I

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

SEC. 2. DEFINITIONS.

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

''(3) PATIENT.—

''(A) IN GENERAL.—In this section, the term 'patient' means, with respect to a covered entity described in subsection (a)(4), an individual who, on a prescription-by-prescription or order-by-order basis—

''(i) is dispensed or administered a covered outpatient drug that is—

''(I) directly related to the service described in clause (iii);

"(II) ordered or prescribed by a covered entity provider described in clause (ii) as a result of the service described in clause (iii); and

"(III) dispensed or administered on site at a covered entity location, a child site (as defined in subsection (a)(5)(E)), or an entity pharmacy (as defined in subsection (a)(5)(F)) listed in the identification system described in subsection (d)(2)(B)(iv), or on site at a contract pharmacy in accordance with subsection (a)(5)(F) or dispensed through a mail order pharmacy in accordance with subsection (a)(5)(F);

"(ii) receives the health care service described in clause (iii) from a 'covered entity provider', meaning a health care professional who either—

"(I) is an employee or independent contractor of the covered entity, such that the covered entity bills for services furnished by the health care professional and is responsible

for the care furnished by such professional; or

''(II) furnishes health care services under an ongoing contractual obligation to the covered entity such that responsibility for the care provided remains with the covered entity and meets the other requirements in this paragraph, in the event State law prohibits or otherwise substantially limits the ability of the covered entity to bill for services of the health care professional;

''(iii) receives a covered outpatient drug in connection with a health care service furnished at the covered entity (including a child site) and such drug and service are paid by the insurer or third-party payor as outpatient items and services (or where third-party reimbursement is not made, such items and services are deemed outpatient if less than 24 hours have elapsed between such individual's hospital registration and discharge);

"(iv) is described in a category of individuals within the scope of, and receives a health care service at the covered entity (including a child site) that is within the scope of—

"(I) the Federal grant, project, or Federal grant-authorizing statute, as applicable, that qualifies such entity for participation in the program under this section, if the covered entity is described in one of subparagraphs (A) through (K) of subsection (a)(4); or

"(II) the contract as required in paragraphs (4)(L)(i) and (11) of subsection (a), if the covered entity is a private nonprofit hospital which has, as the basis for participating in the program under this section, a contract with a State or local government to provide health care services to specified individuals, provided that clause (iv) shall not apply with respect to a covered entity described in subsection (a)(4)(N) or a sole community hos-

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

''(v) has an ongoing relationship with the covered entity such that the covered entity creates and maintains auditable health care records which demonstrate compliance with this paragraph and that the covered entity—

''(I) has a provider-to-patient relationship with the individual;

''(II) is responsible for the individual's health care service that resulted in the prescription or order for the drug; and

''(III)(aa) has provided a health care service to the individual through an in-person visit within the past 12 months, if the covered entity is a hospital described in subparagraph (L) or subparagraph (M) of subsection (a)(4) or is a rural referral center described in subparagraph (O) of such subsection; or

''(bb) has provided a health care service to the individual through an

in-person visit within the past 24 months, if the covered entity is described in one of subparagraphs (A) through (K) of subsection (a)(4), subparagraph (N) of such subsection, or is a sole community hospital described in subparagraph (O) of such subsection.

''(B) TELEHEALTH AND TELEMEDICINE.—

''(i) IN GENERAL.—A prescription for a covered outpatient drug resulting from a health care service furnished to an individual through telehealth, telemedicine, or other remote health care service arrangements shall not qualify for pricing described in subsection (a)(1) unless—

''(I) the covered entity (including child site, as applicable) at which such service is furnished is a covered entity (or a child site of a covered entity, as applicable) described in one of subparagraphs (A) through (K) of subsection (a)(4), subparagraph (N) of 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

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

''(ii) EXCEPTION FOR QUALIFYING REFERRALS.—In the case of a 'qualifying referral', all requirements in subparagraph (A) shall apply, except for clauses (i)(I), (i)(II), (ii), (iii), and (v)(II) of such subparagraph. For purposes of this paragraph, a 'qualifying referral' shall refer to the sequence of occurrences described in this clause for which a covered entity maintains documentation sufficient to demonstrate that—

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

medical record the covered entity creates and maintains for such individual;

''(II) within one year of the date of the encounter and recommendation described in subclause (I), the individual receives a health care service from a medical specialist of the type described in such recommendation;

''(III) within the time period specified in subclause (II), the covered entity provider making the recommendation receives, directly from the medical specialist that furnishes the health care service described in subclause (II), written documentation specifying the service or services furnished to such individual and the diagnoses made in connection with such service or services; and

''(IV) the covered entity retains overall responsibility for the care of the individual.

''(iii) COVERED ENTITY ELIGIBILITY FOR QUALIFYING REFERRALS.—Notwith-

standing any other provision in this section, a covered entity shall not qualify for pricing described in subsection (a)(1) with respect to a prescription or order for a covered outpatient drug resulting from a qualifying referral unless such covered entity—

"(I) is described in subparagraph (N) of subsection (a)(4);

"(II) is a sole community hospital described in subparagraph (O) of such subsection; or

"(III) is described in one of subparagraphs (A) through (K) of such subsection, is not a specified nonhospital covered entity (as defined in subsection (b)(4)), and has a Federal grant that requires such entity to contract or refer for the health care service or services furnished to the individual by the medical specialist described in clause (ii).

"(D) HEALTH CARE SERVICE REQUIRED.—For purposes of this section, an individual 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:

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

"(I) methodologies State Medicaid programs and all covered entities under subsection (a)(4), and their contract pharmacies, shall use to identify and bill drugs purchased under the 340B program in a manner that ensures compliance with applicable prohibitions regarding duplicate discounts or rebates, including the duplicate discount prohibition under this subparagraph and the prohibitions under sections 1927(j)(1) and 1903(m)(2)(A)(xiii) of the Social Security Act, to include the application of such prohibitions to 340B drugs used by Medicaid managed care enrollees; and

"(II) procedures State Medicaid programs shall use to exclude requests for Medicaid rebates on covered out-

patient drugs purchased under the 340B program that are dispensed, administered, or otherwise furnished to a Medicaid managed care enrollee and requirements for State Medicaid programs to promulgate rules to provide affected manufacturers a prompt remedy with respect to any incorrectly billed rebates for such drugs.'';

(2) in subparagraph (C)—

(A) by striking ''A covered entity shall permit'' and inserting:

''(i) DUPLICATE DISCOUNTS AND DRUG RESALE.—A covered entity shall permit'';

(B) by striking ''(A) or (B)'' and inserting ''(A), (B), (J), or (K)''; and

(C) by adding at the end the following:

''(ii) USE OF MARGIN.—A covered entity shall permit the Secretary to audit, at the Secretary's expense, the records of the entity to determine—

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

agreement under this section dispensed or furnished by such entity (or a contract pharmacy described in subsection (a)(5)(F)) is used by such entity; and

''(II) such entity's compliance with subparagraph (L).

''(iii) RECORDS RETENTION.—Covered entities shall retain such records and provide such records and reports as determined necessary by the Secretary for carrying out this subparagraph.''; and

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

SEC. 4. HOSPITAL CHILD SITE REQUIREMENTS.

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

''(E) HOSPITAL CHILD SITE REQUIREMENTS.—

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

with such covered entity for inclusion in the identification system described in subsection (d)(2)(B)(iv) to participate in the program under this section as an integral part of such covered entity if such covered entity demonstrates to the Secretary, in a manner specified by the Secretary, that such facility satisfies each of the requirements in this subparagraph. For purposes of this section, each facility registered to participate in the program under this section and satisfying the requirements in this subparagraph shall be referred to as a 'child site').

''(I) The facility is listed on the covered entity's most recently filed Medicare cost report on a line that is reimbursable under the Medicare program (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the facility would be correctly included on a reimbursable line of a Medicare cost report

if the covered entity filed a cost report).

''(II) Such cost report demonstrates that the services provided at the facility have associated costs and charges for hospital outpatient department services under title XVIII of the Social Security Act (or, if the covered entity is a children's hospital that does not file a Medicare cost report, the covered entity submits to the Secretary a signed statement certifying that the services provided at the facility include outpatient services).

''(III) The facility is wholly owned by the covered entity.

''(IV) The Secretary has made a determination, under the process described in section 413.65(b) of title 42, Code of Federal Regulations (or any successor regulations), that the facility meets the Medicare provider-based standards under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations)

for an off-campus outpatient department of the covered entity.

''(V) The facility provides outpatient health care services that are not limited to only dispensing, administering, or otherwise furnishing covered outpatient drugs.

''(VI) The facility is subject to and adheres to all charity care and sliding fee scale policies of the covered entity and makes such policies publicly available in a manner consistent with requirements established under section 501(r) of the Internal Revenue Code of 1986 applicable to hospital financial assistance policies.

''(VII) The facility is located in an area with a shortage of personal health services that is—

''(aa) initially designated by the Secretary pursuant to section 254b(b)(3) of title 42, United States Code, on or before December 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

charity care (as such term is defined in line 23 of worksheet S–10 to the Medicare cost report, or in any successor form) furnished at such facility during such year, as a share of the facility's total patient service revenue, is greater than or equal to the amount described in item (aa) or item (bb), whichever is greater—

"(aa) for such year, the total cost incurred for charity care, as a share of total patient service revenue, furnished at the covered entity's on-campus locations (as 'campus' is defined in section 413.65(a)(2) of title 42, Code of Federal Regulations (or any successor regulations)); or

"(bb) the average cost incurred for charity care, as a share of total patient service revenue, calculated for the year prior to the most recent year for which data is available, across all hospitals in the State where the

facility is located that receive payments for inpatient hospital services under the prospective payment system established under section 1886(d) of the Social Security Act.

''(X) For the most recent year, the facility's share of total outpatient services revenue derived from base reimbursement to such entity (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis at the facility (including any cost sharing for such items and services) is greater than or equal to the amount described in item (aa) or item (bb), whichever is greater—

"(aa) for such year, the share of total outpatient services revenue derived from base reimbursement to such entity (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis at the on-campus locations of the covered entity with which the facility is associated (including any cost sharing for such items and services) ('campus' shall have the meaning given such term in section 413.65(a)(2) of title 42, Code of Federal Regulations (or any successor regulations)); or

"(bb) the average share of total outpatient services revenue derived from base reimbursement (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis (including any cost sharing for such items and services), calculated for the year prior to the most recent year for which data is available, across all hospitals in the state where the facility is located that receive payments for outpatient hospital services under the prospective payment system for covered outpatient depart-

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

''(XI) The covered entity certifies, at the time such facility is initially registered for inclusion in the identification system described in subsection (d)(2)(B)(iv) to participate in the drug pricing program under this section and annually thereafter as part of the recertification process, that the facility satisfies all applicable requirements under this subparagraph.

''(ii) LIMITATION.—Only an off-campus outpatient facility that meets each of the requirements under this subparagraph may purchase covered outpatient drugs under the 340B program or use covered outpatient drugs purchased under the 340B program by another part of the covered entity that is authorized to participate in such program. Any transfer of 340B drugs to another facility or another part of a covered entity that is not authorized to

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

''(iii) DEREGISTRATION.—If at any time following registration a requirement described in clause (i) is no longer fully satisfied with respect to a facility, the covered entity described in such clause shall immediately notify the Secretary that such facility no longer fully satisfies the relevant requirement, deregister the facility from the program under this section, remove the facility from the identification system described in subsection (d)(2)(B)(iv), and take all necessary actions to prohibit such facility from making any purchases under the program under this section or representing to third parties that such facility may purchase covered outpatient drugs under such program.

''(iv) OBLIGATION TO SELF-DISCLOSE.—A covered entity described in clause (i) 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 or on behalf of the covered entity with respect to a facility that, at the time of the purchase of such drug, did not fully satisfy the requirements in such clause. 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 drug. The covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the noncompliance in an amount equal to the reduction in the price of the drugs provided under paragraph (1), plus interest on such amount, which shall be compounded monthly and equal to the current short-term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

''(v) CIVIL MONETARY PENALTY.—Where a covered entity knowingly and intentionally violates clause (ii) or otherwise

fails to satisfy a requirement in clause (iii) or clause (iv), the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this clause.

''(vi) SECRETARIAL PUBLICATION OF REPORTS.—On an annual basis, the Secretary shall prepare and make available to the public in an electronic, machine readable format separate reports listing facili-

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

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

(c) IMPLEMENTATION OF HOSPITAL CHILD SITE STANDARDS.—Not later than 60 days prior to the effective date of section 340B(a)(5)(E) of the Public Health Service Act, as added by this Act, the Secretary shall issue program instructions directing each covered entity described in section 340B(a)(5)(E)(i) of the Public Health Service Act, as amended by this Act, to, before the effective date of section 340B(a)(5)(E) of the Public Health Service Act, as added by this Act, register in the identification system described in section 340B(d)(2)(B)(iv) of the Public Health Service Act, or update existing registrations in such system for, off-campus outpatient facilities associated with such covered entity that satisfy the requirements in such section. Such instructions shall direct each such covered entity to, on or before the effective date of section 340B(a)(5)(E) of the Public Health Service Act, as added by this Act, remove from such system the existing registration of any off-campus outpatient facility associated with such covered entity that does not satisfy the

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

SEC. 5. CONTRACT PHARMACIES.

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

''(F) CONTRACT PHARMACIES.—

''(i) IN GENERAL.—Subject to the conditions set forth in this subparagraph, a covered entity may enter into written agreements with contract pharmacies to dispense to patients of such entity covered outpatient drugs purchased by such entity under the 340B program. Subject to such conditions, a manufacturer of covered outpatient drugs shall ship or facilitate shipment of such drugs to contract pharmacies 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

outpatient drugs for its patients within the scope of the Federal grant, project, or Federal grant-authorizing statute, as applicable, that qualifies such entity for participation in the program under this section; or

''(bb) be described in one of subparagraphs (L) through (O) of paragraph (4);

''(II) establish and implement compliance procedures to satisfy the requirements described in subparagraphs (A), (B), (G) (as applicable), (H) (as applicable), (J), and (K) of paragraph (5) and section 1193(d) of the Social Security Act with respect to covered outpatient drugs purchased by the covered entity under this section, including with respect to such drugs dispensed by a contract pharmacy, which compliance procedures shall be considered records of the covered entity subject to audit under subparagraph (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.

"(v) REQUIREMENTS FOR USE OF MAIL ORDER PHARMACIES.—

"(I) IN GENERAL.—Notwithstanding any other provision in this section, a covered outpatient drug subject to an agreement under this section may be dispensed to a patient of a covered entity through a mail order pharmacy only if—

"(aa) 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 one of subparagraphs (A) through (K) of paragraph (4), such entity is not a specified non-hospital covered entity (as defined in subsection (b)(4)), and, except for a covered entity described in subparagraph (G) of such subsection, the patient dispensed such drug resides within 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 sufficient to ensure that covered outpatient drugs are not subject to duplicate discounts in violation of subsection (a)(5)(A) (including with respect 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 subparagraph (B), that the patient affordability requirements specified in sub-

paragraphs (G) and (H), as applicable, are appropriately applied at the point of drug dispense or administration, that data and other information is submitted in accordance with subparagraphs (J) and (K), and that the nonduplication requirement in section 1193(d) of the Social Security Act is satisfied; and

''(II) written agreements between covered entities and contract pharmacies described in clause (vii).

''(vii) WRITTEN AGREEMENT REQUIRED.—The written agreement between a covered entity and a contract pharmacy described in this subparagraph shall include binding and enforceable obligations on the contract pharmacy to comply with the covered entity's compliance procedures described in clause (ii)(II) with respect to covered outpatient drugs dispensed to patients of such entity in accordance with this subparagraph. Within 30 days of the applicable effective date of such written agreement, including any amendment or

addendum thereto, the covered entity shall submit a copy of the agreement, together with any amendments or addenda, to the Secretary in a form and manner specified by the Secretary. The Secretary shall review all such agreements, including amendments and addenda, for compliance with the requirements set forth in this subparagraph and may require a covered entity and contract pharmacy to modify an agreement to conform to the requirements of this subparagraph. Such agreements, including amendments and addenda, shall be considered records of the covered entity subject to audit under subparagraph (C).

''(viii) CLARIFICATION FOR COVERED OUTPATIENT DRUGS SUBJECT TO RESTRICTED DISTRIBUTION.—Notwithstanding any other provision in this section, a manufacturer of a covered outpatient drug requiring exclusive use of a specialty pharmacy or a restricted distribution network shall be deemed to have satisfied its obligations under this subparagraph with respect to a contract pharmacy

if such manufacturer offers each covered entity such drug for purchase at or below the applicable ceiling price described in paragraph (1) through a wholesaler, distributor, or pharmacy included in the restricted distribution network for such drug.

''(ix) PENALTIES FOR CONTRACT PHARMACY COMPLIANCE VIOLATIONS.—

''(I) IN GENERAL.—A contract pharmacy that is found to have violated the covered entity compliance procedures described in clause (ii)(II), violated subparagraph (A), or violated subparagraph (B) shall—

''(aa) in the first instance of such violation, be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of such drug (as described in subsection (a)(1)), plus interest on such amount, which shall be compounded monthly and equal to the current short-term interest

rate as determined by the Federal Reserve for the time period for which the covered entity is liable;

"(bb) in the second instance of such violation—

"(AA) be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of the drug (as described in paragraph (1)), plus interest on such amount, which shall be calculated in the manner specified in item (aa); and

"(BB) be required to pay a civil monetary penalty equal to $13,946 for each claim for a covered outpatient drug that is subject to the violation, which amount shall be adjusted for inflation annually to reflect

the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics; and

''(cc) in the third instance of such violation—

''(AA) be liable to a manufacturer of a covered outpatient drug that is the subject of such violation in an amount equal to the reduction in the price of the drug (as described in paragraph (1)), plus interest on such amount, which shall be calculated in the manner specified in item (aa);

''(BB) be required to pay a civil monetary penalty equal to $13,946 for each claim for a covered outpatient drug that is subject to the violation, which amount shall be adjusted for

inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics; and

''(CC) be removed from the program under this section and disqualified from reentry into such program for a period of not less than two years, or such longer period as the Secretary may determine based on the severity of the violation (or violations) and the risk such pharmacy presents to the integrity of the program, with no ability to reenter the program unless and until the Secretary determines such pharmacy has resolved the violation (or violations) and taken reasonable steps to

prevent similar future violations.

"(II) CORRECTIVE ACTION PLAN.—In the first instance of a violation described in subclause (I)(aa), in the second instance of a violation described in subclause (I)(bb), and prior to reentry into the program following a violation described in subclause (I)(cc)—

"(aa) the pharmacy shall conduct an internal review to identify the cause of the violation (or violations) that is inclusive of all calendar quarters within the period in which such violation (or violations) occurred and all covered outpatient drugs subject to an agreement under this section dispensed during such period;

"(bb) the pharmacy shall prepare a written corrective action plan, in a form specified by the Secretary, which shall include, at a minimum, the results

of such internal review, the pharmacy's methodology for identifying the full scope of such violation (or violations), and the pharmacy's proposed corrective actions, and submit such plan to the Secretary in a form and manner specified by the Secretary; and

''(cc) the Secretary shall review such plan, notify the pharmacy of any revisions to such plan, including additional corrective actions, necessary for the Secretary to approve such plan, and publish the approved plan on a public website of the Department of Health and Human Services (with redactions of any confidential or proprietary information).

''(III) CIVIL MONETARY PENALTY FOR VIOLATIONS BY REMOVED PHARMACY.—A contract pharmacy removed from the program under this section

pursuant to subclause (I)(cc) that dispenses a covered outpatient drug subject to an agreement under this section during a time period that such pharmacy is removed from the program and is not approved for reentry shall be required to pay a civil monetary penalty equal to $13,946 for each claim for each such drug dispensed during such period, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics.

''(IV) PROCEDURES AND DELEGATION.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply for purposes of any payment, civil monetary penalty, or removal described in this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspec-

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

"(x) DEFINITIONS.—In this subparagraph:

"(I) CONTRACT PHARMACY.—The term 'contract pharmacy' means, with respect to a covered entity described in clause (ii), any individual pharmacy (as determined by a national provider identifier unique to the pharmacy address) that is—

"(aa) licensed as a pharmacy by the relevant State (or States);

"(bb) authorized to dispense covered outpatient drugs subject to an agreement under this section to patients of such entity (as defined in subsection (b)(3)) pursuant to a valid written agreement with such entity (as described in this subparagraph); and

"(cc) not an entity pharmacy.

"(II) ENTITY PHARMACY.—The term 'entity pharmacy' means any individual pharmacy (as determined by a national provider identifier unique to the pharmacy address) that is—

"(aa)(AA) licensed as a pharmacy by the relevant State (or States); and

"(BB) the same legal entity as the covered entity and located within the covered entity's service area, if the covered entity is described in one of subparagraphs (A) through (K) of paragraph (4) and is not a specified nonhospital covered entity (as defined in subsection (b)(4)); or

"(bb) the same legal entity as the covered entity and located within the covered entity's four walls, if the covered entity is described in one of subparagraphs (L) through (O) of paragraph (4)

or is a specified nonhospital covered entity (as defined in subsection (b)(4)).

''(III) MAIL ORDER PHARMACY.—The term 'mail order pharmacy' is a pharmacy that is licensed as a pharmacy by the State (or States) and that dispenses prescription medications to individuals primarily through the mail, as determined in accordance with guidance issued by the Secretary in connection with part 447, subpart I of title 42 of the Code of Federal Regulations (or any successor regulations).

''(IV) SERVICE AREA.—The term 'service area' means, with respect to a covered entity described in paragraph (4), other than a covered entity described in subparagraph (G) of such paragraph, the Public Use Microdata Area (as defined by the United States Census Bureau) in which such entity is located and up to three additional Public Use Microdata Areas that are

contiguous with the Public Use Microdata Area in which such entity is located, which shall be listed in the identification system described in subsection (d)(2)(B)(iv).

''(xi) RULES OF CONSTRUCTION.—

''(I) LOCATION.—For purposes of this subparagraph, the location of a covered entity shall be determined based on the physical address of the entity listed in the identification system described in subsection (d)(2)(B)(iv) without regard to any off-campus outpatient facilities.

''(II) SAME LEGAL ENTITY.—For purposes of this subparagraph, a pharmacy is the same legal entity as the covered entity if the name, ownership, and employer identification number of the pharmacy is identical to the name, ownership, and employer identification number of the covered entity.''.

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

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

"(G) PATIENT AFFORDABILITY REQUIREMENTS FOR HOSPITAL COVERED ENTITIES.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, a covered entity described in one of subparagraphs (L) through (O) of paragraph (4) shall establish a sliding fee scale that results in the covered entity providing, on behalf of an eligible patient (as defined in clause (iv)), a discount that results in such patient paying no more than the maximum out-of-pocket obligation (as defined in clause (ii)), with respect to each covered outpatient drug subject to an agreement under this section dispensed, furnished, or administered to such patient at such covered entity, any child site, or any entity pharmacy. The sliding fee scale and related policies shall be written and posted prominently at each such covered entity location, including any child site and entity pharmacy, and

shall be included in any billing-related communications sent by such covered entity to any patient dispensed, furnished, or administered a covered outpatient drug at such covered entity location, including any child site or entity pharmacy. Eligibility for a reduced out-of-pocket obligation pursuant to this clause shall be based on insurance and income information provided by the eligible patient. With respect to covered outpatient drugs that are self-administered by an eligible patient, the out-of-pocket reductions described in this clause shall apply at the point of sale.

''(ii) MAXIMUM OUT-OF-POCKET OBLIGATION.—For each dispense or administration of a covered outpatient drug, the maximum out-of-pocket obligation for an eligible patient with family income—

''(I) below the Federal poverty guidelines is $0;

''(II) at or above the Federal poverty guidelines but below 200 percent of the Federal poverty guidelines is the lesser of 20 percent of the oth-

erwise applicable out-of-pocket obligation or $35, which shall be adjusted for inflation annually to reflect rate of the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics; and

''(III) at or above 200 percent of the Federal poverty guidelines is the lesser of 30 percent of the otherwise applicable out-of-pocket obligation or $50, which shall be adjusted for inflation annually to reflect rate of the change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics.

''(iii) APPLICABILITY TO CONTRACT PHARMACIES.—With respect to an eligible patient of a covered entity described in clause (i) dispensed a covered outpatient drug subject to an agreement under this section on behalf of such covered entity at a contract pharmacy pursuant to subparagraph (F), such covered entity shall require such contract pharmacy to provide

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

"(iv) DEFINITIONS.—In this subparagraph:

"(I) CHILD SITE.—The term 'child site' shall have the meaning given such term in subparagraph (E).

"(II) CONTRACT PHARMACY.—The term 'contract pharmacy' shall have the meaning given such term in subparagraph (F).

"(III) ELIGIBLE PATIENT.—The term 'eligible patient' means a patient, as defined in subsection (b)(3), who is not covered under minimum essential coverage as defined under section 5000A(f) of the Internal Revenue Code of 1986 or has family income below 200 percent of the Federal poverty guidelines and is covered under a group health plan, health insurance coverage in the individual market or

group market (as such terms are defined in section 2791 of the Public Health Service Act) or coverage described in section 156.602(a), title 45, Code of Federal Regulations or successor regulation.

''(IV) ENTITY PHARMACY.—The term 'entity pharmacy' shall have the meaning given such term in subparagraph (F).

''(V) FEDERAL POVERTY GUIDELINES.—The term 'Federal poverty guidelines' means the poverty guidelines updated periodically in the Federal Register by the Department of Health and Human Services pursuant to section 9902(2) of title 42, United States Code.

''(VI) OUT-OF-POCKET OBLIGATION.—The term 'out-of-pocket obligation' means any copayment, coinsurance, deductible, or other cost sharing amount or payment required from an eligible patient in connection with such patient's receipt of a spe-

cific health care item or service, including a covered outpatient drug.

''(v) CIVIL MONETARY PENALTY.—A covered entity or contract pharmacy that violates a requirement of this subparagraph shall be subject to a civil monetary penalty of $2,500 for each such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions of this clause.

''(vi) REGULATIONS.—The Secretary shall promulgate regulations through notice and comment rulemaking to implement 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.—

"(i) IN GENERAL.—Notwithstanding any other provision of law, a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) that is required by the Federal statute authorizing the grant, project, or contract that is the basis for such entity's participation in the program under this section to provide affordability assistance to eligible individuals receiving health care items or services from such entity shall, with respect to an eligible patient (as defined in clause (iii)) dispensed or administered a covered outpatient drug subject to an agreement under this section at a covered entity site, including an entity pharmacy, establish a policy that provides a discount to reduce the out-of-pocket obligation of an eligible patient with respect to such drug to an amount sufficient to ensure such patient is not denied access to such drug based on such patient's ability to pay for such drug.

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

clause (i) dispensed a covered outpatient drug subject to an agreement under this section on behalf of such covered entity at a contract pharmacy pursuant to subparagraph (F), such covered entity shall require such contract pharmacy to provide discounts to eligible patients on behalf of such covered entity in accordance with the covered entity's policy described in clause (i).

''(iii) DEFINITIONS.—In this subparagraph:

''(I) CONTRACT PHARMACY.—The term 'contract pharmacy' shall have the meaning given such term in subparagraph (F).

''(II) ELIGIBLE PATIENT.—The term 'eligible patient' means a patient, as defined in subsection (b)(3), who is not covered under minimum essential coverage as defined under section 5000A(f) of the Internal Revenue Code of 1986 or has family income below 200 percent of the Federal poverty guidelines and is covered under a

group health plan, health insurance coverage in the individual market or group market (as such terms are defined in section 2791 of the Public Health Service Act) or coverage described in section 156.602(a), title 45, Code of Federal Regulations or successor regulation.

''(III) ENTITY PHARMACY.—The term 'entity pharmacy' shall have the meaning given such term in subparagraph (F).

''(IV) FEDERAL POVERTY GUIDELINES.—The term 'Federal poverty guidelines' means the poverty guidelines updated periodically in the Federal Register by the Department of Health and Human Services pursuant to section 9902(2) of title 42, United States Code.

''(V) OUT-OF-POCKET OBLIGATION.—The term 'out-of-pocket obligation' means any copayment, coinsurance, deductible, or other cost sharing amount or payment required

from an eligible patient in connection with such patient's receipt of a specific health care item or service, including a covered outpatient drug.''.

SEC. 7. REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES AND SUBGRANTEES.

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

''(I) ADDITIONAL REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES; REQUIREMENTS FOR SUBGRANTEES.—

''(i) ADDITIONAL REQUIREMENTS FOR NONHOSPITAL COVERED ENTITIES.—A covered entity described in one of subparagraphs (A) through (K) of paragraph (4) shall, as a condition of participation in the program under this section—

''(I) be a nonprofit or public entity (as determined by the Secretary);

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

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

''(III) oversee the participation in the program under this section of any subgrantee with which such covered entity enters into an enforceable written agreement in accordance with subclause (IV) and be directly liable for noncompliance by any such subgrantee with any requirement under this section;

''(IV) have an enforceable written agreement with any subgrantee, which shall apply to all registered sites of such subgrantee, and require such subgrantee to comply with all requirements under this section otherwise applicable to the covered entity and to maintain written records, which shall be made available to the Secretary

upon request, sufficient to demonstrate such subgrantee's receipt of eligible Federal funds or an in-kind contribution purchased with such funds, as described in clause (iii), and the grant under which such subgrantee receives such funds or contribution; and

''(V) maintain written records sufficient to demonstrate such entity authorized such subgrantee to, prior to purchasing covered outpatient drugs subject to an agreement under this section, register each subgrantee site in the covered entity identification system established under subsection (d)(2)(B)(iv) to participate in the program under this section as a subgrantee of such entity and provide the Secretary with such registration information as requested to demonstrate such subgrantee's receipt of eligible Federal funds or an in-kind contribution purchased with such funds, as described in clause (iii), and the grant

under which the subgrantee receives such funds or contribution.

''(ii) REQUIREMENTS FOR SUBGRANTEES.—Notwithstanding any other provision in this section, a subrecipient of a Federal grant shall be eligible to participate in the program under this section only if such subrecipient is a subgrantee (as defined in clause (iii)) and such subgrantee—

''(I) is a nonprofit or public entity (as determined by the Secretary);

''(II) prior to purchasing covered outpatient drugs subject to an agreement under this section—

''(aa) enters into an enforceable written agreement with the covered entity providing eligible Federal funds or an in-kind contribution, pursuant to clause (i)(IV);

''(bb) maintains written records, which shall be made available to the Secretary upon request, sufficient to demonstrate

such subgrantee's receipt of eligible Federal funds or an in-kind contribution purchased with such funds, as described in clause (iii), and the grant under which such subgrantee receives such funds or contribution; and

"(cc) registers each subgrantee site to participate in the program under this section in the covered entity identification system established under subsection (d)(2)(B)(iv);

"(III) purchases covered outpatient drugs subject to an agreement under this section only with respect to a patient receiving a health care service at a registered subgrantee site, and such service and such drug are within the scope and time period of the Federal grant, project, or grant-authorizing statute, as applicable, that qualifies such subgrantee for participation in the program under this section;

"(IV) in the case of a subgrantee that receives an in-kind contribution from a covered entity described in paragraph (4)(K), demonstrates to such covered entity and to the Secretary, upon initial registration to participate in the program under this section and on an annual basis thereafter, that the number of individuals aged 19 to 64 years receiving a health care service at the registered subgrantee site during the most recent calendar year who are enrolled under a State plan under title XIX of the Social Security Act (or a waiver of such plan), as a share of all individuals aged 19 to 64 years receiving a health care service at the registered subgrantee site during such calendar year, exceeds the number of individuals aged 19 to 64 years who reside in the State where such subgrantee site is located and are enrolled under a State plan under title XIX of such Act (or a waiver of such plan), as a

share of all individuals aged 19 to 64 who reside in such State, each as measured by data available from the American Community Survey of the Bureau of the Census for the calendar year preceding the most recent calendar year;

''(V) in the case of a subgrantee that receives an in-kind contribution from a covered entity described in paragraph (4)(K), submits to such covered entity and to the Secretary, upon receipt of each in-kind contribution described in clause (iii)—

''(aa) a written plan in a form specified by the Secretary describing how such contribution will be used to further the goals of the relevant Federal grant, how such subgrantee will ensure that purchases of covered outpatient drugs under the program under this section are consistent with the goals of such grant, and how such subgrantee will ensure

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

''(bb) a written plan in a form specified by the Secretary and using criteria established by the Secretary to determine the date upon which its eligibility to participate in the program under this section, as a result of such contribution, shall terminate (absent such subgrantee's receipt of additional funds or contributions described in clause (iii));

''(VI) subject to subclause (VII), immediately notifies the Secretary, disenrolls from the program under this section, and discontinues making purchases under such program and representing to third parties that it may purchase under such program as of the date described in subclause (V)(bb) or if, at any time during its participation in the program under this section, it no longer meets one or

more applicable requirements under this section; and

''(VII) not later than 30 days following the date on which the covered entity with which such subgrantee has an agreement pursuant to clause (i) ceases participation in the program under this section, such subgrantee either—

''(aa) disenrolls from the program under this section and discontinues making purchases under such program and representing to third parties that such subgrantee may purchase under such program; or

''(bb) enters into an enforceable written agreement with a different covered entity described in one of subparagraphs (A) through (K) of paragraph (4) that is participating in the program under this section, and satisfies all applicable requirements

under this section with respect to such different covered entity.

"(iii) SUBGRANTEE DEFINED.—

"(I) IN GENERAL.—In this subparagraph, the term 'subgrantee' means a subrecipient of a Federal grant that—

"(aa) receives eligible Federal funds from a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) in the form of non-nominal and ongoing payments by such covered entity directly to such subrecipient to directly support the provision of health care services by such subrecipient to individuals within the scope and time period of the Federal grant, project, or Federal grant-authorizing statute, as applicable, that qualifies such covered entity for participation in the program under this section; or

"(bb) receives in-kind contributions from a covered entity described in paragraph (4)(K) and such contributions—

"(AA) are ongoing and are in the form of real property, equipment, supplies, or services;

"(BB) subject to subclause (II), have a value exceeding $25,000 per year, which shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics and determined by the subrecipient and approved by the covered entity providing such contribution in a manner specified by the Secretary;

"(CC) are specifically identifiable and provided by

such covered entity directly to such subrecipient; and

''(DD) directly support the provision of health care items and services by such subrecipient solely to individuals within the scope and time period of the Federal grant that qualifies such covered entity for participation in the program under this section.

''(II) EXCLUSION.—The requirement specified in subclause (I)(bb)(BB) shall not apply with respect to a subrecipient of a Federal grant that receives in-kind contributions from a covered entity described in paragraph (4)(K) if—

''(aa) as of January 1, 2024, such subrecipient is participating in the program under this section as such a subrecipient and is in compliance with all requirements under this

section otherwise applicable to such subrecipient; and

"(bb) with respect to any in-kind contribution such subrecipient receives after January 1, 2024, such subrecipient has continuously participated in the program under this section as such a subrecipient in compliance with all requirements under this section for the period beginning on January 1, 2024 and continuing through the date on which program participation ends as determined in the plan submitted to the Secretary pursuant to clause (ii)(V)(bb) or any such earlier date on which program participation ends.

"(iv) RULE OF CONSTRUCTION.—For purposes of this section, any subgrantee that is not itself a covered entity described in one of subparagraphs (A) through (K) of paragraph (4) shall be subject to the obligations under this section applicable to

the covered entity with which such subgrantee has an enforceable written agreement pursuant to clause (i). Further, for purposes of this section, each registered site of such subgrantee shall be subject to the requirements set forth in subparagraph (F) as if such site were the covered entity with which such subgrantee has an enforceable written agreement pursuant to clause (i).''.

SEC. 8. CLAIMS MODIFIERS; COVERED ENTITY DATA SUBMISSION.

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

''(J) CLAIMS MODIFIER AND COVERED ENTITY DATA SUBMISSION.—

''(i) CLAIMS MODIFIER.—All claims submitted to a payor, including, without limitation, Medicare and Medicaid, by a covered entity or a contract pharmacy under a contract with a covered entity in compliance with subparagraph (F) for reimbursement of a unit of a covered outpatient drug purchased under the program

under this section shall include the relevant 340B modifier established by the Secretary under Medicare Part B (that is 'JG', 'TB', or any successor modifier) or the Submission Clarification Code of '20' or any successor modifier developed by the National Council for Prescription Drug Programs (NCPDP) to identify claims for covered outpatient drugs purchased under such program. All claims submitted by a covered entity or a contract pharmacy described in this clause to a payor, including, without limitation, Medicare and Medicaid, for reimbursement of a unit of a covered outpatient drug not purchased under such program shall also include a relevant non-340B modifier, which shall be established by the Secretary, or a non-340B modifier developed by the NCPCP to identify such claims.

''(ii) COVERED ENTITY DATA SUBMISSION.—A covered entity described in paragraph (4) shall (and shall cause any entity acting on its behalf to) furnish to the 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.

"(iii) CLAIM LEVEL DATA ELEMENTS.—The data described in this clause shall include the following, as applicable:

"(I) SELF-ADMINISTERED DRUGS.—With respect to a self-administered drug dispensed at a pharmacy, by a mail order service, or by another dispenser—

"(aa) prescription number;

"(bb) prescribed date;

"(cc) prescription fill date;

"(dd) national drug code (NDC) of the drug;

"(ee) quantity dispensed;

"(ff) bank identification number, processor control number, and group number of the plan receiving the claim (as applicable);

"(gg) national provider identifier (NPI) of the prescriber;

"(hh) NPI of the dispensing pharmacy;

"(ii) name and 340B identifier of the covered entity dis-

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

"(jj) 340B/non-340B claim modifier;

"(kk) wholesaler invoice number; and

"(ll) an indicator, which shall be specified by the clearinghouse or the Secretary, denoting that the drug was or was not dispensed as a result of a qualifying referral described in subsection (b)(3).

"(II) PROVIDER-ADMINISTERED DRUGS.—With respect to a drug furnished or administered by a physician or other provider of services or a supplier—

"(aa) drug billing and payment code/HCPCS code;

"(bb) NDC of the drug;

"(cc) claim number;

"(dd) Medicare provider number of prescriber (as applicable);

"(ee) NPI of the prescriber;

"(ff) name and 340B identifier of the covered entity furnishing or administering the drug;

"(gg) date drug furnished or administered;

"(hh) claim adjudication date;

"(ii) quantity furnished or administered;

"(jj) 340B/non-340B claim modifier; and

"(kk) an indicator, which shall be specified by the clearinghouse or the Secretary, denoting that the drug was or was not furnished or administered as a result of a qualifying referral described in subsection (b)(3).

"(iv) INFORMATION PRIVACY AND SECURITY.—A covered entity described in paragraph (4) shall provide the data specified in clause (iii) to the clearinghouse in a secure manner, consistent with such enti-

ty's obligations under the Security Standards for the Protection of Electronic Protected Health Information described in part 164 of subpart C of title 45, Code of Federal Regulations (or any successor regulations). A covered entity shall not be required to obtain an individual authorization under part 164 of subpart E of title 45, Code of Federal Regulations (or any successor regulations) for its reporting of such data to the clearinghouse.

''(v) STANDARDIZATION OF REPORTED DATA ELEMENTS; PROHIBITION ON MODIFICATIONS.—A covered entity described in paragraph (4) shall take reasonable steps to ensure the data specified in clause (iii) submitted to the clearinghouse fully complies with the data submission standards (including field descriptors and definitions) specified by the clearinghouse or the Secretary following consultation with relevant stakeholders, including manufacturers of covered outpatient drugs. A covered entity described in paragraph (4) is prohibited, and shall prohibit any entity acting on its

behalf (including any affiliate of such entity), from taking or refraining from taking any action that would cause such information to no longer comply with the standards described in this clause. In specifying the data submission standards described in this clause, the clearinghouse and the Secretary, as applicable, shall seek to minimize administrative burden on covered entities while ensuring such data satisfies the intent of this subparagraph.

''(vi) COVERED ENTITIES THAT FAIL TO REPORT.—A covered entity that fails to furnish the information as required under this subparagraph shall be subject to a civil monetary penalty in the amount of $2,500 for each day of such violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause

in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions of this clause.''.

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

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

''(K) REPORTING ON SCOPE OF GRANT, CONTRACT, AND PROJECT.—A covered entity described in one of subparagraphs (A) through (K) of paragraph (4) shall submit information specified by the Secretary to the identification system described in subsection (d)(2)(B)(iv) at least annually, in a form and manner specified by the Secretary, describing the scope of its Federal grant or project, or the Federal grant-authorizing statute, as applicable, that is the basis for such entity's eligibility for the program under this section. Such information shall include copies of agreements between such entity and any subgrantee, as described in subpara-

graph (I). Access to information described in this subparagraph shall be made available to a manufacturer of a covered outpatient drug, upon request, in a manner specified by the Secretary.''.

SEC. 10. ENSURING COVERED ENTITY TRANSPARENCY.

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

''(L) REPORTING.—

''(i) IN GENERAL.—During the first year beginning on or after the date that is 14 months after the date of enactment of this subparagraph and during each subsequent year, each covered entity described in subparagraph (L) of paragraph (4) (and any other covered entity specified by the Secretary) shall report to the Secretary (at a time and in a form and manner specified by the Secretary) the following information with respect to the preceding year:

''(I) With respect to such covered entity and each child site, as applicable, of such entity—

''(aa) the total number of individuals who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section; and

''(bb) the number of such individuals described in a category specified in clause (iii), broken down by each such category.

''(II) With respect to such covered entity and each child site, as applicable, of such entity—

''(aa) the percentage of the total number of individuals furnished items and services during such preceding year who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section; and

''(bb) for each category specified in clause (iii), the percentage of the total number of

individuals described in such category furnished items and services during such preceding year who were dispensed or administered covered outpatient drugs during such preceding year that were subject to an agreement under this section.

''(III) With respect to such covered entity and each child site, as applicable, of such entity, the total costs incurred during the year at each such site and the cost incurred at each such site for charity care (as defined in line 23 of worksheet S–10 to the Medicare cost report, or in any successor form).

''(IV) With respect to such covered entity and each child site, as applicable, of such entity, the costs incurred during the year of furnishing items and services at each such entity or site to patients of such entity who were entitled to benefits under part A of title XVIII of the Social Security

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

"(aa) payments under title XVIII of such Act for such items and services (including any cost sharing for such items and services);

"(bb) payments under title XIX of such Act for such items and services (including any cost sharing for such items and services); and

"(cc) payments by uninsured patients for such items and services.

"(V) With respect to such covered entity and each child site, as applicable, of such entity, the margin (as defined in clause (iv)) generated on covered outpatient drugs subject to an agreement under this section dispensed or furnished by such entity or

site (and any entity pharmacy or contract pharmacy dispensing such drugs on behalf of such entity in accordance with subparagraph (F)), with each component of the margin calculation described in item (aa) through (cc) of such clause listed as a separate line item.

''(VI) To the extent the Secretary requires covered entities described in one of subparagraphs (A) through (K) of paragraph (4) to report information pursuant to this subparagraph, with respect to each such covered entity, use of margin (as defined in clause (iv)) generated on covered outpatient drugs subject to an agreement under this section in the following categories of expenditures, if applicable, which the Secretary shall define in interim final regulations in a manner consistent with reporting under the Health Resources and Services Administration Uniform Data System (UDS)—

"(aa) medical care;

"(bb) dental care;

"(cc) mental health;

"(dd) pharmaceuticals, which shall include margin used to provide free and discounted covered outpatient drugs subject to an agreement under this section dispensed or furnished to eligible patients (as defined in subparagraph (H)), notwithstanding any UDS reporting requirement that may limit or interfere with the inclusion of margin used for such purpose;

"(ee) sliding fee discounts;

"(ff) case management;

"(gg) transportation;

"(hh) patient and community education;

"(ii) community health workers;

"(jj) outreach;

"(kk) eligibility assistance; and

"(ll) nutritional assessment and referral.

"(ii) PUBLICATION.—The Secretary shall publish data reported under clause (i) with respect to a year annually on the public website of the Department of Health and Human Services in an electronic and searchable format, which may include the 340B Office of Pharmacy Affairs Information System (or a successor to such system), in a manner that shows each category of data reported in the aggregate and identified by the specific covered entity submitting such data. The Secretary shall include in such publication the disproportionate patient percentage (as defined in section 1886(d)(5)(F)(vi) of the Social Security Act) of each such covered entity (if applicable) for each cost reporting period occurring during such year.

"(iii) CATEGORIES SPECIFIED.—For purposes of clause (i), the categories specified in this clause are the following:

"(I) Individuals covered under a group health plan or group or indi-

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

''(II) Individuals entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act.

''(III) Individuals enrolled under a State plan under title XIX of such Act (or a waiver of such plan).

''(IV) Individuals enrolled under a State child health plan under title XXI of such Act (or a waiver of such plan).

''(V) Individuals not described in any preceding subclause and not covered under any Federal health care program (as defined in section 1128B of such Act but including the program established under chapter 89 of title 5, United States Code).

''(iv) DEFINITIONS.—In this subparagraph:

"(I) CHILD SITE.—The term 'child site' shall have the meaning given such term in subparagraph (E).

"(II) ENTITY PHARMACY.—The term 'entity pharmacy' shall have the meaning given such term in subparagraph (F).

"(III) MARGIN.—The term 'margin' means, with respect to covered outpatient drugs purchased by a covered entity under an agreement under this section, the following amount for such drugs dispensed, furnished, or administered to an individual by such entity or a child site of such entity (and any entity pharmacy or contract pharmacy dispensing such drugs on behalf of such entity in accordance with subparagraph (F))—

"(aa) aggregate payments received by the covered entity for such drugs from individuals (including cost-sharing amounts) 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 subceiling 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.".

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

SEC. 11. REVISIONS TO EXISTING 340B HOSPITAL ELIGIBILITY REQUIREMENTS.

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

(1) in subparagraph (L)(i)—

(A) by inserting ''and that was registered with the 340B program in the covered entity identification system established under subsection (d)(2)(B)(iv) as such a hospital on or before December 1, 2023'' after ''formally granted governmental powers by a unit of state or local government''; and

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

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

''(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act (42 U.S.C. 1395i–4(c)(2))) or a rural emergency hospital (as determined under the requirements in section 1861(kkk) of the Social Security Act (42 U.S.C. 1395x(kkk) and in implementing regulations set forth in parts 419, 424, 485, 488, and 489 of title 42 of the Code of Federal Regulations in effect as of January 1, 2023)), and that meets the requirements of subparagraph (L)(i).''; and

(3) in subparagraph (O) by inserting ''that demonstrates to the Secretary that at least 60 percent of annual inpatient discharges for cost reporting periods beginning after December 1, 2023 are for inpatients who reside in a county that is not part of a Metropolitan Statistical Area, as defined by the Director of the Office of Management and Budget'' before '', or a sole community hospital''.

SEC. 12. ADDITIONAL REQUIREMENTS FOR 340B HOSPITALS.

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

''(11) CLARIFICATION OF ELIGIBILITY STANDARDS FOR PRIVATE NONPROFIT HOSPITALS WITH A CONTRACT WITH A STATE OR LOCAL GOVERNMENT TO PROVIDE HEALTH CARE SERVICES.—

''(A) CONTRACT REQUIREMENTS.—For purposes of paragraph (4)(L)(i) and cross-references to subparagraph (L) or clause (i) of such paragraph appearing in subparagraph (M) and subparagraph (O) of such paragraph with respect to a rural referral center, a private nonprofit hospital has a contract with a State or local government to provide health care services to low-income individuals who are uninsured if—

''(i) the hospital submits a copy of the contract (including any appendices or addenda or subsequent amendments) to the Secretary for review;

''(ii) the Secretary determines that the contract creates an enforceable obligation for the hospital to provide direct medical care to low-income individuals who are uninsured in an amount that represents at least 10 percent of the hospital's total costs of care;

"(iii) the Secretary further determines, based on a review of the contract (as described in clause (i)) that the contract creates an enforceable obligation for the hospital to furnish the individuals described in clause (ii) the full range of services provided at the hospital (including any child sites); and

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

"(B) DEREGISTRATION.—If at any time a hospital not owned or operated by a unit of State or local government that has been participating in the program under this section on the basis of having a contract with a State or local government to provide health care services that is subject to subparagraph (A) no longer satisfies a requirement under such subparagraph, the hospital shall immediately notify the Secretary that the hospital no longer satisfies the relevant requirement, deregister the hospital 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.

''(C) OBLIGATION TO SELF-DISCLOSE.—A covered entity described in subparagraph (B) 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 subparagraph (A). 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 drug. The covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the noncompliance in an amount equal to the reduction in the price of the drugs provided under subsection (a)(1), plus interest on such

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

''(D) CIVIL MONETARY PENALTY.—Where a covered entity fails to satisfy a requirement in subparagraph (B) or (C), the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this subparagraph.

''(E) DEFINITIONS.—In this paragraph:

''(i) FEDERAL POVERTY GUIDELINES.—The term 'Federal poverty guidelines' means the poverty guidelines updated periodically in the Federal Register by the Department of Health and Human Services pursuant to section 9902(2) of title 42, United States Code.

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

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

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

''(A) IN GENERAL.—A covered entity described in paragraph (4)(L)(i) that is either a private nonprofit hospital that has as the basis for its participation in the program under this

section a contract with a State or local government as described in such paragraph and in paragraph (11), or that is a private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, and such entity is located in a county that is part of a Metropolitan Statistical Area, as defined by the Office of Management and Budget, must, for the preceding year, fall within the top 40 percent of hospitals on each of the lists described in subparagraphs (B) and (C) prepared by the Secretary with respect to the State in which the covered entity is located. As described further in subparagraph (D), placement in the top 40 percent of hospitals on both of such lists is a condition of such covered entity's participation in the program under this section and failure to meet this condition shall require deregistration and self-disclosure using the procedures described in subparagraphs (B) and (C) of paragraph (11). Such covered entity shall be subject to a civil monetary penalty described in paragraph (11)(D) for failure to deregister and self-disclose in accordance with the preceding sentence.

"(B) MEDICAID AND CHIP OUTPATIENT REVENUE.—Within 90 days following the conclusion of a year, the Secretary shall prepare and make available to the public in an electronic, machine-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 share of total outpatient services revenue derived from base reimbursement to such hospital (excluding supplemental and indirect reimbursement) under title XIX of the Social Security Act (including with respect to individuals also entitled to benefits under part A of title XVIII of such Act or enrolled in part B of title XVIII of such Act) and payments under title XXI of such Act for items and services furnished on an outpatient basis at the hospital (including any cost sharing for such items and services). The Secretary shall specify the threshold for the top 40 percent of hospitals on the list.

"(C) UNCOMPENSATED OUTPATIENT CARE.—Within 90 days following the conclusion of a year, the Secretary shall prepare and make 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

drug. The covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the noncompliance in an amount equal to the reduction in the price of the drugs provided under paragraph (1), plus interest on such amount, which shall be compounded monthly and equal to the current short-term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

''(F) CIVIL MONETARY PENALTY.—Where a covered entity fails to satisfy a requirement in subparagraph (D) or (E), the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector Gen-

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

''(13) PROHIBITION AGAINST EXTRAORDINARY COLLECTION ACTIONS.—

''(A) ECAS PROHIBITED.—A covered entity described in subparagraphs (L) through (O) of paragraph (4) is prohibited from engaging in extraordinary collection actions (ECAs), as such term is described in section 501(r)(6) of the Internal Revenue Code and its implementing regulations set forth in section 1.501(r)–6 of title 26 of the Code of Federal Regulations (or any successor regulations), with respect to health care items and services furnished to uninsured individuals or low-income individuals.

''(B) AUDITS.—The Secretary shall audit for covered entity compliance with this paragraph, establish a process for individuals to report suspected violations of this paragraph to the Secretary, and promptly and fully investigate such reports of suspected violations.

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

paragraph, the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each extraordinary collection action taken with respect to an individual described in this paragraph, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this paragraph.

''(D) DEFINITIONS.—In this paragraph, the terms 'low-income individual' and 'uninsured' have the meanings given such terms in paragraph (11).

''(14) ADDITIONAL REQUIREMENT FOR CERTAIN HOSPITALS.—

"(A) IN GENERAL.—During the first calendar year beginning on or after the date that is 24 months after the date of enactment of this paragraph and during each subsequent calendar year, a covered entity described in paragraph (4)(L) shall determine by October 1 of each such year, based on the most recent year of data it has reported to the Secretary under paragraph (5)(L) at that point in time, whether the annual charity care costs it incurred for the year reported were greater than or equal to the margin it realized under the program under this section for that same year. As described further in subparagraph (D), for the period specified in the preceding sentence, having annual charity care costs that equal or exceed the margin for the most recently reported year is a condition of such covered entity's participation in the program under this section for the upcoming calendar year, and failure to meet this condition shall require deregistration and self-disclosure using the procedures described in subparagraphs (D) and (E). Such covered entity shall be subject to a civil monetary penalty described in subparagraph (F) for failure to deregister

and self-disclose in accordance with the preceding sentence.

"(B) ANNUAL CHARITY CARE COSTS.—The term 'annual charity care costs' means the total costs incurred during the year by the covered entity and its child sites (as defined in paragraph (5)(E)(i)) for charity care (as defined in line 23 of worksheet S–10 to the Medicare cost report, or in any successor form).

"(C) MARGIN.—The term 'margin' means the margin reported by the covered entity for the year pursuant to paragraph (5)(L)(i)(V).

"(D) DEREGISTRATION AND CONDITIONS FOR SUBSEQUENT REGISTRATION.—

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

the condition of participation under this paragraph for the upcoming calendar year, deregister the entity from the program under this section and the identification system described in subsection (d)(2)(B)(iv) for the upcoming calendar year, cease making purchases under such program as of the start of the upcoming calendar year, cease representing to third parties that it may purchase under such program beyond the current calendar year, and refrain from purchasing covered outpatient drugs under this section in quantities exceeding such entity's bona fide needs for the remainder of the current calendar year.

''(ii) REGISTRATION FOLLOWING DEREGISTRATION.—

''(I) REGISTRATION UNDER ANOTHER COVERED ENTITY CATEGORY.—A covered entity that must deregister under this subparagraph shall not be prohibited from registering to participate in the program under this section under another cov-

ered entity category described in paragraph (4) if such entity meets the criteria for such a category and applicable requirements under this section.

"(II) REGISTRATION UNDER PARAGRAPH (4)(L).—In order to register under paragraph (4)(L), a hospital that has been required to deregister under this subparagraph must demonstrate to the Secretary (in a form and manner specified by the Secretary, and in addition to demonstrating that it satisfies the other applicable registration criteria under paragraph (4)(L)) that its annual charity care cost (as defined in subparagraph (B)) for the most recent year that the hospital would have reported under paragraph (4)(L) absent the deregistration exceeded by at least one percent point the annual charity care cost for the year preceding deregistration by the hospital. If the hospital is found to meet this requirement and approved by the Secretary

for registration under paragraph (4)(L), then the hospital will be required to resume reporting under paragraph (5)(L) and (once the entity has reported at least one year of data to the Secretary under paragraph (5)(L)) to meet the condition of participation described in this paragraph for the most recently reported year as of October 1 of each year.

''(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 it made under this section during a calendar year in which it was ineligible to participate in the program under this section. Any such purchase shall require the covered entity promptly to conduct an audit supervised by the Secretary to identify the full scope of noncompliance and to provide the written results of such audit to the Secretary and the manufacturer of the affected covered outpatient drug. The covered entity shall be liable to the manufacturer of the covered outpatient

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

''(F) CIVIL MONETARY PENALTY.—Where a covered entity fails to satisfy a requirement in subparagraph (D) or (E), the covered entity shall be required to pay a civil monetary penalty equal to $2,500 for each violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to

the imposition of civil monetary penalties under this subparagraph.''.

SEC. 13. 340B PROGRAM.

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

''(15) 340B PROGRAM.—The intent of this section is to provide for manufacturer price reductions that enable covered entities, whose mission is to serve underserved or otherwise vulnerable communities, to increase access to affordable drugs and health services for these communities.''.

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

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

''(vi) The conducting of annual audits by the Secretary of contracts between a covered entity described in subparagraph (L) or subparagraph (M) of subsection (a)(4), or subparagraph (O) of such subsection with respect to a rural referral center, that is a private nonprofit hospital subject to the requirements in subsections

(a)(4)(L)(i) and (a)(11) and a State or local government for at least 10 percent of all such entities participating in the program under this section. The Secretary shall develop and publicly disclose standards used to determine whether such contracts satisfy the applicable requirements described in subsections (a)(4)(L)(i) and (a)(11) and publicly disclose the findings from such audits. The Secretary shall remove from the program under this section any such entity that does not have a contract in effect with a State or local government that satisfies the applicable requirements set forth in subsections (a)(4)(L)(i) and (a)(11), and such removal shall require such covered entity to promptly conduct an audit supervised by the Secretary to identify discounts on covered outpatient drugs purchased at a discount under this section to which such covered entity was not eligible and provide the written results of such audit to the Secretary and the manufacturer of the affected covered outpatient drug. Such covered entity shall be

liable to the manufacturer of such covered outpatient drug in an amount equal to the reduction in the price of the drugs provided under subsection (a)(1), plus interest on such amount, which shall be compounded monthly and equal to the current short-term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable. Where a covered entity described in this clause knowingly and intentionally violates a requirement in subsection (a)(4)(L)(i) or (a)(11), the covered entity shall be required to pay a civil monetary penalty equal to $1,000 for each claim for a covered outpatient drug that is subject to the violation, which amount shall be adjusted for inflation annually to reflect the rate of change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this clause in the same manner as such

provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this clause.''.

SEC. 15. ENSURING COVERED ENTITY COMPLIANCE WITH TRANSPARENCY REQUIREMENTS.

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

''(vii) The imposition of civil monetary penalties in amounts determined appropriate by the Secretary in the case that the Secretary determines that a covered entity is not in compliance with subsection (a)(5)(L).''.

SEC. 16. 340B CLAIMS DATA CLEARINGHOUSE.

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

''(C) 340B CLAIMS DATA CLEARINGHOUSE.—

"(i) IN GENERAL.—The improvements described in subparagraph (A) shall include the establishment of a claims data clearinghouse described in this subparagraph. Not later than one year after the date of enactment of this subparagraph, the Secretary shall enter into a contract with a third-party entity that meets the criteria specified in clause (ii) (such entity is hereinafter referred to as the 'clearinghouse') for purposes of—

"(I) identifying claims for covered outpatient drugs purchased under the program under this section for which reimbursement was made under a State plan (or waiver of such plan) and ensuring such claims are or were not included in any State rebate request under section 1927 of the Social Security Act in violation of sections 1903(m)(2)(A)(xiii) or 1927(j)(1) of such Act or section 340B(a)(5)(A) of this Act;

"(II) identifying claims for covered outpatient drugs purchased

under the program under this section that are selected drugs (as defined in section 1192(c) of the Social Security Act) and ensuring that, for each such claim, the nonduplication requirements of section 1193(d) of such Act have been met;

''(III) identifying claims for covered outpatient drugs purchased under the program under this section that are either Part B rebatable drugs or Part D rebatable drugs and providing all relevant information regarding such claims to the Secretary to ensure that claims that are subject to a discount under the program under this section are excluded from inflation rebate calculations pursuant to section 1847A(i)(3)(B)(ii)(I) of the Social Security Act (with respect to Part B rebatable drugs) and section 1860D–14B(b)(1)(B) of such Act (with respect to Part D rebatable drugs);

''(IV) identifying duplicate claims for a rebate or discount submitted by two or more covered entities (or an entity or entities acting on their behalf) with respect to the same unit of a covered outpatient drug purchased under the program under this section and implementing a process to ensure a manufacturer of such a drug does not pay more than one rebate or discount under this section with respect to such unit; and

''(V) providing to manufacturers of covered outpatient drugs, in a form and manner specified by the Secretary in consultation with manufacturers, access to the data described in subsection (a)(5)(J) with respect to each dispense or administration of a manufacturer's covered outpatient drugs for which a covered entity receives a discount under this section.

''(ii) CRITERIA FOR CLEARINGHOUSE.—The criteria described in this clause include the following:

''(I) The clearinghouse shall not be owned by, overseen by, or affiliated with a covered entity described in subsection (a)(4) and shall not currently be a party to a contractual arrangement with the Health Resources and Services Administration.

''(II) The clearinghouse shall have demonstrated experience adjudicating claims for health care items and services in real time for self- and provider-administered drugs and working with protected health information and confidential pricing information.

''(III) The clearinghouse shall agree to confidentiality obligations that prohibit the clearinghouse from using information it receives under this subparagraph for any purpose other than a purpose set forth in this subparagraph, or disclosing such information to any individual or entity other than the Secretary, provided the Secretary shall not use such informa-

tion for purposes of making reimbursement or coverage determinations, or a manufacturer in accordance with this subparagraph (and only with respect to such manufacturer's covered outpatient drugs).

"(IV) The clearinghouse shall maintain the security of the data reported pursuant to this subsection (a)(5)(J) in a manner consistent with the HIPAA Security Standards set forth in sections 164.304–164.312 and 164.316 of title 45, Code of Federal Regulations (or any successor regulations), as if the clearinghouse were subject to those standards as a HIPAA covered entity.

"(iii) DUTIES OF CLEARINGHOUSE.—The clearinghouse shall—

"(I) review claims level data for covered outpatient drugs described in subsection (a)(5)(J) submitted by covered entities in accordance with such subsection;

"(II) review claims level data, including rebate file data, submitted to the clearinghouse by State agencies and Medicaid managed care organizations for covered outpatient drugs subject to an agreement under this section dispensed or administered to individuals enrolled under a State plan (or a waiver of such plan) and claims level data submitted by Medicare Administrative Contractors, Medicare Advantage organizations (including Medicare Advantage Organizations offering an MA–PD plan), and PDP sponsors for covered outpatient drugs subject to an agreement under this section dispensed or administered to individuals enrolled under Part B, Part C, or Part D of title XVIII of the Social Security Act;

"(III) within 5 days of identification, provide written notice of a duplicate discount or rebate to the State agency, the Secretary, the covered entity, and the affected drug manufac-

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

''(IV) within 5 days of identification, provide written notice to the Secretary, the covered entity (or entities, as applicable), and the affected drug manufacturer itemizing any violation described in subclauses (II) or (IV) of clause (i);

''(V) have access to the internet website described in paragraph (1)(B)(iii) containing applicable ceiling prices for covered outpatient drugs for purposes of identifying violations described in clause (i)(II);

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

''(VII) upon request by the Centers for Medicare & Medicaid Services, make the data described in subclauses (I) and (II) available for purposes of

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

''(VIII) identify claims for covered outpatient drugs subject to an agreement under this section that are submitted by pharmacies removed from the 340B program pursuant to subsection (a)(5)(F)(ix)(III) and notify the Secretary of the submission of any such claims by any such pharmacies.

''(iv) RESOLUTION OF VIOLATIONS.—

''(I) MEDICAID DUPLICATE DISCOUNTS.—The Secretary, in consultation with the State, as appropriate, shall take prompt action to fairly and adequately resolve violations described in clause (i)(I) reported by the clearinghouse in accordance with clause (iii)(III).

"(II) NONDUPLICATION WITH MAXIMUM FAIR PRICE.—The Secretary shall take prompt action to fairly and adequately resolve violations described in clause (i)(II) reported by the clearinghouse in accordance with clause (iii)(IV).

"(III) DUPLICATE COVERED ENTITY DISCOUNTS.—The Secretary shall develop and implement a process to resolve duplicate claims for a rebate or discount under this section described in clause (i)(IV) such that the manufacturer pays only one rebate or discount under this section with respect to the same unit of a covered outpatient drug purchased under the program under this section. Covered entities (and any entities acting on their behalf) shall be subject to determinations made by the Secretary to resolve such duplicate claims (and the Secretary may contract this function to the clearinghouse to make such determinations). In making such deter-

minations, the Secretary shall investigate duplicate claims for rebates or discounts and require covered entities (and any entities acting on their behalf) to take action to avoid or pay refunds to reverse a duplicate claim.

''(IV) REFUNDS TO MANUFACTURERS.—The Secretary shall be responsible for promptly refunding affected manufacturers of covered outpatient drugs for violations described in subclauses (I) and (II) of clause (i) and seeking subsequent repayment from covered entities or States (with respect to violations described in clause (i)(I)), or providers or dispensers (with respect to violations described in clause (i)(II)). Subject to the determination by the Secretary or clearinghouse under subclause (III), the covered entity (or entities) shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation described in clause (i)(IV) in an amount equal to

the reduction in the price of the drug (as described in subsection (a)(1)) and shall repay such amount to such manufacturer within 60 days of receiving a notice described in clause (iii)(IV).''.

(b) PROVISION OF DRUG CLAIMS DATA BY MEDICAID; REMOVAL OF DUPLICATE CLAIMS.—

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

(A) in paragraph (86), by striking ''and'' at the end;

(B) in paragraph (87)(D), by striking the period and inserting ''; and''; and

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

''(88) provide for a mechanism for the State agency to furnish, and for the State agency to require each Medicaid managed care organization (as defined in section 1903(m)(1)(A)) to furnish, to the clearinghouse, in a machine-readable format, within 5 days following the date of claim payment, claims level data, including rebate file data, for covered outpatient drugs dispensed, furnished, or administered to individuals enrolled under a State plan (or a waiv-

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

(c) PROVISION OF DRUG CLAIMS DATA BY MEDICARE.—

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

''(v) PROVISION OF DRUG CLAIMS DATA; MECHANISM TO REFUND DUPLICATED AMOUNTS.—Each Medicare administrative contractor shall furnish to the clearinghouse, in a machine-readable format, claims level data for covered outpatient drugs furnished or administered to individuals enrolled under this part that includes, with respect to each furnishing or administration of such a drug, the data elements described in section 340B(a)(5)(J)(iii) of the Public Health Service Act. Each Medicare administrative contractor shall furnish such data to the clearing-

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

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

''(6) PROVISION OF DRUG CLAIMS DATA; MECHANISM TO REFUND DUPLICATED AMOUNTS.—A contract under this part shall require a Medicare+Choice organization to furnish to the clearinghouse, in a machine-readable format, claims level data for covered outpatient drugs furnished or administered to individuals enrolled with the organization under this part that includes, with respect to each furnishing or administration of such a drug, the data elements described in section 340B(a)(5)(J)(iii) of the Public Health Service Act. Such contract shall require the Medicare+Choice organization to furnish such data to the clearinghouse within 5 days following the date the claim for such drug is paid by the Medicare+Choice organization.''.

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

''(9) PROVISION OF DRUG CLAIMS DATA; MECHANISM TO REFUND DUPLICATED AMOUNTS.—A contract under this part shall require a PDP sponsor to furnish to the clearinghouse in a machine-readable format, claims level data for covered outpatient drugs dispensed to individuals enrolled in a prescription drug plan offered by such sponsor under this part that includes, with respect to each dispense of such drug, the data elements described in section 340B(a)(5)(J)(iii) of the Public Health Service Act. Such contract shall require a PDP sponsor to furnish such data to the clearinghouse within 5 days following the date the claim for such drug is paid by the PDP sponsor.''.

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

''(E) PROVISION OF DRUG CLAIMS DATA; MECHANISM TO REFUND DUPLICATED AMOUNTS.—Section 1860D–12(b)(9).''.

SEC. 17. LIMITATION ON ADMINISTRATOR SERVICE FEES AND CONTRACT PHARMACY FEES.

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

"(f) REQUIREMENTS FOR TPA AND CONTRACT PHARMACY REMUNERATION.—

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

"(A) such remuneration is a flat dollar amount not directly or indirectly based on any price of, or discount or other remuneration provided with respect to, a covered outpatient drug, paid for each unit of service furnished to the covered entity, regardless of whether a prescription was dispensed to an individual who is a patient of the covered entity;

"(B) the amount of such remuneration is consistent with fair market value in an arm's-length transaction for the bona fide, itemized 340B-related services actually performed on behalf of the covered entity; and

"(C) such remuneration complies with applicable State and Federal law, including section 1128B(b) of the Social Security Act.

"(2) CONTRACT PHARMACY FEES.—A contract pharmacy that has entered into a written agreement with a covered entity pursuant to and satisfies the applicable requirements in subsection (a)(5)(F) may receive remuneration from such covered entity for the performance of services associated with dispensing covered outpatient drugs subject to an agreement under this section to individuals who are patients of the covered entity (as defined in subsection (b)(3)) only if—

"(A) such remuneration is a flat dollar amount not directly or indirectly based on any price of, or discount or other remuneration provided with respect to, a covered outpatient drug, paid for each dispense of such a drug to a patient of the covered entity;

"(B) the amount of remuneration for each dispense does not exceed 125 percent of the average per-prescription dispensing fee paid to such pharmacy by all third-party payors, based on data from the most recent full calendar year for which such data is available;

"(C) the amount of such remuneration is consistent with fair market value in an arm's-length transaction for the bona fide, itemized 340B-related services actually performed on behalf of the covered entity; and

"(D) such remuneration complies with applicable State and Federal law, including section 1128B(b) of the Social Security Act.

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

"(3) AUDITABLE RECORDS.—A covered entity shall retain copies of written agreements with third-party administrators or contract pharmacies described in this subsection for a period of time specified by the Secretary and shall make copies of such agreements available to the Secretary or their designee upon request.

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

in this subsection that fails to comply with the applicable requirements specified in this subsection shall be required to pay a civil monetary penalty equal to 10 times the amount such third-party administrator or contract pharmacy received for the performance of relevant services described in this subsection. The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The Office of Inspector General of the Department of Health and Human Services shall carry out the provisions related to the imposition of civil monetary penalties under this paragraph.''.

SEC. 18. CLARIFICATION.

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

''(g) CLARIFICATION.—The provisions of this section supersede any provision or requirement of State or local law insofar as that State or local law may establish, implement, or continue in effect a standard or requirement that differs from or relates in any way to the provisions of this section or, except for any State regulations issued to carry

out subsection (a)(5)(A)(iii), relates in any way to the drug discount program under this section or covered outpatient drugs subject to an agreement under this section, including the distribution of such drugs. Except for any State regulations issued to carry out subsection (a)(5)(A)(iii), no provision or requirement of State or local law shall grant additional rights or impose additional obligations related to the 340B program.''.

SEC. 19. ENSURING THE EQUITABLE TREATMENT OF 340B COVERED ENTITIES AND PHARMACIES PARTICIPATING IN THE 340B DRUG DISCOUNT PROGRAM.

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

''SEC. 2730. REQUIREMENTS RELATING TO THE 340B DRUG DISCOUNT PROGRAM.

''(a) IN GENERAL.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager acting on behalf of such plan or issuer, may not discriminate against a covered entity (as defined in subsection (e)(1)), a contract pharmacy (as defined in subsection (e)(2)), or a par-

ticipant, beneficiary, or enrollee of such plan or coverage by imposing requirements, exclusions, reimbursement terms, or other conditions on such entity or pharmacy that differ from those applied to entities or pharmacies that are not covered entities or contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or pharmacy dispenses 340B drugs, by taking any action prohibited under subsection (b).

''(b) SPECIFIED PROHIBITED ACTIONS.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager acting on behalf of such plan or issuer, may not discriminate against a covered entity, a contract pharmacy, or a participant, beneficiary, or enrollee of such plan or coverage by doing any of the following:

''(1) Reimbursing a covered entity or contract pharmacy for a quantity of a 340B drug (as defined in subsection (e)) in an amount less than such plan, issuer, or pharmacy benefit manager (as applicable) would pay to any other similarly situated (as specified by the Secretary) entity or pharmacy that is not a covered entity or a contract pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or contract phar-

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

''(2) Imposing any terms or conditions on covered entities or contract pharmacies with respect to any of the following that differ from such terms or conditions applied to other similarly situated entities or pharmacies that are not covered entities or contract pharmacies on the basis that the entity or pharmacy is a covered entity or contract pharmacy or that the entity or pharmacy dispenses 340B drugs:

''(A) Fees, chargebacks, clawbacks, adjustments, or other assessments.

''(B) Professional dispensing fees.

''(C) Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

''(D) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles.

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

340B in accordance with applicable requirements under such section.

''(3) Interfering with an individual's choice to receive a 340B drug from a covered entity or contract pharmacy, whether in person or via direct delivery, mail, or other form of shipment, as permitted under section 340B.

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

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

''(A) the entity or pharmacy is a covered entity or a contract pharmacy; or

''(B) the entity or pharmacy is described in any of subparagraphs (A) through (O) of section 340B(a)(4).

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

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

"(c) PROHIBITED ACTIONS IN DEROGATION OF SECTION 340B AFFORDABILITY ASSISTANCE PROVISIONS.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager acting on behalf of such plan or issuer shall not prohibit or restrict, in contracts with pharmacies in their network that are contract pharmacies or entity pharmacies, or in any other manner, any reduction in or subsidy for the out-of-pocket amount for a 340B drug charged to an individual (including a participant, beneficiary, or enrollee of such plan or coverage) that is required or authorized by subparagraphs (G) or (H) of section 340B(a)(5). Any general prohibition or restriction on reducing or subsidizing the out-of-pocket amount for a drug charged to an individual that lacks an express exemption for any reductions in or subsidies for the out-of-pocket amount for a 340B drug that are required or authorized by subparagraphs (G) or (H) of section 340B(a)(5) is a violation of this subsection. Any contractual provision that violates this subsection in any manner shall be void and unenforceable.

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

monetary penalty on any pharmacy benefit manager that violates the requirements of this section. Such penalty shall not exceed $5,000 per violation per day. The Secretary shall issue proposed regulations to implement this subsection not later than 60 days after the date of the enactment of this subsection and shall finalize such regulations not later than 180 days after such date of enactment.

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

''(1) 340B DRUG.—The term '340B drug' means a drug that is—

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

''(B) purchased under an agreement in effect under such section.

''(2) CONTRACT PHARMACY.—The term 'contract pharmacy' has the meaning given such term in section 340B(a)(5)(F).

''(3) COVERED ENTITY.—The term 'covered entity' has the meaning given such term in section 340B(a)(4).

''(4) ENTITY PHARMACY.—The term 'entity pharmacy' has the meaning given such term in section 340B(a)(5)(F).''.

(b) APPLICATION OF REQUIREMENTS TO MEDICARE.—

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

''(10) APPLICATION OF REQUIREMENTS RELATING TO THE 340B DRUG DISCOUNT PROGRAM.—Each contract entered into under this subsection with a PDP sponsor shall provide that the requirements of section 2730 of the Public Health Service Act apply to such sponsor, and to any pharmacy benefit manager that contracts with such sponsor, in the same manner as such requirements apply with respect to a group health plan, a health insurance issuer, or a pharmacy benefit manager described in such section.''.

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

''(F) 340B DRUG DISCOUNT PROGRAM.—Section 1860D–12(b)(10).''.

SEC. 20. EFFECTIVE DATE.

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

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