

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

A BILL

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

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “340B Protection and
5 Accountability Act of 2019”.

6 **SEC. 2. STRENGTHENING 340B PROGRAM INTEGRITY AND**
7 **ENHANCING LOW-INCOME PATIENT BENE-**
8 **FITS FOR SAFETY NET PROVIDERS.**

9 (a) DEFINITION OF PATIENT.—Section 340B(b) of
10 the Public Health Service Act (42 U.S.C. 256b(b)) is

1 amended by adding at the end the following new para-
2 graph:

3 “(3) PATIENT.—

4 “(A) IN GENERAL.—In this section, the
5 term ‘patient’ means, with respect to a covered
6 entity described in subparagraph (L) or (M) of
7 subsection (a)(4), an individual who, on a pre-
8 scription-by-prescription or order-by-order
9 basis—

10 “(i) receives a health care service at a
11 covered entity or an outpatient hospital fa-
12 cility described in subsection (c)(3) which
13 is registered for the drug discount program
14 under this section and listed on the public
15 internet website of the Department of
16 Health and Human Services relating to
17 this section;

18 “(ii) receives an outpatient in-person
19 health care service from a health care pro-
20 vider employed by the covered entity or
21 who is an independent contractor of the
22 covered entity, such that the covered entity
23 bills for services on behalf of the provider;

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

1 vider, including any renewals of existing
2 prescriptions, as a result of the service de-
3 scribed in clause (ii);

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

12 “(v) is classified as an outpatient
13 when the drug is ordered or prescribed, as
14 demonstrated by how the service was reim-
15 bursed by the applicable payer, or, where
16 the covered entity does not seek such reim-
17 bursement, how the service would have
18 been reimbursed under title XVIII of the
19 Social Security Act; and

20 “(vi) has a relationship with the cov-
21 ered entity such that the covered entity
22 creates and maintains auditable health
23 care records which demonstrate that—

1 “(I) the covered entity has a pro-
2 vider-to-patient relationship with the
3 individual; and

4 “(II) responsibility for the indi-
5 vidual’s health care service that re-
6 sulted in the prescription or order for
7 the drug described in clause (iii) is
8 with the covered entity.

9 “(B) EXCLUSIONS.—For purposes of this
10 section, an individual shall not be considered a
11 patient of a covered entity described in sub-
12 paragraph (L) or (M) of subsection (a)(4) if—

13 “(i) the individual is an inmate of a
14 correctional facility;

15 “(ii) the health care service described
16 in clause (ii) of subparagraph (A) received
17 by the individual from the covered entity
18 consists only of the administration or infu-
19 sion of a drug or drugs, or the dispensing
20 of a drug or drugs for subsequent self-ad-
21 ministration or administration in the home
22 setting, without a covered entity provider-
23 to-patient encounter;

24 “(iii) the health care service described
25 in clause (ii) of subparagraph (A) received

1 by the individual from the covered entity is
2 provided by a health care organization that
3 has only an affiliation arrangement with
4 the covered entity, even if the covered enti-
5 ty has access to the affiliated organiza-
6 tion's records; or

7 “(iv) the primary relationship between
8 the individual and the covered entity is one
9 of employment.

10 “(C) REGULATIONS.—Not later than 180
11 days after the date of enactment of the 340B
12 Protection and Accountability Act of 2019, the
13 Secretary shall promulgate final regulations
14 through notice-and-comment rulemaking to de-
15 fine the term ‘patient’ with respect to covered
16 entities described in subparagraph (L) or (M)
17 of subsection (a)(4) to reflect the requirements
18 described in subparagraphs (A) and (B) of this
19 paragraph.

20 “(D) DEFINITION RELATING TO OTHER
21 COVERED ENTITIES.—In this section, the term
22 ‘patient’, with respect to a covered entity de-
23 scribed in subparagraphs (A) through (K) of
24 subsection (a)(4), has the meaning given such
25 term in the October 24, 1996, HRSA Final No-

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

4 “(E) RECORD RETENTION.—A covered en-
5 tity described in subparagraph (L) or (M) of
6 subsection (a)(4) shall retain auditable health
7 care records which demonstrate the existence of
8 a patient relationship in accordance with this
9 paragraph for each prescription or order for a
10 rolling period of not less than five years, or
11 longer to the extent required by State or Fed-
12 eral law.”.

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

17 “(11) CONTRACTED SERVICES.—In the case of
18 a covered entity described in subparagraph (L) or
19 (M) of subsection (a)(4) that elects to enter into a
20 contractual arrangement with a third party for serv-
21 ices related to the drug discount program under this
22 section, such as to dispense covered outpatient drugs
23 subject to an agreement under this section to pa-
24 tients of the covered entity, to administer contracted
25 pharmacy services, or to provide any other service

1 related to the drug discount program under this sec-
2 tion, the remuneration for which is based in whole
3 or in part on the volume of dispensed covered out-
4 patient drugs subject to an agreement under this
5 section, such covered entity shall—

6 “(A) have a contractual agreement in place
7 between the covered entity and each contracted
8 entity, including with each location of a phar-
9 macy contracted to dispense covered outpatient
10 drugs subject to an agreement under this sec-
11 tion to patients (as so defined) of the covered
12 entity, which shall specify that the contracted
13 entity shall adhere to all requirements of the
14 drug discount program under this section, but
15 that ultimate responsibility for program compli-
16 ance and oversight of compliance by each con-
17 tracted entity shall remain with the covered en-
18 tity and that all covered outpatient drugs sub-
19 ject to an agreement under this section shall be
20 purchased by the covered entity;

21 “(B) register each such agreement with
22 the Secretary, include in such registration such
23 information as shall be specified by the Sec-
24 retary, and make available such agreement
25 upon request by the Secretary;

1 “(C) ensure the compliance of each such
2 agreement with the requirements of this section
3 to prevent drug diversion in violation of sub-
4 paragraph (B) of paragraph (5) and to prevent
5 duplicate discounts in violation of subparagraph
6 (A) of such paragraph before utilizing the serv-
7 ices of the contracted entity, including by—

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

12 “(ii) developing and implementing,
13 with each such contracted entity, a mecha-
14 nism for tracking the inventory of covered
15 outpatient drugs that are subject to an
16 agreement under this section that is suit-
17 able to prevent diversion in violation of
18 subparagraph (B) of paragraph (5) and to
19 prevent duplicate discounts in violation of
20 subparagraph (A) of such paragraph, such
21 as a separate inventory for such drugs;
22 and

23 “(iii) establishing a mechanism with
24 each such contracted entity and each appli-
25 cable State Medicaid agency that is suit-

1 able to prevent duplicate discounts for cov-
2 ered outpatient drugs that are subject to
3 an agreement under this section, including
4 such drugs dispensed to enrollees of Med-
5 icaid managed care organizations, and
6 complies with regulations on methodologies
7 to prevent duplicate discounts issued by
8 the Secretary;

9 “(D) make available, to the extent the cov-
10 ered entity offers a charity care policy or has
11 an obligation under subsection (a)(5)(E) to
12 have a sliding fee scale, patient access to a cov-
13 ered entity’s prescription drug charity care ben-
14 efit and its sliding fee scale, and developing and
15 implementing, with each such contracted entity,
16 a mechanism for documenting the income and
17 insurance status of each patient (as so defined)
18 of the covered entity and the amount each such
19 patient pays to receive covered outpatient drugs
20 that are subject to an agreement under this sec-
21 tion;

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

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

3 “(F) establish a process for, and conduct,
4 periodic comparisons of the covered entity’s pre-
5 scribing records with the dispensing records of
6 each such contracted entity, as applicable, to
7 detect potential irregularities and to ensure that
8 all drugs dispensed by the contracted entity are
9 for patients (as so defined) of the covered enti-
10 ty;

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

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

1 the Secretary that seeks authorization to estab-
2 lish a particular contract pharmacy arrange-
3 ment in a higher-income census tract and ex-
4 plains the reason in that particular case such a
5 contract pharmacy would best meet the needs of
6 low-income patients of the covered entity, and
7 the Secretary decides to grant the request to es-
8 tablish one of the 5 contract pharmacies in the
9 census tract requested;

10 “(I) ensure, as applicable, that patients (as
11 so defined) of the covered entity have access to
12 the covered entity’s prescription drug charity
13 care benefit through each contract pharmacy lo-
14 cation at the time of purchase of each covered
15 outpatient drug subject to an agreement under
16 this section to the same extent such patients
17 have access to the benefit with respect to such
18 drugs purchased directly through the covered
19 entity; and

20 “(J) limit any amount paid by the covered
21 entity, or any agent of the covered entity, to the
22 contracted entity for dispensing covered out-
23 patient drugs subject to an agreement under
24 this section or for any other service related to
25 the drug discount program under this section to

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

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

9 “(12) AUDITING.—A covered entity described in
10 subparagraph (L) or (M) of subsection (a)(4) and a
11 contracted entity that enter into a contractual ar-
12 rangement described in paragraph (11) shall per-
13 mit—

14 “(A) the Secretary to audit the records of
15 the covered entity and of the contracted entity
16 that pertain to the covered entity’s and the con-
17 tracted entity’s compliance with the require-
18 ments described in such paragraph; and

19 “(B) the manufacturer of a covered out-
20 patient drug that is subject to an agreement
21 under this section (or its designee) to audit
22 such records of the covered entity and of the
23 contracted entity solely with respect to such
24 drugs of the manufacturer.

25 “(13) REGULATIONS.—

1 “(A) Not later than 180 days after the
2 date of enactment of this paragraph, the Sec-
3 retary shall promulgate final regulations
4 through notice-and-comment rulemaking to im-
5 plement the requirements of paragraph (11)
6 and paragraph (12). Such regulations shall in-
7 clude model terms for the contractual agree-
8 ment described in subparagraph (A) of para-
9 graph (11).

10 “(B) Not later than 180 days after the
11 date of enactment of this paragraph, the Sec-
12 retary shall promulgate final regulations
13 through notice-and-comment rulemaking to es-
14 tablish procedures, in the case in which the Sec-
15 retary determines that a violation of the annual
16 contract pharmacy independent on-site audit re-
17 quirement in subparagraph (F) of paragraph
18 (11), with respect to a contract pharmacy ar-
19 rangement, was knowing and intentional—

20 “(i) for removing the contract phar-
21 macy arrangement from a covered entity’s
22 contract pharmacy network and disquali-
23 fying the entity from adding any additional
24 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

1 agreement under this section, and any addi-
2 tional safeguards or limitations necessary and
3 appropriate to reduce those compliance con-
4 cerns.

5 “(B) REGULATIONS.—Not later than 180
6 days after the submission of the report under
7 subparagraph (A), the Secretary shall promul-
8 gate final regulations applicable to covered enti-
9 ties described in such subparagraph, through
10 notice-and-comment rulemaking, to implement
11 any additional safeguards or limitations rec-
12 ommended by the study.

13 “(15) CONTRACT PHARMACY MORATORIUM.—
14 No covered entity described in subparagraphs (L) or
15 (M) of subsection (a)(4) shall enter into a new or ex-
16 panded contractual arrangement pursuant to which
17 a third party dispenses covered outpatient drugs
18 subject to an agreement under this section to pa-
19 tients (as so defined) of the covered entity during
20 the period beginning on the date of the enactment
21 of this paragraph and ending on the latter of—

22 “(A) the effective date of final regulations
23 described in paragraph (13);

24 “(B) the effective date of final regulations
25 described in paragraph (14);

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

8 (c) REGULATIONS TO REDUCE DUPLICATE DIS-
9 COUNT RISKS.—Subsection (a)(5)(A) of section 340B of
10 the Public Health Service Act (42 U.S.C. 256b) is amend-
11 ed by adding at the end the following new clause:

12 “(iii) Not later than one year after
13 the date of the enactment of this clause,
14 the Secretary shall promulgate final regu-
15 lations through notice-and-comment rule-
16 making, describing methodologies for State
17 Medicaid programs and all covered entities
18 under subsection (a)(4) to identify and bill
19 drugs subject to an agreement under this
20 section in a manner that ensures compli-
21 ance with 340B Program prohibitions re-
22 garding duplicate discounts, including the
23 duplicate discount prohibition under sec-
24 tion 1927(j)(1) of the Social Security Act,
25 to include the application of such prohibi-

1 tions to Medicaid managed care enrollees.
2 Such methodologies shall include the use of
3 340B-specific claims identifiers, and the
4 provision of claims-level data by covered
5 entities to States as well as manufacturers
6 of covered outpatient drugs sufficient to
7 identify claims that include drugs subject
8 to an agreement under this section and to
9 prevent duplicate discounts.”.

10 (d) AMOUNT CHARGED TO LOW-INCOME PA-
11 TIENTS.—

12 (1) IN GENERAL.—Subsection (a)(5) of section
13 340B of the Public Health Service Act (42 U.S.C.
14 256b) is amended by adding at the end the following
15 new subparagraphs:

16 “(E) AMOUNT CHARGED TO LOW-INCOME
17 PATIENTS.—As a condition of certification or
18 recertification under subparagraph (E) of para-
19 graph (7), each covered entity described in sub-
20 paragraph (L) or (M) of subsection (a)(4) must
21 establish a sliding scale fee schedule for pro-
22 viding covered outpatient drugs that are subject
23 to an agreement under this section, directly or
24 under a contractual arrangement pursuant to

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

3 “(i) low-income individuals; and

4 “(ii) not covered under minimum es-
5 sential coverage, as defined in section
6 5000A(f) of the Internal Revenue Code.

7 “(F) REGULATIONS.—Not later than 180
8 days after the date of enactment of this sub-
9 paragraph, the Secretary shall promulgate final
10 regulations through notice-and-comment rule-
11 making, to implement the requirements under
12 subparagraph (E). Such regulations shall—

13 “(i) define the term ‘low-income indi-
14 vidual’;

15 “(ii) provide a methodology for estab-
16 lishing the sliding scale fee schedule, which
17 shall apply, where otherwise applicable to a
18 covered entity, regardless of whether the
19 covered outpatient drug is dispensed by the
20 covered entity directly or a child site of the
21 covered entity or by a contracted entity de-
22 scribed in paragraph (11); and

23 “(iii) ensure the security and protec-
24 tion of privileged or otherwise confidential

1 data from unauthorized disclosure or re-
 2 disclosure.”.

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

5 (1) DEFINITION.—Subparagraph (L) of section
 6 340B(a)(4) of the Public Health Service Act (42
 7 U.S.C. 256b(a)(4)) is amended to read as follows:

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

11 “(i) is—

12 “(I) owned or operated by a unit
 13 of State or local government;

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

18 “(III) a private non-profit hos-
 19 pital which has a contract with a
 20 State or local government to provide
 21 health care services, which include the
 22 ordering or prescribing of covered out-
 23 patient drugs that are subject to an
 24 agreement under this section, to low-
 25 income individuals who are not enti-

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

6 “(ii) for the most recent cost report-
7 ing period that ended before the calendar
8 quarter involved, had a disproportionate
9 share adjustment percentage (as deter-
10 mined under section 1886(d)(5)(F) of the
11 Social Security Act) greater than 11.75
12 percent or was described in section
13 1886(d)(5)(F)(i)(II) of such Act; and

14 “(iii) does not obtain covered out-
15 patient drugs through a group purchasing
16 organization or other group purchasing ar-
17 rangement.

18 If the Secretary determines that a hospital that
19 is eligible for participation in the 340B pro-
20 gram under this subparagraph obtained covered
21 outpatient drugs through a group purchasing
22 organization or another group purchasing ar-
23 rangement while that hospital was participating
24 in the drug discount program under this sec-
25 tion, then the Secretary shall remove such hos-

1 pital from such program and the hospital shall
2 not be permitted to seek re-enrollment for a pe-
3 riod of at least 12 months after its removal
4 from the program.”.

5 (2) STUDY AND REPORT; MORATORIUM; OUT-
6 PATIENT HOSPITAL FACILITIES; AUDITS.—Sub-
7 section (c) of section 340B of the Public Health
8 Service Act (42 U.S.C. 256b) is amended to read as
9 follows:

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

12 “(1) STUDY AND REPORT.—

13 “(A) STUDY.—The Comptroller General of
14 the United States shall conduct a study on the
15 relationship between the disproportionate share
16 adjustment percentages of private covered enti-
17 ties described in subclauses (II) and (III) of
18 subsection (a)(4)(L)(i) and the levels of charity
19 care provided by such entities to outpatients.

20 “(B) REPORT.—Not later than 180 days
21 after the date of enactment of the 340B Protec-
22 tion and Accountability Act of 2019, the Comp-
23 troller General shall submit to the appropriate
24 committees of Congress a report on the results
25 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.—

1 “(i) IN GENERAL.—For purposes of
2 subparagraph (B), subject to clause (ii),
3 the effective date described in this sub-
4 paragraph is the effective date specified in
5 legislation that, with respect to private cov-
6 ered entities described in subclauses (II)
7 and (III) of subsection (a)(4)(L)(i)—

8 “(I) replaces the metric described
9 in clause (ii) of subsection (a)(4)(L)
10 with a metric that more accurately re-
11 flects the levels of outpatient charity
12 care as a percentage of overall ex-
13 penses for outpatient care provided by
14 such entities; and

15 “(II) takes into account the re-
16 port submitted under paragraph (1),
17 including by addressing the Comp-
18 troller General’s recommendations in-
19 cluded in such report.

20 “(ii) EXCEPTION.—If legislation de-
21 scribed in clause (i) is not enacted by the
22 date that is one year after the date of sub-
23 mission of the report under paragraph
24 (1)—

1 “(I) the Secretary shall promul-
2 gate final regulations that implement,
3 to the extent practicable, the Comp-
4 troller General’s recommendations in-
5 cluded within such report not later
6 than the date that is 180 days after
7 such one-year date; and

8 “(II) for purposes of subpara-
9 graph (B), the effective date described
10 in this subparagraph is the effective
11 date of such final regulations.

12 “(3) OUTPATIENT HOSPITAL FACILITIES.—A
13 facility or organization may participate in the drug
14 discount program under this section as a child site
15 of a covered entity described in subparagraph (L) or
16 (M) of subsection (a)(4) only if such facility or orga-
17 nization—

18 “(A) is wholly owned by a covered entity
19 described in subparagraph (L) or (M) of sub-
20 section (a)(4);

21 “(B) except in the case in which the parent
22 covered entity is a children’s hospital described
23 in subparagraph (M) of subsection (a)(4) which
24 does not file a Medicare cost report, is listed on
25 the Medicare cost report most recently filed by

1 the parent covered entity on a line that is reim-
2 bursable under this title, if such cost report
3 demonstrates that the services provided at the
4 facility or organization have associated out-
5 patient costs and charges under this title, and
6 if the parent covered entity has provided a copy
7 of such cost report to the Office of Pharmacy
8 Affairs of the Health Resources and Services
9 Administration;

10 “(C) in the case that the parent covered
11 entity is a children’s hospital described in sub-
12 paragraph (M) of subsection (a)(4) which does
13 not file a Medicare cost report, would be cor-
14 rectly included on a reimbursable line with as-
15 sociated outpatient costs and charges under
16 title XVIII on a Medicare cost report of the
17 parent covered entity, if filed, and the parent
18 covered entity authorizing official has submitted
19 a signed statement to the Secretary which cer-
20 tifies the foregoing and that the requested out-
21 patient facility is an integral part of the chil-
22 dren’s hospital and is providing health care
23 services to patients of such hospital;

24 “(D) meets the provider-based status re-
25 quirements under section 413.65 of title 42,

1 Code of Federal Regulations or under any suc-
2 cessor to such section;

3 “(E) provides outpatient health care serv-
4 ices and is not limited to providing only drugs
5 or drug administration;

6 “(F) provides a level of free or discounted
7 health care services to individuals who meet the
8 parent covered entity’s criteria for financial as-
9 sistance and are unable to pay for all or a por-
10 tion of the services, as reported at cost to the
11 Internal Revenue Service under section
12 501(r)(4) of the Internal Revenue Code for the
13 calendar year, that is similar to that of the par-
14 ent covered entity; and

15 “(G) adheres to the parent covered entity’s
16 sliding scale fee schedule for providing covered
17 outpatient drugs that are subject to an agree-
18 ment under this section to patients who are (i)
19 low-income individuals; and (ii) not covered
20 under minimum essential coverage, as defined
21 in section 5000A(f) of the Internal Revenue
22 Code. Such sliding fee schedules must be made
23 publicly available in a similar manner to a
24 501(c)(3) hospital’s financial assistance policy

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

3 “(4) CERTIFICATION AND AUDITING.—

4 “(A) A covered entity described in sub-
5 clause (III) of subsection (a)(4)(L)(i) shall—

6 “(i) not less than annually, provide to
7 the Secretary a certification executed by
8 the hospital’s 340B Program authorizing
9 official and an appropriate government of-
10 ficial (such as the governor, county execu-
11 tive, mayor, or an individual authorized to
12 represent and bind the governmental enti-
13 ty), certifying that—

14 “(I) a contract is currently in
15 force between such covered entity and
16 the State or local government to pro-
17 vide health care services, to include
18 direct medical care and the ordering
19 or prescribing of covered outpatient
20 drugs that are subject to an agree-
21 ment under this section, to low-income
22 individuals who are not entitled to
23 benefits under title XVIII of the So-
24 cial Security Act or eligible for assist-

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

3 “(II) such contract creates en-
4 forceable expectations for such cov-
5 ered entity for the provision of the
6 health care services described in sub-
7 clause (I) to the individuals described
8 in such subclause; and

9 “(III) the health care services de-
10 scribed in subclause (I) represent a
11 significant portion of the hospital’s
12 operating revenues, and are not for
13 services the covered entity is otherwise
14 obligated to provide under State or
15 Federal law;

16 “(ii) make available the contract de-
17 scribed in subclause (III) of subsection
18 (a)(4)(L)(i) to the Secretary for publica-
19 tion on the public internet website of the
20 Department of Health and Human Serv-
21 ices relating to this section; and

22 “(iii) permit the Secretary to audit
23 the records of the covered entity that per-
24 tain to its compliance with the require-

1 ments described in subclause (III) of sub-
2 section (a)(4)(L)(i) and this subparagraph.

3 “(B) A facility or organization that partici-
4 pates in the drug discount program under this
5 section pursuant to paragraph (3) shall permit
6 the Secretary to audit the records of such facil-
7 ity or organization that pertain to its compli-
8 ance with the requirements described in such
9 paragraph.

10 “(C) The Secretary shall issue guidelines
11 to implement the requirements described in this
12 paragraph, which shall, at a minimum, define
13 the term ‘low-income individuals’ for purposes
14 of subclause (I) of subparagraph (A)(i), and
15 identify the applicable methodology and thresh-
16 old for determining that the health care services
17 described in such subclause represent a signifi-
18 cant portion of the hospital’s operating reve-
19 nues.”.

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

23 “(f) REPORTING REQUIREMENTS FOR COVERED EN-
24 TITIES.—

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

7 “(A) the number and percentage of pa-
8 tients of the covered entity, disaggregated by
9 insurance status (including at least the Medi-
10 care program under title XVIII of the Social
11 Security Act, the Medicaid program under title
12 XIX of such Act, the Children’s Health Insur-
13 ance Program under title XXI of such Act, the
14 TRICARE program under chapter 55 of title
15 10, United States Code, health insurance cov-
16 erage or a group health plan, and uninsured),
17 and by the type of site of the dispensing of the
18 covered outpatient drug subject to an agree-
19 ment under this section (parent covered entity,
20 facility or organization described in subsection
21 (c)(3), contracted entity described in subsection
22 (a)(11));

23 “(B) the aggregate amount of gross reim-
24 bursement received by the covered entity (cal-
25 culated before subtracting any administrative or

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

8 “(C) the aggregate acquisition cost for cov-
9 ered outpatient drugs subject to an agreement
10 under this section dispensed during the year;

11 “(D) the aggregate amount paid by the
12 covered entity, or any agent of the covered enti-
13 ty, to contracted entities described in subsection
14 (a)(11) for dispensing covered outpatient drugs
15 subject to an agreement under this section or
16 for any other service related to the drug dis-
17 count program under this section;

18 “(E) how the entity prevents duplicate dis-
19 counts under subparagraph (A) of subsection
20 (a)(5) and drug diversion under subparagraph
21 (B) of such subsection;

22 “(F) the volume of covered outpatient
23 drugs subject to an agreement under this sec-
24 tion dispensed by the covered entity and, in the
25 case of a covered entity that has entered into

1 a contractual arrangement pursuant to which a
2 third party dispenses covered outpatient drugs
3 subject to an agreement under this section to
4 patients of the covered entity, by each such con-
5 tracted entity;

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

14 “(H) the name of any third-party vendor
15 or other similar entity (if any) that the covered
16 entity retains to administer the covered entity’s
17 inventory management system or contract phar-
18 macy arrangement; and

19 “(I) other reporting requirements as the
20 Secretary determines is necessary or appro-
21 priate for effective management and oversight
22 of the drug discount program under this sec-
23 tion.

24 “(2) TIMING OF FIRST REPORT.—The first re-
25 port 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

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

9 “(g) REPORTS TO CONGRESS.—

10 “(1) REPORT BY THE SECRETARY.—Not later
11 than two years after the date of the enactment of
12 this subsection, the Secretary shall submit to the
13 Committee on Energy and Commerce of the House
14 of Representatives and the Committee on Health,
15 Education, Labor, and Pensions of the Senate a re-
16 port, which shall contain—

17 “(A) with respect to covered entities de-
18 scribed in subparagraph (L) or (M) of sub-
19 section (a)(4), the information contained in the
20 first report submitted by such entities to the
21 Secretary under subsection (f); and

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

1 such audits, and actions taken by the Secretary
2 in response to such audits, as well as actions
3 taken by the Secretary in response to audits
4 conducted by manufacturers pursuant to such
5 subparagraph.

6 “(2) REPORT BY THE COMPTROLLER GEN-
7 ERAL.—Not later than one year after the date of the
8 enactment of this subsection, the Comptroller Gen-
9 eral of the United States shall submit to the Com-
10 mittee on Energy and Commerce of the House of
11 Representatives and the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate a report
13 on the use by covered entities of contractual ar-
14 rangements pursuant to which a third party dis-
15 penses covered outpatient drugs subject to an agree-
16 ment under this section to patients of the covered
17 entity, disaggregated by covered entity types and the
18 physical distance of the contracted entity’s location
19 from the respective parent covered entity location.

20 “(3) ANNUAL REPORTS BY THE INSPECTOR
21 GENERAL.—Not later than July 1 of each year (be-
22 ginning with 2018), the Inspector General of the
23 Department of Health and Human Services shall
24 submit to appropriate committees of Congress a re-
25 port 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

1 by a covered entity using purchase data sub-
2 mitted by covered entities described in para-
3 graph (1), and using data submitted by manu-
4 facturers on sales to covered entities of covered
5 outpatient drugs subject to an agreement under
6 this section, pursuant to regulations to be
7 issued by the Secretary. Such amount, with re-
8 spect to a covered entity and year, shall not ex-
9 ceed 0.1 percent of the total paid during the
10 previous year by such covered entity to manu-
11 facturers for purchases of covered outpatient
12 drugs subject to an agreement under this sec-
13 tion.

14 “(5) USE OF FEES.—

15 “(A) IN GENERAL.—Any fee collected
16 under paragraph (1) shall be used for purposes
17 of administering this section, enhancing pro-
18 gram integrity and oversight activities under
19 this section (including through audits under
20 this section of covered entities and manufactur-
21 ers), and promoting access to clinical and cost-
22 effective pharmacy services among safety net
23 clinics and hospitals that participate under this
24 section, such as through—

1 “(i) the development of a multi-func-
2 tional web-based system to collect fees
3 under paragraph (1);

4 “(ii) the improvement of the integrity,
5 transparency, security, and reliability of
6 the Office of Pharmacy Affairs Informa-
7 tion System, including to ensure that the
8 database continues to meet the needs of
9 external stakeholders; and

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

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

20 “(6) AVAILABILITY OF FEES.—Fees authorized
21 under paragraph (1) shall be collected and available
22 for obligation only to the extent and in the amount
23 provided in advance in appropriations Acts. Such
24 fees are authorized to remain available until ex-
25 pended.

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

6 “(8) OVERSIGHT OF USER FEE PROGRAM.—

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

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

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

23 “(5) DIRECT-HIRE AUTHORITY.—Notwith-
24 standing section 3304(a)(3) of title 5, United States
25 Code, and sections 3309 through 3318 of such title,

1 and section 337 of title 5 of the Code of Federal
2 Regulations (or any successor regulations), the Sec-
3 retary may, beginning on the date of the enactment
4 of this paragraph, exercise direct-hire authority to
5 appoint a minimum of ten qualified candidates to
6 permanent positions within the competitive service in
7 order to carry out management and oversight activi-
8 ties under this section.”.

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

○