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115TH CONGRESS
2D SESSION

H. R. 6240

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 27, 2018

Mr. COLLINS of New York (for himself and Mr. CARTER of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Discount Accountability Act''.

SEC. 2. USER FEES UNDER THE 340B DRUG DISCOUNT PROGRAM.

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

''(f) USER FEES.—

''(1) IN GENERAL.—Subject to paragraph (6), the Secretary shall assess and collect a user fee from covered entities described in subparagraph (L), (M), (N), or (O) of subsection (a)(4). In carrying out this subsection, the Secretary shall not require manufacturers to collect any user fee or to administer the user fee program established under this subsection.

''(2) PAYMENT.—A covered entity described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) shall pay to the Secretary a fee assessed under paragraph (1) by such date that is the later of—

''(A) the date of the certification or recertification of the covered entity, as applicable; or

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

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

''(4) DETERMINATION OF AMOUNT OF FEE.—

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

fiscal year that begins after September 30, 2019, establish, for the next fiscal year, the amount of the fee payable under this subsection by a covered entity using purchase data submitted by covered entities described in paragraph (1), and using data submitted by manufacturers on sales to covered entities of covered outpatient drugs subject to an agreement under this section, pursuant to regulations to be issued by the Secretary. Such amount, with respect to a covered entity and year, shall not exceed 0.1 percent of the total paid during the previous year by such covered entity to manufacturers for purchases of covered outpatient drugs subject to an agreement under this section.

''(5) USE OF FEES.—

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

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

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

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

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

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

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

fees are authorized to remain available until expended.

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

''(8) OVERSIGHT OF USER FEE PROGRAM.—

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

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

SEC. 3. DIRECT-HIRE AUTHORITY.

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

''(5) DIRECT-HIRE AUTHORITY.—Notwithstanding section 3304(a)(3) of title 5, United States Code, and sections 3309 through 3318 of such title, and section 337 of title 5 of the Code of Federal Regulations (or any successor regulations), the Secretary may, beginning on the date of the enactment of this paragraph, exercise direct-hire authority to appoint a minimum of ten qualified candidates to permanent positions within the competitive service in order to carry out management and oversight activities under this section.''.

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