

118TH CONGRESS
2D SESSION

H. R. 8574

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

IN THE HOUSE OF REPRESENTATIVES

MAY 28, 2024

Mr. BUCSHON (for himself, Mr. CARTER of Georgia, 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

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 a qualifying referral described in clause (ii), a covered outpatient drug

1 prescribed or ordered for an individual by
2 a health care professional who is not a cov-
3 ered entity provider shall not qualify for
4 pricing described in subsection (a)(1).

5 “(ii) EXCEPTION FOR QUALIFYING
6 REFERRALS.—In the case of a ‘qualifying
7 referral’, all requirements in subparagraph
8 (A) shall apply, except for clauses (i)(I),
9 (i)(II), (ii), (iii), and (v)(II) of such sub-
10 paragraph. For purposes of this para-
11 graph, a ‘qualifying referral’ shall refer to
12 the sequence of occurrences described in
13 this clause for which a covered entity
14 maintains documentation sufficient to dem-
15 onstrate that—

16 “(I) a covered entity provider
17 evaluates and recommends to the indi-
18 vidual, during an encounter at the
19 covered entity (including child site, as
20 applicable), that such individual re-
21 ceive a specified type of specialty
22 health care not available at the cov-
23 ered entity and such recommendation
24 is contemporaneously documented, at
25 the time of such encounter, in the

1 medical record the covered entity cre-
2 ates and maintains for such indi-
3 vidual;

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

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

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

24 “(iii) COVERED ENTITY ELIGIBILITY
25 FOR QUALIFYING REFERRALS.—Notwith-

1 standing any other provision in this sec-
2 tion, a covered entity shall not qualify for
3 pricing described in subsection (a)(1) with
4 respect to a prescription or order for a cov-
5 ered outpatient drug resulting from a
6 qualifying referral unless such covered en-
7 tity—

8 “(I) is described in subparagraph
9 (N) of subsection (a)(4);

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

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

23 “(D) HEALTH CARE SERVICE RE-
24 QUIRED.—For purposes of this section, an indi-
25 vidual shall not be considered a patient of the

covered entity described in subsection (a)(4) if the individual receives from the covered entity only the administration or infusion of a drug or drugs, or the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting, without a covered entity provider-to-patient encounter involving the provision of a health care service.”.

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

“(4) SPECIFIED NONHOSPITAL COVERED ENTITY.—In this section, the term ‘specified nonhospital covered entity’ means a covered entity that—

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

“(i) has average annual operating revenues exceeding \$1,000,000,000 calculated over the most recent three-year period for which data are available, which revenue threshold shall be adjusted for inflation annually to reflect rate of change in the Con-

sumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics; or

“(ii) is an affiliate of a hospital; or
“(B) is described in subsection (a)(4)(A) and becomes affiliated with a hospital on or after December 1, 2023.

For purposes of this definition, the term ‘affiliate’ shall mean an entity that, directly or indirectly, controls, is controlled by, or is under common control with the referenced entity, including the referenced entity’s parent, and the term ‘control’ shall mean the power to direct the management and policies of an entity, directly or indirectly, whether through the ownership of voting securities, by contract, or otherwise.”.

SEC. 3. PREVENTION OF MEDICAID DUPLICATE DISCOUNTS; OVERSIGHT OF COVERED ENTITIES.

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

(1) in subparagraph (A)—

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

(B) by adding at the end the following:

1 “(iii) REGULATIONS.—Not later than
2 1 year after the date of enactment of this
3 clause, the Secretary shall promulgate final
4 regulations through notice-and-comment
5 rulemaking describing—

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

23 “(II) procedures State Medicaid
24 programs shall use to exclude requests
25 for Medicaid rebates on covered out-

1 patient drugs purchased under the
 2 340B program that are dispensed, ad-
 3 ministered, or otherwise furnished to
 4 a Medicaid managed care enrollee and
 5 requirements for State Medicaid pro-
 6 grams to promulgate rules to provide
 7 affected manufacturers a prompt rem-
 8 edy with respect to any incorrectly
 9 billed rebates for such drugs.”;

10 (2) in subparagraph (C)—

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

13 “(i) DUPLICATE DISCOUNTS AND
 14 DRUG RESALE.—A covered entity shall per-
 15 mit”;

16 (B) by striking “(A) or (B)” and inserting
 17 “(A), (B), (J), or (K)”;

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

19 “(ii) USE OF MARGIN.—A covered en-
 20 tity shall permit the Secretary to audit, at
 21 the Secretary’s expense, the records of the
 22 entity to determine—

23 “(I) how the margin (as defined
 24 in subparagraph (L)(iv)) generated on
 25 covered outpatient drugs subject to an

1 agreement under this section dis-
 2 pensed or furnished by such entity (or
 3 a contract pharmacy described in sub-
 4 section (a)(5)(F)) is used by such en-
 5 tity; and

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

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

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

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

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

20 “(E) HOSPITAL CHILD SITE REQUIRE-
 21 MENTS.—

22 “(i) IN GENERAL.—A covered entity
 23 described in one of subparagraphs (L)
 24 through (O) of paragraph (4) may register
 25 an off-campus outpatient facility associated

1 with such covered entity for inclusion in
2 the identification system described in sub-
3 section (d)(2)(B)(iv) to participate in the
4 program under this section as an integral
5 part of such covered entity if such covered
6 entity demonstrates to the Secretary, in a
7 manner specified by the Secretary, that
8 such facility satisfies each of the require-
9 ments in this subparagraph. For purposes
10 of this section, each facility registered to
11 participate in the program under this sec-
12 tion and satisfying the requirements in this
13 subparagraph shall be referred to as a
14 ‘child site’).

15 “(I) The facility is listed on the
16 covered entity’s most recently filed
17 Medicare cost report on a line that is
18 reimbursable under the Medicare pro-
19 gram (or, if the covered entity is a
20 children’s hospital that does not file a
21 Medicare cost report, the covered enti-
22 ty submits to the Secretary a signed
23 statement certifying that the facility
24 would be correctly included on a reim-
25 bursable line of a Medicare cost report

1 if the covered entity filed a cost re-
2 port).

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

15 “(III) The facility is wholly
16 owned by the covered entity.

17 “(IV) The Secretary has made a
18 determination, under the process de-
19 scribed in section 413.65(b) of title
20 42, Code of Federal Regulations (or
21 any successor regulations), that the
22 facility meets the Medicare provider-
23 based standards under section 413.65
24 of title 42, Code of Federal Regula-
25 tions (or any successor regulations)

1 for an off-campus outpatient depart-
2 ment of the covered entity.

3 “(V) The facility provides out-
4 patient health care services that are
5 not limited to only dispensing, admin-
6 istering, or otherwise furnishing cov-
7 ered outpatient drugs.

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

17 “(VII) The facility is located in
18 an area with a shortage of personal
19 health services that is—

20 “(aa) initially designated by
21 the Secretary pursuant to section
22 254b(b)(3) of title 42, United
23 States Code, on or before Decem-
24 ber 1, 2023; or

“(bb) designated by the Secretary pursuant to subparagraphs (A) through (C) of section 254b(b)(3) of title 42, United States Code, after December 1, 2023, using the scoring methodology and criteria specified by the Secretary as of December 1, 2023.

“(VIII) In the case of a covered entity described in one of subparagraphs (L) through (O) of paragraph (4) that is 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 to provide health care services to low-income individuals who are uninsured, as described in paragraphs (4)(L)(i) and (11), the facility independently complies with all requirements applicable to such covered entity with respect to such contract.

“(IX) For the most recent year, the facility’s total cost incurred for

1 charity care (as such term is defined
2 in line 23 of worksheet S-10 to the
3 Medicare cost report, or in any suc-
4 cessor form) furnished at such facility
5 during such year, as a share of the fa-
6 cility's total patient service revenue, is
7 greater than or equal to the amount
8 described in item (aa) or item (bb),
9 whichever is greater—

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

19 “(bb) the average cost in-
20 curred for charity care, as a
21 share of total patient service rev-
22 enue, calculated for the year
23 prior to the most recent year for
24 which data is available, across all
25 hospitals in the State where the

1 facility is located that receive
2 payments for inpatient hospital
3 services under the prospective
4 payment system established
5 under section 1886(d) of the So-
6 cial Security Act.

7 “(X) For the most recent year,
8 the facility’s share of total outpatient
9 services revenue derived from base re-
10 imbursement to such entity (excluding
11 supplemental and indirect reimburse-
12 ment) under title XIX of the Social
13 Security Act (including with respect
14 to individuals also entitled to benefits
15 under part A of title XVIII of such
16 Act or enrolled in part B of title
17 XVIII of such Act) and payments
18 under title XXI of such Act for items
19 and services furnished on an out-
20 patient basis at the facility (including
21 any cost sharing for such items and
22 services) is greater than or equal to
23 the amount described in item (aa) or
24 item (bb), whichever is greater—

1 “(aa) for such year, the
2 share of total outpatient services
3 revenue derived from base reim-
4 bursement to such entity (exclud-
5 ing supplemental and indirect re-
6 imbursement) under title XIX of
7 the Social Security Act (including
8 with respect to individuals also
9 entitled to benefits under part A
10 of title XVIII of such Act or en-
11 rolled in part B of title XVIII of
12 such Act) and payments under
13 title XXI of such Act for items
14 and services furnished on an out-
15 patient basis at the on-campus
16 locations of the covered entity
17 with which the facility is associ-
18 ated (including any cost sharing
19 for such items and services)
20 (‘campus’ shall have the meaning
21 given such term in section
22 413.65(a)(2) of title 42, Code of
23 Federal Regulations (or any suc-
24 cessor regulations)); or

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

1 ment services established under
2 section 1833(t) of such Act.

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

14 “(ii) LIMITATION.—Only an off-cam-
15 pus outpatient facility that meets each of
16 the requirements under this subparagraph
17 may purchase covered outpatient drugs
18 under the 340B program or use covered
19 outpatient drugs purchased under the
20 340B program by another part of the cov-
21 ered entity that is authorized to participate
22 in such program. Any transfer of 340B
23 drugs to another facility or another part of
24 a covered entity that is not authorized to

1 participate in the 340B program shall be
2 deemed a violation of subparagraph (B).

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

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

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

23 “(v) CIVIL MONETARY PENALTY.—
24 Where a covered entity knowingly and in-
25 tentiously violates clause (ii) or otherwise

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

20 “(vi) SECRETARIAL PUBLICATION OF
21 REPORTS.—On an annual basis, the Sec-
22 retary shall prepare and make available to
23 the public in an electronic, machine read-
24 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 \$13,946 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 \$13,946 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 \$13,946 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 up to three additional
25 Public Use Microdata Areas that are

1 contiguous with the Public Use
2 Microdata Area in which such entity
3 is located, which shall be listed in the
4 identification system described in sub-
5 section (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 2024, 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, 2024, 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, 2024 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 NCPDP 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 a qualifying
12 referral 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 a qualifying referral 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-

ernment and private payors;
minus

“(bb) aggregate costs to acquire such drugs at either the ceiling price described in paragraph (1) or any voluntary sub-ceiling price at which the covered entity purchased such drug or drugs, as applicable; minus

“(cc) aggregate costs incurred by the covered entity that are necessary for such entity to participate in the program under this section and to comply with such program’s requirements, including program-related compliance, legal, educational, and administrative costs (such costs shall be determined in accordance with Generally Accepted Accounting Principles), and compensation paid to third-party administrators or contract pharmacies to carry out program-related functions.”.

1 (b) RULEMAKING.—Not later than 180 days after the
2 date of enactment of this Act, the Secretary of Health and
3 Human Services shall issue an interim final rule to carry
4 out section 340B(a)(5)(L) of the Public Health Service
5 Act, as added by subsection (a).

6 **SEC. 11. REVISIONS TO EXISTING 340B HOSPITAL ELIGI-**
7 **BILITY REQUIREMENTS.**

8 Section 340B(a)(4) of the Public Health Service Act
9 (42 U.S.C. 256b(a)(4)) is amended—

10 (1) in subparagraph (L)(i)—

11 (A) by inserting “and that was registered
12 with the 340B program in the covered entity
13 identification system established under sub-
14 section (d)(2)(B)(iv) as such a hospital on or
15 before December 1, 2023” after “formally
16 granted governmental powers by a unit of state
17 or local government”; and

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

23 (2) by amending subparagraph (N) to read as
24 follows:

1 “(N) An entity that is a critical access hos-
 2 pital (as determined under section 1820(c)(2)
 3 of the Social Security Act (42 U.S.C. 1395i–
 4 4(c)(2))) or a rural emergency hospital (as de-
 5 termined under the requirements in section
 6 1861(kkk) of the Social Security Act (42
 7 U.S.C. 1395x(kkk) and in implementing regula-
 8 tions set forth in parts 419, 424, 485, 488, and
 9 489 of title 42 of the Code of Federal Regula-
 10 tions in effect as of January 1, 2023)), and
 11 that meets the requirements of subparagraph
 12 (L)(i).”; and

13 (3) in subparagraph (O) by inserting “that
 14 demonstrates to the Secretary that at least 60 per-
 15 cent of annual inpatient discharges for cost report-
 16 ing periods beginning after December 1, 2023 are
 17 for inpatients who reside in a county that is not part
 18 of a Metropolitan Statistical Area, as defined by the
 19 Director of the Office of Management and Budget”
 20 before “, or a sole community hospital”.

21 **SEC. 12. ADDITIONAL REQUIREMENTS FOR 340B HOS-**
 22 **PITALS.**

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

1 “(11) CLARIFICATION OF ELIGIBILITY STAND-
2 ARDS FOR PRIVATE NONPROFIT HOSPITALS WITH A
3 CONTRACT WITH A STATE OR LOCAL GOVERNMENT
4 TO PROVIDE HEALTH CARE SERVICES.—

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

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

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

1 “(iii) the Secretary further deter-
2 mines, based on a review of the contract
3 (as described in clause (i)) that the con-
4 tract creates an enforceable obligation for
5 the hospital to furnish the individuals de-
6 scribed in clause (ii) the full range of serv-
7 ices provided at the hospital (including any
8 child sites); and

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

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

1 identification system described in subsection
2 (d)(2)(B)(iv), and cease making purchases
3 under such program and representing to third
4 parties that it may purchase under such pro-
5 gram.

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

1 amount, which shall be compounded monthly
2 and equal to the current short-term interest
3 rate as determined by the Federal Reserve for
4 the time period for which the covered entity is
5 liable.

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

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

1 “(i) FEDERAL POVERTY GUIDE-
2 LINES.—The term ‘Federal poverty guide-
3 lines’ means the poverty guidelines updated
4 periodically in the Federal Register by the
5 Department of Health and Human Serv-
6 ices pursuant to section 9902(2) of title
7 42, United States Code.

8 “(ii) LOW-INCOME INDIVIDUAL.—The
9 term ‘low-income individual’ means an in-
10 dividual with family income at or below
11 200 percent of the Federal poverty guide-
12 lines.

13 “(iii) UNINSURED.—The term ‘unin-
14 sured’ means lacking minimum essential
15 coverage, as defined in subsection
16 5000A(f) of the Internal Revenue Code (26
17 U.S.C. 5000A(f)) and implementing regu-
18 lations.

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

22 “(A) IN GENERAL.—A covered entity de-
23 scribed in paragraph (4)(L)(i) that is either a
24 private nonprofit hospital that has as the basis
25 for its participation in the program under this

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

1 “(B) MEDICAID AND CHIP OUTPATIENT
2 REVENUE.—Within 90 days following the con-
3 clusion of a year, the Secretary shall prepare
4 and make available to the public in an elec-
5 tronic, machine-readable format for each State
6 for the concluded year, a list that ranks all
7 acute care hospitals in such State in descending
8 order based on each hospital’s share of total
9 outpatient services revenue derived from base
10 reimbursement to such hospital (excluding sup-
11 plemental and indirect reimbursement) under
12 title XIX of the Social Security Act (including
13 with respect to individuals also entitled to bene-
14 fits under part A of title XVIII of such Act or
15 enrolled in part B of title XVIII of such Act)
16 and payments under title XXI of such Act for
17 items and services furnished on an outpatient
18 basis at the hospital (including any cost sharing
19 for such items and services). The Secretary
20 shall specify the threshold for the top 40 per-
21 cent of hospitals on the list.

22 “(C) UNCOMPENSATED OUTPATIENT
23 CARE.—Within 90 days following the conclusion
24 of a year, the Secretary shall prepare and make
25 available to the public in an electronic, ma-

chine-readable format for each State for the concluded year, a list that ranks all acute care hospitals in such State in descending order based on each hospital's total cost of uncompensated care for items and services furnished on an outpatient basis as a share of the hospital's total outpatient services revenue. For purposes of this list, costs of uncompensated outpatient care shall be determined in a manner consistent with the instructions on worksheet S-10 to the Medicare cost report (or any successor form), with adjustments to limit uncompensated outpatient care costs to those incurred in providing items and services on an outpatient basis at the hospital. The Secretary shall specify the threshold for the top 40 percent of hospitals on the list.

“(D) DEREGISTRATION.—Within 30 days following the Secretary's publication of the lists described in subparagraphs (B) and (C), each covered entity subject to this paragraph that is not included in the top 40 percent of hospitals on both lists shall notify the Secretary that the covered entity does not satisfy one or more requirements described in this paragraph,

deregister the entity from the program under this section and the identification system described in subsection (d)(2)(B)(iv), and cease making purchases under such program and representing to third parties that it may purchase under such program. Such an entity may seek to register under another covered entity category described in paragraph (4) if such entity meets the criteria for such a category and applicable requirements under this section.

“(E) OBLIGATION TO SELF-DISCLOSE.—A covered entity described in subparagraph (D) shall immediately disclose to the Secretary and the manufacturer of the affected covered outpatient drug any purchase made under the program under this section by such covered entity that, at the time of the purchase of such drug, did not fully satisfy the requirements in subparagraphs (B) and (C). Any such purchase shall require the covered entity to promptly conduct an audit supervised by the Secretary to identify the full scope of noncompliance with such requirements and to provide the written results of such audit to the Secretary and the manufacturer of the affected covered outpatient

1 drug. The covered entity shall be liable to the
2 manufacturer of the covered outpatient drug
3 that is the subject of the noncompliance in an
4 amount equal to the reduction in the price of
5 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 “(13) PROHIBITION AGAINST EXTRAORDINARY
6 COLLECTION ACTIONS.—

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

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

24 “(C) CIVIL MONETARY PENALTY.—Where
25 a covered entity violates the prohibition in this

1 paragraph, the covered entity shall be required
2 to pay a civil monetary penalty equal to \$2,500
3 for each extraordinary collection action taken
4 with respect to an individual described in this
5 paragraph, which amount shall be adjusted for
6 inflation annually to reflect the rate of change
7 in the Consumer Price Index for All Urban
8 Consumers published by the Bureau of Labor
9 Statistics. The provisions of section 1128A of
10 the Social Security Act (other than subsections
11 (a) and (b)) shall apply to a civil monetary pen-
12 alty under this paragraph in the same manner
13 as such provisions apply to a penalty or pro-
14 ceeding under section 1128A(a). The Office of
15 Inspector General of the Department of Health
16 and Human Services shall carry out the provi-
17 sions related to the imposition of civil monetary
18 penalties under this paragraph.

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

23 “(14) ADDITIONAL REQUIREMENT FOR CER-
24 TAIN HOSPITALS.—

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

1 and self-disclose in accordance with the pre-
2 ceding sentence.

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

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

13 “(D) DEREGISTRATION AND CONDITIONS
14 FOR SUBSEQUENT REGISTRATION.—

15 “(i) DE-REGISTRATION.—On October
16 1 of each year beginning on or after the
17 date that is 24 months after the date of
18 enactment of this paragraph, each covered
19 entity subject to this paragraph that has
20 reported at least one year of data to the
21 Secretary under paragraph (5)(L) and that
22 does not have, for the most recently re-
23 ported year, annual charity care costs
24 greater than or equal to the margin, shall
25 notify the Secretary that it does not meet

1 the condition of participation under this
2 paragraph for the upcoming calendar year,
3 deregister the entity from the program
4 under this section and the identification
5 system described in subsection
6 (d)(2)(B)(iv) for the upcoming calendar
7 year, cease making purchases under such
8 program as of the start of the upcoming
9 calendar year, cease representing to third
10 parties that it may purchase under such
11 program beyond the current calendar year,
12 and refrain from purchasing covered out-
13 patient drugs under this section in quan-
14 tities exceeding such entity's bona fide
15 needs for the remainder of the current cal-
16 endar year.

17 “(ii) REGISTRATION FOLLOWING DE-
18 REGISTRATION.—

19 “(I) REGISTRATION UNDER AN-
20 OTHER COVERED ENTITY CAT-
21 EGORY.—A covered entity that must
22 deregister under this subparagraph
23 shall not be prohibited from reg-
24 istering to participate in the program
25 under this section under another cov-

1 ered entity category described in para-
2 graph (4) if such entity meets the cri-
3 teria for such a category and applica-
4 ble requirements under this section.

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

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

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

1 drug that is the subject of the noncompliance in
2 an amount equal to the reduction in the price
3 of 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 **SEC. 13. 340B PROGRAM.**

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

7 “(15) 340B PROGRAM.—The intent of this sec-
8 tion is to provide for manufacturer price reductions
9 that enable covered entities, whose mission is to
10 serve underserved or otherwise vulnerable commu-
11 nities, to increase access to affordable drugs and
12 health services for these communities.”.

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

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

18 “(vi) The conducting of annual audits
19 by the Secretary of contracts between a
20 covered entity described in subparagraph
21 (L) or subparagraph (M) of subsection
22 (a)(4), or subparagraph (O) of such sub-
23 section with respect to a rural referral cen-
24 ter, that is a private nonprofit hospital
25 subject to the requirements in subsections

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

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

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

8 **SEC. 15. ENSURING COVERED ENTITY COMPLIANCE WITH**
9 **TRANSPARENCY REQUIREMENTS.**

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

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

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

20 (a) 340B CLAIMS DATA CLEARINGHOUSE.—Section
21 340B(d)(2) of the Public Health Service Act (42 U.S.C.
22 256b(d)(2)) is amended by adding at the end the fol-
23 lowing:

24 “(C) 340B CLAIMS DATA CLEARING-
25 HOUSE.—

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

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

24 “(II) identifying claims for cov-
25 ered outpatient drugs purchased

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

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

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

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

23 “(ii) CRITERIA FOR CLEARING-
24 HOUSE.—The criteria described in this
25 clause include the following:

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

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

16 “(III) The clearinghouse shall
17 agree to confidentiality obligations
18 that prohibit the clearinghouse from
19 using information it receives under
20 this subparagraph for any purpose
21 other than a purpose set forth in this
22 subparagraph, or disclosing such in-
23 formation to any individual or entity
24 other than the Secretary, provided the
25 Secretary shall not use such informa-

1 tion for purposes of making reim-
2 bursement or coverage determinations,
3 or a manufacturer in accordance with
4 this subparagraph (and only with re-
5 spect to such manufacturer’s covered
6 outpatient drugs).

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

18 “(iii) DUTIES OF CLEARINGHOUSE.—

19 The clearinghouse shall—

20 “(I) review claims level data for
21 covered outpatient drugs described in
22 subsection (a)(5)(J) submitted by cov-
23 ered entities in accordance with such
24 subsection;

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

21 “(III) within 5 days of identifica-
22 tion, provide written notice of a dupli-
23 cate discount or rebate to the State
24 agency, the Secretary, the covered en-
25 tity, and the affected drug manufac-

1 turer itemizing any violation described
2 in clause (i)(I);

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

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

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

22 “(VII) upon request by the Cen-
23 ters for Medicare & Medicaid Services,
24 make the data described in subclauses
25 (I) and (II) available for purposes of

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

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

17 “(iv) RESOLUTION OF VIOLATIONS.—

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

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

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

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

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

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

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

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

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

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

15 (C) by inserting after paragraph (87) the
 16 following new paragraph:

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

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

10 (c) PROVISION OF DRUG CLAIMS DATA BY MEDI-
 11 CARE.—

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

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

1 house within 5 days following the date the claim for such
2 drug is paid by the Medicare administrative contractor.”.

3 (2) MEDICARE ADVANTAGE ORGANIZATIONS.—

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

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

22 (3) PRESCRIPTION DRUG PLANS.—Section
23 1860D–12(b) of the Social Security Act (42 U.S.C.
24 1395w–112(b)) is amended by adding at the end the
25 following:

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

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

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

21 **SEC. 17. LIMITATION ON ADMINISTRATOR SERVICE FEES**
 22 **AND CONTRACT PHARMACY FEES.**

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

1 “(f) REQUIREMENTS FOR TPA AND CONTRACT
2 PHARMACY REMUNERATION.—

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

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

21 “(B) the amount of such remuneration is
22 consistent with fair market value in an arm’s-
23 length transaction for the bona fide, itemized
24 340B-related services actually performed on be-
25 half of the covered entity; and

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

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

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

20 “(B) the amount of remuneration for each
21 dispense does not exceed 125 percent of the av-
22 erage per-prescription dispensing fee paid to
23 such pharmacy by all third-party payors, based
24 on data from the most recent full calendar year
25 for which such data is available;

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

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

17 “(3) AUDITABLE RECORDS.—A covered entity
18 shall retain copies of written agreements with third-
19 party administrators or contract pharmacies de-
20 scribed in this subsection for a period of time speci-
21 fied by the Secretary and shall make copies of such
22 agreements available to the Secretary or their des-
23 ignee upon request.

24 “(4) CIVIL MONETARY PENALTY.—A third-
25 party administrator or contract pharmacy described

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

16 **SEC. 18. CLARIFICATION.**

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

20 “(g) CLARIFICATION.—The provisions of this section
21 supersede any provision or requirement of State or local
22 law insofar as that State or local law may establish, imple-
23 ment, or continue in effect a standard or requirement that
24 differs from or relates in any way to the provisions of this
25 section or, except for any State regulations issued to carry

1 out subsection (a)(5)(A)(iii), relates in any way to the
 2 drug discount program under this section or covered out-
 3 patient drugs subject to an agreement under this section,
 4 including the distribution of such drugs. Except for any
 5 State regulations issued to carry out subsection
 6 (a)(5)(A)(iii), no provision or requirement of State or local
 7 law shall grant additional rights or impose additional obli-
 8 gations related to the 340B program.”.

9 **SEC. 19. ENSURING THE EQUITABLE TREATMENT OF 340B**
 10 **COVERED ENTITIES AND PHARMACIES PAR-**
 11 **TICIPATING IN THE 340B DRUG DISCOUNT**
 12 **PROGRAM.**

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

18 **“SEC. 2730. REQUIREMENTS RELATING TO THE 340B DRUG**
 19 **DISCOUNT PROGRAM.**

20 “(a) IN GENERAL.—A group health plan, a health
 21 insurance issuer offering group or individual health insur-
 22 ance coverage, or a pharmacy benefit manager acting on
 23 behalf of such plan or issuer, may not discriminate against
 24 a covered entity (as defined in subsection (e)(1)), a con-
 25 tract pharmacy (as defined in subsection (e)(2)), or a par-

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

10 “(b) SPECIFIED PROHIBITED ACTIONS.—A group
11 health plan, a health insurance issuer offering group or
12 individual health insurance coverage, or a pharmacy ben-
13 efit manager acting on behalf of such plan or issuer, may
14 not discriminate against a covered entity, a contract phar-
15 macy, or a participant, beneficiary, or enrollee of such
16 plan or coverage by doing any of the following:

17 “(1) Reimbursing a covered entity or contract
18 pharmacy for a quantity of a 340B drug (as defined
19 in subsection (e)) in an amount less than such plan,
20 issuer, or pharmacy benefit manager (as applicable)
21 would pay to any other similarly situated (as speci-
22 fied by the Secretary) entity or pharmacy that is not
23 a covered entity or a contract pharmacy for such
24 quantity of such drug on the basis that the entity
25 or pharmacy is a covered entity or contract phar-

1 macy or that the entity or pharmacy dispenses 340B
2 drugs.

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

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

14 “(B) Professional dispensing fees.

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

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

22 “(E) Any other restrictions, conditions,
23 practices, or policies that interfere with the
24 ability of a covered entity or contract pharmacy
25 to use the discounts provided under section

1 340B in accordance with applicable require-
2 ments under such section.

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

8 “(4) Interfering with, limiting, or prohibiting
9 actions by a covered entity or contract pharmacy to
10 identify, either directly or through a third party,
11 claims for 340B drugs, including by submission of
12 claims data or use of claims modifiers or indicators.

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

18 “(A) the entity or pharmacy is a covered
19 entity or a contract pharmacy; or

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

23 “(6) With respect to a group health plan or
24 health insurance issuer for health insurance cov-

1 erage, denying coverage of a drug on the basis that
2 such drug is a 340B drug.

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

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

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

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

10 “(1) 340B DRUG.—The term ‘340B drug’
11 means a drug that is—

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

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

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

19 “(3) COVERED ENTITY.—The term ‘covered en-
20 tity’ has the meaning given such term in section
21 340B(a)(4).

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

1 (b) APPLICATION OF REQUIREMENTS TO MEDI-
2 CARE.—

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

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

17 (2) PART C.—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) 340B DRUG DISCOUNT PROGRAM.—
21 Section 1860D–12(b)(10).”.

1 **SEC. 20. EFFECTIVE DATE.**

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

○