I

116TH CONGRESS
1ST SESSION

H. R. 1559

To amend the Public Health Service Act to strengthen program integrity and enhance low-income patient benefits for safety net providers.

IN THE HOUSE OF REPRESENTATIVES

MARCH 6, 2019

Mr. COLLINS of New York introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to strengthen program integrity and enhance low-income patient benefits for safety net providers.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''340B Protection and Accountability Act of 2019''.

SEC. 2. STRENGTHENING 340B PROGRAM INTEGRITY AND ENHANCING LOW-INCOME PATIENT BENEFITS FOR SAFETY NET PROVIDERS.

(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 new paragraph:

"(3) PATIENT.—

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

"(i) receives a health care service at a covered entity or an outpatient hospital facility described in subsection (c)(3) which is registered for the drug discount program under this section and listed on the public internet website of the Department of Health and Human Services relating to this section;

"(ii) receives an outpatient in-person health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity, such that the covered entity bills for services on behalf of the provider;

"(iii) receives a drug that is ordered or prescribed by the covered entity pro-

vider, including any renewals of existing prescriptions, as a result of the service described in clause (ii);

"(iv) in the case of a covered entity that has a contract with a State or local government described in subclause (III) of subsection (a)(4)(L)(i), receives a health care service or range of such services, to include the ordering or prescribing of a covered outpatient drug, from the covered entity pursuant to such contract;

"(v) is classified as an outpatient when the drug is ordered or prescribed, as demonstrated by how the service was reimbursed by the applicable payer, or, where the covered entity does not seek such reimbursement, how the service would have been reimbursed under title XVIII of the Social Security Act; and

"(vi) has a relationship with the covered entity such that the covered entity creates and maintains auditable health care records which demonstrate that—

"(I) the covered entity has a provider-to-patient relationship with the individual; and

"(II) responsibility for the individual's health care service that resulted in the prescription or order for the drug described in clause (iii) is with the covered entity.

"(B) EXCLUSIONS.—For purposes of this section, an individual shall not be considered a patient of a covered entity described in subparagraph (L) or (M) of subsection (a)(4) if—

"(i) the individual is an inmate of a correctional facility;

"(ii) the health care service described in clause (ii) of subparagraph (A) received by the individual from the covered entity consists only of 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;

"(iii) the health care service described in clause (ii) of subparagraph (A) received

by the individual from the covered entity is provided by a health care organization that has only an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records; or

"(iv) the primary relationship between the individual and the covered entity is one of employment.

"(C) REGULATIONS.—Not later than 180 days after the date of enactment of the 340B Protection and Accountability Act of 2019, the Secretary shall promulgate final regulations through notice-and-comment rulemaking to define the term 'patient' with respect to covered entities described in subparagraph (L) or (M) of subsection (a)(4) to reflect the requirements described in subparagraphs (A) and (B) of this paragraph.

"(D) DEFINITION RELATING TO OTHER COVERED ENTITIES.—In this section, the term 'patient', with respect to a covered entity described in subparagraphs (A) through (K) of subsection (a)(4), has the meaning given such term in the October 24, 1996, HRSA Final No-

tice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility (61 Fed Reg. 55156).

"(E) RECORD RETENTION.—A covered entity described in subparagraph (L) or (M) of subsection (a)(4) shall retain auditable health care records which demonstrate the existence of a patient relationship in accordance with this paragraph for each prescription or order for a rolling period of not less than five years, or longer to the extent required by State or Federal law.".

(b) TREATMENT OF CONTRACTED SERVICES.—Subsection (a) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following new paragraphs:

"(11) CONTRACTED SERVICES.—In the case of a covered entity described in subparagraph (L) or (M) of subsection (a)(4) that elects to enter into a contractual arrangement with a third party for services related to the drug discount program under this section, such as to dispense covered outpatient drugs subject to an agreement under this section to patients of the covered entity, to administer contracted pharmacy services, or to provide any other service

related to the drug discount program under this section, the remuneration for which is based in whole or in part on the volume of dispensed covered outpatient drugs subject to an agreement under this section, such covered entity shall—

"(A) have a contractual agreement in place between the covered entity and each contracted entity, including with each location of a pharmacy contracted to dispense covered outpatient drugs subject to an agreement under this section to patients (as so defined) of the covered entity, which shall specify that the contracted entity shall adhere to all requirements of the drug discount program under this section, but that ultimate responsibility for program compliance and oversight of compliance by each contracted entity shall remain with the covered entity and that all covered outpatient drugs subject to an agreement under this section shall be purchased by the covered entity;

"(B) register each such agreement with the Secretary, include in such registration such information as shall be specified by the Secretary, and make available such agreement upon request by the Secretary;

"(C) ensure the compliance of each such agreement with the requirements of this section to prevent drug diversion in violation of subparagraph (B) of paragraph (5) and to prevent duplicate discounts in violation of subparagraph (A) of such paragraph before utilizing the services of the contracted entity, including by—

"(i) developing and implementing, with each contracted entity subject to such an agreement, a system to verify eligibility of patients (as so defined) of the entity;

"(ii) developing and implementing, with each such contracted entity, a mechanism for tracking the inventory of covered outpatient drugs that are subject to an agreement under this section that is suitable to prevent diversion in violation of subparagraph (B) of paragraph (5) and to prevent duplicate discounts in violation of subparagraph (A) of such paragraph, such as a separate inventory for such drugs; and

"(iii) establishing a mechanism with each such contracted entity and each applicable State Medicaid agency that is suit-

able to prevent duplicate discounts for covered outpatient drugs that are subject to an agreement under this section, including such drugs dispensed to enrollees of Medicaid managed care organizations, and complies with regulations on methodologies to prevent duplicate discounts issued by the Secretary;

''(D) make available, to the extent the covered entity offers a charity care policy or has an obligation under subsection (a)(5)(E) to have a sliding fee scale, patient access to a covered entity's prescription drug charity care benefit and its sliding fee scale, and developing and implementing, with each such contracted entity, a mechanism for documenting the income and insurance status of each patient (as so defined) of the covered entity and the amount each such patient pays to receive covered outpatient drugs that are subject to an agreement under this section;

''(E) maintain, and ensure that each such contracted entity maintains, auditable records that pertain to the compliance of the covered entity and the contracted entity with the re-

quirements described in this paragraph, for a rolling period of not less than 5 years;

"(F) establish a process for, and conduct, periodic comparisons of the covered entity's prescribing records with the dispensing records of each such contracted entity, as applicable, to detect potential irregularities and to ensure that all drugs dispensed by the contracted entity are for patients (as so defined) of the covered entity;

"(G) provide for annual on-site audits of each such contracted entity to be conducted by an independent outside auditor;

"(H) maintain arrangements to dispense covered outpatient drugs that are subject to an agreement under this section to patients (as so defined) of the covered entity with no more than 5 contract pharmacy locations at any given time, all of which must be located within (or, for mail-order pharmacies, serve patients residing in) lower-income (using American Community Survey data as determined by the Secretary) census tracts served by the covered entity, except in the case that the covered entity files a publicly available exception request with

the Secretary that seeks authorization to establish a particular contract pharmacy arrangement in a higher-income census tract and explains the reason in that particular case such a contract pharmacy would best meet the needs of low-income patients of the covered entity, and the Secretary decides to grant the request to establish one of the 5 contract pharmacies in the census tract requested;

"(I) ensure, as applicable, that patients (as so defined) of the covered entity have access to the covered entity's prescription drug charity care benefit through each contract pharmacy location at the time of purchase of each covered outpatient drug subject to an agreement under this section to the same extent such patients have access to the benefit with respect to such drugs purchased directly through the covered entity; and

"(J) limit any amount paid by the covered entity, or any agent of the covered entity, to the contracted entity for dispensing covered outpatient drugs subject to an agreement under this section or for any other service related to the drug discount program under this section to

a reasonable amount, which shall not exceed the fair market value of such drug dispensing or other service.

In the case the Secretary grants a request under subparagraph (H) to establish a particular contract pharmacy arrangement in a higher-income census tract, the Secretary shall make such decision available on a public website.

"(12) AUDITING.—A covered entity described in subparagraph (L) or (M) of subsection (a)(4) and a contracted entity that enter into a contractual arrangement described in paragraph (11) shall permit—

"(A) the Secretary to audit the records of the covered entity and of the contracted entity that pertain to the covered entity's and the contracted entity's compliance with the requirements described in such paragraph; and

"(B) the manufacturer of a covered outpatient drug that is subject to an agreement under this section (or its designee) to audit such records of the covered entity and of the contracted entity solely with respect to such drugs of the manufacturer.

"(13) REGULATIONS.—

"(A) Not later than 180 days after the date of enactment of this paragraph, the Secretary shall promulgate final regulations through notice-and-comment rulemaking to implement the requirements of paragraph (11) and paragraph (12). Such regulations shall include model terms for the contractual agreement described in subparagraph (A) of paragraph (11).

"(B) Not later than 180 days after the date of enactment of this paragraph, the Secretary shall promulgate final regulations through notice-and-comment rulemaking to establish procedures, in the case in which the Secretary determines that a violation of the annual contract pharmacy independent on-site audit requirement in subparagraph (F) of paragraph (11), with respect to a contract pharmacy arrangement, was knowing and intentional—

"(i) for removing the contract pharmacy arrangement from a covered entity's contract pharmacy network and disqualifying the entity from adding any additional contract pharmacies for a reasonable pe-

1 riod, to be determined by the Secretary, of
2 not less than two years; and
3 "(ii) for requiring that the entity pay
4 a monetary penalty to a manufacturer or
5 manufacturers in the form of interest on
6 sums that are owed to the manufacturer
7 due to violations of subparagraph (A) or
8 (B) of subsection (a)(5) that occurred at
9 one or more contract pharmacies and that
10 were discovered later than such violations
11 would have been if the entity had complied
12 with its obligation to have annual inde-
13 pendent audits of contract pharmacies con-
14 ducted.
15 "(14) MAIL ORDER STUDY AND REGULA-
16 TIONS.—
17 "(A) REPORT.—Not later than 180 days
18 after the date of the enactment of this para-
19 graph, the Secretary shall conduct a study (and
20 submit to Congress a report containing the re-
21 sults of such study) regarding compliance con-
22 cerns associated with covered entities described
23 in subparagraph (L) or (M) of subsection (a)(4)
24 contracting with mail order pharmacies to dis-
25 pense covered outpatient drugs subject to an

agreement under this section, and any additional safeguards or limitations necessary and appropriate to reduce those compliance concerns.

"(B) REGULATIONS.—Not later than 180 days after the submission of the report under subparagraph (A), the Secretary shall promulgate final regulations applicable to covered entities described in such subparagraph, through notice-and-comment rulemaking, to implement any additional safeguards or limitations recommended by the study.

"(15) CONTRACT PHARMACY MORATORIUM.—No covered entity described in subparagraphs (L) or (M) of subsection (a)(4) shall enter into a new or expanded contractual arrangement pursuant to which a third party dispenses covered outpatient drugs subject to an agreement under this section to patients (as so defined) of the covered entity during the period beginning on the date of the enactment of this paragraph and ending on the latter of—

"(A) the effective date of final regulations described in paragraph (13);

"(B) the effective date of final regulations described in paragraph (14);

"(C) the effective date of final regulations issued through Secretarial notice-and-comment rulemaking that take into consideration the findings and recommendations in the report from the Inspector General of the Department of Health and Human Services required under subsection (g)(3).".

(c) REGULATIONS TO REDUCE DUPLICATE DISCOUNT RISKS.—Subsection (a)(5)(A) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following new clause:

"(iii) Not later than one year after the date of the enactment of this clause, the Secretary shall promulgate final regulations through notice-and-comment rulemaking, describing methodologies for State Medicaid programs and all covered entities under subsection (a)(4) to identify and bill drugs subject to an agreement under this section in a manner that ensures compliance with 340B Program prohibitions regarding duplicate discounts, including the duplicate discount prohibition under section 1927(j)(1) of the Social Security Act, to include the application of such prohibi-

tions to Medicaid managed care enrollees. Such methodologies shall include the use of 340B-specific claims identifiers, and the provision of claims-level data by covered entities to States as well as manufacturers of covered outpatient drugs sufficient to identify claims that include drugs subject to an agreement under this section and to prevent duplicate discounts.''.

(d) AMOUNT CHARGED TO LOW-INCOME PATIENTS.—

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

''(E) AMOUNT CHARGED TO LOW-INCOME PATIENTS.—As a condition of certification or recertification under subparagraph (E) of paragraph (7), each covered entity described in subparagraph (L) or (M) of subsection (a)(4) must establish a sliding scale fee schedule for providing covered outpatient drugs that are subject to an agreement under this section, directly or under a contractual arrangement pursuant to

which a third party dispenses such drugs, to patients of the covered entity who are—

"(i) low-income individuals; and

"(ii) not covered under minimum essential coverage, as defined in section 5000A(f) of the Internal Revenue Code.

"(F) REGULATIONS.—Not later than 180 days after the date of enactment of this subparagraph, the Secretary shall promulgate final regulations through notice-and-comment rulemaking, to implement the requirements under subparagraph (E). Such regulations shall—

"(i) define the term 'low-income individual';

"(ii) provide a methodology for establishing the sliding scale fee schedule, which shall apply, where otherwise applicable to a covered entity, regardless of whether the covered outpatient drug is dispensed by the covered entity directly or a child site of the covered entity or by a contracted entity described in paragraph (11); and

"(iii) ensure the security and protection of privileged or otherwise confidential

data from unauthorized disclosure or re-disclosure.''.

(e) PRIVATE NON-PROFIT DSH HOSPITALS AND OUTPATIENT HOSPITAL FACILITIES.—

(1) DEFINITION.—Subparagraph (L) of section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended to read as follows:

''(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

''(i) is—

''(I) owned or operated by a unit of State or local government;

''(II) a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government; or

''(III) a private non-profit hospital which has a contract with a State or local government to provide health care services, which include the ordering or prescribing of covered outpatient drugs that are subject to an agreement under this section, to low-income individuals who are not enti-

tled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan for medical assistance under title XIX of such Act;

"(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

"(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

If the Secretary determines that a hospital that is eligible for participation in the 340B program under this subparagraph obtained covered outpatient drugs through a group purchasing organization or another group purchasing arrangement while that hospital was participating in the drug discount program under this section, then the Secretary shall remove such hos-

pital from such program and the hospital shall not be permitted to seek re-enrollment for a period of at least 12 months after its removal from the program.''.

(2) STUDY AND REPORT; MORATORIUM; OUTPATIENT HOSPITAL FACILITIES; AUDITS.—Subsection (c) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended to read as follows:

''(c) COVERED ENTITIES THAT ARE PRIVATE, NON-PROFIT DSH HOSPITALS.—

''(1) STUDY AND REPORT.—

''(A) STUDY.—The Comptroller General of the United States shall conduct a study on the relationship between the disproportionate share adjustment percentages of private covered entities described in subclauses (II) and (III) of subsection (a)(4)(L)(i) and the levels of charity care provided by such entities to outpatients.

''(B) REPORT.—Not later than 180 days after the date of enactment of the 340B Protection and Accountability Act of 2019, the Comptroller General shall submit to the appropriate committees of Congress a report on the results of the study conducted under subparagraph

(A), including recommendations on a metric that, as applied to a private covered entity described in such subparagraph, reflects a high level of charity care provided to outpatients as a percentage of the covered entity's overall expenses for outpatient care, and could replace the metric described in subclause (ii) of subsection (a)(4)(L). The Comptroller General shall recommend the metric that best aligns with the level of charity care provided to outpatients as a percentage of overall hospital operating expenses on outpatient care if no metric is identified that provides a precise measure of such percentage.

"(2) MORATORIUM.—

"(A) IN GENERAL.—For the period described in subparagraph (B)—

"(i) a private covered entity described in subclauses (II) or (III) of subsection (a)(4)(L)(i) may participate in the drug discount program under this section as a covered entity only if it was properly enrolled as a covered entity in the drug discount program under this section as of the date of the enactment of the 340B Protec-

tion and Accountability Act of 2019 and continuously enrolled thereafter; and

"(ii) with respect to a facility or organization described in paragraph (3) of this subsection that is wholly owned by a private covered entity described in subclause (II) or (III) of subsection (a)(4)(L)(i), only a facility or organization that was properly enrolled as a child site in the drug discount program under this section as of the date of the enactment of the 340B Protection and Accountability Act of 2019 and continuously enrolled thereafter may participate in the drug discount program under this section.

"(B) PERIOD DESCRIBED.—For purposes of subparagraph (A), the period described in this subparagraph is the period beginning on the date of enactment of the 340B Protection and Accountability Act of 2019 and ending on the effective date described in subparagraph (C).

"(C) EFFECTIVE DATE OF REPLACEMENT METRIC.—

"(i) IN GENERAL.—For purposes of subparagraph (B), subject to clause (ii), the effective date described in this subparagraph is the effective date specified in legislation that, with respect to private covered entities described in subclauses (II) and (III) of subsection (a)(4)(L)(i)—

"(I) replaces the metric described in clause (ii) of subsection (a)(4)(L) with a metric that more accurately reflects the levels of outpatient charity care as a percentage of overall expenses for outpatient care provided by such entities; and

"(II) takes into account the report submitted under paragraph (1), including by addressing the Comptroller General's recommendations included in such report.

"(ii) EXCEPTION.—If legislation described in clause (i) is not enacted by the date that is one year after the date of submission of the report under paragraph (1)—

"(I) the Secretary shall promulgate final regulations that implement, to the extent practicable, the Comptroller General's recommendations included within such report not later than the date that is 180 days after such one-year date; and

"(II) for purposes of subparagraph (B), the effective date described in this subparagraph is the effective date of such final regulations.

"(3) OUTPATIENT HOSPITAL FACILITIES.—A facility or organization may participate in the drug discount program under this section as a child site of a covered entity described in subparagraph (L) or (M) of subsection (a)(4) only if such facility or organization—

"(A) is wholly owned by a covered entity described in subparagraph (L) or (M) of subsection (a)(4);

"(B) except in the case in which the parent covered entity is a children's hospital described in subparagraph (M) of subsection (a)(4) which does not file a Medicare cost report, is listed on the Medicare cost report most recently filed by

the parent covered entity on a line that is reimbursable under this title, if such cost report demonstrates that the services provided at the facility or organization have associated outpatient costs and charges under this title, and if the parent covered entity has provided a copy of such cost report to the Office of Pharmacy Affairs of the Health Resources and Services Administration;

"(C) in the case that the parent covered entity is a children's hospital described in subparagraph (M) of subsection (a)(4) which does not file a Medicare cost report, would be correctly included on a reimbursable line with associated outpatient costs and charges under title XVIII on a Medicare cost report of the parent covered entity, if filed, and the parent covered entity authorizing official has submitted a signed statement to the Secretary which certifies the foregoing and that the requested outpatient facility is an integral part of the children's hospital and is providing health care services to patients of such hospital;

"(D) meets the provider-based status requirements under section 413.65 of title 42,

Code of Federal Regulations or under any successor to such section;

"(E) provides outpatient health care services and is not limited to providing only drugs or drug administration;

"(F) provides a level of free or discounted health care services to individuals who meet the parent covered entity's criteria for financial assistance and are unable to pay for all or a portion of the services, as reported at cost to the Internal Revenue Service under section 501(r)(4) of the Internal Revenue Code for the calendar year, that is similar to that of the parent covered entity; and

"(G) adheres to the parent covered entity's sliding scale fee schedule for providing covered outpatient drugs that are subject to an agreement under this section to patients who are (i) low-income individuals; and (ii) not covered under minimum essential coverage, as defined in section 5000A(f) of the Internal Revenue Code. Such sliding fee schedules must be made publicly available in a similar manner to a 501(c)(3) hospital's financial assistance policy

as required under section 501(r) of the Internal Revenue Code of 1986.

"(4) CERTIFICATION AND AUDITING.—

"(A) A covered entity described in subclause (III) of subsection (a)(4)(L)(i) shall—

"(i) not less than annually, provide to the Secretary a certification executed by the hospital's 340B Program authorizing official and an appropriate government official (such as the governor, county executive, mayor, or an individual authorized to represent and bind the governmental entity), certifying that—

"(I) a contract is currently in force between such covered entity and the State or local government to provide health care services, to include direct medical care and the ordering or prescribing of covered outpatient drugs that are subject to an agreement under this section, to low-income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assist-

ance under the State plan under title XIX of such Act;

"(II) such contract creates enforceable expectations for such covered entity for the provision of the health care services described in subclause (I) to the individuals described in such subclause; and

"(III) the health care services described in subclause (I) represent a significant portion of the hospital's operating revenues, and are not for services the covered entity is otherwise obligated to provide under State or Federal law;

"(ii) make available the contract described in subclause (III) of subsection (a)(4)(L)(i) to the Secretary for publication on the public internet website of the Department of Health and Human Services relating to this section; and

"(iii) permit the Secretary to audit the records of the covered entity that pertain to its compliance with the require-

ments described in subclause (III) of subsection (a)(4)(L)(i) and this subparagraph.

"(B) A facility or organization that participates in the drug discount program under this section pursuant to paragraph (3) shall permit the Secretary to audit the records of such facility or organization that pertain to its compliance with the requirements described in such paragraph.

"(C) The Secretary shall issue guidelines to implement the requirements described in this paragraph, which shall, at a minimum, define the term 'low-income individuals' for purposes of subclause (I) of subparagraph (A)(i), and identify the applicable methodology and threshold for determining that the health care services described in such subclause represent a significant portion of the hospital's operating revenues.".

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

"(f) REPORTING REQUIREMENTS FOR COVERED ENTITIES.—

"(1) IN GENERAL.—A covered entity described in subparagraph (L) or (M) of subsection (a)(4) shall annually submit to the Secretary an electronic and searchable data report in a machine-readable format. Such report shall contain, with respect to the year covered by the report, information on—

"(A) the number and percentage of patients of the covered entity, disaggregated by insurance status (including at least the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of such Act, the Children's Health Insurance Program under title XXI of such Act, the TRICARE program under chapter 55 of title 10, United States Code, health insurance coverage or a group health plan, and uninsured), and by the type of site of the dispensing of the covered outpatient drug subject to an agreement under this section (parent covered entity, facility or organization described in subsection (c)(3), contracted entity described in subsection (a)(11));

"(B) the aggregate amount of gross reimbursement received by the covered entity (calculated before subtracting any administrative or

other fees using a methodology provided by the Secretary) for covered outpatient drugs subject to an agreement under this section, including reimbursement received through facilities or organizations described in subsection (c)(3) or pursuant to contractual arrangements described in subsection (a)(11);

"(C) the aggregate acquisition cost for covered outpatient drugs subject to an agreement under this section dispensed during the year;

"(D) the aggregate amount paid by the covered entity, or any agent of the covered entity, to contracted entities described in subsection (a)(11) for dispensing covered outpatient drugs subject to an agreement under this section or for any other service related to the drug discount program under this section;

"(E) how the entity prevents duplicate discounts under subparagraph (A) of subsection (a)(5) and drug diversion under subparagraph (B) of such subsection;

"(F) the volume of covered outpatient drugs subject to an agreement under this section dispensed by the covered entity and, in the case of a covered entity that has entered into

a contractual arrangement pursuant to which a third party dispenses covered outpatient drugs subject to an agreement under this section to patients of the covered entity, by each such contracted entity;

"(G) quantitative data in terms of the amount and percentage of charitable care, as such term is defined for purposes of Medicare cost reporting or other reporting requirements identified by the Secretary, provided to patients of the covered entity by the covered entity in the form of covered outpatient drugs subject to an agreement under this section;

"(H) the name of any third-party vendor or other similar entity (if any) that the covered entity retains to administer the covered entity's inventory management system or contract pharmacy arrangement; and

"(I) other reporting requirements as the Secretary determines is necessary or appropriate for effective management and oversight of the drug discount program under this section.

"(2) TIMING OF FIRST REPORT.—The first report submitted under paragraph (1) shall be sub-

1 mitted not later than 18 months after the date of
2 enactment of this subsection.

3 "(3) ATTESTATION.—Each report submitted
4 under paragraph (1) shall be accompanied by an at-
5 testation, in a form and manner specified by the
6 Secretary, that the information submitted in such
7 report is complete and accurate. Such attestation
8 shall be subject to section 1001 of title 18, United
9 States Code.

10 "(4) SANCTIONS.—If the Secretary finds that a
11 covered entity is in violation of the requirement
12 under paragraph (1) and the Secretary determines
13 that such violation was knowing and intentional, the
14 Secretary shall remove the entity from the drug dis-
15 count program under this section and disqualify the
16 entity from re-entry into such program for a reason-
17 able period of time to be determined by the Sec-
18 retary.

19 "(5) REGULATIONS.—Not later than 180 days
20 after the date of enactment of this subsection, the
21 Secretary shall promulgate final regulations through
22 notice-and-comment rulemaking to implement the re-
23 quirements under paragraphs (1) through (4).

24 "(6) PUBLIC DATABASE.—The Secretary shall
25 make the data reported by covered entities under

this subsection available to the public on the website of the Department of Health and Human Services in an electronic and searchable format, which shall make each category of data reported available both in the aggregate and broken down by parent covered entities, child sites, and contract pharmacies, but shall not identify specific parent covered entities, child sites, or contract pharmacies.

"(g) REPORTS TO CONGRESS.—

"(1) REPORT BY THE SECRETARY.—Not later than two years after the date of the enactment of this subsection, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, which shall contain—

"(A) with respect to covered entities described in subparagraph (L) or (M) of subsection (a)(4), the information contained in the first report submitted by such entities to the Secretary under subsection (f); and

"(B) a description of the audits conducted by the Secretary pursuant to subparagraph (C) of subsection (a)(5), including the methodology used for conducting such audits, the results of

such audits, and actions taken by the Secretary in response to such audits, as well as actions taken by the Secretary in response to audits conducted by manufacturers pursuant to such subparagraph.

"(2) REPORT BY THE COMPTROLLER GENERAL.—Not later than one year after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the use by covered entities of contractual arrangements pursuant to which a third party dispenses covered outpatient drugs subject to an agreement under this section to patients of the covered entity, disaggregated by covered entity types and the physical distance of the contracted entity's location from the respective parent covered entity location.

"(3) ANNUAL REPORTS BY THE INSPECTOR GENERAL.—Not later than July 1 of each year (beginning with 2018), the Inspector General of the Department of Health and Human Services shall submit to appropriate committees of Congress a report on the contractual arrangements between cov-

1 ered entities and third parties described in para-
2 graph (11) of subsection (a), including the methods
3 and amounts of remuneration exchanged between
4 such covered entities and such contracted entities,
5 and the extent to which contract pharmacies are im-
6 proving access to medicines by patients of such cov-
7 ered entities. The first such annual report shall in-
8 clude recommendations, as the Inspector General de-
9 termines appropriate, that address safeguards to re-
10 duce duplicate discounting and diversion within con-
11 tract pharmacy arrangements and reforms to ensure
12 these arrangements are targeted exclusively at im-
13 proving access to medicines for low-income or vul-
14 nerable patients of covered entities. Subsequent re-
15 ports under this paragraph should continue to mon-
16 itor such issues and be updated as changes are made
17 to the drug discount program under this section.''.
18 (g) USER FEES UNDER THE 340B DRUG DISCOUNT
19 PROGRAM.—Section 340B of the Public Health Service
20 Act (42 U.S.C. 256b), as previously amended, is further
21 amended by adding at the end the following new sub-
22 section:
23 ''(h) USER FEES.—
24 ''(1) IN GENERAL.—Subject to paragraph (6),
25 the Secretary shall assess and collect a user fee from

1 covered entities described in subparagraph (L), (M),
2 (N), or (O) of subsection (a)(4). In carrying out this
3 subsection, the Secretary shall not require manufac-
4 turers to collect any user fee or to administer the
5 user fee program established under this subsection.
6 "(2) PAYMENT.—A covered entity described in
7 subparagraph (L), (M), (N), or (O) of subsection
8 (a)(4) shall pay to the Secretary a fee assessed
9 under paragraph (1) by such date that is the later
10 of—
11 "(A) the date of the certification or recer-
12 tification of the covered entity, as applicable; or
13 "(B) the date that is 30 days after the
14 date of the enactment of an appropriations Act
15 providing for the collection and obligation of
16 fees under this subsection for a fiscal year.
17 "(3) AMOUNT OF FEE.—The amount of a fee
18 under paragraph (1) shall be equal to the amount
19 determined by the Secretary under paragraph (4).
20 "(4) DETERMINATION OF AMOUNT OF FEE.—
21 "(A) IN GENERAL.—The Secretary shall,
22 not later than 180 days before the start of each
23 fiscal year that begins after September 30,
24 2019, establish, for the next fiscal year, the
25 amount of the fee payable under this subsection

by a covered entity using purchase data submitted by covered entities described in paragraph (1), and using data submitted by manufacturers on sales to covered entities of covered outpatient drugs subject to an agreement under this section, pursuant to regulations to be issued by the Secretary. Such amount, with respect to a covered entity and year, shall not exceed 0.1 percent of the total paid during the previous year by such covered entity to manufacturers for purchases of covered outpatient drugs subject to an agreement under this section.

"(5) USE OF FEES.—

"(A) IN GENERAL.—Any fee collected under paragraph (1) shall be used for purposes of administering this section, enhancing program integrity and oversight activities under this section (including through audits under this section of covered entities and manufacturers), and promoting access to clinical and cost-effective pharmacy services among safety net clinics and hospitals that participate under this section, such as through—

"(i) the development of a multi-functional web-based system to collect fees under paragraph (1);

"(ii) the improvement of the integrity, transparency, security, and reliability of the Office of Pharmacy Affairs Information System, including to ensure that the database continues to meet the needs of external stakeholders; and

"(iii) improvements to the compliance tool of the Office of Pharmacy Affairs, used to integrate all information related to covered entities and manufacturers with agreements under this section.

"(B) SUPPLEMENT NOT SUPPLANT.—Any fee collected under paragraph (1) shall be used to supplement and not supplant the amount otherwise provided in appropriations Acts to carry out this section.

"(6) AVAILABILITY OF FEES.—Fees authorized under paragraph (1) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended.

"(7) REGULATIONS.—Not later than 180 days after the date of enactment of this subsection, the Secretary shall promulgate final regulations through notice-and-comment rulemaking to implement the user fee collection pursuant to this subsection.

"(8) OVERSIGHT OF USER FEE PROGRAM.—

"(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct an annual review of the user fee program established by this subsection.

"(B) REPORT.—Not later than July 1 of each year (beginning with 2019), the Inspector General of the Department of Health and Human Services shall submit to the appropriate committees of Congress a report on the study conducted under subparagraph (A), together with such recommendations as the Inspector General determines appropriate.".

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

"(5) DIRECT-HIRE AUTHORITY.—Notwithstanding section 3304(a)(3) of title 5, United States Code, and sections 3309 through 3318 of such title,

and section 337 of title 5 of the Code of Federal Regulations (or any successor regulations), the Secretary may, beginning on the date of the enactment of this paragraph, exercise direct-hire authority to appoint a minimum of ten qualified candidates to permanent positions within the competitive service in order to carry out management and oversight activities under this section.''.

(i) APPLICABILITY.—Except as otherwise indicated, the provisions of, including amendments made by, this Act shall not apply to covered entities defined under subparagraphs (A) through (K), (N), or (O) of subsection (a)(4).

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