

119TH CONGRESS  
1ST SESSION

# H. R. 5256

To amend the Public Health Service Act to reform the 340B drug pricing program, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 10, 2025

Mr. CARTER of Georgia (for himself and Mrs. HARSHBARGER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend the Public Health Service Act to reform the 340B drug pricing program, and for other purposes.

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

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

4       (a) SHORT TITLE.—This Act may be cited as the  
5       “340B Affording Care for Communities and Ensuring a  
6       Strong Safety-net Act” or the “340B ACCESS Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.
- Sec. 3. Prevention of Medicaid duplicate discounts; oversight of covered entities.
- Sec. 4. Hospital child site requirements.
- Sec. 5. Contract pharmacies.
- Sec. 6. Ensuring patient affordability of drugs purchased under section 340B.
- Sec. 7. Requirements for nonhospital covered entities and subgrantees.
- Sec. 8. Claims modifiers; covered entity data submission.
- Sec. 9. Covered entity reporting on scope of grant, contract, and project.
- Sec. 10. Ensuring covered entity transparency.
- Sec. 11. Revisions to existing 340B hospital eligibility requirements.
- Sec. 12. Additional requirements for 340B hospitals.
- Sec. 13. 340B program.
- Sec. 14. Audits of private nonhospital contracts with State and local governments.
- Sec. 15. Ensuring covered entity compliance with transparency requirements.
- Sec. 16. 340B claims data clearinghouse.
- Sec. 17. Limitation on administrator service fees and contract pharmacy fees.
- Sec. 18. Clarification.
- Sec. 19. Ensuring the equitable treatment of 340B covered entities and pharmacies participating in the 340B drug discount program.
- Sec. 20. Effective date.

## 1 **SEC. 2. DEFINITIONS.**

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

5 “(3) PATIENT.—

6 “(A) IN GENERAL.—In this section, the  
 7 term ‘patient’ means, with respect to a covered  
 8 entity described in subsection (a)(4), an indi-  
 9 vidual who, on a prescription-by-prescription or  
 10 order-by-order basis—

11 “(i) is dispensed or administered a  
 12 covered outpatient drug that is—

13 “(I) directly related to the service  
 14 described in clause (iii);

1 “(II) ordered or prescribed by a  
2 covered entity provider described in  
3 clause (ii) as a result of the service  
4 described in clause (iii); and

5 “(III) dispensed or administered  
6 on site at a covered entity location, a  
7 child site (as defined in subsection  
8 (a)(5)(E)), or an entity pharmacy (as  
9 defined in subsection (a)(5)(F)) listed  
10 in the identification system described  
11 in subsection (d)(2)(B)(iv), or on site  
12 at a contract pharmacy in accordance  
13 with subsection (a)(5)(F) or dispensed  
14 through a mail order pharmacy in ac-  
15 cordance with subsection (a)(5)(F);

16 “(ii) receives the health care service  
17 described in clause (iii) from a ‘covered en-  
18 tity provider’, meaning a health care pro-  
19 fessional who either—

20 “(I) is an employee or inde-  
21 pendent contractor of the covered en-  
22 tity, such that the covered entity bills  
23 for services furnished by the health  
24 care professional and is responsible

1 for the care furnished by such profes-  
2 sional; or

3 “(II) furnishes health care serv-  
4 ices under an ongoing contractual ob-  
5 ligation to the covered entity such  
6 that responsibility for the care pro-  
7 vided remains with the covered entity  
8 and meets the other requirements in  
9 this paragraph, in the event State law  
10 prohibits or otherwise substantially  
11 limits the ability of the covered entity  
12 to bill for services of the health care  
13 professional;

14 “(iii) receives a covered outpatient  
15 drug in connection with a health care serv-  
16 ice furnished at the covered entity (includ-  
17 ing a child site) and such drug and service  
18 are paid by the insurer or third-party  
19 payor as outpatient items and services (or  
20 where third-party reimbursement is not  
21 made, such items and services are deemed  
22 outpatient if less than 24 hours have  
23 elapsed between such individual’s hospital  
24 registration and discharge);

1 “(iv) is described in a category of in-  
2 dividuals within the scope of, and receives  
3 a health care service at the covered entity  
4 (including a child site) that is within the  
5 scope of—

6 “(I) the Federal grant, project,  
7 or Federal grant-authorizing statute,  
8 as applicable, that qualifies such enti-  
9 ty for participation in the program  
10 under this section, if the covered enti-  
11 ty is described in one of subpara-  
12 graphs (A) through (K) of subsection  
13 (a)(4); or

14 “(II) the contract as required in  
15 paragraphs (4)(L)(i) and (11) of sub-  
16 section (a), if the covered entity is a  
17 private nonprofit hospital which has,  
18 as the basis for participating in the  
19 program under this section, a contract  
20 with a State or local government to  
21 provide health care services to speci-  
22 fied individuals, provided that clause  
23 (iv) shall not apply with respect to a  
24 covered entity described in subsection  
25 (a)(4)(N) or a sole community hos-

1                   pital       described       in       subsection  
2                   (a)(4)(O); and

3                   “(v) has an ongoing relationship with  
4       the covered entity such that the covered  
5       entity creates and maintains auditable  
6       health care records which demonstrate  
7       compliance with this paragraph and that  
8       the covered entity—

9                   “(I) has a provider-to-patient re-  
10                  lationship with the individual;

11                  “(II) is responsible for the indi-  
12                  vidual’s health care service that re-  
13                  sulted in the prescription or order for  
14                  the drug; and

15                  “(III)(aa) has provided a health  
16                  care service to the individual through  
17                  an in-person visit within the past 12  
18                  months, if the covered entity is a hos-  
19                  pital described in subparagraph (L) or  
20                  subparagraph (M) of subsection (a)(4)  
21                  or is a rural referral center described  
22                  in subparagraph (O) of such sub-  
23                  section; or

24                  “(bb) has provided a health care  
25                  service to the individual through an

1 in-person visit within the past 24  
2 months, if the covered entity is de-  
3 scribed in one of subparagraphs (A)  
4 through (K) of subsection (a)(4), sub-  
5 paragraph (N) of such subsection, or  
6 is a sole community hospital described  
7 in subparagraph (O) of such sub-  
8 section.

9 “(B) TELEHEALTH AND TELEMEDICINE.—

10 “(i) IN GENERAL.—A prescription for  
11 a covered outpatient drug resulting from a  
12 health care service furnished to an indi-  
13 vidual through telehealth, telemedicine, or  
14 other remote health care service arrange-  
15 ments shall not qualify for pricing de-  
16 scribed in subsection (a)(1) unless—

17 “(I) the covered entity (including  
18 child site, as applicable) at which such  
19 service is furnished is a covered entity  
20 (or a child site of a covered entity, as  
21 applicable) described in one of sub-  
22 paragraphs (A) through (K) of sub-  
23 section (a)(4), subparagraph (N) of  
24 such subsection, or is a sole commu-

nity hospital described in subparagraph (O) of such subsection; and

“(II) subject to the exception in clause (ii), a covered entity provider has conducted an in-person examination of the individual within the 6-month time period immediately preceding the health care service resulting in the prescription or order for the drug.

“(ii) EXCEPTION.—The requirement in clause (i)(II) shall not apply with respect to an individual for whom the covered entity maintains auditable records sufficient to demonstrate that such entity verified such individual is determined eligible for benefits under either title II of the Social Security Act or title XVI of such Act in accordance with the provisions of such applicable title.

“(C) PRESCRIPTIONS FROM NON-COVERED ENTITY PROVIDERS INELIGIBLE.—

“(i) IN GENERAL.—Subject to the exception for care coordination described in clause (ii), a covered outpatient drug pre-



scribed or ordered for an individual by a health care professional who is not a covered entity provider shall not qualify for pricing described in subsection (a)(1).

“(ii) EXCEPTION FOR CARE COORDINATION.—In the case of a covered outpatient drug prescribed or ordered for an individual resulting from care coordination provided by the covered entity, all requirements in subparagraph (A) shall apply, except for clauses (i)(I), (i)(II), (ii), (iii), and (v)(II) of such subparagraph. For purposes of this paragraph, ‘care coordination’ shall refer to the sequence of occurrences described in this clause for which a covered entity maintains documentation sufficient to demonstrate that—

“(I) a covered entity provider evaluates and recommends to the individual, during an encounter at the covered entity (including child site, as applicable), that such individual receive a specified type of specialty health care not available at the covered entity and such recommendation

1 is contemporaneously documented, at  
2 the time of such encounter, in the  
3 medical record the covered entity cre-  
4 ates and maintains for such indi-  
5 vidual;

6 “(II) within one year of the date  
7 of the encounter and recommendation  
8 described in subclause (I), the indi-  
9 vidual receives a health care service  
10 from a medical specialist of the type  
11 described in such recommendation;

12 “(III) within the time period  
13 specified in subclause (II), the covered  
14 entity provider making the rec-  
15 ommendation receives, directly from  
16 the medical specialist that furnishes  
17 the health care service described in  
18 subclause (II), written documentation  
19 specifying the service or services fur-  
20 nished to such individual and the di-  
21 agnoses made in connection with such  
22 service or services; and

23 “(IV) the covered entity retains  
24 overall responsibility for the care of  
25 the individual.

1 “(iii) COVERED ENTITY ELIGIBILITY  
2 FOR CARE COORDINATION.—Notwith-  
3 standing any other provision in this sec-  
4 tion, a covered entity shall not qualify for  
5 pricing described in subsection (a)(1) with  
6 respect to a prescription or order for a cov-  
7 ered outpatient drug resulting from care  
8 coordination provided by the covered entity  
9 unless such covered entity—

10 “(I) is described in subparagraph  
11 (N) of subsection (a)(4);

12 “(II) is a sole community hos-  
13 pital described in subparagraph (O) of  
14 such subsection; or

15 “(III) is described in one of sub-  
16 paragraphs (A) through (K) of such  
17 subsection, is not a specified nonhos-  
18 pital covered entity (as defined in sub-  
19 section (b)(4)), and has a Federal  
20 grant that requires such entity to con-  
21 tract or refer for the health care serv-  
22 ice or services furnished to the indi-  
23 vidual by the medical specialist de-  
24 scribed in clause (ii).

1                   “(D) HEALTH CARE SERVICE RE-  
 2                   QUIRED.—For purposes of this section, an indi-  
 3                   vidual shall not be considered a patient of the  
 4                   covered entity described in subsection (a)(4) if  
 5                   the individual receives from the covered entity  
 6                   only the administration or infusion of a drug or  
 7                   drugs, or the dispensing of a drug or drugs for  
 8                   subsequent self-administration or administra-  
 9                   tion in the home setting, without a covered enti-  
 10                  ty provider-to-patient encounter involving the  
 11                  provision of a health care service.”.

12           (b) DEFINITION OF SPECIFIED NONHOSPITAL COV-  
 13   ERED ENTITY.—Section 340B(b) of the Public Health  
 14   Service Act (42 U.S.C. 256b(b)) is further amended by  
 15   adding at the end the following:

16                   “(4) SPECIFIED NONHOSPITAL COVERED ENTI-  
 17                  TY.—In this section, the term ‘specified nonhospital  
 18                  covered entity’ means a covered entity that—

19                   “(A) is described in one of subparagraphs  
 20                  (B) through (K) of subsection (a)(4), other  
 21                  than a covered entity described in subparagraph  
 22                  (G) of such subsection, and—

23                   “(i) has average annual operating rev-  
 24                  enues exceeding \$1,000,000,000 calculated  
 25                  over the most recent three-year period for

1 which data are available, which revenue  
 2 threshold shall be adjusted for inflation an-  
 3 nually to reflect rate of change in the Con-  
 4 sumer Price Index for All Urban Con-  
 5 sumers published by the Bureau of Labor  
 6 Statistics; or

7 “(ii) is an affiliate of a hospital; or

8 “(B) is described in subsection (a)(4)(A)

9 and becomes affiliated with a hospital on or  
 10 after December 1, 2024.

11 For purposes of this definition, the term ‘affiliate’  
 12 shall mean an entity that, directly or indirectly, con-  
 13 trols, is controlled by, or is under common control  
 14 with the referenced entity, including the referenced  
 15 entity’s parent, and the term ‘control’ shall mean  
 16 the power to direct the management and policies of  
 17 an entity, directly or indirectly, whether through the  
 18 ownership of voting securities, by contract, or other-  
 19 wise.”.

20 **SEC. 3. PREVENTION OF MEDICAID DUPLICATE DIS-**  
 21 **COUNTS; OVERSIGHT OF COVERED ENTITIES.**

22 Section 340B(a)(5) of the Public Health Service Act  
 23 (42 U.S.C. 256b(a)(5)) is amended—

24 (1) in subparagraph (A)—

1 (A) in clause (ii), by striking “The Sec-  
2 retary” and inserting “Subject to subsection  
3 (d)(2)(C), the Secretary”; and

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

5 “(iii) REGULATIONS.—Not later than  
6 1 year after the date of enactment of this  
7 clause, the Secretary shall promulgate final  
8 regulations through notice-and-comment  
9 rulemaking describing—

10 “(I) methodologies State Med-  
11 icaid programs and all covered entities  
12 under subsection (a)(4), and their  
13 contract pharmacies, shall use to iden-  
14 tify and bill drugs purchased under  
15 the 340B program in a manner that  
16 ensures compliance with applicable  
17 prohibitions regarding duplicate dis-  
18 counts or rebates, including the dupli-  
19 cate discount prohibition under this  
20 subparagraph and the prohibitions  
21 under sections 1927(j)(1) and  
22 1903(m)(2)(A)(xiii) of the Social Se-  
23 curity Act, to include the application  
24 of such prohibitions to 340B drugs

1 used by Medicaid managed care en-  
2 rollees; and

3 “(II) procedures State Medicaid  
4 programs shall use to exclude requests  
5 for Medicaid rebates on covered out-  
6 patient drugs purchased under the  
7 340B program that are dispensed, ad-  
8 ministered, or otherwise furnished to  
9 a Medicaid managed care enrollee and  
10 requirements for State Medicaid pro-  
11 grams to promulgate rules to provide  
12 affected manufacturers a prompt rem-  
13 edy with respect to any incorrectly  
14 billed rebates for such drugs.”;

15 (2) in subparagraph (C)—

16 (A) by striking “A covered entity shall per-  
17 mit” and inserting:

18 “(i) DUPLICATE DISCOUNTS AND  
19 DRUG RESALE.—A covered entity shall per-  
20 mit”;

21 (B) by striking “(A) or (B)” and inserting  
22 “(A), (B), (J), or (K)”;

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

24 “(ii) USE OF MARGIN.—A covered en-  
25 tity shall permit the Secretary to audit, at

the Secretary’s expense, the records of the  
entity to determine—

“(I) how the margin (as defined  
in subparagraph (L)(iv)) generated on  
covered outpatient drugs subject to an  
agreement under this section dis-  
pensed or furnished by such entity (or  
a contract pharmacy described in sub-  
section (a)(5)(F)) is used by such en-  
tity; and

“(II) such entity’s compliance  
with subparagraph (L).

“(iii) RECORDS RETENTION.—Covered  
entities shall retain such records and pro-  
vide such records and reports as deter-  
mined necessary by the Secretary for car-  
rying out this subparagraph.”; and

(3) in subparagraph (D), by striking “(A) or  
(B)” and inserting “(A), (B), (J), or (K)”.

#### **SEC. 4. HOSPITAL CHILD SITE REQUIREMENTS.**

(a) HOSPITAL CHILD SITE REQUIREMENTS.—Sec-  
tion 340B(a)(5) of the Public Health Service Act (42  
U.S.C. 256b(a)(5)) is amended by adding at the end the  
following:



1           “(E) HOSPITAL CHILD SITE REQUIRE-  
2           MENTS.—

3           “(i) IN GENERAL.—A covered entity  
4           described in one of subparagraphs (L)  
5           through (O) of paragraph (4) may register  
6           an off-campus outpatient facility associated  
7           with such covered entity for inclusion in  
8           the identification system described in sub-  
9           section (d)(2)(B)(iv) to participate in the  
10          program under this section as an integral  
11          part of such covered entity if such covered  
12          entity demonstrates to the Secretary, in a  
13          manner specified by the Secretary, that  
14          such facility satisfies each of the require-  
15          ments in this subparagraph. For purposes  
16          of this section, each facility registered to  
17          participate in the program under this sec-  
18          tion and satisfying the requirements in this  
19          subparagraph shall be referred to as a  
20          ‘child site’.

21          “(I) The facility is listed on the  
22          covered entity’s most recently filed  
23          Medicare cost report on a line that is  
24          reimbursable under the Medicare pro-  
25          gram (or, if the covered entity is a

1 children’s hospital that does not file a  
2 Medicare cost report, the covered enti-  
3 ty submits to the Secretary a signed  
4 statement certifying that the facility  
5 would be correctly included on a reim-  
6 bursable line of a Medicare cost report  
7 if the covered entity filed a cost re-  
8 port).

9 “(II) Such cost report dem-  
10 onstrates that the services provided at  
11 the facility have associated costs and  
12 charges for hospital outpatient depart-  
13 ment services under title XVIII of the  
14 Social Security Act (or, if the covered  
15 entity is a children’s hospital that  
16 does not file a Medicare cost report,  
17 the covered entity submits to the Sec-  
18 retary a signed statement certifying  
19 that the services provided at the facil-  
20 ity include outpatient services).

21 “(III) The facility is wholly  
22 owned by the covered entity.

23 “(IV) The Secretary has made a  
24 determination, under the process de-  
25 scribed in section 413.65(b) of title

1 42, Code of Federal Regulations (or  
2 any successor regulations), that the  
3 facility meets the Medicare provider-  
4 based standards under section 413.65  
5 of title 42, Code of Federal Regula-  
6 tions (or any successor regulations)  
7 for an off-campus outpatient depart-  
8 ment of the covered entity.

9 “(V) The facility provides out-  
10 patient health care services that are  
11 not limited to only dispensing, admin-  
12 istering, or otherwise furnishing cov-  
13 ered outpatient drugs.

14 “(VI) The facility is subject to  
15 and adheres to all charity care and  
16 sliding fee scale policies of the covered  
17 entity and makes such policies pub-  
18 licly available in a manner consistent  
19 with requirements established under  
20 section 501(r) of the Internal Revenue  
21 Code of 1986 applicable to hospital fi-  
22 nancial assistance policies.

23 “(VII) The facility is located in  
24 an area with a shortage of personal  
25 health services that is—

1 “(aa) initially designated by  
2 the Secretary pursuant to section  
3 254b(b)(3) of title 42, United  
4 States Code, on or before Decem-  
5 ber 1, 2024; or

6 “(bb) designated by the Sec-  
7 retary pursuant to subpara-  
8 graphs (A) through (C) of section  
9 254b(b)(3) of title 42, United  
10 States Code, after December 1,  
11 2024, using the scoring method-  
12 ology and criteria specified by the  
13 Secretary as of December 1,  
14 2024.

15 “(VIII) In the case of a covered  
16 entity described in one of subpara-  
17 graphs (L) through (O) of paragraph  
18 (4) that is a private nonprofit hospital  
19 that has, as the basis for its participa-  
20 tion in the program under this sec-  
21 tion, a contract with a State or local  
22 government to provide health care  
23 services to low-income individuals who  
24 are uninsured, as described in para-  
25 graphs (4)(L)(i) and (11), the facility

1 independently complies with all re-  
2 quirements applicable to such covered  
3 entity with respect to such contract.

4 “(IX) For the most recent year,  
5 the facility’s total cost incurred for  
6 charity care (as such term is defined  
7 in line 23 of worksheet S–10 to the  
8 Medicare cost report, or in any suc-  
9 cessor form) furnished at such facility  
10 during such year, as a share of the fa-  
11 cility’s total patient service revenue, is  
12 greater than or equal to the amount  
13 described in item (aa) or item (bb),  
14 whichever is greater—

15 “(aa) for such year, the  
16 total cost incurred for charity  
17 care, as a share of total patient  
18 service revenue, furnished at the  
19 covered entity’s on-campus loca-  
20 tions (as ‘campus’ is defined in  
21 section 413.65(a)(2) of title 42,  
22 Code of Federal Regulations (or  
23 any successor regulations)); or

24 “(bb) the average cost in-  
25 curred for charity care, as a

1 share of total patient service rev-  
2 enue, calculated for the year  
3 prior to the most recent year for  
4 which data is available, across all  
5 hospitals in the State where the  
6 facility is located that receive  
7 payments for inpatient hospital  
8 services under the prospective  
9 payment system established  
10 under section 1886(d) of the So-  
11 cial Security Act.

12 “(X) For the most recent year,  
13 the facility’s share of total outpatient  
14 services revenue derived from base re-  
15 imbursement to such entity (excluding  
16 supplemental and indirect reimburse-  
17 ment) under title XIX of the Social  
18 Security Act (including with respect  
19 to individuals also entitled to benefits  
20 under part A of title XVIII of such  
21 Act or enrolled in part B of title  
22 XVIII of such Act) and payments  
23 under title XXI of such Act for items  
24 and services furnished on an out-  
25 patient basis at the facility (including

1 any cost sharing for such items and  
2 services) is greater than or equal to  
3 the amount described in item (aa) or  
4 item (bb), whichever is greater—

5 “(aa) for such year, the  
6 share of total outpatient services  
7 revenue derived from base reim-  
8 bursement to such entity (exclud-  
9 ing supplemental and indirect re-  
10 imbursement) under title XIX of  
11 the Social Security Act (including  
12 with respect to individuals also  
13 entitled to benefits under part A  
14 of title XVIII of such Act or en-  
15 rolled in part B of title XVIII of  
16 such Act) and payments under  
17 title XXI of such Act for items  
18 and services furnished on an out-  
19 patient basis at the on-campus  
20 locations of the covered entity  
21 with which the facility is associ-  
22 ated (including any cost sharing  
23 for such items and services)  
24 (‘campus’ shall have the meaning  
25 given such term in section

1 413.65(a)(2) of title 42, Code of  
2 Federal Regulations (or any suc-  
3 cessor regulations)); or

4 “(bb) the average share of  
5 total outpatient services revenue  
6 derived from base reimbursement  
7 (excluding supplemental and indi-  
8 rect reimbursement) under title  
9 XIX of the Social Security Act  
10 (including with respect to individ-  
11 uals also entitled to benefits  
12 under part A of title XVIII of  
13 such Act or enrolled in part B of  
14 title XVIII of such Act) and pay-  
15 ments under title XXI of such  
16 Act for items and services fur-  
17 nished on an outpatient basis (in-  
18 cluding any cost sharing for such  
19 items and services), calculated  
20 for the year prior to the most re-  
21 cent year for which data is avail-  
22 able, across all hospitals in the  
23 state where the facility is located  
24 that receive payments for out-  
25 patient hospital services under



1 the prospective payment system  
2 for covered outpatient depart-  
3 ment services established under  
4 section 1833(t) of such Act.

5 “(XI) The covered entity cer-  
6 tifies, at the time such facility is ini-  
7 tially registered for inclusion in the  
8 identification system described in sub-  
9 section (d)(2)(B)(iv) to participate in  
10 the drug pricing program under this  
11 section and annually thereafter as  
12 part of the recertification process,  
13 that the facility satisfies all applicable  
14 requirements under this subpara-  
15 graph.

16 “(ii) LIMITATION.—Only an off-cam-  
17 pus outpatient facility that meets each of  
18 the requirements under this subparagraph  
19 may purchase covered outpatient drugs  
20 under the 340B program or use covered  
21 outpatient drugs purchased under the  
22 340B program by another part of the cov-  
23 ered entity that is authorized to participate  
24 in such program. Any transfer of 340B  
25 drugs to another facility or another part of

1 a covered entity that is not authorized to  
2 participate in the 340B program shall be  
3 deemed a violation of subparagraph (B).

4 “(iii) DEREGISTRATION.—If at any  
5 time following registration a requirement  
6 described in clause (i) is no longer fully  
7 satisfied with respect to a facility, the cov-  
8 ered entity described in such clause shall  
9 immediately notify the Secretary that such  
10 facility no longer fully satisfies the relevant  
11 requirement, deregister the facility from  
12 the program under this section, remove the  
13 facility from the identification system de-  
14 scribed in subsection (d)(2)(B)(iv), and  
15 take all necessary actions to prohibit such  
16 facility from making any purchases under  
17 the program under this section or rep-  
18 resenting to third parties that such facility  
19 may purchase covered outpatient drugs  
20 under such program.

21 “(iv) OBLIGATION TO SELF-DIS-  
22 CLOSE.—A covered entity described in  
23 clause (i) shall immediately disclose to the  
24 Secretary and the manufacturer of the af-  
25 fected covered outpatient drug any pur-

1 chase made under the program under this  
2 section by or on behalf of the covered enti-  
3 ty with respect to a facility that, at the  
4 time of the purchase of such drug, did not  
5 fully satisfy the requirements in such  
6 clause. Any such purchase shall require the  
7 covered entity to promptly conduct an  
8 audit supervised by the Secretary to iden-  
9 tify the full scope of noncompliance with  
10 such requirements and to provide the writ-  
11 ten results of such audit to the Secretary  
12 and the manufacturer of the affected cov-  
13 ered outpatient drug. The covered entity  
14 shall be liable to the manufacturer of the  
15 covered outpatient drug that is the subject  
16 of the noncompliance in an amount equal  
17 to the reduction in the price of the drugs  
18 provided under paragraph (1), plus inter-  
19 est on such amount, which shall be com-  
20 pounded monthly and equal to the current  
21 short-term interest rate as determined by  
22 the Federal Reserve for the time period for  
23 which the covered entity is liable.

24 “(v) CIVIL MONETARY PENALTY.—

25 Where a covered entity knowingly and in-

1 tentionally violates clause (ii) or otherwise  
2 fails to satisfy a requirement in clause (iii)  
3 or clause (iv), the covered entity shall be  
4 required to pay a civil monetary penalty  
5 equal to \$2,500 for each such violation,  
6 which amount shall be adjusted for infla-  
7 tion annually to reflect the rate of change  
8 in the Consumer Price Index for All Urban  
9 Consumers published by the Bureau of  
10 Labor Statistics. The provisions of section  
11 1128A of the Social Security Act (other  
12 than subsections (a) and (b)) shall apply to  
13 a civil monetary penalty under this clause  
14 in the same manner as such provisions  
15 apply to a penalty or proceeding under sec-  
16 tion 1128A(a). The Office of Inspector  
17 General of the Department of Health and  
18 Human Services shall carry out the provi-  
19 sions related to the imposition of civil mon-  
20 etary penalties under this clause.

21 “(vi) SECRETARIAL PUBLICATION OF  
22 REPORTS.—On an annual basis, the Sec-  
23 retary shall prepare and make available to  
24 the public in an electronic, machine read-  
25 able format separate reports listing facili-

1                   ties that satisfy the requirements in each  
2                   of subclauses (IX) and (X) of clause (i).”.

3           (b) EFFECTIVE DATE.—The provisions in section  
4 340B(a)(5)(E) of the Public Health Service Act, as added  
5 by this Act, shall become effective 120 days after the date  
6 of enactment of this Act.

7           (c) IMPLEMENTATION OF HOSPITAL CHILD SITE  
8 STANDARDS.—Not later than 60 days prior to the effec-  
9 tive date of section 340B(a)(5)(E) of the Public Health  
10 Service Act, as added by this Act, the Secretary shall issue  
11 program instructions directing each covered entity de-  
12 scribed in section 340B(a)(5)(E)(i) of the Public Health  
13 Service Act, as amended by this Act, to, before the effec-  
14 tive date of section 340B(a)(5)(E) of the Public Health  
15 Service Act, as added by this Act, register in the identi-  
16 fication system described in section 340B(d)(2)(B)(iv) of  
17 the Public Health Service Act, or update existing registra-  
18 tions in such system for, off-campus outpatient facilities  
19 associated with such covered entity that satisfy the re-  
20 quirements in such section. Such instructions shall direct  
21 each such covered entity to, on or before the effective date  
22 of section 340B(a)(5)(E) of the Public Health Service Act,  
23 as added by this Act, remove from such system the exist-  
24 ing registration of any off-campus outpatient facility asso-  
25 ciated with such covered entity that does not satisfy the

1 requirements in section 340B(a)(5)(E)(i) of the Public  
 2 Health Service Act. Clauses (iii) through (v) of section  
 3 340B(a)(5)(E) of the Public Health Service Act shall  
 4 apply with respect to any covered entity described in one  
 5 of subparagraphs (L) through (O) of section 340B(a)(4)  
 6 of the Public Health Service Act that fails to remove a  
 7 facility described in the immediately preceding sentence on  
 8 or before the effective date of section 340B(a)(5)(E) of  
 9 the Public Health Service Act, as added by this Act.

10 **SEC. 5. CONTRACT PHARMACIES.**

11 Section 340B(a)(5) of the Public Health Service Act  
 12 (42 U.S.C. 256b(a)(5)) is further amended by adding at  
 13 the end the following:

14 “(F) CONTRACT PHARMACIES.—

15 “(i) IN GENERAL.—Subject to the  
 16 conditions set forth in this subparagraph,  
 17 a covered entity may enter into written  
 18 agreements with contract pharmacies to  
 19 dispense to patients of such entity covered  
 20 outpatient drugs purchased by such entity  
 21 under the 340B program. Subject to such  
 22 conditions, a manufacturer of covered out-  
 23 patient drugs shall ship or facilitate ship-  
 24 ment of such drugs to contract pharmacies  
 25 at the request of such covered entity. Ex-

cept with respect to covered outpatient drugs shipped to and dispensed by a contract pharmacy as provided in this subparagraph, and notwithstanding any other provision in this section, a manufacturer of covered outpatient drugs shall have no obligation to pay a discount or rebate under this section with respect to covered outpatient drugs delivered or otherwise transferred to any location other than a registered address of the covered entity (including an entity pharmacy or child site, as applicable) listed in the identification system described in subsection (d)(2)(B)(iv).

“(ii) CONDITIONS FOR COVERED ENTITY USE OF CONTRACT PHARMACIES.—In order for a covered entity to enter into a written agreement with a contract pharmacy to dispense to patients of such entity covered outpatient drugs purchased by such entity under the program under this section, the entity shall—

“(I)(aa) be described in one of subparagraphs (A) through (K) of paragraph (4) and purchase covered

1 outpatient drugs for its patients with-  
2 in the scope of the Federal grant,  
3 project, or Federal grant-authorizing  
4 statute, as applicable, that qualifies  
5 such entity for participation in the  
6 program under this section; or

7 “(bb) be described in one of sub-  
8 paragraphs (L) through (O) of para-  
9 graph (4);

10 “(II) establish and implement  
11 compliance procedures to satisfy the  
12 requirements described in subpara-  
13 graphs (A), (B), (G) (as applicable),  
14 (H) (as applicable), (J), and (K) of  
15 paragraph (5) and section 1193(d) of  
16 the Social Security Act with respect to  
17 covered outpatient drugs purchased by  
18 the covered entity under this section,  
19 including with respect to such drugs  
20 dispensed by a contract pharmacy,  
21 which compliance procedures shall be  
22 considered records of the covered enti-  
23 ty subject to audit under subpara-  
24 graph (C);



“(III) prior to purchasing covered outpatient drugs subject to an agreement under this section to be shipped to or dispensed by such pharmacy, register such pharmacy in the identification system described in subsection (d)(2)(B)(iv) as a contract pharmacy, to include such pharmacy’s national provider identifier, and certify to the Secretary upon initial registration of such pharmacy in such system and annually thereafter that such pharmacy complies with all requirements under this subparagraph, including the covered entity compliance procedures described in subclause (II); and

“(IV) as applicable, comply with the requirements and limitations set forth in clauses (iii) through (vii) of this subparagraph.

“(iii) LIMITATION ON CONTRACT PHARMACIES FOR CERTAIN HOSPITAL COVERED ENTITIES.—Notwithstanding clause (ii), a covered entity described in para-

graph (4)(L), a free-standing cancer hospital described in paragraph (4)(M), and a rural referral center described in paragraph (4)(O) may not enter into written agreements with more than 5 contract pharmacies to dispense covered outpatient drugs purchased by the covered entity under this section to patients of such entity under this subparagraph. For purposes of this clause, a contract pharmacy shall not include a mail order pharmacy.

“(iv) SERVICE AREA REQUIREMENT FOR ELIGIBLE CONTRACT PHARMACIES.— A contract pharmacy with which a covered entity enters into a written agreement to dispense covered outpatient drugs to patients of such entity subject to the conditions in this subparagraph shall be located in the service area of the covered entity (as defined in clause (x)(IV)). Notwithstanding any other provision in this subparagraph, this clause (iv) shall not apply with respect to a covered entity described in paragraph (4)(G) or a contract pharmacy that is a mail order pharmacy.

1 “(v) REQUIREMENTS FOR USE OF  
2 MAIL ORDER PHARMACIES.—

3 “(I) IN GENERAL.—Notwith-  
4 standing any other provision in this  
5 section, a covered outpatient drug  
6 subject to an agreement under this  
7 section may be dispensed to a patient  
8 of a covered entity through a mail  
9 order pharmacy only if—

10 “(aa) the covered entity dis-  
11 pensing such drug (or on whose  
12 behalf such drug is dispensed)  
13 through a mail order pharmacy  
14 to such a patient is described in  
15 one of subparagraphs (A)  
16 through (K) of paragraph (4),  
17 such entity is not a specified non-  
18 hospital covered entity (as de-  
19 fined in subsection (b)(4)), and,  
20 except for a covered entity de-  
21 scribed in subparagraph (G) of  
22 such subsection, the patient dis-  
23 pensed such drug resides within  
24 the service area of the covered

entity (as defined in clause (x)(IV)); or

“(bb) the covered entity dispensing such drug (or on whose behalf such drug is dispensed) through a mail order pharmacy to such a patient is described in subparagraph (N) of paragraph (4) or is a sole community hospital described in subparagraph (O) of such paragraph, and the patient dispensed such drug resides in a county that is not part of a Metropolitan Statistical Area, as defined by the Office of Management and Budget.

“(II) REQUIREMENTS FOR USE OF MAIL ORDER CONTRACT PHARMACIES.—Subject to the conditions set forth in this subparagraph, a covered entity described in item (aa) or (bb) of subclause (I) may enter into written agreements with contract pharmacies that are mail order pharmacies to dispense to patients de-

scribed in such relevant clause covered  
outpatient drugs purchased by such  
entity under the 340B program.

“(vi) REQUIREMENTS FOR COVERED  
ENTITY COMPLIANCE PROCEDURES AND  
WRITTEN AGREEMENTS.—Not later than  
180 days following the date of enactment  
of the 340B ACCESS Act, the Secretary  
shall issue guidance to covered entities  
specifying requirements for—

“(I) covered entity compliance  
procedures described in clause (ii)(II)  
that the Secretary determines are suf-  
ficient to ensure that covered out-  
patient drugs are not subject to dupli-  
cate discounts in violation of sub-  
section (a)(5)(A) (including with re-  
spect to such drugs used by Medicaid  
managed care enrollees), that such  
drugs cannot be resold or otherwise  
transferred to persons who do not  
meet the definition of a patient of the  
covered entity in violation of subpara-  
graph (B), that the patient afford-  
ability requirements specified in sub-

1 paragraphs (G) and (H), as applica-  
2 ble, are appropriately applied at the  
3 point of drug dispense or administra-  
4 tion, that data and other information  
5 is submitted in accordance with sub-  
6 paragraphs (J) and (K), and that the  
7 nonduplication requirement in section  
8 1193(d) of the Social Security Act is  
9 satisfied; and

10 “(II) written agreements between  
11 covered entities and contract phar-  
12 macies described in clause (vii).

13 “(vii) WRITTEN AGREEMENT RE-  
14 QUIRED.—The written agreement between  
15 a covered entity and a contract pharmacy  
16 described in this subparagraph shall in-  
17 clude binding and enforceable obligations  
18 on the contract pharmacy to comply with  
19 the covered entity’s compliance procedures  
20 described in clause (ii)(II) with respect to  
21 covered outpatient drugs dispensed to pa-  
22 tients of such entity in accordance with  
23 this subparagraph. Within 30 days of the  
24 applicable effective date of such written  
25 agreement, including any amendment or

1           addendum thereto, the covered entity shall  
2           submit a copy of the agreement, together  
3           with any amendments or addenda, to the  
4           Secretary in a form and manner specified  
5           by the Secretary. The Secretary shall re-  
6           view all such agreements, including amend-  
7           ments and addenda, for compliance with  
8           the requirements set forth in this subpara-  
9           graph and may require a covered entity  
10          and contract pharmacy to modify an agree-  
11          ment to conform to the requirements of  
12          this subparagraph. Such agreements, in-  
13          cluding amendments and addenda, shall be  
14          considered records of the covered entity  
15          subject to audit under subparagraph (C).

16               “(viii) CLARIFICATION FOR COVERED  
17          OUTPATIENT DRUGS SUBJECT TO RE-  
18          STRICTED           DISTRIBUTION.—Notwith-  
19          standing any other provision in this sec-  
20          tion, a manufacturer of a covered out-  
21          patient drug requiring exclusive use of a  
22          specialty pharmacy or a restricted distribu-  
23          tion network shall be deemed to have satis-  
24          fied its obligations under this subpara-  
25          graph with respect to a contract pharmacy

1 if such manufacturer offers each covered  
2 entity such drug for purchase at or below  
3 the applicable ceiling price described in  
4 paragraph (1) through a wholesaler, dis-  
5 tributor, or pharmacy included in the re-  
6 stricted distribution network for such drug.

7 “(ix) PENALTIES FOR CONTRACT  
8 PHARMACY COMPLIANCE VIOLATIONS.—

9 “(I) IN GENERAL.—A contract  
10 pharmacy that is found to have vio-  
11 lated the covered entity compliance  
12 procedures described in clause (ii)(II),  
13 violated subparagraph (A), or violated  
14 subparagraph (B) shall—

15 “(aa) in the first instance of  
16 such violation, be liable to a man-  
17 ufacturer of a covered outpatient  
18 drug that is the subject of such  
19 violation in an amount equal to  
20 the reduction in the price of such  
21 drug (as described in subsection  
22 (a)(1)), plus interest on such  
23 amount, which shall be com-  
24 pounded monthly and equal to  
25 the current short-term interest



1 rate as determined by the Fed-  
2 eral Reserve for the time period  
3 for which the covered entity is  
4 liable;

5 “(bb) in the second instance  
6 of such violation—

7 “(AA) be liable to a  
8 manufacturer of a covered  
9 outpatient drug that is the  
10 subject of such violation in  
11 an amount equal to the re-  
12 duction in the price of the  
13 drug (as described in para-  
14 graph (1)), plus interest on  
15 such amount, which shall be  
16 calculated in the manner  
17 specified in item (aa); and

18 “(BB) be required to  
19 pay a civil monetary penalty  
20 equal to \$3,000 for each  
21 claim for a covered out-  
22 patient drug that is subject  
23 to the violation, which  
24 amount shall be adjusted for  
25 inflation annually to reflect

1 the rate of change in the  
2 Consumer Price Index for  
3 All Urban Consumers pub-  
4 lished by the Bureau of  
5 Labor Statistics; and

6 “(cc) in the third instance of  
7 such violation—

8 “(AA) be liable to a  
9 manufacturer of a covered  
10 outpatient drug that is the  
11 subject of such violation in  
12 an amount equal to the re-  
13 duction in the price of the  
14 drug (as described in para-  
15 graph (1)), plus interest on  
16 such amount, which shall be  
17 calculated in the manner  
18 specified in item (aa);

19 “(BB) be required to  
20 pay a civil monetary penalty  
21 equal to \$3,000 for each  
22 claim for a covered out-  
23 patient drug that is subject  
24 to the violation, which  
25 amount shall be adjusted for

1                   inflation annually to reflect  
2                   the rate of change in the  
3                   Consumer Price Index for  
4                   All Urban Consumers pub-  
5                   lished by the Bureau of  
6                   Labor Statistics; and  
7                   “(CC) be removed from  
8                   the program under this sec-  
9                   tion and disqualified from  
10                  reentry into such program  
11                  for a period of not less than  
12                  two years, or such longer pe-  
13                  riod as the Secretary may  
14                  determine based on the se-  
15                  verity of the violation (or  
16                  violations) and the risk such  
17                  pharmacy presents to the in-  
18                  tegrity of the program, with  
19                  no ability to reenter the pro-  
20                  gram unless and until the  
21                  Secretary determines such  
22                  pharmacy has resolved the  
23                  violation (or violations) and  
24                  taken reasonable steps to

1 prevent similar future viola-  
2 tions.

3 “(II) CORRECTIVE ACTION  
4 PLAN.—In the first instance of a vio-  
5 lation described in subclause (I)(aa),  
6 in the second instance of a violation  
7 described in subclause (I)(bb), and  
8 prior to reentry into the program fol-  
9 lowing a violation described in sub-  
10 clause (I)(cc)—

11 “(aa) the pharmacy shall  
12 conduct an internal review to  
13 identify the cause of the violation  
14 (or violations) that is inclusive of  
15 all calendar quarters within the  
16 period in which such violation (or  
17 violations) occurred and all cov-  
18 ered outpatient drugs subject to  
19 an agreement under this section  
20 dispensed during such period;

21 “(bb) the pharmacy shall  
22 prepare a written corrective ac-  
23 tion plan, in a form specified by  
24 the Secretary, which shall in-  
25 clude, at a minimum, the results

1 of such internal review, the phar-  
2 macy's methodology for identi-  
3 fying the full scope of such viola-  
4 tion (or violations), and the phar-  
5 macy's proposed corrective ac-  
6 tions, and submit such plan to  
7 the Secretary in a form and man-  
8 ner specified by the Secretary;  
9 and

10 “(cc) the Secretary shall re-  
11 view such plan, notify the phar-  
12 macy of any revisions to such  
13 plan, including additional correc-  
14 tive actions, necessary for the  
15 Secretary to approve such plan,  
16 and publish the approved plan on  
17 a public website of the Depart-  
18 ment of Health and Human  
19 Services (with redactions of any  
20 confidential or proprietary infor-  
21 mation).

22 “(III) CIVIL MONETARY PENALTY  
23 FOR VIOLATIONS BY REMOVED PHAR-  
24 MACY.—A contract pharmacy removed  
25 from the program under this section

1           pursuant to subclause (I)(cc) that dis-  
2           penses a covered outpatient drug sub-  
3           ject to an agreement under this sec-  
4           tion during a time period that such  
5           pharmacy is removed from the pro-  
6           gram and is not approved for reentry  
7           shall be required to pay a civil mone-  
8           tary penalty equal to \$3,000 for each  
9           claim for each such drug dispensed  
10          during such period, which amount  
11          shall be adjusted for inflation annu-  
12          ally to reflect the rate of change in  
13          the Consumer Price Index for All  
14          Urban Consumers published by the  
15          Bureau of Labor Statistics.

16               “(IV) PROCEDURES AND DELE-  
17               GATION.—The provisions of section  
18               1128A of the Social Security Act  
19               (other than subsections (a) and (b))  
20               shall apply for purposes of any pay-  
21               ment, civil monetary penalty, or re-  
22               moval described in this clause in the  
23               same manner as such provisions apply  
24               to a penalty or proceeding under sec-  
25               tion 1128A(a). The Office of Inspec-

1 tor General of the Department of  
2 Health and Human Services shall  
3 carry out the provisions of this clause.

4 “(x) DEFINITIONS.—In this subpara-  
5 graph:

6 “(I) CONTRACT PHARMACY.—

7 The term ‘contract pharmacy’ means,  
8 with respect to a covered entity de-  
9 scribed in clause (ii), any individual  
10 pharmacy (as determined by a na-  
11 tional provider identifier unique to the  
12 pharmacy address) that is—

13 “(aa) licensed as a phar-  
14 macy by the relevant State (or  
15 States);

16 “(bb) authorized to dispense  
17 covered outpatient drugs subject  
18 to an agreement under this sec-  
19 tion to patients of such entity (as  
20 defined in subsection (b)(3)) pur-  
21 suant to a valid written agree-  
22 ment with such entity (as de-  
23 scribed in this subparagraph);  
24 and

1                   “(cc) not an entity phar-  
2                   macy.

3                   “(II) ENTITY PHARMACY.—The  
4                   term ‘entity pharmacy’ means any in-  
5                   dividual pharmacy (as determined by  
6                   a national provider identifier unique  
7                   to the pharmacy address) that is—

8                   “(aa)(AA) licensed as a  
9                   pharmacy by the relevant State  
10                  (or States); and

11                  “(BB) the same legal entity  
12                  as the covered entity and located  
13                  within the covered entity’s service  
14                  area, if the covered entity is de-  
15                  scribed in one of subparagraphs  
16                  (A) through (K) of paragraph (4)  
17                  and is not a specified nonhospital  
18                  covered entity (as defined in sub-  
19                  section (b)(4)); or

20                  “(bb) the same legal entity  
21                  as the covered entity and located  
22                  within the covered entity’s four  
23                  walls, if the covered entity is de-  
24                  scribed in one of subparagraphs  
25                  (L) through (O) of paragraph (4)



1 or is a specified nonhospital cov-  
2 ered entity (as defined in sub-  
3 section (b)(4)).

4 “(III) MAIL ORDER PHAR-  
5 MACY.—The term ‘mail order phar-  
6 macy’ is a pharmacy that is licensed  
7 as a pharmacy by the State (or  
8 States) and that dispenses prescrip-  
9 tion medications to individuals pri-  
10 marily through the mail, as deter-  
11 mined in accordance with guidance  
12 issued by the Secretary in connection  
13 with part 447, subpart I of title 42 of  
14 the Code of Federal Regulations (or  
15 any successor regulations).

16 “(IV) SERVICE AREA.—The term  
17 ‘service area’ means, with respect to a  
18 covered entity described in paragraph  
19 (4), other than a covered entity de-  
20 scribed in subparagraph (G) of such  
21 paragraph, the Public Use Microdata  
22 Area (as defined by the United States  
23 Census Bureau) in which such entity  
24 is located and all Public Use  
25 Microdata Areas that are contiguous

1 with the Public Use Microdata Area  
2 in which such entity is located, each  
3 of which shall be listed in the identi-  
4 fication system described in subsection  
5 (d)(2)(B)(iv).

6 “(xi) RULES OF CONSTRUCTION.—

7 “(I) LOCATION.—For purposes  
8 of this subparagraph, the location of a  
9 covered entity shall be determined  
10 based on the physical address of the  
11 entity listed in the identification sys-  
12 tem described in subsection  
13 (d)(2)(B)(iv) without regard to any  
14 off-campus outpatient facilities.

15 “(II) SAME LEGAL ENTITY.—For  
16 purposes of this subparagraph, a  
17 pharmacy is the same legal entity as  
18 the covered entity if the name, owner-  
19 ship, and employer identification num-  
20 ber of the pharmacy is identical to the  
21 name, ownership, and employer identi-  
22 fication number of the covered enti-  
23 ty.”.

1 **SEC. 6. ENSURING PATIENT AFFORDABILITY OF DRUGS**  
2 **PURCHASED UNDER SECTION 340B.**

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

6 “(G) PATIENT AFFORDABILITY REQUIRE-  
7 MENTS FOR HOSPITAL COVERED ENTITIES.—

8 “(i) IN GENERAL.—Notwithstanding  
9 any other provision of law, a covered entity  
10 described in one of subparagraphs (L)  
11 through (O) of paragraph (4) shall estab-  
12 lish a sliding fee scale that results in the  
13 covered entity providing, on behalf of an  
14 eligible patient (as defined in clause (iv)),  
15 a discount that results in such patient pay-  
16 ing no more than the maximum out-of-  
17 pocket obligation (as defined in clause (ii)),  
18 with respect to each covered outpatient  
19 drug subject to an agreement under this  
20 section dispensed, furnished, or adminis-  
21 tered to such patient at such covered enti-  
22 ty, any child site, or any entity pharmacy.  
23 The sliding fee scale and related policies  
24 shall be written and posted prominently at  
25 each such covered entity location, including  
26 any child site and entity pharmacy, and

1 shall be included in any billing-related  
2 communications sent by such covered enti-  
3 ty to any patient dispensed, furnished, or  
4 administered a covered outpatient drug at  
5 such covered entity location, including any  
6 child site or entity pharmacy. Eligibility  
7 for a reduced out-of-pocket obligation pur-  
8 suant to this clause shall be based on in-  
9 surance and income information provided  
10 by the eligible patient. With respect to cov-  
11 ered outpatient drugs that are self-admin-  
12 istered by an eligible patient, the out-of-  
13 pocket reductions described in this clause  
14 shall apply at the point of sale.

15 “(ii) MAXIMUM OUT-OF-POCKET OBLI-  
16 GATION.—For each dispense or adminis-  
17 tration of a covered outpatient drug, the  
18 maximum out-of-pocket obligation for an  
19 eligible patient with family income—

20 “(I) below the Federal poverty  
21 guidelines is \$0;

22 “(II) at or above the Federal  
23 poverty guidelines but below 200 per-  
24 cent of the Federal poverty guidelines  
25 is the lesser of 20 percent of the oth-

1 otherwise applicable out-of-pocket obliga-  
2 tion or \$35, which shall be adjusted  
3 for inflation annually to reflect rate of  
4 the change in the Consumer Price  
5 Index for All Urban Consumers pub-  
6 lished by the Bureau of Labor Statis-  
7 tics; and

8 “(III) at or above 200 percent of  
9 the Federal poverty guidelines is the  
10 lesser of 30 percent of the otherwise  
11 applicable out-of-pocket obligation or  
12 \$50, which shall be adjusted for infla-  
13 tion annually to reflect rate of the  
14 change in the Consumer Price Index  
15 for All Urban Consumers published by  
16 the Bureau of Labor Statistics.

17 “(iii) APPLICABILITY TO CONTRACT  
18 PHARMACIES.—With respect to an eligible  
19 patient of a covered entity described in  
20 clause (i) dispensed a covered outpatient  
21 drug subject to an agreement under this  
22 section on behalf of such covered entity at  
23 a contract pharmacy pursuant to subpara-  
24 graph (F), such covered entity shall re-  
25 quire such contract pharmacy to provide

1 discounts to eligible patients on behalf of  
2 such covered entity and comply with all  
3 other requirements described in clauses (i)  
4 and (ii) as if such contract pharmacy were  
5 a covered entity described in clause (i).

6 “(iv) DEFINITIONS.—In this subpara-  
7 graph:

8 “(I) CHILD SITE.—The term  
9 ‘child site’ shall have the meaning  
10 given such term in subparagraph (E).

11 “(II) CONTRACT PHARMACY.—  
12 The term ‘contract pharmacy’ shall  
13 have the meaning given such term in  
14 subparagraph (F).

15 “(III) ELIGIBLE PATIENT.—The  
16 term ‘eligible patient’ means a pa-  
17 tient, as defined in subsection (b)(3),  
18 who is not covered under minimum es-  
19 sential coverage as defined under sec-  
20 tion 5000A(f) of the Internal Revenue  
21 Code of 1986 or has family income  
22 below 200 percent of the Federal pov-  
23 erty guidelines and is covered under a  
24 group health plan, health insurance  
25 coverage in the individual market or

1 group market (as such terms are de-  
2 fined in section 2791 of the Public  
3 Health Service Act) or coverage de-  
4 scribed in section 156.602(a), title 45,  
5 Code of Federal Regulations or suc-  
6 cessor regulation.

7 “(IV) ENTITY PHARMACY.—The  
8 term ‘entity pharmacy’ shall have the  
9 meaning given such term in subpara-  
10 graph (F).

11 “(V) FEDERAL POVERTY GUIDE-  
12 LINES.—The term ‘Federal poverty  
13 guidelines’ means the poverty guide-  
14 lines updated periodically in the Fed-  
15 eral Register by the Department of  
16 Health and Human Services pursuant  
17 to section 9902(2) of title 42, United  
18 States Code.

19 “(VI) OUT-OF-POCKET OBLIGA-  
20 TION.—The term ‘out-of-pocket obli-  
21 gation’ means any copayment, coin-  
22 surance, deductible, or other cost  
23 sharing amount or payment required  
24 from an eligible patient in connection  
25 with such patient’s receipt of a spe-

1           cific health care item or service, in-  
2           cluding a covered outpatient drug.

3           “(v) CIVIL MONETARY PENALTY.—A  
4           covered entity or contract pharmacy that  
5           violates a requirement of this subpara-  
6           graph shall be subject to a civil monetary  
7           penalty of \$2,500 for each such violation,  
8           which amount shall be adjusted for infla-  
9           tion annually to reflect the rate of change  
10          in the Consumer Price Index for All Urban  
11          Consumers published by the Bureau of  
12          Labor Statistics. The provisions of section  
13          1128A of the Social Security Act (other  
14          than subsections (a) and (b)) shall apply to  
15          a civil monetary penalty under this clause  
16          in the same manner as such provisions  
17          apply to a penalty or proceeding under sec-  
18          tion 1128A(a). The Office of Inspector  
19          General of the Department of Health and  
20          Human Services shall carry out the provi-  
21          sions of this clause.

22          “(vi) REGULATIONS.—The Secretary  
23          shall promulgate regulations through no-  
24          tice and comment rulemaking to implement  
25          the requirements described in this subpara-



graph and shall issue final regulations not later than 90 days after the date of enactment of this subparagraph. The authority to promulgate regulations under this clause is limited to specifying the obligations of covered entities and contract pharmacies under this subparagraph and other details necessary to carry out the requirements of this subparagraph efficiently, effectively, and in conformity with this subparagraph.

“(vii) **OIG STUDIES.**—The Office of Inspector General of the Department of Health and Human Services shall conduct and publish annual studies of covered entity (including child site and entity pharmacy) and contract pharmacy practices with respect to the requirements under this subparagraph and evaluate whether eligible patients are receiving assistance to reduce their out-of-pocket obligations in accordance with this subparagraph.

“(H) **PATIENT AFFORDABILITY REQUIREMENTS FOR CERTAIN NONHOSPITAL COVERED ENTITIES.**—

1           “(i) IN GENERAL.—Notwithstanding  
2           any other provision of law, a covered entity  
3           described in one of subparagraphs (A)  
4           through (K) of paragraph (4) that is re-  
5           quired by the Federal statute authorizing  
6           the grant, project, or contract that is the  
7           basis for such entity’s participation in the  
8           program under this section to provide af-  
9           fordability assistance to eligible individuals  
10          receiving health care items or services from  
11          such entity shall, with respect to an eligible  
12          patient (as defined in clause (iii)) dis-  
13          pensed or administered a covered out-  
14          patient drug subject to an agreement  
15          under this section at a covered entity site,  
16          including an entity pharmacy, establish a  
17          policy that provides a discount to reduce  
18          the out-of-pocket obligation of an eligible  
19          patient with respect to such drug to an  
20          amount sufficient to ensure such patient is  
21          not denied access to such drug based on  
22          such patient’s ability to pay for such drug.

23          “(ii) APPLICABILITY TO CONTRACT  
24          PHARMACIES.—With respect to an eligible  
25          patient of a covered entity described in

1 clause (i) dispensed a covered outpatient  
2 drug subject to an agreement under this  
3 section on behalf of such covered entity at  
4 a contract pharmacy pursuant to subpara-  
5 graph (F), such covered entity shall re-  
6 quire such contract pharmacy to provide  
7 discounts to eligible patients on behalf of  
8 such covered entity in accordance with the  
9 covered entity's policy described in clause  
10 (i).

11 “(iii) DEFINITIONS.—In this subpara-  
12 graph:

13 “(I) CONTRACT PHARMACY.—

14 The term ‘contract pharmacy’ shall  
15 have the meaning given such term in  
16 subparagraph (F).

17 “(II) ELIGIBLE PATIENT.—The

18 term ‘eligible patient’ means a pa-  
19 tient, as defined in subsection (b)(3),  
20 who is not covered under minimum es-  
21 sential coverage as defined under sec-  
22 tion 5000A(f) of the Internal Revenue  
23 Code of 1986 or has family income  
24 below 200 percent of the Federal pov-  
25 erty guidelines and is covered under a

1 group health plan, health insurance  
2 coverage in the individual market or  
3 group market (as such terms are de-  
4 fined in section 2791 of the Public  
5 Health Service Act) or coverage de-  
6 scribed in section 156.602(a), title 45,  
7 Code of Federal Regulations or suc-  
8 cessor regulation.

9 “(III) ENTITY PHARMACY.—The  
10 term ‘entity pharmacy’ shall have the  
11 meaning given such term in subpara-  
12 graph (F).

13 “(IV) FEDERAL POVERTY GUIDE-  
14 LINES.—The term ‘Federal poverty  
15 guidelines’ means the poverty guide-  
16 lines updated periodically in the Fed-  
17 eral Register by the Department of  
18 Health and Human Services pursuant  
19 to section 9902(2) of title 42, United  
20 States Code.

21 “(V) OUT-OF-POCKET OBLIGA-  
22 TION.—The term ‘out-of-pocket obli-  
23 gation’ means any copayment, coin-  
24 surance, deductible, or other cost  
25 sharing amount or payment required

1 from an eligible patient in connection  
 2 with such patient’s receipt of a spe-  
 3 cific health care item or service, in-  
 4 cluding a covered outpatient drug.”.

5 **SEC. 7. REQUIREMENTS FOR NONHOSPITAL COVERED EN-**  
 6 **TITIES AND SUBGRANTEES.**

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

10 “(I) ADDITIONAL REQUIREMENTS FOR  
 11 NONHOSPITAL COVERED ENTITIES; REQUIRE-  
 12 MENTS FOR SUBGRANTEES.—

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

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

21 “(II) be eligible to purchase a  
 22 covered outpatient drug subject to an  
 23 agreement under this section only  
 24 with respect to a patient receiving a  
 25 health care service at a registered cov-

1           ered entity site, and such service and  
2           such drug are within the scope and  
3           time period of the Federal grant,  
4           project, or Federal grant-authorizing  
5           statute, as applicable, that qualifies  
6           such covered entity for participation  
7           in the program under this section;

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

17                   “(IV) have an enforceable written  
18          agreement with any subgrantee, which  
19          shall apply to all registered sites of  
20          such subgrantee, and require such  
21          subgrantee to comply with all require-  
22          ments under this section otherwise ap-  
23          plicable to the covered entity and to  
24          maintain written records, which shall  
25          be made available to the Secretary

1           upon request, sufficient to dem-  
2           onstrate such subgrantee's receipt of  
3           eligible Federal funds or an in-kind  
4           contribution purchased with such  
5           funds, as described in clause (iii), and  
6           the grant under which such sub-  
7           grantee receives such funds or con-  
8           tribution; and

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

1 under which the subgrantee receives  
2 such funds or contribution.

3 “(ii) REQUIREMENTS FOR SUB-  
4 GRANTEES.—Notwithstanding any other  
5 provision in this section, a subrecipient of  
6 a Federal grant shall be eligible to partici-  
7 pate in the program under this section  
8 only if such subrecipient is a subgrantee  
9 (as defined in clause (iii)) and such sub-  
10 grantee—

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

13 “(II) prior to purchasing covered  
14 outpatient drugs subject to an agree-  
15 ment under this section—

16 “(aa) enters into an enforce-  
17 able written agreement with the  
18 covered entity providing eligible  
19 Federal funds or an in-kind con-  
20 tribution, pursuant to clause  
21 (i)(IV);

22 “(bb) maintains written  
23 records, which shall be made  
24 available to the Secretary upon  
25 request, sufficient to demonstrate



1 such subgrantee’s receipt of eligi-  
2 ble Federal funds or an in-kind  
3 contribution purchased with such  
4 funds, as described in clause (iii),  
5 and the grant under which such  
6 subgrantee receives such funds or  
7 contribution; and

8 “(cc) registers each sub-  
9 grantee site to participate in the  
10 program under this section in the  
11 covered entity identification sys-  
12 tem established under subsection  
13 (d)(2)(B)(iv);

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

1                   “(IV) in the case of a subgrantee  
2                   that receives an in-kind contribution  
3                   from a covered entity described in  
4                   paragraph (4)(K), demonstrates to  
5                   such covered entity and to the Sec-  
6                   retary, upon initial registration to  
7                   participate in the program under this  
8                   section and on an annual basis there-  
9                   after, that the number of individuals  
10                  aged 19 to 64 years receiving a health  
11                  care service at the registered sub-  
12                  grantee site during the most recent  
13                  calendar year who are enrolled under  
14                  a State plan under title XIX of the  
15                  Social Security Act (or a waiver of  
16                  such plan), as a share of all individ-  
17                  uals aged 19 to 64 years receiving a  
18                  health care service at the registered  
19                  subgrantee site during such calendar  
20                  year, exceeds the number of individ-  
21                  uals aged 19 to 64 years who reside  
22                  in the State where such subgrantee  
23                  site is located and are enrolled under  
24                  a State plan under title XIX of such  
25                  Act (or a waiver of such plan), as a

1 share of all individuals aged 19 to 64  
2 who reside in such State, each as  
3 measured by data available from the  
4 American Community Survey of the  
5 Bureau of the Census for the calendar  
6 year preceding the most recent cal-  
7 endar year;

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

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

1 compliance with the requirements  
2 under subparagraph (A) and (B);  
3 and

4 “(bb) a written plan in a  
5 form specified by the Secretary  
6 and using criteria established by  
7 the Secretary to determine the  
8 date upon which its eligibility to  
9 participate in the program under  
10 this section, as a result of such  
11 contribution, shall terminate (ab-  
12 sent such subgrantee’s receipt of  
13 additional funds or contributions  
14 described in clause (iii));

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

1 more applicable requirements under  
2 this section; and

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

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

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

1 under this section with respect to  
2 such different covered entity.

3 “(iii) SUBGRANTEE DEFINED.—

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

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

1 “(bb) receives in-kind con-  
2 tributions from a covered entity  
3 described in paragraph (4)(K)  
4 and such contributions—

5 “(AA) are ongoing and  
6 are in the form of real prop-  
7 erty, equipment, supplies, or  
8 services;

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

24 “(CC) are specifically  
25 identifiable and provided by

1           such covered entity directly  
2           to such subrecipient; and

3                   “(DD) directly support  
4           the provision of health care  
5           items and services by such  
6           subrecipient solely to indi-  
7           viduals within the scope and  
8           time period of the Federal  
9           grant that qualifies such  
10          covered entity for participa-  
11          tion in the program under  
12          this section.

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

20                   “(aa) as of January 1,  
21          2025, such subrecipient is par-  
22          ticipating in the program under  
23          this section as such a sub-  
24          recipient and is in compliance  
25          with all requirements under this



1 section otherwise applicable to  
2 such subrecipient; and

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

20 “(iv) RULE OF CONSTRUCTION.—For  
21 purposes of this section, any subgrantee  
22 that is not itself a covered entity described  
23 in one of subparagraphs (A) through (K)  
24 of paragraph (4) shall be subject to the ob-  
25 ligations under this section applicable to

1 the covered entity with which such sub-  
 2 grantee has an enforceable written agree-  
 3 ment pursuant to clause (i). Further, for  
 4 purposes of this section, each registered  
 5 site of such subgrantee shall be subject to  
 6 the requirements set forth in subparagraph  
 7 (F) as if such site were the covered entity  
 8 with which such subgrantee has an en-  
 9 forceable written agreement pursuant to  
 10 clause (i).”.

11 **SEC. 8. CLAIMS MODIFIERS; COVERED ENTITY DATA SUB-**  
 12 **MISSION.**

13 Section 340B(a)(5) of the Public Health Service Act  
 14 (42 U.S.C. 256b(a)(5)) is further amended by adding at  
 15 the end the following:

16 “(J) CLAIMS MODIFIER AND COVERED EN-  
 17 TITY DATA SUBMISSION.—

18 “(i) CLAIMS MODIFIER.—All claims  
 19 submitted to a payor, including, without  
 20 limitation, Medicare and Medicaid, by a  
 21 covered entity or a contract pharmacy  
 22 under a contract with a covered entity in  
 23 compliance with subparagraph (F) for re-  
 24 imbursement of a unit of a covered out-  
 25 patient drug purchased under the program

1 under this section shall include the rel-  
2 evant 340B modifier established by the  
3 Secretary under Medicare Part B (that is  
4 ‘JG’, ‘TB’, or any successor modifier) or  
5 the Submission Clarification Code of ‘20’  
6 or any successor modifier developed by the  
7 National Council for Prescription Drug  
8 Programs (NCPDP) to identify claims for  
9 covered outpatient drugs purchased under  
10 such program. All claims submitted by a  
11 covered entity or a contract pharmacy de-  
12 scribed in this clause to a payor, including,  
13 without limitation, Medicare and Medicaid,  
14 for reimbursement of a unit of a covered  
15 outpatient drug not purchased under such  
16 program shall also include a relevant non-  
17 340B modifier, which shall be established  
18 by the Secretary, or a non-340B modifier  
19 developed by the NCPCP to identify such  
20 claims.

21 “(ii) COVERED ENTITY DATA SUBMIS-  
22 SION.—A covered entity described in para-  
23 graph (4) shall (and shall cause any entity  
24 acting on its behalf to) furnish to the  
25 clearinghouse described in subsection

(d)(2)(C) the data described in clause (iii), in a machine-readable format, with respect to each covered outpatient drug dispensed, furnished, or administered by the covered entity (including such drugs dispensed by a contract pharmacy under contract with such covered entity in compliance with subparagraph (F)), for which such covered entity seeks or has received discounted pricing under this section. Such covered entity shall provide, or cause to be provided, such data to the clearinghouse within 45 days after the date on which the covered outpatient drug was dispensed, furnished, or administered (or such shorter time period as may be specified by the Secretary through notice-and-comment rulemaking) in an electronic format specified by the Secretary. The covered entity shall require (and shall cause any entity acting on its behalf to require) that data on pharmacy-dispensed drugs described in this subparagraph be submitted to the clearinghouse directly by the pharmacy dispensing such drug.

1 “(iii) CLAIM LEVEL DATA ELE-  
2 MENTS.—The data described in this clause  
3 shall include the following, as applicable:

4 “(I) SELF-ADMINISTERED  
5 DRUGS.—With respect to a self-ad-  
6 ministered drug dispensed at a phar-  
7 macy, by a mail order service, or by  
8 another dispenser—

9 “(aa) prescription number;

10 “(bb) prescribed date;

11 “(cc) prescription fill date;

12 “(dd) national drug code  
13 (NDC) of the drug;

14 “(ee) quantity dispensed;

15 “(ff) bank identification  
16 number, processor control num-  
17 ber, and group number of the  
18 plan receiving the claim (as ap-  
19 plicable);

20 “(gg) national provider iden-  
21 tifier (NPI) of the prescriber;

22 “(hh) NPI of the dispensing  
23 pharmacy;

24 “(ii) name and 340B identi-  
25 fier of the covered entity dis-

1           pensing the drug, or on whose  
2           behalf the drug is dispensed;

3           “(jj) 340B/non-340B claim  
4           modifier;

5           “(kk) wholesaler invoice  
6           number; and

7           “(ll) an indicator, which  
8           shall be specified by the clearing-  
9           house or the Secretary, denoting  
10          that the drug was or was not dis-  
11          pensed as a result of care coordi-  
12          nation described in subsection  
13          (b)(3).

14          “(II) PROVIDER-ADMINISTERED  
15          DRUGS.—With respect to a drug fur-  
16          nished or administered by a physician  
17          or other provider of services or a sup-  
18          plier—

19               “(aa) drug billing and pay-  
20               ment code/HCPSC code;

21               “(bb) NDC of the drug;

22               “(cc) claim number;

23               “(dd) Medicare provider  
24               number of prescriber (as applica-  
25               ble);

1 “(ee) NPI of the prescriber;

2 “(ff) name and 340B identi-  
3 fier of the covered entity fur-  
4 nishing or administering the  
5 drug;

6 “(gg) date drug furnished or  
7 administered;

8 “(hh) claim adjudication  
9 date;

10 “(ii) quantity furnished or  
11 administered;

12 “(jj) 340B/non-340B claim  
13 modifier; and

14 “(kk) an indicator, which  
15 shall be specified by the clearing-  
16 house or the Secretary, denoting  
17 that the drug was or was not fur-  
18 nished or administered as a re-  
19 sult of care coordination de-  
20 scribed in subsection (b)(3).

21 “(iv) INFORMATION PRIVACY AND SE-  
22 CURITY.—A covered entity described in  
23 paragraph (4) shall provide the data speci-  
24 fied in clause (iii) to the clearinghouse in  
25 a secure manner, consistent with such enti-

1           ty’s obligations under the Security Stand-  
2           ards for the Protection of Electronic Pro-  
3           tected Health Information described in  
4           part 164 of subpart C of title 45, Code of  
5           Federal Regulations (or any successor reg-  
6           ulations). A covered entity shall not be re-  
7           quired to obtain an individual authoriza-  
8           tion under part 164 of subpart E of title  
9           45, Code of Federal Regulations (or any  
10          successor regulations) for its reporting of  
11          such data to the clearinghouse.

12               “(v) STANDARDIZATION OF REPORTED  
13           DATA ELEMENTS; PROHIBITION ON MODI-  
14           FICATIONS.—A covered entity described in  
15           paragraph (4) shall take reasonable steps  
16           to ensure the data specified in clause (iii)  
17           submitted to the clearinghouse fully com-  
18           plies with the data submission standards  
19           (including field descriptors and definitions)  
20           specified by the clearinghouse or the Sec-  
21           retary following consultation with relevant  
22           stakeholders, including manufacturers of  
23           covered outpatient drugs. A covered entity  
24           described in paragraph (4) is prohibited,  
25           and shall prohibit any entity acting on its



1           behalf (including any affiliate of such enti-  
2           ty), from taking or refraining from taking  
3           any action that would cause such informa-  
4           tion to no longer comply with the stand-  
5           ards described in this clause. In specifying  
6           the data submission standards described in  
7           this clause, the clearinghouse and the Sec-  
8           retary, as applicable, shall seek to mini-  
9           mize administrative burden on covered en-  
10          tities while ensuring such data satisfies the  
11          intent of this subparagraph.

12                 “(vi) COVERED ENTITIES THAT FAIL  
13           TO REPORT.—A covered entity that fails to  
14           furnish the information as required under  
15           this subparagraph shall be subject to a  
16           civil monetary penalty in the amount of  
17           \$2,500 for each day of such violation,  
18           which amount shall be adjusted for infla-  
19           tion annually to reflect the rate of change  
20           in the Consumer Price Index for All Urban  
21           Consumers published by the Bureau of  
22           Labor Statistics. The provisions of section  
23           1128A of the Social Security Act (other  
24           than subsections (a) and (b)) shall apply to  
25           a civil monetary penalty under this clause

1 in the same manner as such provisions  
2 apply to a penalty or proceeding under sec-  
3 tion 1128A(a). The Office of Inspector  
4 General of the Department of Health and  
5 Human Services shall carry out the provi-  
6 sions of this clause.”.

7 **SEC. 9. COVERED ENTITY REPORTING ON SCOPE OF**  
8 **GRANT, CONTRACT, AND PROJECT.**

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

12 “(K) REPORTING ON SCOPE OF GRANT,  
13 CONTRACT, AND PROJECT.—A covered entity  
14 described in one of subparagraphs (A) through  
15 (K) of paragraph (4) shall submit information  
16 specified by the Secretary to the identification  
17 system described in subsection (d)(2)(B)(iv) at  
18 least annually, in a form and manner specified  
19 by the Secretary, describing the scope of its  
20 Federal grant or project, or the Federal grant-  
21 authorizing statute, as applicable, that is the  
22 basis for such entity’s eligibility for the pro-  
23 gram under this section. Such information shall  
24 include copies of agreements between such enti-  
25 ty and any subgrantee, as described in subpara-

1 graph (I). Access to information described in  
 2 this subparagraph shall be made available to a  
 3 manufacturer of a covered outpatient drug,  
 4 upon request, in a manner specified by the Sec-  
 5 retary.”.

6 **SEC. 10. ENSURING COVERED ENTITY TRANSPARENCY.**

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

10 “(L) REPORTING.—

11 “(i) IN GENERAL.—During the first  
 12 year beginning on or after the date that is  
 13 14 months after the date of enactment of  
 14 this subparagraph and during each subse-  
 15 quent year, each covered entity described  
 16 in subparagraph (L) of paragraph (4) (and  
 17 any other covered entity specified by the  
 18 Secretary) shall report to the Secretary (at  
 19 a time and in a form and manner specified  
 20 by the Secretary) the following information  
 21 with respect to the preceding year:

22 “(I) With respect to such covered  
 23 entity and each child site, as applica-  
 24 ble, of such entity—

1           “(aa) the total number of  
2 individuals who were dispensed or  
3 administered covered outpatient  
4 drugs during such preceding year  
5 that were subject to an agree-  
6 ment under this section; and

7           “(bb) the number of such in-  
8 dividuals described in a category  
9 specified in clause (iii), broken  
10 down by each such category.

11           “(II) With respect to such cov-  
12 ered entity and each child site, as ap-  
13 plicable, of such entity—

14           “(aa) the percentage of the  
15 total number of individuals fur-  
16 nished items and services during  
17 such preceding year who were  
18 dispensed or administered cov-  
19 ered outpatient drugs during  
20 such preceding year that were  
21 subject to an agreement under  
22 this section; and

23           “(bb) for each category  
24 specified in clause (iii), the per-  
25 centage of the total number of

1 individuals described in such cat-  
2 egory furnished items and serv-  
3 ices during such preceding year  
4 who were dispensed or adminis-  
5 tered covered outpatient drugs  
6 during such preceding year that  
7 were subject to an agreement  
8 under this section.

9 “(III) With respect to such cov-  
10 ered entity and each child site, as ap-  
11 plicable, of such entity, the total costs  
12 incurred during the year at each such  
13 site and the cost incurred at each  
14 such site for charity care (as defined  
15 in line 23 of worksheet S-10 to the  
16 Medicare cost report, or in any suc-  
17 cessor form).

18 “(IV) With respect to such cov-  
19 ered entity and each child site, as ap-  
20 plicable, of such entity, the costs in-  
21 curred during the year of furnishing  
22 items and services at each such entity  
23 or site to patients of such entity who  
24 were entitled to benefits under part A  
25 of title XVIII of the Social Security

1 Act or enrolled under part B of such  
2 title, enrolled in a State plan under  
3 title XIX of such Act (or a waiver of  
4 such plan), or who were uninsured for  
5 services, minus the sum of—

6 “(aa) payments under title  
7 XVIII of such Act for such items  
8 and services (including any cost  
9 sharing for such items and serv-  
10 ices);

11 “(bb) payments under title  
12 XIX of such Act for such items  
13 and services (including any cost  
14 sharing for such items and serv-  
15 ices); and

16 “(cc) payments by uninsured  
17 patients for such items and serv-  
18 ices.

19 “(V) With respect to such cov-  
20 ered entity and each child site, as ap-  
21 plicable, of such entity, the margin (as  
22 defined in clause (iv)) generated on  
23 covered outpatient drugs subject to an  
24 agreement under this section dis-  
25 pensed or furnished by such entity or

1 site (and any entity pharmacy or con-  
2 tract pharmacy dispensing such drugs  
3 on behalf of such entity in accordance  
4 with subparagraph (F)), with each  
5 component of the margin calculation  
6 described in item (aa) through (cc) of  
7 such clause listed as a separate line  
8 item.

9 “(VI) To the extent the Sec-  
10 retary requires covered entities de-  
11 scribed in one of subparagraphs (A)  
12 through (K) of paragraph (4) to re-  
13 port information pursuant to this sub-  
14 paragraph, with respect to each such  
15 covered entity, use of margin (as de-  
16 fined in clause (iv)) generated on cov-  
17 ered outpatient drugs subject to an  
18 agreement under this section in the  
19 following categories of expenditures, if  
20 applicable, which the Secretary shall  
21 define in interim final regulations in a  
22 manner consistent with reporting  
23 under the Health Resources and Serv-  
24 ices Administration Uniform Data  
25 System (UDS)—

1 “(aa) medical care;  
2 “(bb) dental care;  
3 “(cc) mental health;  
4 “(dd) pharmaceuticals,  
5 which shall include margin used  
6 to provide free and discounted  
7 covered outpatient drugs subject  
8 to an agreement under this sec-  
9 tion dispensed or furnished to eli-  
10 gible patients (as defined in sub-  
11 paragraph (H)), notwithstanding  
12 any UDS reporting requirement  
13 that may limit or interfere with  
14 the inclusion of margin used for  
15 such purpose;  
16 “(ee) sliding fee discounts;  
17 “(ff) case management;  
18 “(gg) transportation;  
19 “(hh) patient and commu-  
20 nity education;  
21 “(ii) community health  
22 workers;  
23 “(jj) outreach;  
24 “(kk) eligibility assistance;  
25 and



1                               “(ll) nutritional assessment  
2                               and referral.

3                               “(ii) PUBLICATION.—The Secretary  
4                               shall publish data reported under clause (i)  
5                               with respect to a year annually on the pub-  
6                               lic website of the Department of Health  
7                               and Human Services in an electronic and  
8                               searchable format, which may include the  
9                               340B Office of Pharmacy Affairs Informa-  
10                              tion System (or a successor to such sys-  
11                              tem), in a manner that shows each cat-  
12                              egory of data reported in the aggregate  
13                              and identified by the specific covered entity  
14                              submitting such data. The Secretary shall  
15                              include in such publication the dispropor-  
16                              tionate patient percentage (as defined in  
17                              section 1886(d)(5)(F)(vi) of the Social Se-  
18                              curity Act) of each such covered entity (if  
19                              applicable) for each cost reporting period  
20                              occurring during such year.

21                              “(iii) CATEGORIES SPECIFIED.—For  
22                              purposes of clause (i), the categories speci-  
23                              fied in this clause are the following:

24                              “(I) Individuals covered under a  
25                              group health plan or group or indi-

1           vidual health insurance coverage (as  
2           such terms are defined in section  
3           2791).

4           “(II) Individuals entitled to bene-  
5           fits under part A or enrolled under  
6           part B of title XVIII of the Social Se-  
7           curity Act.

8           “(III) Individuals enrolled under  
9           a State plan under title XIX of such  
10          Act (or a waiver of such plan).

11          “(IV) Individuals enrolled under  
12          a State child health plan under title  
13          XXI of such Act (or a waiver of such  
14          plan).

15          “(V) Individuals not described in  
16          any preceding subclause and not cov-  
17          ered under any Federal health care  
18          program (as defined in section 1128B  
19          of such Act but including the program  
20          established under chapter 89 of title  
21          5, United States Code).

22          “(iv) DEFINITIONS.—In this subpara-  
23          graph:

1           “(I) CHILD SITE.—The term  
2           ‘child site’ shall have the meaning  
3           given such term in subparagraph (E).

4           “(II) ENTITY PHARMACY.—The  
5           term ‘entity pharmacy’ shall have the  
6           meaning given such term in subpara-  
7           graph (F).

8           “(III) MARGIN.—The term ‘mar-  
9           gin’ means, with respect to covered  
10          outpatient drugs purchased by a cov-  
11          ered entity under an agreement under  
12          this section, the following amount for  
13          such drugs dispensed, furnished, or  
14          administered to an individual by such  
15          entity or a child site of such entity  
16          (and any entity pharmacy or contract  
17          pharmacy dispensing such drugs on  
18          behalf of such entity in accordance  
19          with subparagraph (F))—

20               “(aa) aggregate payments  
21               received by the covered entity for  
22               such drugs from individuals (in-  
23               cluding cost-sharing amounts)  
24               and third parties, including gov-  
25               ernment and private payors;

1 “(bb) aggregate costs to ac-  
2 quire such drugs at either the  
3 ceiling price described in para-  
4 graph (1) or any voluntary sub-  
5 ceiling price at which the covered  
6 entity purchased such drug or  
7 drugs, as applicable; minus

8 “(cc) aggregate costs in-  
9 curred by the covered entity that  
10 are necessary for such entity to  
11 participate in the program under  
12 this section and to comply with  
13 such program’s requirements, in-  
14 cluding program-related compli-  
15 ance, legal, educational, and ad-  
16 ministrative costs (such costs  
17 shall be determined in accordance  
18 with Generally Accepted Account-  
19 ing Principles), and compensa-  
20 tion paid to third-party adminis-  
21 trators or contract pharmacies to  
22 carry out program-related func-  
23 tions.”.

24 (b) RULEMAKING.—Not later than 180 days after the  
25 date of enactment of this Act, the Secretary of Health and

1 Human Services shall issue an interim final rule to carry  
2 out section 340B(a)(5)(L) of the Public Health Service  
3 Act, as added by subsection (a).

4 **SEC. 11. REVISIONS TO EXISTING 340B HOSPITAL ELIGI-**  
5 **BILITY REQUIREMENTS.**

6 Section 340B(a)(4) of the Public Health Service Act  
7 (42 U.S.C. 256b(a)(4)) is amended—

8 (1) in subparagraph (L)(i)—

9 (A) by inserting “and that was registered  
10 with the 340B program in the covered entity  
11 identification system established under sub-  
12 section (d)(2)(B)(iv) as such a hospital on or  
13 before December 1, 2024” after “formally  
14 granted governmental powers by a unit of state  
15 or local government”; and

16 (B) by striking “not entitled to benefits  
17 under title XVIII of the Social Security Act”  
18 and all that follows up to the semicolon at the  
19 end and inserting “uninsured, as such terms  
20 are defined in subsection (a)(11)”;

21 (2) by amending subparagraph (N) to read as  
22 follows:

23 “(N) An entity that is a critical access hos-  
24 pital (as determined under section 1820(c)(2)  
25 of the Social Security Act (42 U.S.C. 1395i–

1           4(c)(2))) or a rural emergency hospital (as de-  
 2           termined under the requirements in section  
 3           1861(kkk) of the Social Security Act (42  
 4           U.S.C. 1395x(kkk) and in implementing regula-  
 5           tions set forth in parts 419, 424, 485, 488, and  
 6           489 of title 42 of the Code of Federal Regula-  
 7           tions in effect as of January 1, 2024)), and  
 8           that meets the requirements of subparagraph  
 9           (L)(i).”; and

10          (3) in subparagraph (O) by inserting “that  
 11          demonstrates to the Secretary that at least 60 per-  
 12          cent of annual inpatient discharges for cost report-  
 13          ing periods beginning after December 1, 2024, are  
 14          for inpatients who reside in a county that is not part  
 15          of a Metropolitan Statistical Area, as defined by the  
 16          Director of the Office of Management and Budget”  
 17          before “, or a sole community hospital”.

18 **SEC. 12. ADDITIONAL REQUIREMENTS FOR 340B HOS-**  
 19 **PITALS.**

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

23                 “(11) CLARIFICATION OF ELIGIBILITY STAND-  
 24          ARDS FOR PRIVATE NONPROFIT HOSPITALS WITH A

1 CONTRACT WITH A STATE OR LOCAL GOVERNMENT  
2 TO PROVIDE HEALTH CARE SERVICES.—

3 “(A) CONTRACT REQUIREMENTS.—For  
4 purposes of paragraph (4)(L)(i) and cross-ref-  
5 erences to subparagraph (L) or clause (i) of  
6 such paragraph appearing in subparagraph (M)  
7 and subparagraph (O) of such paragraph with  
8 respect to a rural referral center, a private non-  
9 profit hospital has a contract with a State or  
10 local government to provide health care services  
11 to low-income individuals who are uninsured  
12 if—

13 “(i) the hospital submits a copy of the  
14 contract (including any appendices or ad-  
15 denda or subsequent amendments) to the  
16 Secretary for review;

17 “(ii) the Secretary determines that  
18 the contract creates an enforceable obliga-  
19 tion for the hospital to provide direct med-  
20 ical care to low-income individuals who are  
21 uninsured in an amount that represents at  
22 least 10 percent of the hospital’s total  
23 costs of care;

24 “(iii) the Secretary further deter-  
25 mines, based on a review of the contract

1 (as described in clause (i)) that the con-  
2 tract creates an enforceable obligation for  
3 the hospital to furnish the individuals de-  
4 scribed in clause (ii) the full range of serv-  
5 ices provided at the hospital (including any  
6 child sites); and

7 “(iv) the contract (as described in  
8 clause (i)) is available to the public as part  
9 of the information describing the hospital  
10 in the covered entity identification system  
11 established under subsection (d)(2)(B)(iv).

12 “(B) DEREGISTRATION.—If at any time a  
13 hospital not owned or operated by a unit of  
14 State or local government that has been partici-  
15 pating in the program under this section on the  
16 basis of having a contract with a State or local  
17 government to provide health care services that  
18 is subject to subparagraph (A) no longer satis-  
19 fies a requirement under such subparagraph,  
20 the hospital shall immediately notify the Sec-  
21 retary that the hospital no longer satisfies the  
22 relevant requirement, deregister the hospital  
23 from the program under this section and the  
24 identification system described in subsection  
25 (d)(2)(B)(iv), and cease making purchases



1 under such program and representing to third  
2 parties that it may purchase under such pro-  
3 gram.

4 “(C) OBLIGATION TO SELF-DISCLOSE.—A  
5 covered entity described in subparagraph (B)  
6 shall immediately disclose to the Secretary and  
7 the manufacturer of the affected covered out-  
8 patient drug any purchase made under the pro-  
9 gram under this section by such covered entity  
10 that, at the time of the purchase of such drug,  
11 did not fully satisfy the requirements in sub-  
12 paragraph (A). Any such purchase shall require  
13 the covered entity to promptly conduct an audit  
14 supervised by the Secretary to identify the full  
15 scope of noncompliance with such requirements  
16 and to provide the written results of such audit  
17 to the Secretary and the manufacturer of the  
18 affected covered outpatient drug. The covered  
19 entity shall be liable to the manufacturer of the  
20 covered outpatient drug that is the subject of  
21 the noncompliance in an amount equal to the  
22 reduction in the price of the drugs provided  
23 under subsection (a)(1), plus interest on such  
24 amount, which shall be compounded monthly  
25 and equal to the current short-term interest

1 rate as determined by the Federal Reserve for  
2 the time period for which the covered entity is  
3 liable.

4 “(D) CIVIL MONETARY PENALTY.—Where  
5 a covered entity fails to satisfy a requirement in  
6 subparagraph (B) or (C), the covered entity  
7 shall be required to pay a civil monetary pen-  
8 alty equal to \$2,500 for each violation, which  
9 amount shall be adjusted for inflation annually  
10 to reflect the rate of change in the Consumer  
11 Price Index for All Urban Consumers published  
12 by the Bureau of Labor Statistics. The provi-  
13 sions of section 1128A of the Social Security  
14 Act (other than subsections (a) and (b)) shall  
15 apply to a civil monetary penalty under this  
16 subparagraph in the same manner as such pro-  
17 visions apply to a penalty or proceeding under  
18 section 1128A(a). The Office of Inspector Gen-  
19 eral of the Department of Health and Human  
20 Services shall carry out the provisions related to  
21 the imposition of civil monetary penalties under  
22 this subparagraph.

23 “(E) DEFINITIONS.—In this paragraph:

24 “(i) FEDERAL POVERTY GUIDE-  
25 LINES.—The term ‘Federal poverty guide-

lines’ means the poverty guidelines updated periodically in the Federal Register by the Department of Health and Human Services pursuant to section 9902(2) of title 42, United States Code.

“(ii) LOW-INCOME INDIVIDUAL.—The term ‘low-income individual’ means an individual with family income at or below 200 percent of the Federal poverty guidelines.

“(iii) UNINSURED.—The term ‘uninsured’ means lacking minimum essential coverage, as defined in subsection 5000A(f) of the Internal Revenue Code (26 U.S.C. 5000A(f)) and implementing regulations.

“(12) ADDITIONAL REQUIREMENT FOR PRIVATE NONPROFIT DISPROPORTIONATE SHARE HOSPITALS LOCATED IN URBAN AREAS.—

“(A) IN GENERAL.—A covered entity described in paragraph (4)(L)(i) that is either a private nonprofit hospital that has as the basis for its participation in the program under this section a contract with a State or local government as described in such paragraph and in

1 paragraph (11), or that is a private nonprofit  
2 corporation which is formally granted govern-  
3 mental powers by a unit of State or local gov-  
4 ernment, and such entity is located in a county  
5 that is part of a Metropolitan Statistical Area,  
6 as defined by the Office of Management and  
7 Budget, must, for the preceding year, fall with-  
8 in the top 40 percent of hospitals on each of the  
9 lists described in subparagraphs (B) and (C)  
10 prepared by the Secretary with respect to the  
11 State in which the covered entity is located. As  
12 described further in subparagraph (D), place-  
13 ment in the top 40 percent of hospitals on both  
14 of such lists is a condition of such covered enti-  
15 ty's participation in the program under this sec-  
16 tion and failure to meet this condition shall re-  
17 quire deregistration and self-disclosure using  
18 the procedures described in subparagraphs (B)  
19 and (C) of paragraph (11). Such covered entity  
20 shall be subject to a civil monetary penalty de-  
21 scribed in paragraph (11)(D) for failure to  
22 deregister and self-disclose in accordance with  
23 the preceding sentence.

24 “(B) MEDICAID AND CHIP OUTPATIENT  
25 REVENUE.—Within 90 days following the con-

1           clusion of a year, the Secretary shall prepare  
2           and make available to the public in an elec-  
3           tronic, machine-readable format for each State  
4           for the concluded year, a list that ranks all  
5           acute care hospitals in such State in descending  
6           order based on each hospital's share of total  
7           outpatient services revenue derived from base  
8           reimbursement to such hospital (excluding sup-  
9           plemental and indirect reimbursement) under  
10          title XIX of the Social Security Act (including  
11          with respect to individuals also entitled to bene-  
12          fits under part A of title XVIII of such Act or  
13          enrolled in part B of title XVIII of such Act)  
14          and payments under title XXI of such Act for  
15          items and services furnished on an outpatient  
16          basis at the hospital (including any cost sharing  
17          for such items and services). The Secretary  
18          shall specify the threshold for the top 40 per-  
19          cent of hospitals on the list.

20               “(C)     UNCOMPENSATED     OUTPATIENT  
21          CARE.—Within 90 days following the conclusion  
22          of a year, the Secretary shall prepare and make  
23          available to the public in an electronic, ma-  
24          chine-readable format for each State for the  
25          concluded year, a list that ranks all acute care

1 hospitals in such State in descending order  
2 based on each hospital's total cost of uncompen-  
3 sated care for items and services furnished on  
4 an outpatient basis as a share of the hospital's  
5 total outpatient services revenue. For purposes  
6 of this list, costs of uncompensated outpatient  
7 care shall be determined in a manner consistent  
8 with the instructions on worksheet S-10 to the  
9 Medicare cost report (or any successor form),  
10 with adjustments to limit uncompensated out-  
11 patient care costs to those incurred in providing  
12 items and services on an outpatient basis at the  
13 hospital. The Secretary shall specify the thresh-  
14 old for the top 40 percent of hospitals on the  
15 list.

16 “(D) DEREGISTRATION.—Within 30 days  
17 following the Secretary's publication of the lists  
18 described in subparagraphs (B) and (C), each  
19 covered entity subject to this paragraph that is  
20 not included in the top 40 percent of hospitals  
21 on both lists shall notify the Secretary that the  
22 covered entity does not satisfy one or more re-  
23 quirements described in this paragraph,  
24 deregister the entity from the program under  
25 this section and the identification system de-

1           scribed in subsection (d)(2)(B)(iv), and cease  
2           making purchases under such program and rep-  
3           resenting to third parties that it may purchase  
4           under such program. Such an entity may seek  
5           to register under another covered entity cat-  
6           egory described in paragraph (4) if such entity  
7           meets the criteria for such a category and ap-  
8           plicable requirements under this section.

9           “(E) OBLIGATION TO SELF-DISCLOSE.—A  
10          covered entity described in subparagraph (D)  
11          shall immediately disclose to the Secretary and  
12          the manufacturer of the affected covered out-  
13          patient drug any purchase made under the pro-  
14          gram under this section by such covered entity  
15          that, at the time of the purchase of such drug,  
16          did not fully satisfy the requirements in sub-  
17          paragraphs (B) and (C). Any such purchase  
18          shall require the covered entity to promptly con-  
19          duct an audit supervised by the Secretary to  
20          identify the full scope of noncompliance with  
21          such requirements and to provide the written  
22          results of such audit to the Secretary and the  
23          manufacturer of the affected covered outpatient  
24          drug. The covered entity shall be liable to the  
25          manufacturer of the covered outpatient drug

1           that is the subject of the noncompliance in an  
2           amount equal to the reduction in the price of  
3           the drugs provided under paragraph (1), plus  
4           interest on such amount, which shall be com-  
5           pounded monthly and equal to the current  
6           short-term interest rate as determined by the  
7           Federal Reserve for the time period for which  
8           the covered entity is liable.

9           “(F) CIVIL MONETARY PENALTY.—Where  
10          a covered entity fails to satisfy a requirement in  
11          subparagraph (D) or (E), the covered entity  
12          shall be required to pay a civil monetary pen-  
13          alty equal to \$2,500 for each violation, which  
14          amount shall be adjusted for inflation annually  
15          to reflect the rate of change in the Consumer  
16          Price Index for All Urban Consumers published  
17          by the Bureau of Labor Statistics. The provi-  
18          sions of section 1128A of the Social Security  
19          Act (other than subsections (a) and (b)) shall  
20          apply to a civil monetary penalty under this  
21          subparagraph in the same manner as such pro-  
22          visions apply to a penalty or proceeding under  
23          section 1128A(a). The Office of Inspector Gen-  
24          eral of the Department of Health and Human  
25          Services shall carry out the provisions related to



1 the imposition of civil monetary penalties under  
2 this subparagraph.

3 “(13) PROHIBITION AGAINST EXTRAORDINARY  
4 COLLECTION ACTIONS.—

5 “(A) ECAS PROHIBITED.—A covered entity  
6 described in subparagraphs (L) through (O) of  
7 paragraph (4) is prohibited from engaging in  
8 extraordinary collection actions (ECAs), as such  
9 term is described in section 501(r)(6) of the In-  
10 ternal Revenue Code and its implementing reg-  
11 ulations set forth in section 1.501(r)–6 of title  
12 26 of the Code of Federal Regulations (or any  
13 successor regulations), with respect to health  
14 care items and services furnished to uninsured  
15 individuals or low-income individuals.

16 “(B) AUDITS.—The Secretary shall audit  
17 for covered entity compliance with this para-  
18 graph, establish a process for individuals to re-  
19 port suspected violations of this paragraph to  
20 the Secretary, and promptly and fully inves-  
21 tigate such reports of suspected violations.

22 “(C) CIVIL MONETARY PENALTY.—Where  
23 a covered entity violates the prohibition in this  
24 paragraph, the covered entity shall be required  
25 to pay a civil monetary penalty equal to \$2,500

1           for each extraordinary collection action taken  
2           with respect to an individual described in this  
3           paragraph, which amount shall be adjusted for  
4           inflation annually to reflect the rate of change  
5           in the Consumer Price Index for All Urban  
6           Consumers published by the Bureau of Labor  
7           Statistics. The provisions of section 1128A of  
8           the Social Security Act (other than subsections  
9           (a) and (b)) shall apply to a civil monetary pen-  
10          alty under this paragraph in the same manner  
11          as such provisions apply to a penalty or pro-  
12          ceeding under section 1128A(a). The Office of  
13          Inspector General of the Department of Health  
14          and Human Services shall carry out the provi-  
15          sions related to the imposition of civil monetary  
16          penalties under this paragraph.

17               “(D) DEFINITIONS.—In this paragraph,  
18               the terms ‘low-income individual’ and ‘unin-  
19               sured’ have the meanings given such terms in  
20               paragraph (11).

1           “(14) ADDITIONAL REQUIREMENT FOR CER-  
2       TAIN HOSPITALS.—

3           “(A) IN GENERAL.—During the first cal-  
4       endar year beginning on or after the date that  
5       is 24 months after the date of enactment of this  
6       paragraph and during each subsequent calendar  
7       year, a covered entity described in paragraph  
8       (4)(L) shall determine by October 1 of each  
9       such year, based on the most recent year of  
10      data it has reported to the Secretary under  
11      paragraph (5)(L) at that point in time, whether  
12      the annual charity care costs it incurred for the  
13      year reported were greater than or equal to the  
14      margin it realized under the program under this  
15      section for that same year. As described further  
16      in subparagraph (D), for the period specified in  
17      the preceding sentence, having annual charity  
18      care costs that equal or exceed the margin for  
19      the most recently reported year is a condition  
20      of such covered entity’s participation in the pro-  
21      gram under this section for the upcoming cal-  
22      endar year, and failure to meet this condition  
23      shall require deregistration and self-disclosure  
24      using the procedures described in subpara-  
25      graphs (D) and (E). Such covered entity shall

1 be subject to a civil monetary penalty described  
2 in subparagraph (F) for failure to deregister  
3 and self-disclose in accordance with the pre-  
4 ceding sentence.

5 “(B) ANNUAL CHARITY CARE COSTS.—The  
6 term ‘annual charity care costs’ means the total  
7 costs incurred during the year by the covered  
8 entity and its child sites (as defined in para-  
9 graph (5)(E)(i)) for charity care (as defined in  
10 line 23 of worksheet S–10 to the Medicare cost  
11 report, or in any successor form).

12 “(C) MARGIN.—The term ‘margin’ means  
13 the margin reported by the covered entity for  
14 the year pursuant to paragraph (5)(L)(i)(V).

15 “(D) DEREGISTRATION AND CONDITIONS  
16 FOR SUBSEQUENT REGISTRATION.—

17 “(i) DE-REGISTRATION.—On October  
18 1 of each year beginning on or after the  
19 date that is 24 months after the date of  
20 enactment of this paragraph, each covered  
21 entity subject to this paragraph that has  
22 reported at least one year of data to the  
23 Secretary under paragraph (5)(L) and that  
24 does not have, for the most recently re-  
25 ported year, annual charity care costs

1 greater than or equal to the margin, shall  
2 notify the Secretary that it does not meet  
3 the condition of participation under this  
4 paragraph for the upcoming calendar year,  
5 deregister the entity from the program  
6 under this section and the identification  
7 system described in subsection  
8 (d)(2)(B)(iv) for the upcoming calendar  
9 year, cease making purchases under such  
10 program as of the start of the upcoming  
11 calendar year, cease representing to third  
12 parties that it may purchase under such  
13 program beyond the current calendar year,  
14 and refrain from purchasing covered out-  
15 patient drugs under this section in quan-  
16 tities exceeding such entity's bona fide  
17 needs for the remainder of the current cal-  
18 endar year.

19 “(ii) REGISTRATION FOLLOWING DE-  
20 REGISTRATION.—

21 “(I) REGISTRATION UNDER AN-  
22 OTHER COVERED ENTITY CAT-  
23 EGORY.—A covered entity that must  
24 deregister under this subparagraph  
25 shall not be prohibited from reg-

1           istering to participate in the program  
2           under this section under another cov-  
3           ered entity category described in para-  
4           graph (4) if such entity meets the cri-  
5           teria for such a category and applica-  
6           ble requirements under this section.

7                   “(II)     REGISTRATION     UNDER  
8           PARAGRAPH (4)(L).—In order to reg-  
9           ister under paragraph (4)(L), a hos-  
10          pital that has been required to  
11          deregister under this subparagraph  
12          must demonstrate to the Secretary (in  
13          a form and manner specified by the  
14          Secretary, and in addition to dem-  
15          onstrating that it satisfies the other  
16          applicable registration criteria under  
17          paragraph (4)(L)) that its annual  
18          charity care cost (as defined in sub-  
19          paragraph (B)) for the most recent  
20          year that the hospital would have re-  
21          ported under paragraph (4)(L) absent  
22          the deregistration exceeded by at least  
23          one percent point the annual charity  
24          care cost for the year preceding  
25          deregistration by the hospital. If the

1 hospital is found to meet this require-  
2 ment and approved by the Secretary  
3 for registration under paragraph  
4 (4)(L), then the hospital will be re-  
5 quired to resume reporting under  
6 paragraph (5)(L) and (once the entity  
7 has reported at least one year of data  
8 to the Secretary under paragraph  
9 (5)(L)) to meet the condition of par-  
10 ticipation described in this paragraph  
11 for the most recently reported year as  
12 of October 1 of each year.

13 “(E) OBLIGATION TO SELF-DISCLOSE.—A  
14 covered entity described in subparagraph (D)  
15 shall immediately disclose to the Secretary and  
16 the manufacturer of the affected covered out-  
17 patient drug any purchase it made under this  
18 section during a calendar year in which it was  
19 ineligible to participate in the program under  
20 this section. Any such purchase shall require  
21 the covered entity promptly to conduct an audit  
22 supervised by the Secretary to identify the full  
23 scope of noncompliance and to provide the writ-  
24 ten results of such audit to the Secretary and  
25 the manufacturer of the affected covered out-

1 patient drug. The covered entity shall be liable  
2 to the manufacturer of the covered outpatient  
3 drug that is the subject of the noncompliance in  
4 an amount equal to the reduction in the price  
5 of the drugs provided under paragraph (1), plus  
6 interest on such amount, which shall be com-  
7 pounded monthly and equal to the current  
8 short-term interest rate as determined by the  
9 Federal Reserve for the time period for which  
10 the covered entity is liable.

11 “(F) CIVIL MONETARY PENALTY.—Where  
12 a covered entity fails to satisfy a requirement in  
13 subparagraph (D) or (E), the covered entity  
14 shall be required to pay a civil monetary pen-  
15 alty equal to \$2,500 for each violation, which  
16 amount shall be adjusted for inflation annually  
17 to reflect the rate of change in the Consumer  
18 Price Index for All Urban Consumers published  
19 by the Bureau of Labor Statistics. The provi-  
20 sions of section 1128A of the Social Security  
21 Act (other than subsections (a) and (b)) shall  
22 apply to a civil monetary penalty under this  
23 subparagraph in the same manner as such pro-  
24 visions apply to a penalty or proceeding under  
25 section 1128A(a). The Office of Inspector Gen-



1           eral of the Department of Health and Human  
 2           Services shall carry out the provisions related to  
 3           the imposition of civil monetary penalties under  
 4           this subparagraph.”.

5 **SEC. 13. 340B PROGRAM.**

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

9           “(15) 340B PROGRAM.—The intent of this sec-  
 10          tion is to provide for manufacturer price reductions  
 11          that enable covered entities, whose mission is to  
 12          serve underserved or otherwise vulnerable commu-  
 13          nities, to increase access to affordable drugs and  
 14          health services for these communities.”.

15 **SEC. 14. AUDITS OF PRIVATE NONHOSPITAL CONTRACTS**  
 16 **WITH STATE AND LOCAL GOVERNMENTS.**

17          Section 340B(d)(2)(B) of the Public Health Service  
 18 Act (42 U.S.C. 256b(d)(2)(B)) is amended by adding at  
 19 the end the following:

20                   “(vi) The conducting of annual audits  
 21                   by the Secretary of contracts between a  
 22                   covered entity described in subparagraph  
 23                   (L) or subparagraph (M) of subsection  
 24                   (a)(4), or subparagraph (O) of such sub-  
 25                   section with respect to a rural referral cen-

1 ter, that is a private nonprofit hospital  
2 subject to the requirements in subsections  
3 (a)(4)(L)(i) and (a)(11) and a State or  
4 local government for at least 10 percent of  
5 all such entities participating in the pro-  
6 gram under this section. The Secretary  
7 shall develop and publicly disclose stand-  
8 ards used to determine whether such con-  
9 tracts satisfy the applicable requirements  
10 described in subsections (a)(4)(L)(i) and  
11 (a)(11) and publicly disclose the findings  
12 from such audits. The Secretary shall re-  
13 move from the program under this section  
14 any such entity that does not have a con-  
15 tract in effect with a State or local govern-  
16 ment that satisfies the applicable require-  
17 ments set forth in subsections (a)(4)(L)(i)  
18 and (a)(11), and such removal shall re-  
19 quire such covered entity to promptly con-  
20 duct an audit supervised by the Secretary  
21 to identify discounts on covered outpatient  
22 drugs purchased at a discount under this  
23 section to which such covered entity was  
24 not eligible and provide the written results  
25 of such audit to the Secretary and the

1 manufacturer of the affected covered out-  
2 patient drug. Such covered entity shall be  
3 liable to the manufacturer of such covered  
4 outpatient drug in an amount equal to the  
5 reduction in the price of the drugs pro-  
6 vided under subsection (a)(1), plus interest  
7 on such amount, which shall be com-  
8 pounded monthly and equal to the current  
9 short-term interest rate as determined by  
10 the Federal Reserve for the time period for  
11 which the covered entity is liable. Where a  
12 covered entity described in this clause  
13 knowingly and intentionally violates a re-  
14 quirement in subsection (a)(4)(L)(i) or  
15 (a)(11), the covered entity shall be re-  
16 quired to pay a civil monetary penalty  
17 equal to \$1,000 for each claim for a cov-  
18 ered outpatient drug that is subject to the  
19 violation, which amount shall be adjusted  
20 for inflation annually to reflect the rate of  
21 change in the Consumer Price Index for  
22 All Urban Consumers published by the Bu-  
23 reau of Labor Statistics. The provisions of  
24 section 1128A of the Social Security Act  
25 (other than subsections (a) and (b)) shall

1 apply to a civil monetary penalty under  
2 this clause in the same manner as such  
3 provisions apply to a penalty or proceeding  
4 under section 1128A(a). The Office of In-  
5 spector General of the Department of  
6 Health and Human Services shall carry  
7 out the provisions related to the imposition  
8 of civil monetary penalties under this  
9 clause.”.

10 **SEC. 15. ENSURING COVERED ENTITY COMPLIANCE WITH**  
11 **TRANSPARENCY REQUIREMENTS.**

12 Section 340B(d)(2)(B) of the Public Health Service  
13 Act (42 U.S.C. 256b(d)(2)(B)) is further amended by add-  
14 ing at the end the following:

15 “(vii) The imposition of civil monetary  
16 penalties in amounts determined appro-  
17 priate by the Secretary in the case that the  
18 Secretary determines that a covered entity  
19 is not in compliance with subsection  
20 (a)(5)(L).”.

21 **SEC. 16. 340B CLAIMS DATA CLEARINGHOUSE.**

22 (a) 340B CLAIMS DATA CLEARINGHOUSE.—Section  
23 340B(d)(2) of the Public Health Service Act (42 U.S.C.  
24 256b(d)(2)) is amended by adding at the end the fol-  
25 lowing:

1           “(C) 340B CLAIMS DATA CLEARING-  
2           HOUSE.—

3           “(i) IN GENERAL.—The improvements  
4           described in subparagraph (A) shall in-  
5           clude the establishment of a claims data  
6           clearinghouse described in this subpara-  
7           graph. Not later than one year after the  
8           date of enactment of this subparagraph,  
9           the Secretary shall enter into a contract  
10          with a third-party entity that meets the  
11          criteria specified in clause (ii) (such entity  
12          is hereinafter referred to as the ‘clearing-  
13          house’) for purposes of—

14          “(I) identifying claims for cov-  
15          ered outpatient drugs purchased  
16          under the program under this section  
17          for which reimbursement was made  
18          under a State plan (or waiver of such  
19          plan) and ensuring such claims are or  
20          were not included in any State rebate  
21          request under section 1927 of the So-  
22          cial Security Act in violation of sec-  
23          tions 1903(m)(2)(A)(xiii) or  
24          1927(j)(1) of such Act or section  
25          340B(a)(5)(A) of this Act;

1 “(II) identifying claims for cov-  
2 ered outpatient drugs purchased  
3 under the program under this section  
4 that are selected drugs (as defined in  
5 section 1192(c) of the Social Security  
6 Act) and ensuring that, for each such  
7 claim, the nonduplication require-  
8 ments of section 1193(d) of such Act  
9 have been met;

10 “(III) identifying claims for cov-  
11 ered outpatient drugs purchased  
12 under the program under this section  
13 that are either Part B rebatable drugs  
14 or Part D rebatable drugs and pro-  
15 viding all relevant information regard-  
16 ing such claims to the Secretary to  
17 ensure that claims that are subject to  
18 a discount under the program under  
19 this section are excluded from infla-  
20 tion rebate calculations pursuant to  
21 section 1847A(i)(3)(B)(ii)(I) of the  
22 Social Security Act (with respect to  
23 Part B rebatable drugs) and section  
24 1860D–14B(b)(1)(B) of such Act

1 (with respect to Part D rebatable  
2 drugs);

3 “(IV) identifying duplicate claims  
4 for a rebate or discount submitted by  
5 two or more covered entities (or an  
6 entity or entities acting on their be-  
7 half) with respect to the same unit of  
8 a covered outpatient drug purchased  
9 under the program under this section  
10 and implementing a process to ensure  
11 a manufacturer of such a drug does  
12 not pay more than one rebate or dis-  
13 count under this section with respect  
14 to such unit; and

15 “(V) providing to manufacturers  
16 of covered outpatient drugs, in a form  
17 and manner specified by the Secretary  
18 in consultation with manufacturers,  
19 access to the data described in sub-  
20 section (a)(5)(J) with respect to each  
21 dispense or administration of a manu-  
22 facturer’s covered outpatient drugs for  
23 which a covered entity receives a dis-  
24 count under this section.

1                   “(ii)   CRITERIA   FOR   CLEARING-  
2                   HOUSE.—The criteria described in this  
3                   clause include the following:

4                   “(I) The clearinghouse shall not  
5                   be owned by, overseen by, or affiliated  
6                   with a covered entity described in sub-  
7                   section (a)(4) and shall not currently  
8                   be a party to a contractual arrange-  
9                   ment with the Health Resources and  
10                  Services Administration.

11                  “(II) The clearinghouse shall  
12                  have demonstrated experience adjudi-  
13                  cating claims for health care items  
14                  and services in real time for self- and  
15                  provider-administered drugs and  
16                  working with protected health infor-  
17                  mation and confidential pricing infor-  
18                  mation.

19                  “(III) The clearinghouse shall  
20                  agree to confidentiality obligations  
21                  that prohibit the clearinghouse from  
22                  using information it receives under  
23                  this subparagraph for any purpose  
24                  other than a purpose set forth in this  
25                  subparagraph, or disclosing such in-



1           formation to any individual or entity  
2           other than the Secretary, provided the  
3           Secretary shall not use such informa-  
4           tion for purposes of making reim-  
5           bursement or coverage determinations,  
6           or a manufacturer in accordance with  
7           this subparagraph (and only with re-  
8           spect to such manufacturer’s covered  
9           outpatient drugs).

10           “(IV) The clearinghouse shall  
11           maintain the security of the data re-  
12           ported pursuant to this subsection  
13           (a)(5)(J) in a manner consistent with  
14           the HIPAA Security Standards set  
15           forth in sections 164.304–164.312  
16           and 164.316 of title 45, Code of Fed-  
17           eral Regulations (or any successor  
18           regulations), as if the clearinghouse  
19           were subject to those standards as a  
20           HIPAA covered entity.

21           “(iii) DUTIES OF CLEARINGHOUSE.—

22           The clearinghouse shall—

23           “(I) review claims level data for  
24           covered outpatient drugs described in  
25           subsection (a)(5)(J) submitted by cov-

1           ered entities in accordance with such  
2           subsection;

3                   “(II) review claims level data, in-  
4           cluding rebate file data, submitted to  
5           the clearinghouse by State agencies  
6           and Medicaid managed care organiza-  
7           tions for covered outpatient drugs  
8           subject to an agreement under this  
9           section dispensed or administered to  
10          individuals enrolled under a State  
11          plan (or a waiver of such plan) and  
12          claims level data submitted by Medi-  
13          care Administrative Contractors,  
14          Medicare Advantage organizations (in-  
15          cluding Medicare Advantage Organi-  
16          zations offering an MA–PD plan), and  
17          PDP sponsors for covered outpatient  
18          drugs subject to an agreement under  
19          this section dispensed or administered  
20          to individuals enrolled under Part B,  
21          Part C, or Part D of title XVIII of  
22          the Social Security Act;

23                   “(III) within 5 days of identifica-  
24          tion, provide written notice of a dupli-  
25          cate discount or rebate to the State

1 agency, the Secretary, the covered en-  
2 tity, and the affected drug manufac-  
3 turer itemizing any violation described  
4 in clause (i)(I);

5 “(IV) within 5 days of identifica-  
6 tion, provide written notice to the Sec-  
7 retary, the covered entity (or entities,  
8 as applicable), and the affected drug  
9 manufacturer itemizing any violation  
10 described in subclauses (II) or (IV) of  
11 clause (i);

12 “(V) have access to the internet  
13 website described in paragraph  
14 (1)(B)(iii) containing applicable ceil-  
15 ing prices for covered outpatient  
16 drugs for purposes of identifying vio-  
17 lations described in clause (i)(II);

18 “(VI) subject to clauses (i)(V)  
19 and (ii)(III), make the data described  
20 in subclauses (I) and (II) available to  
21 the manufacturer in electronic format  
22 not later than 10 days after such data  
23 is provided to the clearinghouse;

24 “(VII) upon request by the Cen-  
25 ters for Medicare & Medicaid Services,

1 make the data described in subclauses  
2 (I) and (II) available for purposes of  
3 excluding 340B purchased units of  
4 Part B rebatable drugs or Part D  
5 rebatable drugs from Part B or Part  
6 D inflation rebates pursuant to sec-  
7 tion 1847A(i)(3)(B)(ii)(I) or section  
8 1860D–14B(b)(1)(B) of the Social  
9 Security Act; and

10 “(VIII) identify claims for cov-  
11 ered outpatient drugs subject to an  
12 agreement under this section that are  
13 submitted by pharmacies removed  
14 from the 340B program pursuant to  
15 subsection (a)(5)(F)(ix)(III) and no-  
16 tify the Secretary of the submission of  
17 any such claims by any such phar-  
18 macies.

19 “(iv) RESOLUTION OF VIOLATIONS.—

20 “(I) MEDICAID DUPLICATE DIS-  
21 COUNTS.—The Secretary, in consulta-  
22 tion with the State, as appropriate,  
23 shall take prompt action to fairly and  
24 adequately resolve violations described  
25 in clause (i)(I) reported by the clear-

1 inghouse in accordance with clause  
2 (iii)(III).

3 “(II) NONDUPLICATION WITH  
4 MAXIMUM FAIR PRICE.—The Sec-  
5 retary shall take prompt action to  
6 fairly and adequately resolve viola-  
7 tions described in clause (i)(II) re-  
8 ported by the clearinghouse in accord-  
9 ance with clause (iii)(IV).

10 “(III) DUPLICATE COVERED EN-  
11 TITY DISCOUNTS.—The Secretary  
12 shall develop and implement a process  
13 to resolve duplicate claims for a re-  
14 bate or discount under this section de-  
15 scribed in clause (i)(IV) such that the  
16 manufacturer pays only one rebate or  
17 discount under this section with re-  
18 spect to the same unit of a covered  
19 outpatient drug purchased under the  
20 program under this section. Covered  
21 entities (and any entities acting on  
22 their behalf) shall be subject to deter-  
23 minations made by the Secretary to  
24 resolve such duplicate claims (and the  
25 Secretary may contract this function

1 to the clearinghouse to make such de-  
2 terminations). In making such deter-  
3 minations, the Secretary shall inves-  
4 tigate duplicate claims for rebates or  
5 discounts and require covered entities  
6 (and any entities acting on their be-  
7 half) to take action to avoid or pay re-  
8 funds to reverse a duplicate claim.

9 “(IV) REFUNDS TO MANUFAC-  
10 TURERS.—The Secretary shall be re-  
11 sponsible for promptly refunding af-  
12 fected manufacturers of covered out-  
13 patient drugs for violations described  
14 in subclauses (I) and (II) of clause (i)  
15 and seeking subsequent repayment  
16 from covered entities or States (with  
17 respect to violations described in  
18 clause (i)(I)), or providers or dis-  
19 pensers (with respect to violations de-  
20 scribed in clause (i)(II)). Subject to  
21 the determination by the Secretary or  
22 clearinghouse under subclause (III),  
23 the covered entity (or entities) shall  
24 be liable to the manufacturer of the  
25 covered outpatient drug that is the

1 subject of the violation described in  
 2 clause (i)(IV) in an amount equal to  
 3 the reduction in the price of the drug  
 4 (as described in subsection (a)(1))  
 5 and shall repay such amount to such  
 6 manufacturer within 60 days of re-  
 7 ceiving a notice described in clause  
 8 (iii)(IV).”.

9 (b) PROVISION OF DRUG CLAIMS DATA BY MED-  
 10 ICAID; REMOVAL OF DUPLICATE CLAIMS.—

11 (1) MEDICAID.—Section 1902(a) of the Social  
 12 Security Act (42 U.S.C. 1396a(a)) is amended—

13 (A) in paragraph (86), by striking “and”  
 14 at the end;

15 (B) in paragraph (87)(D), by striking the  
 16 period and inserting “; and”; and

17 (C) by inserting after paragraph (87) the  
 18 following new paragraph:

19 “(88) provide for a mechanism for the State  
 20 agency to furnish, and for the State agency to re-  
 21 quire each Medicaid managed care organization (as  
 22 defined in section 1903(m)(1)(A)) to furnish, to the  
 23 clearinghouse, in a machine-readable format, within  
 24 5 days following the date of claim payment, claims  
 25 level data, including rebate file data, for covered out-

1 patient drugs dispensed, furnished, or administered  
 2 to individuals enrolled under a State plan (or a waiv-  
 3 er of such plan) that includes, with respect to each  
 4 dispense, furnishing, or administration of such a  
 5 drug, the data elements described in subsection  
 6 340B(a)(5)(J)(iii) of the Public Health Service Act,  
 7 and for the State agency to remove from any rebate  
 8 request described in section 340B(d)(2)(C)(i)(I) of  
 9 such Act any claim that is the subject of a notice  
 10 submitted by such entity under section  
 11 340B(d)(2)(C)(iii)(III) of such Act.”.

12 (c) PROVISION OF DRUG CLAIMS DATA BY MEDI-  
 13 CARE.—

14 (1) MEDICARE PART B.—Section 1842 of the  
 15 Social Security Act (42 U.S.C. 1395u) is amended  
 16 by adding at the end the following:

17 “(v) PROVISION OF DRUG CLAIMS DATA; MECHA-  
 18 NISM TO REFUND DUPLICATED AMOUNTS.—Each Medi-  
 19 care administrative contractor shall furnish to the clear-  
 20 inghouse, in a machine-readable format, claims level data  
 21 for covered outpatient drugs furnished or administered to  
 22 individuals enrolled under this part that includes, with re-  
 23 spect to each furnishing or administration of such a drug,  
 24 the data elements described in section 340B(a)(5)(J)(iii)  
 25 of the Public Health Service Act. Each Medicare adminis-



1 trative contractor shall furnish such data to the clearing-  
2 house within 5 days following the date the claim for such  
3 drug is paid by the Medicare administrative contractor.”.

4 (2) MEDICARE ADVANTAGE ORGANIZATIONS.—  
5 Section 1857(e) of the Social Security Act (42  
6 U.S.C. 1395w–27(e)) is amended by adding at the  
7 end the following:

8 “(6) PROVISION OF DRUG CLAIMS DATA; MECH-  
9 ANISM TO REFUND DUPLICATED AMOUNTS.—A con-  
10 tract under this part shall require a  
11 Medicare+Choice organization to furnish to the  
12 clearinghouse, in a machine-readable format, claims  
13 level data for covered outpatient drugs furnished or  
14 administered to individuals enrolled with the organi-  
15 zation under this part that includes, with respect to  
16 each furnishing or administration of such a drug,  
17 the data elements described in section  
18 340B(a)(5)(J)(iii) of the Public Health Service Act.  
19 Such contract shall require the Medicare+Choice or-  
20 ganization to furnish such data to the clearinghouse  
21 within 5 days following the date the claim for such  
22 drug is paid by the Medicare+Choice organization.”.

23 (3) PRESCRIPTION DRUG PLANS.—Section  
24 1860D–12(b) of the Social Security Act (42 U.S.C.

1       1395w–112(b)) is amended by adding at the end the  
2       following:

3               “(9) PROVISION OF DRUG CLAIMS DATA; MECH-  
4       ANISM TO REFUND DUPLICATED AMOUNTS.—A con-  
5       tract under this part shall require a PDP sponsor to  
6       furnish to the clearinghouse in a machine-readable  
7       format, claims level data for covered outpatient  
8       drugs dispensed to individuals enrolled in a prescrip-  
9       tion drug plan offered by such sponsor under this  
10      part that includes, with respect to each dispense of  
11      such drug, the data elements described in section  
12      340B(a)(5)(J)(iii) of the Public Health Service Act.  
13      Such contract shall require a PDP sponsor to fur-  
14      nish such data to the clearinghouse within 5 days  
15      following the date the claim for such drug is paid by  
16      the PDP sponsor.”.

17             (4) MA–PDS.—Section 1857(f)(3) of the Social  
18      Security Act (42 U.S.C. 1395w–27(f)(3)) is amend-  
19      ed by adding at the end the following:

20               “(F) PROVISION OF DRUG CLAIMS DATA;  
21               MECHANISM TO REFUND DUPLICATED  
22               AMOUNTS.—Section 1860D–12(b)(9).”.

1 **SEC. 17. LIMITATION ON ADMINISTRATOR SERVICE FEES**  
2 **AND CONTRACT PHARMACY FEES.**

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

6 “(f) REQUIREMENTS FOR TPA AND CONTRACT  
7 PHARMACY REMUNERATION.—

8 “(1) THIRD-PARTY ADMINISTRATOR FEES.—A  
9 third-party administrator furnishing 340B program-  
10 related services on behalf of a covered entity de-  
11 scribed in subsection (a)(4), including reviewing or  
12 processing claims or other information to identify  
13 covered outpatient drugs dispensed to individuals  
14 who are patients of the covered entity (as defined in  
15 subsection (b)(3)) may receive remuneration from  
16 such covered entity for the performance of such  
17 services only if—

18 “(A) such remuneration is a flat dollar  
19 amount not directly or indirectly based on any  
20 price of, or discount or other remuneration pro-  
21 vided with respect to, a covered outpatient  
22 drug, paid for each unit of service furnished to  
23 the covered entity, regardless of whether a pre-  
24 scription was dispensed to an individual who is  
25 a patient of the covered entity;

1           “(B) the amount of such remuneration is  
2           consistent with fair market value in an arm’s-  
3           length transaction for the bona fide, itemized  
4           340B-related services actually performed on be-  
5           half of the covered entity; and

6           “(C) such remuneration complies with ap-  
7           plicable State and Federal law, including sec-  
8           tion 1128B(b) of the Social Security Act.

9           “(2) CONTRACT PHARMACY FEES.—A contract  
10          pharmacy that has entered into a written agreement  
11          with a covered entity pursuant to and satisfies the  
12          applicable requirements in subsection (a)(5)(F) may  
13          receive remuneration from such covered entity for  
14          the performance of services associated with dis-  
15          pensing covered outpatient drugs subject to an  
16          agreement under this section to individuals who are  
17          patients of the covered entity (as defined in sub-  
18          section (b)(3)) only if—

19               “(A) such remuneration is a flat dollar  
20               amount not directly or indirectly based on any  
21               price of, or discount or other remuneration pro-  
22               vided with respect to, a covered outpatient  
23               drug, paid for each dispense of such a drug to  
24               a patient of the covered entity;

1           “(B) the amount of remuneration for each  
2           dispense does not exceed 125 percent of the av-  
3           erage per-prescription dispensing fee paid to  
4           such pharmacy by all third-party payors, based  
5           on data from the most recent full calendar year  
6           for which such data is available;

7           “(C) the amount of such remuneration is  
8           consistent with fair market value in an arm’s-  
9           length transaction for the bona fide, itemized  
10          340B-related services actually performed on be-  
11          half of the covered entity; and

12          “(D) such remuneration complies with ap-  
13          plicable State and Federal law, including sec-  
14          tion 1128B(b) of the Social Security Act.

15          For purposes of subparagraph (B), if a covered enti-  
16          ty has entered into an agreement for contract phar-  
17          macy services pursuant to subsection (a)(5)(F) that  
18          permits the contract pharmacy service provider to  
19          dispense covered outpatient drugs on behalf of the  
20          covered entity at more than one pharmacy location,  
21          the average dispensing fee shall be calculated across  
22          all pharmacy locations subject to such agreement.

23          “(3) AUDITABLE RECORDS.—A covered entity  
24          shall retain copies of written agreements with third-  
25          party administrators or contract pharmacies de-

1       scribed in this subsection for a period of time speci-  
2       fied by the Secretary and shall make copies of such  
3       agreements available to the Secretary or their des-  
4       ignee upon request.

5           “(4) CIVIL MONETARY PENALTY.—A third-  
6       party administrator or contract pharmacy described  
7       in this subsection that fails to comply with the appli-  
8       cable requirements specified in this subsection shall  
9       be required to pay a civil monetary penalty equal to  
10      10 times the amount such third-party administrator  
11      or contract pharmacy received for the performance  
12      of relevant services described in this subsection. The  
13      provisions of section 1128A of the Social Security  
14      Act (other than subsections (a) and (b)) shall apply  
15      to a civil monetary penalty under this paragraph in  
16      the same manner as such provisions apply to a pen-  
17      alty or proceeding under section 1128A(a). The Of-  
18      fice of Inspector General of the Department of  
19      Health and Human Services shall carry out the pro-  
20      visions related to the imposition of civil monetary  
21      penalties under this paragraph.”.

22   **SEC. 18. CLARIFICATION.**

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

1       “(g) CLARIFICATION.—The provisions of this section  
 2 supersede any provision or requirement of State or local  
 3 law insofar as that State or local law may establish, imple-  
 4 ment, or continue in effect a standard or requirement that  
 5 differs from or relates in any way to the provisions of this  
 6 section or, except for any State regulations issued to carry  
 7 out subsection (a)(5)(A)(iii), relates in any way to the  
 8 drug discount program under this section or covered out-  
 9 patient drugs subject to an agreement under this section,  
 10 including the distribution of such drugs. Except for any  
 11 State regulations issued to carry out subsection  
 12 (a)(5)(A)(iii), no provision or requirement of State or local  
 13 law shall grant additional rights or impose additional obli-  
 14 gations related to the 340B program.”.

15 **SEC. 19. ENSURING THE EQUITABLE TREATMENT OF 340B**  
 16 **COVERED ENTITIES AND PHARMACIES PAR-**  
 17 **TICIPATING IN THE 340B DRUG DISCOUNT**  
 18 **PROGRAM.**

19       (a) GROUP HEALTH PLAN AND HEALTH INSURANCE  
 20 ISSUER REQUIREMENTS.—Subpart II of part A of title  
 21 XXVII of the Public Health Service Act (42 U.S.C.  
 22 300gg–11 et seq.) is amended by adding at the end the  
 23 following:

1   **“SEC. 2730. REQUIREMENTS RELATING TO THE 340B DRUG**  
2                   **DISCOUNT PROGRAM.**

3           “(a) IN GENERAL.—A group health plan, a health  
4 insurance issuer offering group or individual health insur-  
5 ance coverage, or a pharmacy benefit manager acting on  
6 behalf of such plan or issuer, may not discriminate against  
7 a covered entity (as defined in subsection (e)(1)), a con-  
8 tract pharmacy (as defined in subsection (e)(2)), or a par-  
9 ticipant, beneficiary, or enrollee of such plan or coverage  
10 by imposing requirements, exclusions, reimbursement  
11 terms, or other conditions on such entity or pharmacy that  
12 differ from those applied to entities or pharmacies that  
13 are not covered entities or contract pharmacies on the  
14 basis that the entity or pharmacy is a covered entity or  
15 contract pharmacy or that the entity or pharmacy dis-  
16 penses 340B drugs, by taking any action prohibited under  
17 subsection (b).

18           “(b) SPECIFIED PROHIBITED ACTIONS.—A group  
19 health plan, a health insurance issuer offering group or  
20 individual health insurance coverage, or a pharmacy ben-  
21 efit manager acting on behalf of such plan or issuer, may  
22 not discriminate against a covered entity, a contract phar-  
23 macy, or a participant, beneficiary, or enrollee of such  
24 plan or coverage by doing any of the following:

25                   “(1) Reimbursing a covered entity or contract  
26           pharmacy for a quantity of a 340B drug (as defined



1 in subsection (e)) in an amount less than such plan,  
2 issuer, or pharmacy benefit manager (as applicable)  
3 would pay to any other similarly situated (as speci-  
4 fied by the Secretary) entity or pharmacy that is not  
5 a covered entity or a contract pharmacy for such  
6 quantity of such drug on the basis that the entity  
7 or pharmacy is a covered entity or contract phar-  
8 macy or that the entity or pharmacy dispenses 340B  
9 drugs.

10 “(2) Imposing any terms or conditions on cov-  
11 ered entities or contract pharmacies with respect to  
12 any of the following that differ from such terms or  
13 conditions applied to other similarly situated entities  
14 or pharmacies that are not covered entities or con-  
15 tract pharmacies on the basis that the entity or  
16 pharmacy is a covered entity or contract pharmacy  
17 or that the entity or pharmacy dispenses 340B  
18 drugs:

19 “(A) Fees, chargebacks, clawbacks, adjust-  
20 ments, or other assessments.

21 “(B) Professional dispensing fees.

22 “(C) Restrictions or requirements regard-  
23 ing participation in standard or preferred phar-  
24 macy networks.

1           “(D) Requirements relating to the fre-  
2           quency or scope of audits or to inventory man-  
3           agement systems using generally accepted ac-  
4           counting principles.

5           “(E) Any other restrictions, conditions,  
6           practices, or policies that interfere with the  
7           ability of a covered entity or contract pharmacy  
8           to use the discounts provided under section  
9           340B in accordance with applicable require-  
10          ments under such section.

11          “(3) Interfering with an individual’s choice to  
12          receive a 340B drug from a covered entity or con-  
13          tract pharmacy, whether in person or via direct de-  
14          livery, mail, or other form of shipment, as permitted  
15          under section 340B.

16          “(4) Interfering with, limiting, or prohibiting  
17          actions by a covered entity or contract pharmacy to  
18          identify, either directly or through a third party,  
19          claims for 340B drugs, including by submission of  
20          claims data or use of claims modifiers or indicators.

21          “(5) Refusing to contract with a covered entity  
22          or contract pharmacy for reasons other than those  
23          that apply equally to entities or pharmacies that are  
24          not covered entities or contract pharmacies, or on  
25          the basis that—

1           “(A) the entity or pharmacy is a covered  
2           entity or a contract pharmacy; or

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

6           “(6) With respect to a group health plan or  
7           health insurance issuer for health insurance cov-  
8           erage, denying coverage of a drug on the basis that  
9           such drug is a 340B drug.

10          “(c) PROHIBITED ACTIONS IN DEROGATION OF SEC-  
11          TION 340B AFFORDABILITY ASSISTANCE PROVISIONS.—  
12          A group health plan, a health insurance issuer offering  
13          group or individual health insurance coverage, or a phar-  
14          macy benefit manager acting on behalf of such plan or  
15          issuer shall not prohibit or restrict, in contracts with phar-  
16          macies in their network that are contract pharmacies or  
17          entity pharmacies, or in any other manner, any reduction  
18          in or subsidy for the out-of-pocket amount for a 340B  
19          drug charged to an individual (including a participant,  
20          beneficiary, or enrollee of such plan or coverage) that is  
21          required or authorized by subparagraphs (G) or (H) of  
22          section 340B(a)(5). Any general prohibition or restriction  
23          on reducing or subsidizing the out-of-pocket amount for  
24          a drug charged to an individual that lacks an express ex-  
25          emption for any reductions in or subsidies for the out-of-

1 pocket amount for a 340B drug that are required or au-  
2 thorized by subparagraphs (G) or (H) of section  
3 340B(a)(5) is a violation of this subsection. Any contrac-  
4 tual provision that violates this subsection in any manner  
5 shall be void and unenforceable.

6 “(d) ENFORCEMENT MECHANISM FOR PHARMACY  
7 BENEFIT MANAGERS.—The Secretary shall impose a civil  
8 monetary penalty on any pharmacy benefit manager that  
9 violates the requirements of this section. Such penalty  
10 shall not exceed \$5,000 per violation per day. The Sec-  
11 retary shall issue proposed regulations to implement this  
12 subsection not later than 60 days after the date of the  
13 enactment of this subsection and shall finalize such regu-  
14 lations not later than 180 days after such date of enact-  
15 ment.

16 “(e) DEFINITIONS.—For purposes of this section:

17 “(1) 340B DRUG.—The term ‘340B drug’  
18 means a drug that is—

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

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

23 “(2) CONTRACT PHARMACY.—The term ‘con-  
24 tract pharmacy’ has the meaning given such term in  
25 section 340B(a)(5)(F).

1           “(3) COVERED ENTITY.—The term ‘covered en-  
2       tity’ has the meaning given such term in section  
3       340B(a)(4).

4           “(4) ENTITY PHARMACY.—The term ‘entity  
5       pharmacy’ has the meaning given such term in sec-  
6       tion 340B(a)(5)(F).”.

7       (b) APPLICATION OF REQUIREMENTS TO MEDI-  
8       CARE.—

9           (1) PART D.—Section 1860D–12(b) of the So-  
10       cial Security Act (42 U.S.C. 1395w–112(b)) is  
11       amended by adding at the end the following:

12           “(10) APPLICATION OF REQUIREMENTS RELAT-  
13       ING TO THE 340B DRUG DISCOUNT PROGRAM.—Each  
14       contract entered into under this subsection with a  
15       PDP sponsor shall provide that the requirements of  
16       section 2730 of the Public Health Service Act apply  
17       to such sponsor, and to any pharmacy benefit man-  
18       ager that contracts with such sponsor, in the same  
19       manner as such requirements apply with respect to  
20       a group health plan, a health insurance issuer, or a  
21       pharmacy benefit manager described in such sec-  
22       tion.”.

23           (2) PART C.—Section 1857(f)(3) of the Social  
24       Security Act (42 U.S.C. 1395w–27(f)(3)) is amend-  
25       ed by adding at the end the following:

1                   “(G) 340B DRUG DISCOUNT PROGRAM.—  
2                   Section 1860D–12(b)(10).”.

3 **SEC. 20. EFFECTIVE DATE.**

4           Except as otherwise specified, the provisions in this  
5 Act shall become effective on the date that is one year  
6 following the date of enactment of this Act.

○