary shall—

23 “(I) impose civil monetary pen-
24 alties, which—

1 “(aa) shall be assessed ac-
2 cording to standards established
3 in regulations to be promulgated
4 by the Secretary not later than
5 180 days after the date of enact-
6 ment of this subclause; and

7 “(bb) shall not exceed
8 \$5,000 for each instance of non-
9 compliance that may have oc-
10 curred;

11 “(II) where the Secretary deter-
12 mines that a violation of this para-
13 graph was systematic and egregious
14 as well as knowing and intentional,
15 refer matters to appropriate authori-
16 ties within the Office of Inspector
17 General of the Department of Health
18 and Human Services; and

19 “(III) where the Secretary deter-
20 mines that a covered entity may not
21 be in compliance with the require-
22 ments of section 501(r) of the Inter-
23 nal Revenue Code of 1986, refer mat-
24 ters to appropriate authorities within
25 the Internal Revenue Service.

1 “(D) GAO REPORT.—Not later than 2
2 years after the enactment of this subparagraph,
3 and every 2 years thereafter, the Comptroller
4 General of the United States shall submit to
5 the Secretary and to the appropriate commit-
6 tees of Congress a report that—

7 “(i) analyzes covered entity compli-
8 ance with the requirements described in
9 this paragraph; and

10 “(ii) makes recommendations with re-
11 spect to policies intended to improve com-
12 pliance with the requirements described in
13 this paragraph.

14 “(E) INSPECTOR GENERAL REPORT.—The
15 Inspector General of the Department of Health
16 and Human Services shall conduct an annual
17 risk-based assessment of covered entity compli-
18 ance with the requirements of this paragraph.”.

19 **SEC. 6. DATA REPORTING FOR TRANSPARENCY.**

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

23 “(5) REPORTING OF PROGRAM SAVINGS.—

24 “(A) IN GENERAL.—Not later than 1 year
25 after the date of enactment of this paragraph,

1 and annually thereafter, each covered entity
2 shall report to the Secretary, as an addendum
3 to the Medicare cost report most recently sub-
4 mitted by such entity, or in the case of a cov-
5 ered entity that does not submit a Medicare
6 cost report, by direct report to the Secretary,
7 the following information with respect to the
8 entity, including all sites and contract phar-
9 macy arrangements of the entity, for the pre-
10 ceeding year:

11 “(i) The total number of individuals
12 who were dispensed or administered cov-
13 ered outpatient drugs purchased under this
14 section during such preceding year that
15 were subject to an agreement under sub-
16 section (a)(1).

17 “(ii) The total number of prescrip-
18 tions filled with covered outpatient drugs
19 purchased under this section and billed to
20 insurance, organized by type of health in-
21 surance coverage (as specified by the Sec-
22 retary through notice and comment rule-
23 making, including by the Medicare pro-
24 gram under title XVIII of the Social Secu-
25 rity Act, the Medicaid program under title

1 XIX of such Act, the Children’s Health In-
2 surance Program under title XXI of such
3 Act, health insurance coverage offered in
4 the individual or group market or a group
5 health plan (as such terms are defined in
6 section 2791), and uninsured).

7 “(iii)(I) The cost incurred at each site
8 for charity care, based on the charity care
9 level of the covered entity, defined as a
10 fraction, the numerator of which is the
11 amount of charity care reported on work-
12 sheet S–10 of the Medicare cost report (or
13 any successor), and the denominator of
14 which is the total operating cost of the
15 hospital, as reported for the most recent
16 cost reporting period; or

17 “(II) in the case of a covered entity
18 that is not required to submit a Medicare
19 cost report that indicates charity care lev-
20 els, a qualitative description of the charity
21 care provided by such entity, in the aggre-
22 gate, in such manner that is not overly
23 burdensome to covered entities, as the Sec-
24 retary may require through notice and
25 comment rulemaking.

1 “(iv) A description of the covered en-
2 tity’s use of the savings received through
3 participation in the drug discount program
4 under this section, including a description
5 of health care services or health-related
6 benefits used to benefit the patients and
7 communities served by the covered entity,
8 delineated by categories of services and
9 benefits and populations served, including
10 such services and benefits provided to un-
11 derserved and uninsured patients and com-
12 munities.

13 “(v) The financial demographics of
14 patients of the covered entity, including—

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

18 “(II) the percentage of patients
19 who reside in a health professional
20 shortage area (as defined in section
21 332) or a medically underserved com-
22 munity (as defined in section 799B),
23 or who are part of a medically under-
24 served population (as defined in sec-

1 tion 330(b)(3)), and the percentage of
2 uninsured patients;

3 “(III) the percentage patients
4 who are Medicaid beneficiaries;

5 “(IV) the percentage of patients
6 who are Children’s Health Insurance
7 Program beneficiaries;

8 “(V) to the extent data are avail-
9 able, the percentage of patients earn-
10 ing below each of each of the following
11 levels of the Federal Poverty Level:
12 100 percent, 200 percent, 300 per-
13 cent, and 400 percent; and

14 “(VI) the number of patients who
15 receive assistance from another party
16 in paying for a prescription drug and
17 the mean amount of discount or ben-
18 efit received.

19 “(vi) Policies of the covered entity
20 to—

21 “(I) promote access and adher-
22 ence to prescribed medications; and

23 “(II) promote access to prescrip-
24 tion medicines for patients earning

1 under 200 percent of the Federal Pov-
2 erty Level.

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

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

12 “(ix) The funding shortfall for the
13 covered entity attributable to services pro-
14 vided to Medicare and Medicaid bene-
15 ficiaries, as reported on the Internal Rev-
16 enue Service Form 990.

17 “(x) The number of patients using the
18 outpatient services of the covered entity.

19 “(xi) Operation costs to the covered
20 entity related to the drug discount pro-
21 gram under this section.

22 “(xii) The names and addresses of all
23 contract pharmacy locations.

24 “(xii) Utilization rates of outpatient
25 hospital services furnished to patients

1 earning below each of the following level of
2 the Federal Poverty Level: 100 percent,
3 200 percent, 300 percent, and 400 percent.

4 “(B) RECORDS RETENTION.—Covered en-
5 tities shall retain such records for a period of
6 at least 3 years and provide such records and
7 reports pursuant to standards established by
8 the Secretary through notice and comment rule-
9 making for purposes of carrying out this para-
10 graph.

11 “(C) AVAILABILITY OF INFORMATION.—

12 “(i) IN GENERAL.—Not later than 30
13 days after receiving the information re-
14 ported by covered entities under subpara-
15 graph (A), the Secretary shall publish such
16 information on the public website of the
17 Department of Health and Human Serv-
18 ices, which may include the website of the
19 340B Office of Pharmacy Affairs Informa-
20 tion System (or a successor to such sys-
21 tem).

22 “(ii) FORMAT.—Data published under
23 clause (i) shall be published in an elec-
24 tronic and searchable format that shows
25 each category of data reported both in the

1 aggregate and identified by individual cov-
2 ered entity(ies) described in subsection
3 (a)(4). In carrying out this paragraph,
4 with respect to data reported pursuant to
5 subparagraph (A), the Secretary shall en-
6 sure that any proprietary information be
7 redacted from contracts submitted pursu-
8 ant to paragraph (5)(A)(vii) before posting
9 such contracts.

10 “(D) REPORTS TO CONGRESS.—Not later
11 than 1 year after the date of the enactment of
12 this subparagraph, and annually thereafter, the
13 Secretary shall submit a report to Congress on
14 the information collected under subparagraph
15 (A).

16 “(E) REGULATIONS.—The Secretary shall
17 promulgate regulations to carry out this para-
18 graph.”.

19 **SEC. 7. ENHANCING PROGRAM INTEGRITY.**

20 (a) AUDITS.—

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

25 “(g) AUDITS BY THE SECRETARY.—

1 “(1) IN GENERAL.—In addition to the audits
2 otherwise authorized under this section, the Sec-
3 retary may audit covered entities, including the con-
4 tract pharmacies and child sites of such entities, and
5 manufacturers to assess compliance with require-
6 ments under this section, including identifying any
7 statutory violations related to: improperly claiming
8 eligibility for the program under this section, drug
9 diversion, duplicate discounts, use of contract phar-
10 macies, claiming of a discount under this section on
11 a drug that is not a covered outpatient drug pur-
12 chased under this section, or failing to provide an
13 accurate ceiling price.

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

20 “(3) REQUIREMENTS.—The Secretary may not
21 close an audit described in paragraph (1) before a
22 corrective action plan required by the Secretary has
23 been fully implemented, as applicable.

24 “(4) 340B VENDOR INFORMATION.—To meet
25 the requirements for submission of information for

1 audits under this clause, covered entities shall con-
2 tract only with vendors agreeing to—

3 “(A) submit data to the Secretary and
4 independent auditors contracting with covered
5 entities necessary to determine the covered enti-
6 ty’s compliance with statutory and regulatory
7 requirements under this program, prohibitions
8 on drug diversion and duplicate discounts, use
9 of contract pharmacies, and claims for dis-
10 counts on covered outpatient drugs purchased
11 pursuant to agreements under subsection
12 (a)(1); and

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

15 “(5) 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, which may include disenrollment, and that do
23 not treat the failure to meet eligibility criteria as an
24 issue that can be corrected retroactively. Nothing in
25 this subsection shall be construed to limit the au-

1 thority of the Secretary to impose any remedy or
2 consequence otherwise available under this Section.

3 “(6) REGULATIONS.—Not later than 1 year
4 after the date of enactment of this paragraph, the
5 Secretary shall promulgate regulations to establish
6 the audit and reporting procedures required by this
7 subsection.

8 “(h) INDEPENDENT AUDITS OF COVERED ENTITIES
9 AND CONTRACT PHARMACY LOCATIONS.—

10 “(1) On a biennial basis, each covered entity
11 shall engage an independent auditor to conduct an
12 audit of the covered entity’s and each of its child
13 site’s and contract pharmacy location’s compliance
14 with this section. The independent auditor shall
15 not—

16 “(A) have any direct or indirect financial
17 interest in the covered entity or its contract
18 pharmacy;

19 “(B) have any decision-making authority
20 with respect to the covered entity; or

21 “(C) intervene with the governance of the
22 covered entity.

23 “(2) Upon conclusion of each audit, each cov-
24 ered entity shall—

1 “(A) review the methodology used by the
2 auditor to identify the full scope of any non-
3 compliance;

4 “(B) identify and fully correct all viola-
5 tions that have been identified in such inde-
6 pendent audit of the covered entity;

7 “(C) take steps to prevent such violations
8 effectively in the future;

9 “(D) specifically disclose to the Sec-
10 retary—

11 “(i) the methodology used by the inde-
12 pendent auditor described in subparagraph
13 (A);

14 “(ii) the nature and extent of any
15 identified non-compliance; and

16 “(iii) steps taken to prevent such vio-
17 lations effectively in the future;

18 “(E) assign responsibility to certify the
19 audit results make corrections under subpara-
20 graph (B) to a corporate officer of the covered
21 entity; and

22 “(F) within a reasonable time period, dis-
23 close to the manufacturer of the affected cov-
24 ered outpatient drug any purchase made under
25 the drug discount program under this section

1 that, at the time of the purchase of such drug,
2 did not fully satisfy the requirements of the
3 program. If the aggregate amount owed to a
4 manufacturer as a result of an audit under this
5 subsection exceeds the de minimis threshold es-
6 tablished by the Secretary through notice and
7 comment rulemaking, the covered entity shall
8 repay the manufacturer an amount equal to the
9 reduction in the price of the affected drugs,
10 plus interest on such amount calculated using
11 the applicable short-term interest rate deter-
12 mined by the Secretary of the Treasury under
13 section 1274(d) of the Internal Revenue Code
14 of 1986 for the period for which the covered en-
15 tity is liable. In establishing the de minimis
16 threshold, the Secretary shall consider the ad-
17 ministrative costs associated with calculating,
18 processing, and receiving repayments. Amounts
19 may not be divided, allocated, or otherwise
20 structured for the purpose of avoiding the re-
21 payment requirement under this subparagraph.

22 “(3) Not later than 1 year after the date of en-
23 actment of this paragraph, the Secretary shall—

24 “(A) promulgate regulations governing how
25 auditors engaged by covered entities under this

1 subsection shall determine whether and to what
2 extent a covered entity is meeting its require-
3 ments under this section, including require-
4 ments regarding nonprofit status and any con-
5 tract required under subsection (a)(4)(L)(i), as
6 applicable; and

7 “(B) promulgate regulations to establish
8 the audit and reporting procedures required by
9 this subsection.”.

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

13 (A) in clause (v)(II), by inserting “or
14 where the covered entity fails to implement a
15 corrective action plan relating to a violation in-
16 volving improperly claiming eligibility for the
17 drug discount program under this section, drug
18 diversion, duplicate discounts, compliance with
19 contract pharmacy requirements, or claiming a
20 discount or rebate on a drug that is not a cov-
21 ered outpatient drug, within 6 months of the
22 Secretary notifying the entity of the require-
23 ment for such plan” after “knowing and inten-
24 tional,”; and

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

1 “(vi) Increasing the frequency of au-
2 dits conducted for entities previously found
3 to be in violation of requirements of the
4 drug discount program under this section
5 that relate to eligibility, drug diversion, du-
6 plicate discounts, compliance with contract
7 pharmacy requirements, or claiming a dis-
8 count or rebate on a drug that is not a
9 covered outpatient drug, and assigning re-
10 sponsibility for making corrections relating
11 to such a violation to a corporate officer of
12 the entity.

13 “(vii) Establishing—

14 “(I) a process by which the Sec-
15 retary provides for proper and timely
16 notification of a potential violation by
17 a covered entity, including the specific
18 basis for the potential violation and
19 the information relied upon by the
20 Secretary in identifying such potential
21 violation;

22 “(II) a process for a covered enti-
23 ty to develop, submit, and implement
24 a corrective action plan, subject to ap-

1 proval and monitoring by the Sec-
2 retary, which shall—

3 “ (aa) provide two months to
4 submit a corrective action plan
5 following notification of a poten-
6 tial violation under subclause (I);
7 and;

8 “ (bb) require the Secretary,
9 not later than 2 months after the
10 date of submission of such plan,
11 to approve the plan or request
12 changes to the plan; and

13 “ (cc) require such plan to
14 identify the specific basis for the
15 finding of noncompliance and the
16 actions the covered entity will
17 take to correct such noncompli-
18 ance, prevent recurrence, and
19 demonstrate ongoing compliance;

20 “ (III) standards for timelines for
21 correction and demonstration of com-
22 pliance that are reasonable and pro-
23 portionate to the nature, scope, and
24 severity of the violation, including the
25 extent of any affected claims, the risk

1 of diversion or duplicate discounts,
2 and whether the violation reflects iso-
3 lated error, repeated conduct, or will-
4 ful disregard of applicable require-
5 ments;

6 “(IV) circumstances under which,
7 during the period in which a correc-
8 tive action plan is in effect, the Sec-
9 retary may temporarily suspend the
10 covered entity’s eligibility to partici-
11 pate in the drug discount program
12 under this section, if the Secretary de-
13 termines that such suspension is nec-
14 essary to protect program integrity,
15 including cases involving willful dis-
16 regard, repeated or egregious non-
17 compliance, failure to respond to a
18 Secretary-approved audit, or failure to
19 implement a prior corrective action
20 plan; and

21 “(V) a process for the Secretary
22 to publicly report, in a de-identified
23 manner, on the types and scope of
24 violations found in audits conducted
25 under this section.

1 “(viii) Disenrolling from the program
2 covered entities that fail to implement a
3 corrective action plan and correct viola-
4 tions in accordance with the time frame set
5 forth in the Corrective Action Plan pursu-
6 ant to the process described in subpara-
7 graph (B)(vii), related to any statutory vio-
8 lation of this section.

9 “(ix) The imposition of civil monetary
10 penalties, which shall be assessed accord-
11 ing to standards established in regulations
12 to be promulgated by the Secretary, for
13 covered entities that knowingly or inten-
14 tionally continue to contract with third-
15 party administrators or contract phar-
16 macies that are not in compliance with the
17 requirements of subsection (a)(13).

18 “(x) Notwithstanding the foregoing, if
19 the Secretary determines that a covered
20 entity has engaged in a pattern of non-
21 compliance, as evidenced by: (1) 3 or more
22 separate final audit reports finding viola-
23 tions of the requirements of this section
24 within a 2-year period, or (2) 5 or more
25 such reports within a 5-year period. The

1 Secretary may take any one or more of the
2 following actions with respect to such re-
3 peat noncompliant entity: (A) require the
4 entity to implement an accelerated correc-
5 tive action plan within a timeframe deter-
6 mined appropriate by the Secretary; (B)
7 impose civil monetary penalties without
8 providing an additional period for correc-
9 tive action; or (C) remove the entity from
10 the drug discount program under this sec-
11 tion and disqualify the entity from re-entry
12 into such program for a period of time de-
13 termined by the Secretary.”.

14 (b) PRIVATE NON-PROFIT HOSPITAL ELIGIBILITY
15 BASED ON CONTRACTS WITH STATE OR LOCAL GOVERN-
16 MENTS MEETING SPECIFIED CRITERIA.—Section
17 340B(a)(5) of the Public Health Service Act (42 U.S.C.
18 256b(a)(5)), as amended by the preceding sections, is fur-
19 ther amended by adding at the end the following:

20 “(E) PRIVATE NON-PROFIT HOSPITAL ELI-
21 GIBILITY BASED ON CONTRACTS WITH STATE
22 OR LOCAL GOVERNMENTS MEETING SPECIFIED
23 CRITERIA.—In the case of a hospital, whether
24 registered or seeking to register for the drug
25 discount program under this section as a cov-

1 ered entity described under subparagraph (L),
2 (M), (N), or (O) of paragraph (4), that claims
3 to be eligible for the program by virtue of being
4 a private non-profit hospital that has a contract
5 with a State or local government to provide
6 health care services to low-income individuals
7 who are not eligible for Medicaid or Medicare,
8 the Secretary shall take all of the following
9 steps, each of which shall be documented:

10 “(i) Prior to registering or approving
11 annual recertification of such a hospital (or
12 while carrying out any program audit of
13 such a hospital), the Secretary shall obtain
14 and review the hospital’s contract with a
15 State or local government and shall verify
16 and document that—

17 “(I) the document provided by
18 the hospital is a contract, in that it is
19 a mutually binding agreement for the
20 hospital to provide health care services
21 or supplies in exchange for something
22 of value;

23 “(II) the contract clearly lists the
24 name of the hospital and the unit of
25 State or local government that are

1 parties to the contract and is signed
2 and appropriately dated by appro-
3 priate officials of the hospital and the
4 unit of State or local government;

5 “(III) the contract specifies an
6 effective date;

7 “(IV) the contract clearly is in
8 effect and not expired at the time of
9 registration (or at the time of recer-
10 tification, in the case of annual recer-
11 tification, or for the full period exam-
12 ined in an audit, in the case of an
13 audit); and

14 “(V) the contract explicitly re-
15 quires that the hospital provide health
16 care services, and that such services
17 must be provided to individuals who
18 are both low-income and not eligible
19 for either the Medicaid program or
20 the Medicare program.

21 “(ii) The Secretary shall verify the ex-
22 istence of contracts meeting the require-
23 ments of clause (i) for all covered entities
24 described in this subparagraph and reg-
25 istered as of the date of enactment of this

1 clause by no later than 1 year after the
2 date of enactment of this clause.

3 “(iii) The Secretary shall not register
4 or recertify any covered entity described in
5 this subparagraph if the entity’s contract
6 with a State or local government does not
7 satisfy subclauses (I) through (V) of clause
8 (i).”.

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

16 (d) AMENDMENT.—Section 340B(a)(7) of the Public
17 Health Service Act (42 U.S.C. 256b(a)(7)) is amended by
18 inserting at the end the following:

19 “(F) NON-PROFIT STATUS.—The Secretary
20 shall verify the non-profit status of any hos-
21 pital, whether registered or seeking to register
22 for the drug discount program as a covered en-
23 tity described under subparagraph (L), (M),
24 (N), or (O) of subsection (a)(4), that claims, in
25 connection with drug discount program reg-

1 istration, annual recertification, or an audit, to
2 meet drug discount program eligibility criteria
3 in part by being a private non-profit hospital.
4 The Secretary shall verify the non-profit status
5 of all such hospitals using reliable publicly
6 available information, such as by matching data
7 reported by hospitals against data from the In-
8 ternal Revenue Service or from the Centers for
9 Medicare and Medicaid Services on the hos-
10 pital’s federal tax status. The Secretary shall
11 verify all registered covered entities described
12 under this section are in compliance with these
13 requirements within one year of the enactment
14 of this subparagraph.”.

15 **SEC. 8. FACILITATING DATA EXCHANGE TO IMPROVE PRO-**
16 **GRAM INTEGRITY.**

17 Part A of title XI of the Social Security Act (42
18 U.S.C. 1301 et seq.) is amended by adding the following
19 new section:

20 **“SEC. 1150D. 340B DRUG DISCOUNT PROGRAM DATA CLEAR-**
21 **INGHOUSE.**

22 “(a) GENERAL.—For a period of four (4) years from
23 the enactment of this section, a manufacturer shall offer
24 covered outpatient drugs at the ceiling price required
25 under section 340B(a)(1) of the Public Health Service Act

1 as a reduction in the purchase price and not through ret-
2 rospective rebates or other post-sale payments. This obli-
3 gation shall not apply to rebates for the AIDS Drug As-
4 sistance Programs who have implemented a rebate model
5 prior to the effective date of this section.

6 “(b) CLEARINGHOUSE PERFORMANCE.—Notwith-
7 standing any other provision of this section, the obligation
8 under subsection (a) shall automatically conclude at the
9 end of the period described in such subsection if the Sec-
10 retary has not certified, in a public report validated by
11 the Office of Inspector General, that the conditions de-
12 scribed in paragraphs (1) through (4) have been satisfied.
13 If such certification is not made as of the end of the period
14 described in subsection (a), no provision of this subsection
15 shall be construed to impose any additional or continuing
16 limitation on the form, timing, or mechanism by which a
17 manufacturer makes available the ceiling price required
18 under section 340B(a)(1) of the Public Health Service
19 Act—

20 “(1) all claims for 340B drugs described in
21 subsection (g) are submitted to, and processed
22 through, the clearinghouse entity with a contract in
23 effect under subsection (f);

24 “(2) not less than 90 percent of the value of
25 such claims submitted during the most recent 12-

1 month period are identified by such clearinghouse
2 entity as unique transactions that do not result in
3 duplicate discounts or other applicable overlapping
4 price concessions;

5 “(3) not less than 90 percent of the value of
6 claims for 340B drugs as described in subsection (g)
7 are adjudicated, including identification of any du-
8 plicate discounts, rebates, or other overlapping price
9 concessions, within timeframes established by the
10 Secretary through notice and comment rulemaking;
11 and

12 “(4) not less than 95 percent of the value of
13 claims for 340B drugs as described in subsection (g)
14 contain the data elements required by the Secretary
15 and are determined to be complete and accurate at
16 the time of initial submission.

17 “(c) ONGOING VALIDATION OF CLEARINGHOUSE
18 PERFORMANCE.—

19 “(1) PERIODIC OIG REPORTS.—If the obligation
20 under subsection (a) remains in effect after the end
21 of the 4-year period described in subsection (a), the
22 Inspector General of the Department of Health and
23 Human Services shall issue public reports evaluating
24 whether the clearinghouse entity with a contract in
25 effect under subsection (f) continues to satisfy the

1 performance benchmarks described in subsection (b).

2 Such reports shall be issued—

3 “(A) not later than 2 years after the end
4 of the 4-year period described in subsection (a);

5 “(B) not later than 5 years after the end
6 of the 4-year period described in subsection (a);

7 and

8 “(C) every 5 years thereafter.

9 “(2) CONTENTS.—Each report under para-
10 graph (1) shall assess, with respect to the most re-
11 cent 12-month period for which data are available,
12 whether the performance benchmarks described in
13 subsection (b) continue to be satisfied.

14 “(3) CORRECTIVE PERIOD.—If a report issued
15 under paragraph (1) determines that one or more of
16 the performance benchmarks described in subsection
17 (b) are not being maintained, the clearinghouse enti-
18 ty shall have 6 months from the date of issuance of
19 such report to cure the deficiency.

20 “(4) FOLLOW-UP REPORT.—Not later than 60
21 days after the end of the 6-month corrective period
22 described in paragraph (3), the Inspector General
23 shall issue a follow-up public report evaluating
24 whether the deficiency has been cured and whether

1 the applicable performance benchmarks are being
2 maintained.

3 “(5) FAILURE TO MAINTAIN PERFORMANCE
4 BENCHMARKS.—The obligation under subsection (a)
5 shall cease to apply if the follow-up report issued
6 under paragraph (4) determines that the deficiency
7 has not been cured or that one or more of the appli-
8 cable performance benchmarks are not being main-
9 tained.

10 “(d) INTERIM PERFORMANCE REPORT.—Not later
11 than 2 years after the date of enactment of this section,
12 the Secretary shall issue a preliminary public report, vali-
13 dated by the Office of Inspector General, detailing the
14 progress made towards accomplishing the goals and stand-
15 ards in subsection (b). The report shall include the data,
16 methodology, and assumptions used by the Secretary and
17 identify any material operational, data-quality, or compli-
18 ance barriers affecting achievement of such benchmarks.

19 “(e) SPECIAL RULE FOR SELECTED DRUGS.—Not-
20 withstanding subsection (b) and any other provision of
21 this section requiring a covered entity to submit data to
22 the third-party entity with a contract in effect under sub-
23 section (f), with respect to a drug that is a selected drug
24 (as defined in section 1192(c))—

1 “(1) each covered entity shall transmit directly
2 to the manufacturer, in a timely manner and in ac-
3 cordance with standards established by the Secretary
4 through notice and comment rulemaking, claims-
5 level data sufficient to enable the manufacturer to
6 prevent duplicate discounts, rebates, or other over-
7 lapping price concessions and to validate compliance
8 with the requirements of this section and section
9 1191, et seq.; and

10 “(2) a covered entity that fails to comply with
11 paragraph (1) shall, following written notice from
12 the Secretary identifying the specific failure and a
13 30-day period to cure such failure, be subject to civil
14 monetary penalties in an amount of \$5,000 per day
15 during the period of such non-compliance following
16 the expiration of such cure period.

17 The provisions of section 1128A (other than subsections
18 (a) and (b)) shall apply to a civil monetary penalty under
19 this section in the same manner as such provisions apply
20 to a penalty or proceeding under section 1128A(a).

21 “(f) CLEARINGHOUSE CONTRACTING ENTITY.—Not
22 later than 1 year after the date of enactment of this sec-
23 tion, the Secretary shall enter into a contract with an inde-
24 pendent, third-party clearinghouse entity (who shall be
25 free of conflicts of interest with covered entities, manufac-

1 turers, health plans, pharmacy benefit managers, and of
2 other conflicts of interest as specified by the Secretary)
3 for purposes of carrying out the clearinghouse duties
4 under subsection (g) with respect to the drug discount
5 program under section 340B of the Public Health Service
6 Act to facilitate robust and verifiable data exchange be-
7 tween relevant parties in order to improve program integ-
8 rity under section 340B of the Public Health Service Act.
9 Such contract shall provide that the third-party entity
10 shall perform the duties described in subsection (g) and
11 shall be for a 4-year term that may be renewed after a
12 subsequent bidding process or using competitive proce-
13 dures, as defined in section 132 of title 41, United States
14 Code.

15 “(g) DUTIES.—With respect to any 340B drug dis-
16 pensed or administered to an individual, without regard
17 to the individual’s insurance status or the type or source
18 of payment for the drug, a third-party entity with a con-
19 tract in effect under subsection (f) shall—

20 “(1) establish a procedure for collecting data
21 elements specified in subparagraph (A), including
22 any additional data elements required by the sec-
23 retary pursuant to subparagraph (A)(iv) to improve
24 program integrity of the drug discount program

1 under section 340B of the Public Health Service
2 Act, such that—

3 “(A) pharmacy benefit and medical benefit
4 claims-level data elements reported under this
5 section shall include the data elements specified
6 in clauses (i) through (iv) of this subpara-
7 graph—

8 “(i) with respect to a pharmacy ben-
9 efit claim—

10 “(I) the date of service;

11 “(II) the date on which the drug
12 was prescribed;

13 “(III) the prescription number;

14 “(IV) the fill number;

15 “(V) the 11-digit National Drug
16 Code for the drug dispensed;

17 “(VI) the quantity dispensed;

18 “(VII) the prescriber identifier;

19 “(VIII) the identifier of the dis-
20 pensing pharmacy or other service
21 provider, including the National Pro-
22 vider Identifier, as applicable;

23 “(IX) the 340B identification
24 number of the covered entity;

1 “(X) the prescription benefit
2 bank identification number; and
3 “(XI) the prescription benefit
4 processor control number;
5 “(ii) with respect to a medical benefit
6 claim—
7 “(I) the date of service;
8 “(II) the claim number;
9 “(III) the claim line number;
10 “(IV) the quantity of the drug
11 furnished;
12 “(V) the unit of measure;
13 “(VI) the physician or other fur-
14 nishing provider identifier;
15 “(VII) the applicable Healthcare
16 Common Procedure Coding System
17 code and any applicable modifiers;
18 “(VIII) the 11-digit National
19 Drug Code for the drug furnished;
20 “(IX) the National Provider
21 Identifier of the billing provider;
22 “(X) the 340B identification
23 number of the covered entity;
24 “(XI) the health plan identifier;
25 and

1 “(XII) the name of the health
2 plan;

3 “(iii) with respect to a pharmacy ben-
4 efit claim or medical benefit claim de-
5 scribed in clause (i) or (ii)—

6 “(I) the name of the wholesaler;

7 “(II) the wholesaler account
8 number;

9 “(III) the invoice date;

10 “(IV) the invoice number;

11 “(V) the National Provider Iden-
12 tifier of the pharmacy or other loca-
13 tion to which the drug was shipped;

14 “(VI) the 11-digit National Drug
15 Code for the drug purchased;

16 “(VII) the number of package
17 units purchased; and

18 “(VIII) the 340B identification
19 number of the covered entity; and

20 “(iv) such additional data elements as
21 the Secretary determines necessary to
22 carry out this section to improve the integ-
23 rity of the drug discount program under
24 section 340B of the Public Health Service
25 Act;

1 “(B) claims-level data under this section
2 shall be submitted and must be adjudicated
3 within timeframes established by the Secretary
4 through notice and comment rulemaking, with
5 such timeframes taking into account operational
6 capabilities of covered entities; and

7 “(C) reclassification of historical claims by
8 covered entities from non-340B to 340B beyond
9 6 months after the drug is furnished is prohib-
10 ited, except that the Secretary may permit such
11 reclassification upon a showing of good cause
12 by the covered entity;

13 “(2) request and receive, in the most efficient
14 and least burdensome manner practicable, with an
15 established timeframe for such reporting—

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

18 “(B) claims-level data from covered enti-
19 ties and, to the extent necessary, contract phar-
20 macies, health plans, entities providing phar-
21 macy benefit management services to health
22 plans;

23 “(C) claims-level rebate file data from
24 commercially paid claims that are eligible under
25 Section 340B; and

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

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

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

9 “(5) notify the covered entity, the Secretary,
10 the State Medicaid agency, and the manufacturer of
11 any violation described in section 340B(a)(5)(A) of
12 the Public Health Service Act to allow for remedi-
13 ation;

14 “(6) 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 “(7) where feasible, share with a covered entity,
21 the Secretary, a State Medicaid agency, and a man-
22 ufacturer, 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 or duplicate discounts

1 for a selected drug under section 1847A(i), section
2 1860D–14B, section 1192;

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

10 “(9) determine total sales of 340B drugs to
11 such individuals for purposes of being used as the
12 basis for determining user fees under section
13 340B(a)(17) of such Act;

14 “(10) identify claims and provide manufacturer
15 access to claims data for covered outpatient drugs
16 purchased under the drug discount program under
17 Section 340B of the Public Health Service Act
18 that—

19 “(A) are selected drugs (as defined in sec-
20 tion 1192(c)) to enable manufacturers to meet
21 the nonduplication requirements of section
22 1193(d);

23 “(B) are subject to inflation rebates under
24 section 1847A(i) or section 1860D–14B;

1 “(C) for a rebate or discount submitted by
2 two or more covered entities or child sites with
3 respect to the same unit of a covered outpatient
4 drug purchased under the drug discount pro-
5 gram; or

6 “(D) received reimbursement under a
7 State plan (or waiver of such plan) and ensur-
8 ing such claims are or were not included in any
9 State rebate request under section 1927 in vio-
10 lation of sections 1903(m)(2)(A)(xiii) or
11 1927(j)(1) or section 340B(a)(5)(A) of the
12 Public Health Service Act;

13 “(11) connect claims data and purchasing order
14 data received under this section in a streamlined,
15 timely, and efficient way;

16 “(12) provide access to state Medicaid agencies
17 to data that is reasonably necessary to prevent du-
18 plicate discounts prohibited by section 340B(a)(5) of
19 the Public Health Service Act;

20 “(13) establish procedures for covered entity re-
21 porting that may provide the same function for state
22 Medicaid agencies as covered entity reporting to
23 state Medicaid agencies;

24 “(14) respond to requests from covered entities
25 or manufacturers within a number of days estab-

1 lished by the Secretary through notice and comment
2 rulemaking;

3 “(15) facilitate manufacturer reasonable good
4 faith inquiries, reasonable manufacturer audits, du-
5 plicate-discount reviews, diversion reviews, and other
6 program integrity activities under section 340B of
7 the Public Health Service Act by receiving, vali-
8 dating, matching, analyzing, and producing claims-
9 level data, validation results, or other outputs nec-
10 essary to resolve such inquiries, audits, reviews, or
11 activities within timeframes established by the Sec-
12 retary through notice and comment rulemaking, as
13 well as all standards specified by the Secretary to be
14 promulgated pursuant to section 1150D(g)(16);

15 “(16) establish, subject to standards established
16 by the Secretary through notice and comment rule-
17 making, which standards shall be consistent with ap-
18 plicable law, including applicable Federal and State
19 data privacy and security laws and regulations (in-
20 cluding, without limitation, the Health Insurance
21 Portability and Accountability Act of 1996 and its
22 implementing regulations), uniform confidentiality,
23 access, use, retention, and data-security terms appli-
24 cable to information submitted to, maintained by, or
25 transmitted through the clearinghouse, including

1 terms governing manufacturer access to and receipt
2 of claims-level data, validation results, or other out-
3 puts under this section;

4 “(17) ensure that the terms described in para-
5 graph (16) apply uniformly to covered entities, man-
6 ufacturers, health plans, pharmacy benefit man-
7 agers, and other participating entities and are not
8 subject to individualized negotiation as a condition
9 of submitting information to, receiving information
10 from, or otherwise participating in the clearinghouse
11 process;

12 “(18) establish procedures to document any
13 failure by a covered entity to timely submit complete
14 and accurate information required under this section
15 and to notify the Secretary and any affected manu-
16 facturer of such failure; and

17 “(19) maintain, with appropriate safeguards,
18 submitted data elements for a period of 10 years.

19 “(h) RESTRICTIONS ON CLEARINGHOUSE CON-
20 TRACTING ENTITY.—The entity receiving a contract under
21 subsection (f) shall—

22 “(1) ensure that it has no conflicts of interest,
23 including no direct contractual involvement with any
24 covered entity, or manufacturer participating in the
25 drug discount program under section 340B of the

1 Public Health Service Act or any payer that makes
2 payments for drugs purchased through such pro-
3 gram;

4 “(2) not disclose confidential information ob-
5 tained through carrying out the clearinghouse duties
6 under this section other than as necessary to carry
7 out the purposes of this section, including for pro-
8 gram integrity functions;

9 “(3) not sell or otherwise generate revenue by
10 licensing or making available the data described in
11 subsection (g)(1); and

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

15 “(i) DUTIES OF COVERED ENTITY.—

16 “(1) IN GENERAL.—Covered entities shall facili-
17 tate and participate in data transmission with the
18 third-party clearinghouse entity with a contract in
19 effect under subsection (f), including submission of
20 data elements established by the Secretary through
21 notice and comment rulemaking. Such data trans-
22 mission requirements shall also apply with respect to
23 data relating to 340B drugs dispensed through any
24 external contract pharmacy arrangement, and shall
25 include data maintained by or on behalf of the cov-

1 ered entity by a contract pharmacy or third-party
2 administrator.

3 “(2) TIMELY AND COMPLETE SUBMISSION.—A
4 covered entity shall timely submit complete and ac-
5 curate information required under this section to the
6 clearinghouse contracting entity in the form, man-
7 ner, and time specified by the Secretary through no-
8 tice and comment rulemaking.

9 “(3) FAILURE TO TIMELY SUBMIT INFORMA-
10 TION.—If a covered entity fails to timely submit
11 complete and accurate information required under
12 this section to the clearinghouse contracting entity,
13 such failure shall be treated as a failure to partici-
14 pate in the clearinghouse process and the affected
15 manufacturer shall provide written notice to the cov-
16 ered entity and the Secretary identifying the specific
17 deficiency. If the covered entity does not cure such
18 failure within 30 days of receipt of such notice, the
19 affected manufacturer may suspend the availability
20 of discounts under section 340B(a)(1) of the Public
21 Health Service Act with respect to such covered enti-
22 ty, in whole or in part, until the covered entity cures
23 such failure.

24 “(4) LIMITATION ON SEPARATE CONFIDEN-
25 TIALITY TERMS.—A covered entity may not condi-

1 tion, delay, or deny submission of information to the
2 clearinghouse contracting entity, or otherwise condi-
3 tion, delay, or deny participation in the clearing-
4 house process, on the execution or individualized ne-
5 gotiation of a confidentiality agreement, data use
6 agreement, or similar agreement that is duplicative
7 of, inconsistent with, or more restrictive than the
8 uniform confidentiality, access, use, retention, and
9 data-security terms established by the Secretary
10 through notice and comment rulemaking under this
11 section.

12 “(j) RESTRICTIONS ON MANUFACTURER AND PBM
13 USE OF DATA.—

14 “(1) IN GENERAL.—A manufacturer who re-
15 ceives data under subsection (g) may use such data
16 only for the purpose of preventing duplicate dis-
17 counts and diversion under section 340B(a)(5) of
18 the Public Health Service Act, preventing duplicate
19 discounts in connection with inflation rebates under
20 section 1847(A)(i) and 1860D–14B as well as for
21 selected drugs (as defined in section 1192(c)) to en-
22 able a manufacturer to meet the nonduplication re-
23 quirements of section 1193(d), and validating com-
24 pliance with other requirements under the drug dis-

1 count program under section 340B of the Public
2 Health Service Act.

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

9 “(3) ENFORCEMENT.—Any manufacturer or
10 other person found by the Secretary to have used
11 data received under subsection (g) for uses other
12 than those described in paragraphs (1) and (2), such
13 as for pricing or marketing, shall be subject to civil
14 monetary penalties, established by the Secretary
15 through notice and comment rulemaking.

16 “(k) PRIVACY, CONFIDENTIALITY, AND DATA SECUR-
17 RITY REQUIREMENTS.—

18 “(1) IN GENERAL.—The information exchange
19 required under this section shall occur pursuant to
20 standards established by the Secretary through no-
21 tice and comment rulemaking, including uniform
22 confidentiality, access, use, retention, and data-secu-
23 rity terms applicable to information submitted to,
24 maintained by, or transmitted through the clearing-
25 house contracting entity, including terms governing

1 manufacturer access to claims-level data, validation
2 results, or other outputs under this section, and in
3 a manner consistent with applicable Federal and
4 State data privacy, security, and breach notification
5 laws.

6 “(2) PURPOSE OF CLEARINGHOUSE.—The use
7 of the clearinghouse contracting entity under this
8 section is intended to facilitate secure exchange of
9 information for 340B program integrity activities,
10 and the clearinghouse contracting entity shall be re-
11 quired to qualify as a covered entity under the pri-
12 vacy, security, and breach notification regulations
13 promulgated under section 264(c) of the Health In-
14 surance Portability and Accountability Act of 1996,
15 provided, however, that no manufacturer shall be re-
16 quired to qualify as a covered entity or business as-
17 sociate under HIPAA in order to obtain and use
18 data from the clearinghouse for only the purposes
19 identified in this Act.

20 “(3) RULE OF CONSTRUCTION.—Nothing in
21 this section shall be construed to—

22 “(A) limit, narrow, or create any new pre-
23 condition to the disclosure of claims-level, utili-
24 zation, or other information that may otherwise

1 be disclosed under applicable law for purposes
2 of 340B program integrity activities; or

3 “(B) require the execution or individual-
4 ized negotiation of a confidentiality agreement,
5 data use agreement, or similar agreement not
6 otherwise required by law as a condition of dis-
7 closing, submitting, receiving, maintaining, or
8 using information in accordance with this sec-
9 tion.

10 “(l) REPAYMENT TO MANUFACTURERS.—The Sec-
11 retary shall, establish through notice and comment rule-
12 making, establish a process to require covered entities to
13 work with affected manufacturers regarding identified du-
14 plicate discounts and diversion of 340B drugs, regardless
15 of the method used to dispense the 340B drug, which shall
16 include repayment plus accrued interest—

17 “(1) by the covered entity as a result of the
18 covered entity’s noncompliance with section 340B of
19 the Public Health Service Act; or

20 “(2) by a State Medicaid program of rebates
21 improperly requested by the State Medicaid pro-
22 gram.

23 “(m) PROHIBITED ACTIONS OF GROUP HEALTH
24 PLANS AND PBMS.—

1 “(1) IN GENERAL.—A group health plan, a
2 health insurance issuer offering group or individual
3 coverage (as such terms are defined in section 2791
4 of the Public Health Service Act (42 U.S.C. 300gg–
5 91)), or an entity providing pharmacy benefit man-
6 agement services may not interfere with the ability
7 of covered entities, contract pharmacies (as such
8 terms are defined in section 340B of the Public
9 Health Service Act (42 U.S.C. 256b)), or manufac-
10 turers of drugs to prevent duplicate discounts or to
11 recoup the full amount of any identified duplicate
12 discounts pursuant to the drug discount program
13 under section 340B of the Public Health Service Act
14 (42 U.S.C. 254b).

15 “(2) ENFORCEMENT.—The Secretary of Health
16 and Human Services shall impose civil monetary
17 penalties on any group health plan, health insurance
18 issuer, or entity providing pharmacy benefit manage-
19 ment services that violates paragraph (1).

20 “(n) STATE MEDICAID AGENCIES.—In accordance
21 with requirements established by the Secretary through
22 notice and comment rulemaking, each State’s agency re-
23 sponsible for the administration of a state plan under sec-
24 tion 1902(a)(5) of the Social Security Act (42 U.S.C.

1 1396a(a)(5)) shall establish and publish written proce-
2 dures that—

3 “(1) specify the extent to which a 340B drug
4 may be dispensed to a Medicaid beneficiary, includ-
5 ing beneficiaries of managed care programs;

6 “(2) effectively identify when a 340B drug is
7 dispensed to a Medicaid beneficiary; and

8 “(3) exclude 340B drugs dispensed to Medicaid
9 beneficiaries from requests for rebates under section
10 1927.

11 “(o) DEFINITIONS.—In this section:

12 “(1) COVERED ENTITY.—The term ‘covered en-
13 tity’ means an entity described in section
14 340B(a)(4) of the Public Health Service Act.

15 “(2) FEDERAL HEALTH CARE PROGRAM.—The
16 term ‘Federal health care program’ has the meaning
17 given that term in section 1128B(f).

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

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

24 “(5) 340B DRUG.—The term ‘340B drug’
25 means a drug that is—

1 “(A) a covered outpatient drug (as defined
2 for purposes of section 340B of the Public
3 Health Service Act); and

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

6 “(p) OVERSIGHT.—Not later than 1 year after imple-
7 mentation of the clearinghouse, the Secretary shall:

8 “(1) engage an independent auditor to conduct
9 an annual audit of the clearinghouse contracting en-
10 tity to ensure compliance with this section, including
11 but not limited to timely and accurate adjudication
12 of claims; timely and complete transmission of data
13 to relevant parties; and timely and substantive en-
14 gagement with covered entities and manufacturers,
15 when requested. If the Secretary finds through these
16 audits that the clearinghouse contracting entity is
17 not in compliance with this section, the Secretary
18 shall take appropriate action to ensure compliance,
19 which may include the imposition of civil monetary
20 penalties against the clearinghouse contracting enti-
21 ty, or early termination of its contract, provided an-
22 other compliant solution is available.

23 “(2) issue a report to Congress detailing coordi-
24 nated efforts, including through the use of existing
25 resources to address requests from covered entities

1 (as defined in section 340B(a)(4) of the Public
2 Health Service Act (42 U.S.C. 256b(a)(4))) for pay-
3 ment under title XIX of the Social Security Act (42
4 U.S.C. 1396 et seq.) for medical assistance for a
5 drug that is subject to an agreement under section
6 340B(a) of the Public Health Service Act (42
7 U.S.C. 256b(a)) if the drug is subject to the pay-
8 ment of a rebate to the State under section 1927 of
9 the Social Security Act (42 U.S.C. 1396r–8), as pro-
10 hibited under section 340B(a)(5)(A) of the Public
11 Health Service Act (42 U.S.C. 256b(a)(5)(A)), and
12 to prevent the duplicate discounts for covered out-
13 patient drugs that are— selected drugs (as defined
14 in section 1192(c) of the Social Security Act) to en-
15 able manufacturers to meet the nonduplication re-
16 quirements of section 1193(d) of such Act; or sub-
17 ject to inflation rebates under as defined by section
18 1847A(i) or section 1860D–14B of the Social Secu-
19 rity Act.

20 “(q) REGULATIONS.—The Secretary of Health and
21 Human Services, in consultation with the Administrator
22 of the Centers for Medicare & Medicaid Services and the
23 Administrator of the Health Resources and Services Ad-
24 ministration, shall, through notice and comment rule-
25 making, promulgate such regulations as are necessary to

1 implement the provisions of this section, advance the pur-
2 pose of the drug discount program under section 340B
3 of the Public Health Service Act (42 U.S.C. 256b) and
4 prevent duplicate discounts and diversion through the
5 clearinghouse established by the amendment made by this
6 section.”.

7 **SEC. 9. PROHIBITION ON DISCRIMINATORY PRACTICES**
8 **AND CONTRACTING.**

9 (a) IN GENERAL.—Part A of title XXVII of the Pub-
10 lic Health Service Act (42 U.S.C. 300gg et seq.) is amend-
11 ed by inserting after section 2729 (42 U.S.C. 300gg-19b)
12 the following:

13 **“SEC. 2730. ANTI-DISCRIMINATION AND PERMISSIBLE 340B**
14 **ARRANGEMENTS.**

15 “(a) IN GENERAL.—A group health plan, a health
16 insurance issuer offering group or individual health insur-
17 ance coverage, or a pharmacy benefit manager may not
18 discriminate against a covered entity (as defined in section
19 340B(a)(4)) or a contract pharmacy (as defined in section
20 340B(b)(5)), or a participant, beneficiary, or enrollee of
21 such plan or coverage by imposing requirements, exclu-
22 sions, reimbursement terms, or other conditions on such
23 entity or pharmacy that differ from those applied to enti-
24 ties or pharmacies that are not covered entities or contract
25 pharmacies on the basis that the entity or pharmacy is

1 a covered entity or contract pharmacy or that the entity
2 or pharmacy dispenses covered outpatient drugs (as de-
3 fined in section 1927(k) of the Social Security Act), in-
4 cluding by taking any action prohibited under subsection
5 (b).

6 “(b) SPECIFIED PROHIBITED ACTIONS.—A group
7 health plan, a health insurance issuer offering group or
8 individual health insurance coverage, or a pharmacy ben-
9 efit manager may not discriminate against a covered enti-
10 ty, a contract pharmacy, or a participant or beneficiary
11 in a group health plan or health insurance offered by a
12 health insurance issuer offering group or individual health
13 insurance by doing any of the following:

14 “(1) Reimbursing a covered entity or contract
15 pharmacy for a quantity of a covered outpatient
16 drug purchased under section 340B in an amount
17 less than such plan, issuer, or pharmacy benefit
18 manager, as applicable, would pay to any other simi-
19 larly situated (as specified by the Secretary through
20 notice and comment rulemaking) entity or pharmacy
21 that is not a covered entity or a contract pharmacy
22 for such quantity of such drug on the basis that the
23 entity or pharmacy is a covered entity or contract
24 pharmacy or that the entity or pharmacy dispenses

1 covered outpatient drugs purchased under section
2 340B.

3 “(2) Imposing any terms or conditions on cov-
4 ered entities or contract 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 con-
8 tract pharmacies on the basis that the entity or
9 pharmacy is a covered entity or contract pharmacy
10 or that the entity or pharmacy dispenses covered
11 outpatient drugs purchased under this section—

12 “(A) fees, chargebacks, clawbacks, adjust-
13 ments, or other assessments;

14 “(B) professional dispensing fees;

15 “(C) restrictions or requirements regarding
16 participation in standard or preferred pharmacy
17 networks;

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

22 “(E) any other restrictions, conditions,
23 practices, or policies that, as specified by the
24 Administrator of the Health Resources and
25 Services Administration through notice and

1 comment rulemaking, interfere with the ability
2 of a covered entity to maximize the value of dis-
3 counts provided under section 340B.

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

9 “(4) Requiring a covered entity or specified
10 pharmacy to identify, either directly or through a
11 third party, covered outpatient drug purchased
12 under the 340B program. Other than through the
13 340B Data Clearinghouse established at section
14 1150D.

15 “(5) Refusing to contract with a covered entity
16 or contract pharmacy for reasons other than those
17 that apply equally to entities or pharmacies that are
18 not covered entities or contract pharmacies, or on
19 the basis that the covered entity is described in sec-
20 tion 340B(a)(4).

21 “(6) Denying coverage of a covered outpatient
22 drug purchased under the 340B program on the
23 basis of its status as a 340B eligible drug if the
24 group health plan or health insurance issuer other-

1 wise covers the identical drug not purchased under
2 340B.

3 “(c) PROHIBITION.—A group health plan, a health
4 insurance issuer offering group or individual health insur-
5 ance coverage, or a pharmacy benefit manager may not
6 enter into a contract or other agreement, or any other ar-
7 rangement regardless of whether such arrangement is me-
8 morialized in writing, with a covered entity (as defined in
9 section 340B(a)(4)) in which the covered entity provides
10 a share of any discount or savings for a covered outpatient
11 drug under section 340B to the group health plan, health
12 insurance issuer, or pharmacy benefit manager, and may
13 not condition network participation, preferred formulary
14 placement, claim routing, or any other benefit on the cov-
15 ered entity’s agreement to share any such discount or sav-
16 ings.

17 “(d) ENFORCEMENT MECHANISM.—The Secretary
18 shall impose a civil monetary penalty on any pharmacy
19 benefit manager that violates the requirements of this sec-
20 tion. Such penalty shall not exceed \$5,000 per violation
21 per day. The Secretary shall issue proposed regulations
22 to implement this subsection not later than 60 days after
23 the date of the enactment of this subsection and shall fi-
24 nalize such regulations not later than 180 days after such
25 date of enactment.”.

1 (b) SSA.—Section 1860D(12) of the Social Security
2 Act (42 U.S.C. 1395w–112) is amended by adding at the
3 end the following new subsection:

4 “(i) NONDISCRIMINATION.—PDP sponsors may not
5 include any provision in a prescription drug plan that re-
6 quires covered entities under Section 340B of the Public
7 Health Service Act to make use of contract pharmacy sites
8 that do not meet the requirements set forth in Section
9 340B for the use of contract pharmacies or are otherwise
10 inconsistent with patient need and access.”.

11 (c) 340B.—Section 340B of the Public Health Serv-
12 ice Act (42 U.S.C. 256b), as amended, is amended by add-
13 ing at the end the following new subsection:

14 “(i) PERMITTED THIRD PARTY ADMINISTRATOR AR-
15 RANGEMENTS.—

16 “(1) A covered entity under this section may
17 only contract with a third-party administrator for
18 the purposes of administering the dispensing of cov-
19 ered drugs under this section if compensation for the
20 third-party administrator is in the form of bona fide
21 services fees.

22 “(2) Bona fide service fees as described in
23 paragraph (1) may not be determined as a percent-
24 age of revenue to the covered entity for covered
25 drugs under this section or by any other metric tied

1 to revenue for covered drugs to the covered entity or
2 volume of covered drugs dispensed by the covered
3 entity.

4 “(3) HRSA may, pursuant to standards estab-
5 lished through notice and comment rulemaking, levy
6 Civil Monetary Penalties upon covered entities for
7 knowing and intentional non-compliance with re-
8 quirements under paragraphs (1) and (2).”.

9 (d) CONFORMING AMENDMENTS.—

10 (1) EMPLOYEE RETIREMENT INCOME SECURITY
11 ACT (ERISA).—Section 715(a)(1) of ERISA (29
12 U.S.C. 1185d(a)(1)) is amended by inserting “and
13 subsequent legislation” after “as amended by the
14 Patient Protection and Affordable Care Act”.

15 (2) INTERNAL REVENUE CODE.—Section
16 9815(a)(1) of the Internal Revenue Code of 1986
17 (26 U.S.C. 9815(a)(1)) is amended by inserting
18 “and subsequent legislation” after “as amended by
19 the Patient Protection and Affordable Care Act”.

20 **SEC. 10. ENSURING HRSA HAS ADEQUATE RESOURCES TO**
21 **OVERSEE THE PROGRAM.**

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

1 “(17) USER FEE PROGRAM.—

2 “(A) IN GENERAL.—Beginning in fiscal
3 year 2027, the Secretary shall assess and col-
4 lect fees from covered entities participating in
5 the program under this section, in accordance
6 with this paragraph.

7 “(B) FEE AMOUNTS.—The fees described
8 in subparagraph (A) shall be assessed and col-
9 lected from each covered entity on an annual
10 basis, in an amount determined by the Sec-
11 retary through procedures established through
12 notice and comment rulemaking. In general, the
13 fee shall be 0.1 percent of the dollar amount
14 paid by the covered entity for covered out-
15 patient drugs under this section in the previous
16 year.

17 “(C) USE OF FEES.—Any fees collected
18 under this paragraph from covered entities shall
19 be used by the Secretary for purposes of admin-
20 istering this section and enhancing program in-
21 tegrity and oversight activities under this sec-
22 tion, including—

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

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

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

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

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

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

22 “(D) SUPPLEMENT NOT SUPPLANT.—Any
23 fees collected under this paragraph shall be
24 used to supplement and not supplant amounts

1 otherwise provided in appropriations Acts to
2 carry out this section.

3 “(E) REGULATIONS.—The Secretary shall
4 promulgate regulations as necessary to imple-
5 ment the user fee program under this para-
6 graph, which shall include establishment of a
7 process to provide for exceptions to the fee
8 amount under subparagraph (B), including the
9 circumstances under which such exceptions may
10 apply to certain covered entities.

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

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

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

24 (b) CONFORMING AMENDMENT.—Section 340B(a)(4)
25 of the Public Health Service Act (42 U.S.C. 256b(a)(4))

1 is amended, in the matter preceding subparagraph (A),
2 by inserting “, has submitted user fees to the Secretary
3 in the amount assessed under paragraph (17) for the cur-
4 rent year,” after “paragraph (5)”. Section 340B(a)(1) of
5 the Public Health Service Act (42 U.S.C. 256b(a)(1)) is
6 further amended by inserting “, and has submitted user
7 fees to the Secretary in the amount assessed under para-
8 graph (17) for the current year,” after the first reference
9 to “agreement” in such paragraph.

10 (c) FUNDING.—Section 340B of the Public Health
11 Service Act (42 U.S.C. 256b) is amended by adding at
12 the end the following new subsection:

13 “(j) AUTHORIZATIONS OF APPROPRIATIONS.—

14 “(1) AUTHORIZATION OF APPROPRIATIONS FOR
15 AUDITS, INVESTIGATIONS, AND OTHER OVERSIGHT
16 AND ENFORCEMENT ACTIVITIES.—In addition to
17 amounts made available under subsection (d)(4),
18 there are authorized to be appropriated \$3,000,000
19 for each of fiscal years 2027 through 2031, for pur-
20 poses of conducting audits, investigations, and other
21 oversight and enforcement activities with respect to
22 the drug discount program under this section, in-
23 cluding audits of covered entities and manufactur-
24 ers.

1 “(2) AUTHORIZATION OF APPROPRIATION FOR
2 GENERAL PURPOSES.—In addition to amounts made
3 available under paragraph (1) and subsection (d)(4),
4 there are authorized to be appropriated \$9,000,000
5 for each of fiscal years 2028 through 2031, for pur-
6 poses of implementing the activities under this sec-
7 tion, including audits of covered entities and manu-
8 facturers.”.

9 (d) DIRECT HIRE AUTHORITY.—Section 340B(d) of
10 the Public Health Service Act (42 U.S.C. 256b(d)) is
11 amended by adding at the end the following new para-
12 graph:

13 “(6) DIRECT-HIRE AUTHORITY.—Notwith-
14 standing section 3304(a)(3) of title 5, United States
15 Code, and sections 3309 through 3318 of such title,
16 and section 337 of title 5 of the Code of Federal
17 Regulations (or any successor regulations), the Sec-
18 retary may, beginning on the date of the enactment
19 of this paragraph, exercise direct-hire authority to
20 appoint a minimum of twenty qualified candidates to
21 permanent positions within the competitive service in
22 order to carry out management and oversight activi-
23 ties under this section, with respect to covered enti-
24 ties and manufacturers participating in the drug dis-
25 count program under this section.”.

1 **SEC. 11. STUDIES AND REPORTS.**

2 (a) COST OF DISPENSING STUDIES AND REPORT.—

3 (1) STUDY.—Not later than 1 year after the
4 date of the enactment of this section, the Secretary
5 shall conduct a study on dispensing fees and reim-
6 bursements that health plans and pharmacy benefit
7 managers pay to pharmacies, separated by each cat-
8 egory of payer (at a minimum, Medicare, Medicaid,
9 and commercial payors) and whether the drug is
10 purchased under section 340B. The Secretary shall
11 repeat this study not less than every 24 months
12 thereafter.

13 (2) REPORT.—Not later than 90 days after the
14 completion of each study conducted under paragraph
15 (1), the Secretary shall submit to Congress a report
16 containing the results of such study, including—

17 (A) the amount of dispensing fees for cov-
18 ered outpatient drugs purchased under section
19 340B and covered outpatient drugs not pur-
20 chased under section 340B;

21 (B) whether such fees are reasonable; and

22 (C) any recommendations for further Con-
23 gressional action with respect to dispensing fees
24 and the establishment of acceptable standards
25 for dispensing fees.

1 (b) COMPTROLLER GENERAL STUDY AND REPORT
2 ON 340B DISCOUNT.—

3 (1) STUDY.—Not later than 1 year after the
4 date of the enactment of this section, the Comp-
5 troller General of the United States shall conduct a
6 study of the 340B discount (the unit rebate amount
7 referenced in section 340B(a)(1) of the Public
8 Health Service Act) that is retained by—

- 9 (A) contract pharmacies;
10 (B) health plans;
11 (C) pharmacy benefit managers;
12 (D) third-party vendors;
13 (E) patients; and
14 (F) covered entities.

15 (2) REPORT.—Not later than 2 years after en-
16 actment, the Comptroller General of the United
17 States shall submit to Congress a report detailing
18 the results of this study.

19 (A) Information shall be aggregated for
20 each type of covered entity, and by arrange-
21 ments the covered entity has with each different
22 entity specified in subparagraphs (A) through
23 (D) of paragraph (1), describing the amount of
24 the 340B discount retained by the covered enti-

1 ty and the entities specified in subparagraphs
2 (A) through (D) of paragraph (1).

3 (B) The report shall include recommenda-
4 tions to Congress on a standardized set of defi-
5 nitions to collect this information and a calcula-
6 tion methodology.

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

15 (d) REPORTS TO CONGRESS.—

16 (1) INITIAL REPORT.—Not later than 1 year
17 after the date of the enactment of this subsection,
18 the Comptroller General of the United States shall
19 submit a report to Congress on the following:

20 (A) analyzing such contracts between state
21 and local governments and covered entities de-
22 scribed in subparagraph (L), (M), (N), or (O)
23 of subsection (a)(4) that claim to be eligible for
24 the drug discount program under this section
25 by virtue of being a private non-profit hospital

1 that has a contract with a state or local govern-
2 ment to provide health care services to low-in-
3 come individuals who are not eligible for Med-
4 icaid or Medicare;

5 (B) assessing the amount of care the con-
6 tracts described in subparagraph (A) obligate
7 the covered entity to provide to individuals at or
8 below 400 percent of the Federal Poverty Level,
9 who are ineligible for Medicare under title
10 XVIII of the Social Security Act and Medicaid
11 under title XIX of such Act;

12 (C) assessing the amount of charity care
13 and uncompensated care covered entities report-
14 ing under this section provide to individuals
15 earning at or below 400 percent of the Federal
16 Poverty Level;

17 (D) analyzing the difference between the
18 aggregate gross reimbursement and aggregate
19 acquisition costs received by each covered entity
20 for covered outpatient drugs purchased under
21 the 340B program;

22 (E) analyzing the degree to which Feder-
23 ally Qualified Health Centers, as such term is
24 defined in subsection (a)(4)(A), are subject to
25 the violations under section 2730(b) of the Pub-

1 lic Health Service Act, and the effect of these
2 violations on Federally Qualified Health Cen-
3 ters' ability to provide affordable care to under-
4 served populations; and

5 (F) analyzing how the contracts described
6 in subparagraph (A) define low-income individ-
7 uals and whether the Secretary reviews such de-
8 terminations.

9 (2) SUBSEQUENT REPORT.—Not later than 2
10 years after the date of the enactment of this sub-
11 section, the Comptroller General of the United
12 States shall submit to Congress a final report on the
13 information collected under paragraph (1) regarding
14 the difference between the aggregate payment re-
15 ceived by each such covered entity (including child
16 sites of such entity and adding information on all
17 sources of payment received by the covered entity
18 and its child sites) for drugs purchased under this
19 section and the aggregate costs paid by the covered
20 entity (including its child sites) to acquire such
21 drugs.

22 (3) CLARIFICATION.—When submitting these
23 reports, the Comptroller General of the United
24 States shall not provide copies of unredacted con-

1 tracts or any work materials to Congress or any
2 other parties.

3 **SEC. 12. MEANINGS.**

4 Section 340B(b) of the Public Health Service Act (42
5 U.S.C. 256b(b)), as amended by the preceding sections,
6 is further amended by adding at the end the following:

7 “(4) CHILD SITE.—In this section, the term
8 ‘child site’ means any outpatient department, clinic,
9 or facility that is separately registered under this
10 section as an outpatient facility of a covered entity
11 described in subparagraph (L), (M), (N), or (O) of
12 subsection (a)(4) and that is not itself the covered
13 entity’s principal operating location or the location
14 through which the covered entity satisfies the re-
15 quirements for eligibility under subsection (a)(4).

16 “(5) CONTRACT PHARMACY.—In this section,
17 the term ‘contract pharmacy’ means a pharmacy
18 that, pursuant to a contract or other arrangement
19 with a covered entity, dispense or otherwise fur-
20 nishes covered outpatient drugs to patients on behalf
21 of the covered entity, whether in person, by mail, or
22 through any other delivery method.”.

1 **SEC. 13. REQUIREMENTS FOR NONHOSPITAL COVERED EN-**
2 **TITIES AND SUBGRANTEES.**

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

6 “(F) ADDITIONAL REQUIREMENTS FOR
7 NONHOSPITAL COVERED ENTITIES; REQUIRE-
8 MENTS FOR SUBGRANTEES.—

9 “(i) ADDITIONAL REQUIREMENTS FOR
10 NONHOSPITAL COVERED ENTITIES.—A
11 covered entity described in one of subpara-
12 graphs (A) through (K) of paragraph (4)
13 shall, as a condition of participation in the
14 program under this section—

15 “(I) be a nonprofit or public enti-
16 ty (as determined by the Secretary);

17 “(II) be eligible to purchase a
18 covered outpatient drug subject to an
19 agreement under this section only
20 with respect to a patient receiving a
21 health care service at a registered cov-
22 ered entity site, and such service and
23 such drug are within the scope and
24 time period of the Federal grant,
25 project, or Federal grant-authorizing
26 statute, as applicable, that qualifies

1 such covered entity for participation
2 in the program under this section;

3 “(III) oversee the participation in
4 the program under this section of any
5 subgrantee with which such covered
6 entity enters into an enforceable writ-
7 ten agreement in accordance with sub-
8 clause (IV) and be directly liable for
9 noncompliance by any such sub-
10 grantee with any requirement under
11 this section;

12 “(IV) have an enforceable written
13 agreement with any subgrantee, which
14 shall apply to all registered sites of
15 such subgrantee, and require such
16 subgrantee to comply with all require-
17 ments under this section otherwise ap-
18 plicable to the covered entity and to
19 maintain written records, which shall
20 be made available to the Secretary
21 upon request, sufficient to dem-
22 onstrate such subgrantee’s receipt of
23 eligible Federal funds or an in-kind
24 contribution purchased with such
25 funds, as described in clause (iii), and

1 the grant under which such sub-
2 grantee receives such funds or con-
3 tribution; and

4 “(V) maintain written records
5 sufficient to demonstrate such entity
6 authorized such subgrantee to, prior
7 to purchasing covered outpatient
8 drugs subject to an agreement under
9 this section, register each subgrantee
10 site in the covered entity identification
11 system established under subsection
12 (d)(2)(B)(iv) to participate in the pro-
13 gram under this section as a sub-
14 grantee of such entity and provide the
15 Secretary with such registration infor-
16 mation as requested to demonstrate
17 such subgrantee’s receipt of eligible
18 Federal funds or an in-kind contribu-
19 tion purchased with such funds, as de-
20 scribed in clause (iii), and the grant
21 under which the subgrantee receives
22 such funds or contribution.

23 “(ii) REQUIREMENTS FOR SUB-
24 GRANTEES.—Notwithstanding any other
25 provision in this section, a subrecipient of

1 a Federal grant shall be eligible to partici-
2 pate in the program under this section
3 only if such subrecipient is a subgrantee
4 (as defined in clause (iii)) and such sub-
5 grantee—

6 “(I) is a nonprofit or public enti-
7 ty (as determined by the Secretary);

8 “(II) prior to purchasing covered
9 outpatient drugs subject to an agree-
10 ment under this section—

11 “(aa) enters into an enforce-
12 able written agreement with the
13 covered entity providing eligible
14 Federal funds or an in-kind con-
15 tribution, pursuant to clause
16 (i)(IV);

17 “(bb) maintains written
18 records, which shall be made
19 available to the Secretary upon
20 request, sufficient to demonstrate
21 such subgrantee’s receipt of eligi-
22 ble Federal funds or an in-kind
23 contribution purchased with such
24 funds, as described in clause (iii),
25 and the grant under which such

1 subgrantee receives such funds or
2 contribution; and

3 “(cc) registers each sub-
4 grantee site to participate in the
5 program under this section in the
6 covered entity identification sys-
7 tem established under subsection
8 (d)(2)(B)(iv);

9 “(III) purchases covered out-
10 patient drugs subject to an agreement
11 under this section only with respect to
12 a patient receiving a health care serv-
13 ice at a registered subgrantee site,
14 and such service and such drug are
15 within the scope and time period of
16 the Federal grant, project, or grant-
17 authorizing statute, as applicable, that
18 qualifies such subgrantee for partici-
19 pation in the program under this sec-
20 tion;

21 “(IV) in the case of a subgrantee
22 that receives an in-kind contribution
23 from a covered entity described in
24 paragraph (4)(K), demonstrates to
25 such covered entity and to the Sec-

1 retary, upon initial registration to
2 participate in the program under this
3 section and on an annual basis there-
4 after, that the number of individuals
5 aged 19 to 64 years receiving a health
6 care service at the registered sub-
7 grantee site during the most recent
8 calendar year who are enrolled under
9 a State plan under title XIX of the
10 Social Security Act (or a waiver of
11 such plan), as a share of all individ-
12 uals aged 19 to 64 years receiving a
13 health care service at the registered
14 subgrantee site during such calendar
15 year, exceeds the number of individ-
16 uals aged 19 to 64 years who reside
17 in the State where such subgrantee
18 site is located and are enrolled under
19 a State plan under title XIX of such
20 Act (or a waiver of such plan), as a
21 share of all individuals aged 19 to 64
22 who reside in such State, each as
23 measured by data available from the
24 American Community Survey of the
25 Bureau of the Census for the calendar

1 year preceding the most recent cal-
2 endar year;

3 “(V) in the case of a subgrantee
4 that receives an in-kind contribution
5 from a covered entity described in
6 paragraph (4)(K), submits to such
7 covered entity and to the Secretary,
8 upon receipt of each in-kind contribu-
9 tion described in clause (iii)—

10 “(aa) a written plan in a
11 form specified by the Secretary
12 describing how such contribution
13 will be used to further the goals
14 of the relevant Federal grant,
15 how such subgrantee will ensure
16 that purchases of covered out-
17 patient drugs under the program
18 under this section are consistent
19 with the goals of such grant, and
20 how such subgrantee will ensure
21 compliance with the requirements
22 under subparagraph (A) and (B);
23 and

24 “(bb) a written plan in a
25 form specified by the Secretary

1 and using criteria established by
2 the Secretary through notice and
3 comment rulemaking to deter-
4 mine the date upon which its eli-
5 gibility to participate in the pro-
6 gram under this section, as a re-
7 sult of such contribution, shall
8 terminate (absent such sub-
9 grantee's receipt of additional
10 funds or contributions described
11 in clause (iii));

12 “(VI) subject to subclause (VII),
13 immediately notifies the Secretary,
14 disenrolls from the program under
15 this section, and discontinues making
16 purchases under such program and
17 representing to third parties that it
18 may purchase under such program as
19 of the date described in subclause
20 (V)(bb) or if, at any time during its
21 participation in the program under
22 this section, it no longer meets one or
23 more applicable requirements under
24 this section; and

1 “(VII) not later than 30 days fol-
2 lowing the date on which the covered
3 entity with which such subgrantee has
4 an agreement pursuant to clause (i)
5 ceases participation in the program
6 under this section, such subgrantee ei-
7 ther—

8 “(aa) disenrolls from the
9 program under this section and
10 discontinues making purchases
11 under such program and rep-
12 resenting to third parties that
13 such subgrantee may purchase
14 under such program; or

15 “(bb) enters into an enforce-
16 able written agreement with a
17 different covered entity described
18 in one of subparagraphs (A)
19 through (K) of paragraph (4)
20 that is participating in the pro-
21 gram under this section, and sat-
22 isfies all applicable requirements
23 under this section with respect to
24 such different covered entity.

25 “(iii) SUBGRANTEE DEFINED.—

1 “(I) IN GENERAL.—In this sub-
2 paragraph, the term ‘subgrantee’
3 means a subrecipient of a Federal
4 grant that—

5 “(aa) receives eligible Fed-
6 eral funds from a covered entity
7 described in one of subpara-
8 graphs (A) through (K) of para-
9 graph (4) in the form of non-
10 nominal and ongoing payments
11 by such covered entity directly to
12 such subrecipient to directly sup-
13 port the provision of health care
14 services by such subrecipient to
15 individuals within the scope and
16 time period of the Federal grant,
17 project, or Federal grant-author-
18 izing statute, as applicable, that
19 qualifies such covered entity for
20 participation in the program
21 under this section; or

22 “(bb) receives in-kind con-
23 tributions from a covered entity
24 described in paragraph (4)(K)
25 and such contributions—

1 “(AA) are ongoing and
2 are in the form of real prop-
3 erty, equipment, supplies, or
4 services;

5 “(BB) subject to sub-
6 clause (II), have a value ex-
7 ceeding \$25,000 per year,
8 which shall be adjusted for
9 inflation annually to reflect
10 the rate of change in the
11 Consumer Price Index for
12 All Urban Consumers pub-
13 lished by the Bureau of
14 Labor Statistics and deter-
15 mined by the subrecipient
16 and approved by the covered
17 entity providing such con-
18 tribution in a manner speci-
19 fied by the Secretary;

20 “(CC) are specifically
21 identifiable and provided by
22 such covered entity directly
23 to such subrecipient; and

24 “(DD) directly support
25 the provision of health care

1 items and services by such
2 subrecipient solely to indi-
3 viduals within the scope and
4 time period of the Federal
5 grant that qualifies such
6 covered entity for participa-
7 tion in the program under
8 this section.

9 “(II) EXCLUSION.—The require-
10 ment specified in subclause
11 (I)(bb)(BB) shall not apply with re-
12 spect to a subrecipient of a Federal
13 grant that receives in-kind contribu-
14 tions from a covered entity described
15 in paragraph (4)(K) if—

16 “(aa) as of January 1,
17 2025, such subrecipient is par-
18 ticipating in the program under
19 this section as such a sub-
20 recipient and is in compliance
21 with all requirements under this
22 section otherwise applicable to
23 such subrecipient; and

24 “(bb) with respect to any in-
25 kind contribution such sub-

1 recipient receives after January
2 1, 2025, such subrecipient has
3 continuously participated in the
4 program under this section as
5 such a subrecipient in compliance
6 with all requirements under this
7 section for the period beginning
8 on January 1, 2025, and con-
9 tinuing through the date on
10 which program participation ends
11 as determined in the plan sub-
12 mitted to the Secretary pursuant
13 to clause (ii)(V)(bb) or any such
14 earlier date on which program
15 participation ends.

16 “(iv) RULE OF CONSTRUCTION.—For
17 purposes of this section, any subgrantee
18 that is not itself a covered entity described
19 in one of subparagraphs (A) through (K)
20 of paragraph (4) shall be subject to the ob-
21 ligations under this section applicable to
22 the covered entity with which such sub-
23 grantee has an enforceable written agree-
24 ment pursuant to clause (i). Further, for
25 purposes of this section, each registered

1 site of such subgrantee shall be subject to
2 the requirements set forth in subparagraph
3 (F) as if such site were the covered entity
4 with which such subgrantee has an en-
5 forceable written agreement pursuant to
6 clause (i).”.

7 **SEC. 14. EFFECTIVE DATE.**

8 (a) IN GENERAL.—Except as otherwise expressly
9 provided in this Act, the amendments made by this Act
10 shall take effect on the date of enactment of this Act.

11 (b) REGULATIONS; TRANSITION PERIOD.—

12 (1) REGULATIONS.—Not later than 180 days
13 after the date of enactment of this Act, the Sec-
14 retary shall, through notice and comment rule-
15 making, promulgate such final regulations as are
16 necessary to implement this Act and the amend-
17 ments made by this Act, including any such regula-
18 tions required elsewhere in this Act or in amend-
19 ments made by this Act.

20 (2) TRANSITION PERIOD.—In promulgating the
21 regulations required under paragraph (1), the Sec-
22 retary shall establish appropriate transition periods
23 for covered entities, manufacturers, contract phar-
24 macies, and other affected parties to come into com-
25 pliance with the requirements imposed by this Act

1 and the amendments made by this Act. Such transi-
2 tion periods shall not be less than 180 days from the
3 date of enactment for any substantive new compli-
4 ance obligation imposed on a covered entity or man-
5 ufacturer by this Act, unless a longer or shorter
6 transition period is specifically provided elsewhere in
7 this Act.

8 (c) CONSTRUCTION.—Any reference in this Act to the
9 “date of enactment of this section” shall be construed as
10 referring to the date of enactment of this Act unless the
11 context clearly requires otherwise.