

[DISCUSSION DRAFT]

115TH CONGRESS
2^D SESSION

H. R. _____

To amend the Public Health Service Act to provide for certain user fees under the 340B drug discount program.

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 provide for certain user fees under the 340B drug discount program.

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”.

5 **SEC. 2. USER FEES UNDER THE 340B DRUG DISCOUNT PRO-**
6 **GRAM.**

7 Section 340B of the Public Health Service Act (42
8 U.S.C. 256b) is amended by adding at the end the fol-
9 lowing new subsection:

1 “(f) USER FEES.—

2 “(1) IN GENERAL.—Subject to paragraph (6),
3 the Secretary shall assess and collect a user fee from
4 covered entities described in subparagraph **[(A),**
5 **(L), (M)[, (N), or (O)]** of subsection (a)(4). In car-
6 rying out this subsection, the Secretary shall not re-
7 quire manufacturers to collect any user fee or to ad-
8 minister the user fee program established under this
9 subsection.

10 “(2) PAYMENT.—A covered entity described in
11 subparagraph (L) or (M) of subsection (a)(4) shall
12 pay to the Secretary a fee assessed under paragraph
13 (1) by such date that is the later of—

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

16 “(B) the date that is 30 days after the
17 date of the enactment of an appropriations Act
18 providing for the collection and obligation of
19 fees under this subsection for a fiscal year.

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

23 “(4) DETERMINATION OF AMOUNT OF FEE.—

24 “(A) IN GENERAL.—The Secretary shall,
25 not later than 180 days before the start of each

1 fiscal year that begins [after September 30,
2 2018], establish, for the next fiscal year, the
3 amount of the fee payable under this subsection
4 by a covered entity using purchase data sub-
5 mitted by covered entities described in para-
6 graph (1), and using data submitted by manu-
7 facturers on sales to covered entities of covered
8 outpatient drugs subject to an agreement under
9 this section, pursuant to regulations to be
10 issued by the Secretary. Such amount, with re-
11 spect to a covered entity and year, shall not ex-
12 ceed 0.1 percent of the total paid during the
13 previous year by such covered entity to manu-
14 facturers for purchases of covered outpatient
15 drugs subject to an agreement under this sec-
16 tion.

17 “(5) USE OF FEES.—

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

1 clinics and hospitals that participate under this
2 section, such as through—

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

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

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

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

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

1 fees are authorized to remain available until ex-
2 pended.

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

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

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

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

21 **SEC. 3. DIRECT-HIRE AUTHORITY.**

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

1 “(5) DIRECT-HIRE AUTHORITY.—Notwith-
2 standing section 3304(a)(3) of title 5, United States
3 Code, and sections 3309 through 3318 of such title,
4 and section 337 of title 5 of the Code of Federal
5 Regulations (or any successor regulations), the Sec-
6 retary may, beginning on the date of the enactment
7 of this paragraph, exercise direct-hire authority to
8 appoint a minimum of ten qualified candidates to
9 permanent positions within the competitive service in
10 order to carry out management and oversight activi-
11 ties under this section.”.