

[DISCUSSION DRAFT]

115TH CONGRESS
1ST SESSION

H. R. _____

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

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

A BILL

To **[**amend the Public Health Service Act to strengthen
program integrity and enhance low-income patient bene-
fits 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 “_____ Act of
5 2017”.

1 **SEC. 2. STRENGTHENING 340B PROGRAM INTEGRITY AND**
2 **ENHANCING LOW-INCOME PATIENT BENE-**
3 **FITS FOR [IS THIS INDICATING SOME SAFETY NET**
4 **PROVIDERS ARE NOT “TRUE”?; TRUE] SAFETY**
5 **NET PROVIDERS.**

6 (a) DEFINITION OF PATIENT.—Section 340B(b) of
7 the Public Health Service Act (42 U.S.C. 256b(b)) is
8 amended by adding at the end the following new para-
9 graph:

10 “(3) PATIENT.—

11 “(A) IN GENERAL.—In this section, the
12 term ‘patient’ means, with respect to a covered
13 entity described in subparagraphs (L) through
14 (O) of subsection (a)(4), an individual who, on
15 a prescription-by-prescription or order-by-order
16 basis—

17 “(i) receives a health care service at a
18 covered entity or an outpatient hospital fa-
19 cility described in subsection (c)(3) which
20 is registered for the drug discount program
21 under this section and listed on the on the
22 public Internet website of the Department
23 of Health and Human Services relating to
24 this section;

25 “(ii) receives an outpatient in-person
26 health care service from a health care pro-

1 vider employed by the covered entity or
2 who is an independent contractor of the
3 covered entity, such that the covered entity
4 bills for services on behalf of the provider;

5 “(iii) receives a drug that is ordered
6 or prescribed by the covered entity pro-
7 vider, including any renewals of existing
8 prescriptions, as a result of the service de-
9 scribed in clause (ii);

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

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

1 “(vi) has a relationship with the cov-
2 ered entity such that the covered entity
3 creates and maintains auditable health
4 care records which demonstrate that—

5 “(I) the covered entity has a pro-
6 vider-to-patient relationship with the
7 individual; and

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

13 “(B) EXCLUSIONS.—For purposes of this
14 *【Should this refer to the entire section?】*
15 **【sub】**section, an individual shall not be consid-
16 ered a patient of a covered entity described in
17 subparagraphs (L) through (O) of subsection
18 (a)(4) if—

19 “(i) the individual is an inmate of a
20 correctional facility;

21 “(ii) the health care service described
22 in clause (ii) of subparagraph (A) received
23 by the individual from the covered entity
24 consists only of the administration or infu-
25 sion of a drug or drugs, or the dispensing

1 of a drug or drugs for subsequent self-ad-
2 ministration or administration in the home
3 setting, without a covered entity provider-
4 to-patient encounter;

5 “(iii) the health care service described
6 in clause (ii) of subparagraph (A) received
7 by the individual from the covered entity is
8 provided by a health care organization that
9 has only an affiliation arrangement with
10 the covered entity, even if the covered enti-
11 ty has access to the affiliated organiza-
12 tion’s records; or

13 “(iv) the primary relationship between
14 the individual and the covered entity is one
15 of employment.

16 “(C) REGULATIONS.—**【**Not later than 180
17 days after the date of enactment of the
18 **【**_____ Act of 2017**】**, the Secretary shall
19 promulgate final regulations through notice-
20 and-comment rulemaking to define the term
21 ‘patient’ with respect to covered entities de-
22 scribed in subparagraphs (L) through (O) of
23 subsection (a)(4) to reflect the requirements de-
24 scribed in subparagraphs (A) and (B) of this
25 paragraph.

1 “(D) DEFINITION RELATING TO OTHER
2 COVERED ENTITIES.—[In this section, the term
3 ‘patient’, with respect to a covered entity de-
4 scribed in subparagraphs (A) through (K) of
5 subsection (a)(4),] has the meaning given such
6 term in the October 24, 1996 HRSA Final No-
7 tice Regarding Section 602 of the Veterans
8 Health Care Act of 1992 Patient and Entity
9 Eligibility (61 Fed Reg. 55156).

10 “(E) RECORD RETENTION.—A covered en-
11 tity described in subparagraphs ((L) through
12 (O) of subsection (a)(4) shall retain auditable
13 health care records which demonstrate the ex-
14 istence of a patient relationship in accordance
15 with this paragraph for each prescription or
16 order for a rolling period of not less than five
17 years, or longer to the extent required by State
18 or Federal law.”.

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

23 “(11) CONTRACTED SERVICES.—In the case of
24 a covered entity described in subparagraphs (L)
25 through (O) of subsection (a)(4) that elects to enter

1 into a contractual arrangement with a third party
2 for services related to the drug discount program
3 under this section, such as to dispense covered out-
4 patient drugs subject to an agreement under this
5 section to patients (*Review: This parenthetical and*
6 *each subsequent related parenthetical is not needed*
7 *since the term ‘patient’ is defined for the entire sec-*
8 *tion 340B:J*) as defined in paragraph (3) of sub-
9 section (b) and any regulations issued by the Sec-
10 retary pursuant to subparagraph (C) of such para-
11 graph) of the covered entity, to administer con-
12 tracted pharmacy services, or to provide any other
13 service related to the drug discount program under
14 this section, the remuneration for which is based in
15 whole or in part on the volume of dispensed covered
16 outpatient drugs subject to an agreement under this
17 section, such covered entity shall—

18 “(A) have a contractual agreement in place
19 between the covered entity and each contracted
20 entity, including with each location of a phar-
21 macy contracted to dispense covered outpatient
22 drugs subject to an agreement under this sec-
23 tion to patients (as so defined) of the covered
24 entity, which shall specify that the contracted
25 entity shall adhere to all requirements of the

1 drug discount program under this section, but
2 that ultimate responsibility for program compli-
3 ance and oversight of compliance by each con-
4 tracted entity shall remain with the covered en-
5 tity and that all covered outpatient drugs sub-
6 ject to an agreement under this section shall be
7 purchased by the covered entity;

8 “(B) register each such agreement with
9 the Secretary, include in such registration such
10 information as shall be specified by the Sec-
11 retary, and make available such agreement
12 upon request by the Secretary;

13 “(C) ensure the compliance of each such
14 agreement with the requirements of this section
15 to prevent drug diversion in violation of sub-
16 paragraph (B) of paragraph (5) and to prevent
17 duplicate discounts in violation of subparagraph
18 (A) of such paragraph before utilizing the serv-
19 ices of the contracted entity, including by—

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

24 “(ii) developing and implementing,
25 with each such contracted entity, a mecha-

nism 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 suitable 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 ben-

1 efit and its sliding fee scale, and developing and
2 implementing, with each such contracted entity,
3 a mechanism for documenting the income and
4 insurance status of each patient (as so defined)
5 of the covered entity and the amount each such
6 patient pays to receive covered outpatient drugs
7 that are subject to an agreement under this sec-
8 tion;

9 “(E) maintain, and ensure that each such
10 contracted entity maintains, auditable records
11 that pertain to the compliance of the covered
12 entity and the contracted entity with the re-
13 quirements described in this paragraph, for a
14 rolling period of not less than 5 years;

15 “(F) establish a process for, and conduct,
16 periodic comparisons of the covered entity’s pre-
17 scribing records with the dispensing records of
18 each such contracted entity, as applicable, to
19 detect potential irregularities and to ensure that
20 all drugs dispensed by the contracted entity are
21 for patients (as so defined) of the covered enti-
22 ty;

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

1 “(H) maintain arrangements to dispense
2 covered outpatient drugs that are subject to an
3 agreement under this section to patients (as so
4 defined) of the covered entity with no more
5 than 5 contract pharmacy locations at any
6 given time, all of which must be located within
7 (or, for mail-order pharmacies, serve patients
8 residing in) lower-income (using American
9 Community Survey data as determined by the
10 Secretary) census tracts served by the covered
11 entity, except in the case that the covered entity
12 files a publicly available exception request with
13 the Secretary that seeks authorization to estab-
14 lish a particular contract pharmacy arrange-
15 ment in a higher-income census tract and ex-
16 plains the reason in that particular case such a
17 contract pharmacy would best meet the needs of
18 low-income patients of the covered entity, and
19 the Secretary decides to grant the request to es-
20 tablish one of the 5 contract pharmacies in the
21 census tract requested;

22 “(I) ensure, as applicable, that patients (as
23 so defined) of the covered entity have access to
24 the covered entity’s prescription drug charity
25 care benefit through each contract pharmacy lo-

1 cation at the time of purchase of each covered
2 outpatient drug subject to an agreement under
3 this section to the same extent such patients
4 have access to the benefit with respect to such
5 drugs purchased directly through the covered
6 entity; and

7 “(J) limit any amount paid by the covered
8 entity, or any agent of the covered entity, to the
9 contracted entity for dispensing covered out-
10 patient drugs subject to an agreement under
11 this section or for any other service related to
12 the drug discount program under this section to
13 a reasonable amount, which shall not exceed the
14 fair market value of such drug dispensing or
15 other service.

16 In the case the Secretary grants a request under
17 subparagraph (H) to establish a particular contract
18 pharmacy arrangement in a higher-income census
19 tract, the Secretary shall make such decision **【Public**
20 *in the federal register? On a public website?***】** publicly
21 available.

22 “(12) AUDITING.—A covered entity described in
23 subparagraphs (L) through (O) of subsection (a)(4)
24 and a contracted entity that enter into a contractual

1 arrangement described in paragraph (11) shall per-
2 mit—

3 “(A) the Secretary to audit the records of
4 the covered entity and of the contracted entity
5 that pertain to the covered entity’s and the con-
6 tracted entity’s compliance with the require-
7 ments described in such paragraph; and

8 “(B) the manufacturer of a covered out-
9 patient drug that is subject to an agreement
10 under this section (or its designee) to audit
11 such records of the covered entity and of the
12 contracted entity solely with respect to such
13 drugs of the manufacturer.

14 “(13) REGULATIONS.—

15 “(A) Not later than 180 days after the
16 date of enactment of this paragraph, the Sec-
17 retary shall promulgate final regulations
18 through notice-and-comment rulemaking to im-
19 plement the requirements of paragraph (11)
20 and paragraph (12). Such regulations shall in-
21 clude model terms for the contractual agree-
22 ment described in subparagraph (A) of para-
23 graph (11).

24 “(B) Not later than 180 days after the
25 date of enactment of this paragraph, the Sec-

1 retary shall promulgate final regulations
2 through notice-and-comment rulemaking to es-
3 tablish procedures, in the case in which the Sec-
4 retary determines that a violation of the annual
5 contract pharmacy independent on-site audit re-
6 quirement in subparagraph (F) of paragraph
7 (11), with respect to a contract pharmacy ar-
8 rangement, was systematic and egregious as
9 well as knowing and intentional—

10 “(i) for removing the contract phar-
11 macy arrangement from a covered entity’s
12 contract pharmacy network and disquali-
13 fying the entity from adding any additional
14 contract pharmacies for a reasonable pe-
15 riod, to be determined by the Secretary, of
16 not less than two years; and

17 “(ii) for requiring that the entity **【Is**
18 *this allowing the Secretary to set the pen-*
19 *alty amount without any boundaries as to*
20 *how high such an interest rate may be?:* pay
21 a monetary penalty to a manufacturer or
22 manufacturers in the form of interest**】** on
23 sums that are owed to the manufacturer
24 due to violations of subparagraph (A) or
25 (B) of subsection (a)(5) that occurred at

1 one or more contract pharmacies and that
2 were discovered *【How is this to be prov-*
3 *en?:】* later than such violations would have
4 been if the entity had complied with its ob-
5 ligation to have annual independent audits
6 of contract pharmacies conducted.

7 “(14) MAIL ORDER STUDY AND REGULA-
8 TIONS.—

9 “(A) REPORT.—Not later than 180 days
10 after the date of the enactment of this para-
11 graph, the Secretary shall conduct a study (and
12 submit to **【Congress】** a report containing the
13 results of such study) regarding compliance
14 concerns associated with covered entities de-
15 scribed in subparagraphs (L) through (O) of
16 subsection (a)(4) contracting with mail order
17 pharmacies to dispense covered outpatient
18 drugs subject to an agreement under this sec-
19 tion, and any additional safeguards or limita-
20 tions necessary and appropriate to reduce those
21 compliance concerns.

22 “(B) REGULATIONS.— Not later than 180
23 days after the submission of the report under
24 subparagraph (A), the Secretary shall promul-
25 gate final regulations applicable to covered enti-

1 ties described in such subparagraph, through
2 notice-and-comment rulemaking, to implement
3 any additional safeguards or limitations rec-
4 ommended by the study.

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

14 “(A) the effective date of final regulations
15 described in paragraph (13);

16 “(B) the effective date of final regulations
17 described in paragraph (14);

18 “(C) the effective date of final regulations
19 issued through Secretarial notice-and-comment
20 rulemaking that take into consideration the
21 findings and recommendations in the report
22 from the Inspector General of the Department
23 of Health and Human Services required under
24 subsection (g)(3).”.

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

5 “(iii) Not later than one year after
6 the date of the enactment of this clause,
7 the Secretary shall promulgate final regu-
8 lations through notice-and-comment rule-
9 making, describing methodologies for State
10 Medicaid programs and all covered entities
11 under subsection (a)(4) to identify and bill
12 drugs subject to an agreement under this
13 section in a manner that ensures compli-
14 ance with 340B Program prohibitions re-
15 garding duplicate discounts, including the
16 duplicate discount prohibition under sec-
17 tion 1927(j)(1) of the Social Security Act,
18 to include the application of such prohibi-
19 tions to Medicaid managed care enrollees.
20 Such methodologies shall include the use of
21 340B-specific claims identifiers, and the
22 provision of claims-level data by covered
23 entities to States as well as manufacturers
24 of covered outpatient drugs sufficient to
25 identify claims that include drugs subject

1 to an agreement under this section and to
2 prevent duplicate discounts.”.

3 (d) AMOUNT CHARGED TO LOW-INCOME PA-
4 TIENTS.—

5 (1) IN GENERAL.—Subsection (a)(5) of section
6 340B of the Public Health Service Act (42 U.S.C.
7 256b) is amended by adding at the end the following
8 new subparagraphs:

9 “(E) AMOUNT CHARGED TO LOW-INCOME
10 PATIENTS.—As a condition of certification or
11 recertification under subparagraph (E) of para-
12 graph (7), each covered entity described in sub-
13 paragraphs (L) through (O) of subsection
14 (a)(4) must establish a sliding scale fee sched-
15 ule for providing covered outpatient drugs that
16 are subject to an agreement under this section,
17 directly or under a contractual arrangement
18 pursuant to which a third party dispenses such
19 drugs, to patients of the covered entity who
20 are—

21 “(i) low-income individuals; and

22 “(ii) not covered under minimum es-
23 sential coverage, as defined in section
24 5000A(f) of the Internal Revenue Code.

1 “(F) REGULATIONS.—Not later than 180
2 days after the date of enactment of this sub-
3 paragraph, the Secretary shall promulgate final
4 regulations through notice-and-comment rule-
5 making, to implement the requirements under
6 subparagraph (E). Such regulations shall—

7 “(i) define the term ‘low-income indi-
8 vidual’;

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

17 “(iii) ensure the security and protec-
18 tion of privileged or otherwise confidential
19 data from unauthorized disclosure or re-
20 disclosure.”.

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

23 (1) DEFINITION.—Subparagraph (L) of section
24 340B(a)(4) of the Public Health Service Act (42
25 U.S.C. 256b(a)(4)) is amended to read as follows:

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

4 “(i) is—

5 “(I) owned or operated by a unit
6 of State or local government;

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

11 “(III) a private non-profit hos-
12 pital which has a contract with a
13 State or local government to provide
14 health care services, which include the
15 ordering or prescribing of covered out-
16 patient drugs that are subject to an
17 agreement under this section, to low
18 income individuals who are not enti-
19 tled to benefits under title XVIII of
20 the Social Security Act or eligible for
21 assistance under the State plan for
22 medical assistance under title XIX of
23 such Act;

24 “(ii) for the most recent cost report-
25 ing period that ended before the calendar

1 quarter involved, had a disproportionate
2 share adjustment percentage (as deter-
3 mined under section 1886(d)(5)(F) of the
4 Social Security Act) greater than 11.75
5 percent or was described in section
6 1886(d)(5)(F)(i)(II) of such Act; and

7 “(iii) does not obtain covered out-
8 patient drugs through a group purchasing
9 organization or other group purchasing ar-
10 rangement.

11 If the Secretary determines that a hospital that
12 is eligible for participation in the 340B pro-
13 gram under this subparagraph obtained covered
14 outpatient drugs through a group purchasing
15 organization or another group purchasing ar-
16 rangement while that hospital was participating
17 in the drug discount program under this sec-
18 tion, then the Secretary shall remove such hos-
19 pital from such program and the hospital shall
20 not be permitted to seek re-enrollment for a pe-
21 riod of at least 12 months after its removal
22 from the program.”.

23 (2) STUDY AND REPORT; MORATORIUM; OUT-
24 PATIENT HOSPITAL FACILITIES; AUDITS.—Sub-
25 section (c) of section 340B of the Public Health

1 Service Act (42 U.S.C. 256b) is amended to read as
2 follows:

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

5 “(1) STUDY AND REPORT.—

6 “(A) STUDY.—The Comptroller General of
7 the United States shall conduct a study on the
8 relationship between the disproportionate share
9 adjustment percentages of private covered enti-
10 ties described in subclauses (II) and (III) of
11 subsection (a)(4)(L)(i) and the levels of charity
12 care provided by such entities to outpatients.

13 “(B) REPORT.—Not later than 180 days
14 after the date of enactment of [_____ Act
15 of 2017], the Comptroller General shall submit
16 to the appropriate committees of Congress a re-
17 port on the results of the study conducted
18 under subparagraph (A), including rec-
19 ommendations on a metric that, as applied to a
20 private covered entity described in such sub-
21 paragraph, reflects a high level of charity care
22 provided to outpatients as a percentage of the
23 covered entity’s overall expenses for outpatient
24 care, and could replace the metric described in
25 subclause (ii) of subsection (a)(4)(L). The

1 Comptroller General shall recommend the met-
2 ric that best aligns with the level of charity care
3 provided to outpatients as a percentage of over-
4 all hospital operating expenses on outpatient
5 care if no metric is identified that provides a
6 precise measure of such percentage.

7 “(2) MORATORIUM.—

8 “(A) IN GENERAL.—For the period de-
9 scribed in subparagraph (B)—

10 “(i) a private covered entity described
11 in subclauses (II) or (III) of subsection
12 (a)(4)(L)(i) may participate in the drug
13 discount program under this section as a
14 covered entity only if it was properly en-
15 rolled as a covered entity in the drug dis-
16 count program under this section as of the
17 date of the enactment of the [_____
18 Act of 2017] and continuously enrolled
19 thereafter; and

20 “(ii) with respect to a facility or orga-
21 nization described in paragraph (3) of this
22 subsection that is wholly-owned by a pri-
23 vate covered entity described in subclause
24 (II) or (III) of subsection (a)(4)(L)(i), only
25 a facility or organization that was properly

1 enrolled as a child site in the drug discount
2 program under this section as of the date
3 of the enactment of the [_____ Act of
4 2017] and continuously enrolled thereafter
5 may participate in the drug discount pro-
6 gram under this section.

7 “(B) PERIOD DESCRIBED.—For purposes
8 of subparagraph (A), the period described in
9 this subparagraph is the period beginning on
10 the date of enactment of [_____ Act of
11 2017] and ending on the effective date de-
12 scribed in subparagraph (C).

13 “(C) EFFECTIVE DATE OF REPLACEMENT
14 METRIC.—

15 “(i) IN GENERAL.—For purposes of
16 subparagraph (B), subject to clause (ii),
17 the effective date described in this sub-
18 paragraph is the date on which [Review if
19 this is to point to the date of enactment of
20 the legislation or the effective date of the
21 policy contained in such enacted legisla-
22 tion?: there is enacted into law] legislation
23 [with the following long title: ‘_____’]
24 that, with respect to private covered enti-

1 ties described in subclauses (II) and (III)
2 of subsection (a)(4)(L)(i)—

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

10 “(II) takes into account the re-
11 port submitted under paragraph (1),
12 including by addressing the Comp-
13 troller General’s recommendations in-
14 cluded in such report.

15 “(ii) EXCEPTION.—**[Review if this is**
16 **intent:]** If legislation described in clause
17 (i) is not enacted by the date that is one
18 year after the date of submission of the re-
19 port under paragraph (1)—

20 “(I) the Secretary shall promul-
21 gate final regulations that implement,
22 to the extent practicable, the Comp-
23 troller General’s recommendations in-
24 cluded within such report not later

1 than the date that is 180 days after
2 such one-year date; and

3 “(II) for purposes of subpara-
4 graph (B), the effective date described
5 in this subparagraph is the effective
6 date of such final regulations.

7 “(3) OUTPATIENT HOSPITAL FACILITIES.—A
8 facility or organization may participate in the drug
9 discount program under this section as a child site
10 of a covered entity described in subparagraphs (L)
11 through (O) of subsection (a)(4) only if such facility
12 or organization—

13 “(A) is wholly-owned by a covered entity
14 described in subparagraphs (L) through (O) of
15 subsection (a)(4);

16 “(B) except in the case in which the parent
17 covered entity is a children’s hospital described
18 in subparagraph (M) of subsection (a)(4) which
19 does not file a Medicare cost report, is listed on
20 the Medicare cost report most recently filed by
21 the parent covered entity on a line that is reim-
22 bursable under this title, *[Review: What are the*
23 *following requirements conditions of, i.e. what*
24 *happens if either of the following elements are*
25 *not satisfied? Do they then not have to be listed*

1 *on the cost report to satisfy this subparagraph?:*
2 if such cost report demonstrates that the serv-
3 ices provided at the facility or organization have
4 associated outpatient costs and charges under
5 this title, and if the parent covered entity has
6 provided a copy of such cost report to the Of-
7 fice of Pharmacy Affairs of the Health Re-
8 sources and Services Administration】;

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

23 “(D) meets the provider-based status re-
24 quirements under 【*Is this specifically section*
25 *413.65 of title 42, CFR?:*】 subpart E of part

1 413 of title 42, Code of Federal Regulations [,
2 as such requirements were in effect as of the
3 date of the enactment of the [____Act]]/[or
4 under any successor to such [subpart]]/[sec-
5 tion]];

6 “(E) provides outpatient health care serv-
7 ices and is not limited to providing only drugs
8 or drug administration;

9 “(F) provides a level of free or discounted
10 health care services to individuals who meet the
11 parent covered entity’s criteria for financial as-
12 sistance and are unable to pay for all or a por-
13 tion of the services, as reported at cost to the
14 Internal Revenue Service under section
15 501(r)(4) of the Internal Revenue Code for the
16 calendar year, that is similar to that of the par-
17 ent covered entity; and

18 “(G) adheres to the parent covered entity’s
19 sliding scale fee schedule for providing covered
20 outpatient drugs that are subject to an agree-
21 ment under this section to patients (as defined
22 in paragraph (3) of subsection (b) and any reg-
23 ulations issued by the Secretary pursuant to
24 subparagraph (C) of that paragraph) who are
25 (i) low-income individuals; and (ii) not covered

1 under minimum essential coverage, as defined
2 in section 5000A(f) of the Internal Revenue
3 Code. Such sliding fee schedules must be made
4 publicly available in a similar manner to a
5 501(c)(3) hospital's financial assistance policy
6 as required under section 501(r) of the Internal
7 Revenue Code of 1986.

8 “(4) CERTIFICATION AND AUDITING.—

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

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

19 “(I) a contract is currently in
20 force between such covered entity and
21 the State or local government to pro-
22 vide health care services, to include
23 direct medical care and the ordering
24 or prescribing of covered outpatient
25 drugs that are subject to an agree-

1 ment under this section, to low-income
2 individuals who are not entitled to
3 benefits under title XVIII of the So-
4 cial Security Act **【What is this ref-**
5 *erencing? Under 340B? Under the*
6 *Medicaid State plan under title XIX of*
7 *the SSA?:* or eligible for assistance
8 under the State plan under this sub-
9 chapter**】**;

10 “(II) such contract creates en-
11 forceable expectations for such cov-
12 ered entity for the provision of the
13 health care services described in sub-
14 clause (I) to the individuals described
15 in such subclause; and

16 “(III) the health care services de-
17 scribed in subclause (I) represent a
18 significant portion of the hospital’s
19 operating revenues, and are not for
20 services the covered entity is otherwise
21 obligated to provide under State or
22 Federal law;

23 “(ii) make available the contract de-
24 scribed in subclause (III) of subsection
25 (a)(4)(L)(i) to the Secretary for publica-

1 tion on the public Internet website of the
2 Department of Health and Human Serv-
3 ices relating to this section; and

4 “(iii) permit the Secretary to audit
5 the records of the covered entity that per-
6 tain to its compliance with the require-
7 ments described in subclause (III) of sub-
8 section (a)(4)(L)(i) and this subparagraph.

9 “(B) A facility or organization that partici-
10 pates in the drug discount program under this
11 section pursuant to paragraph (3) shall permit
12 the Secretary to audit the records of such facil-
13 ity or organization that pertain to its compli-
14 ance with the requirements described in such
15 paragraph.

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

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

4 “(f) REPORTING REQUIREMENTS FOR COVERED EN-
5 TITIES.—

6 “(1) IN GENERAL.—A covered entity described
7 in subparagraphs (L) through (O) of subsection
8 (a)(4) shall annually submit to the Secretary an
9 electronic and searchable data report in a machine-
10 readable format. Such report shall contain, with re-
11 spect to the year covered by the report, information
12 on—

13 “(A) the number and percentage of pa-
14 tients (as defined in paragraph (3) of sub-
15 section (b) and any regulations issued by the
16 Secretary pursuant to subparagraph (C) of such
17 paragraph) of the covered entity, disaggregated
18 by insurance status (including at least the
19 Medicare program under title XVIII of the So-
20 cial Security Act, the Medicaid program under
21 title XIX of such Act, the Children’s Health In-
22 surance Program under title XXI of such Act,
23 the TRICARE program under chapter 55 of
24 title 10, United States Code, health insurance
25 coverage or a group health plan, and unin-

1 sured), and by the type of site of the dispensing
2 of the covered outpatient drug subject to an
3 agreement under this section (parent covered
4 entity, facility or organization described in sub-
5 section (c)(3), contracted entity described in
6 subsection (a)(11));

7 “(B) the aggregate amount of gross reim-
8 bursement received by the covered entity (cal-
9 culated before subtracting any administrative or
10 other fees using a methodology provided by the
11 Secretary) for covered outpatient drugs subject
12 to an agreement under this section, including
13 reimbursement received through facilities or or-
14 ganizations described in subsection (c)(3) or
15 pursuant to contractual arrangements described
16 in subsection (a)(11);

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

20 “(D) the aggregate amount paid by the
21 covered entity, or any agent of the covered enti-
22 ty, to contracted entities described in subsection
23 (a)(11) for dispensing covered outpatient drugs
24 subject to an agreement under this section or

1 for any other service related to the drug dis-
2 count program under this section;

3 “(E) how the entity prevents duplicate dis-
4 counts under subparagraph (A) of subsection
5 (a)(5) and drug diversion under subparagraph
6 (B) of such subsection;

7 “(F) the volume of covered outpatient
8 drugs subject to an agreement under this sec-
9 tion dispensed by the covered entity and, in the
10 case of a covered entity that has entered into
11 a contractual arrangement pursuant to which a
12 third party dispenses covered outpatient drugs
13 subject to an agreement under this section to
14 patients of the covered entity, by each such con-
15 tracted entity;

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

24 “(H) the name of any third party vendor
25 or other similar entity (if any) that the covered

1 entity retains to administer the covered entity's
2 inventory management system or contract phar-
3 macy arrangement; and

4 “(I) other reporting requirements as the
5 Secretary determines is necessary or appro-
6 priate for effective management and oversight
7 of the drug discount program under this sec-
8 tion.

9 “(2) TIMING OF FIRST REPORT.—The first re-
10 port submitted under paragraph (1) shall be sub-
11 mitted not later than 18 months after the date of
12 enactment of this subsection.

13 “(3) ATTESTATION.—Each report submitted
14 under paragraph (1) shall be accompanied by an at-
15 testation, in a form and manner specified by the
16 Secretary, that the information submitted in such
17 report is complete and accurate. Such attestation
18 shall be subject to section 1001 of title 18, United
19 States Code.

20 “(4) SANCTIONS.—If the Secretary finds that a
21 covered entity is in violation of the requirement
22 under paragraph (1) and the Secretary determines
23 that such violation was knowing and intentional, the
24 Secretary shall remove the entity from the drug dis-
25 count program under this section and disqualify the

1 entity from re-entry into such program for a reason-
2 able period of time to be determined by the Sec-
3 retary.

4 “(5) REGULATIONS.—Not later than 180 days
5 after the date of enactment of this subsection, the
6 Secretary shall promulgate final regulations through
7 notice-and-comment rulemaking to implement the re-
8 quirements under paragraphs (1) through (4).

9 “(6) PUBLIC DATABASE.—The Secretary shall
10 make the data reported by covered entities under
11 this subsection available to the public on the website
12 of the Department of Health and Human Services in
13 an electronic and searchable format, which shall
14 make each category of data reported available both
15 in the aggregate and broken down by parent covered
16 entities, child sites, and contract pharmacies, but
17 shall not identify specific parent covered entities,
18 child sites, or contract pharmacies.

19 “(g) REPORTS TO CONGRESS.—

20 “(1) REPORT BY THE SECRETARY.—Not later
21 than two years after the date of the enactment of
22 this subsection, the Secretary shall submit to the
23 Committee on Energy and Commerce of the House
24 of Representatives and the Committee on Health,

1 Education, Labor and Pensions of the Senate a re-
2 port, which shall contain—

3 “(A) with respect to covered entities de-
4 scribed in subparagraphs (L) through (O) of
5 subsection (a)(4), the information contained in
6 the first report submitted by such entities to
7 the Secretary under subsection (f); and

8 “(B) a description of the audits conducted
9 by the Secretary pursuant to subparagraph (C)
10 of subsection (a)(5), including the methodology
11 used for conducting such audits, the results of
12 such audits, and actions taken by the Secretary
13 in response to such audits, as well as actions
14 taken by the Secretary in response to audits
15 conducted by manufacturers pursuant to such
16 subparagraph.

17 “(2) REPORT BY THE COMPTROLLER GEN-
18 ERAL.—Not later than one year after the date of the
19 enactment of this subsection, the Comptroller Gen-
20 eral of the United States shall submit to the Com-
21 mittee on Energy and Commerce of the House of
22 Representatives and the Committee on Health, Edu-
23 cation, Labor and Pensions of the Senate a report
24 on the use by covered entities of contractual ar-
25 rangements pursuant to which a third party dis-

1 penses covered outpatient drugs subject to an agree-
2 ment under this section to patients of the covered
3 entity, disaggregated by covered entity types and the
4 physical distance of the contracted entity's location
5 from the respective parent covered entity location.

6 “(3) ANNUAL REPORTS BY THE INSPECTOR
7 GENERAL.—**[***Review first required date of July 1,*
8 *2017: Not later than July 1 of each year (beginning*
9 *with 2017)***]**, the Inspector General of the Depart-
10 ment of Health and Human Services shall submit to
11 appropriate committees of Congress a report on the
12 contractual arrangements between covered entities
13 and third parties described in paragraph (11) of
14 subsection (a), including the methods and amounts
15 of remuneration exchanged between such covered en-
16 tities and such contracted entities, and the extent to
17 which contract pharmacies are improving access to
18 medicines by patients of such covered entities. The
19 first such annual report shall include recommenda-
20 tions, as the Inspector General determines appro-
21 priate, that address safeguards to reduce duplicate
22 discounting and diversion within contract pharmacy
23 arrangements and reforms to ensure these arrange-
24 ments are targeted exclusively at improving access to
25 medicines for low-income or vulnerable patients of

1 covered entities. Subsequent reports under this para-
2 graph should continue to monitor such issues and be
3 updated as changes are made to the drug discount
4 program under this section.”.

5 (g) USER FEES.—Section 340B of the Public Health
6 Service Act (42 U.S.C. 256b), as previously amended, is
7 further amended by adding at the end the following new
8 subsection:

9 “(h) USER FEES.—

10 “(1) IN GENERAL.—Subject to paragraph (6),
11 the Secretary shall assess and collect a user fee from
12 covered entities described in subparagraphs (L)
13 through (O) of subsection (a)(4). In carrying out
14 this subsection, the Secretary shall not require man-
15 ufacturers to collect any user fee or to administer
16 the user fee program established under this sub-
17 section.

18 “(2) PAYMENT.—*Who is this requirement*
19 *placed upon?* Any fee collected under paragraph (1)
20 shall be due upon **]/[**A covered entity described in
21 subparagraphs (L) through (O) of subsection (a)(4)
22 shall pay to the Secretary a fee assessed under para-
23 graph (1) by such date that is **]** the later of—

24 “(A) the date of the certification or recer-
25 tification of the covered entity, as applicable; or

1 “(B) *【What is the meaning of this? Is this*
2 *saying that fees wouldn’t be collected until an*
3 *appropriations Act is passed that obligates to what*
4 *source/purpose the collected funds would go?】* the
5 date that is 30 days after the date of the enact-
6 ment of an appropriations Act providing for the
7 collection and obligation of fees under this sub-
8 section for a fiscal year.

9 “(3) AMOUNT OF FEE.—The amount of a fee
10 under paragraph (1) shall be equal to the amount
11 determined by the Secretary under paragraph (4).

12 “(4) DETERMINATION OF AMOUNT OF FEE.—
13 The Secretary shall, not later than 180 days before
14 the start of each fiscal year that begins after Sep-
15 tember 30, 2016, establish, for the next fiscal year,
16 the amount of the fee payable under this subsection
17 by a covered entity using purchase data submitted
18 by covered entities pursuant to regulations to be
19 issued by the Secretary. Such amount shall not ex-
20 ceed the sum of 0.1 percent of the total purchases
21 of covered outpatient drugs subject to an agreement
22 under this section made by the covered entity under
23 the drug discount program under this section during
24 the previous year.

1 “(5) USE OF FEES.—Any fee collected under
2 paragraph (1) shall be used for the general costs of
3 the oversight and administration of this section, in-
4 cluding activities conducted for purposes of enhanc-
5 ing program integrity, as well as review, audit, and
6 enforcement actions. Any such fee shall be used to
7 supplement and not supplant the amount otherwise
8 provided in appropriations Acts to carry out this sec-
9 tion.

10 “(6) AVAILABILITY OF FEES.—*【Review: Approp-*
11 *riations Acts usually appropriate funds, not require*
12 *the collection of funds:】* Fees authorized under para-
13 graph (1) shall be collected and available for obliga-
14 tion only to the extent and in the amount provided
15 in advance in appropriations Acts. Such fees are au-
16 thorized to remain available *【To whom? For what*
17 *purpose? These fees are being collected by the Sec-*
18 *retary, correct? Usually this type of provision is with*
19 *respect to funds provided by the Federal Government*
20 *to other entities.】* until expended.

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

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

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

6 “(B) REPORT.—Not later than *Review if*
7 *the first date (July 1, 2017), is possible from an*
8 *administrative perspective: July 1 of each year*
9 *(beginning with 2017)*], the Inspector General
10 of the Department of Health and Human Serv-
11 ices shall submit to the appropriate committees
12 of Congress a report on the study conducted
13 under subparagraph (A), together with such
14 recommendations as the Inspector General de-
15 termines appropriate.”.

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

20 “(5) DIRECT-HIRE AUTHORITY.—Notwith-
21 standing section 3304(a)(3) of title 5, United States
22 Code, and *Is this specifically intending to reference*
23 *section 337 of title 5, CFR?: 5 C.F.R. 337 Subpart*
24 *B]* (or any successor regulations), *How is this in-*
25 *tended to be different than the ‘notwithstanding con-*

1 *struct’, i.e., why not just say up front: Notwith-*
2 *standing sections 3304(a)(3) of title 5, USC, and sec-*
3 *tions 3309 through 3318 of such title...?: and without*
4 regard to the provisions of sections 3309 through
5 3318 of **【Is this referring to title 5, USC?: such**
6 **title】**, the Secretary may, beginning on the date of
7 the enactment of this paragraph, exercise direct-hire
8 authority to appoint not more than ten qualified
9 candidates to permanent positions within the com-
10 petitive service in order to carry out management
11 and oversight activities under this section.”.

12 (i) APPLICABILITY.—Except as otherwise indicated,
13 the **【requirements in】/【provisions of, including amend-**
14 **ments made by,】** this Act shall not apply to covered enti-
15 ties defined under subparagraphs (A) through (K) under
16 subsection (a)(4).