

[DISCUSSION DRAFT]

115TH CONGRESS
2^D SESSION

H. R. _____

To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program to establish certain fee amounts charged to certain low-income patients for 340B drugs.

IN THE HOUSE OF REPRESENTATIVES

Mr. BURGESS introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Public Health Service Act to require certain covered entities under the 340B drug discount program to establish certain fee amounts charged to certain low-income patients for 340B drugs.

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”.

1 **SEC. 2. AMOUNTS CHARGED TO CERTAIN LOW-INCOME PA-**
2 **TIENTS UNDER 340B DRUG DISCOUNT PRO-**
3 **GRAM.**

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

8 “(E) AMOUNT CHARGED TO LOW-INCOME
9 PATIENTS.—

10 “(i) IN GENERAL.—Beginning **[Janu-**
11 **ary 1, 2020]**, as a condition of certifi-
12 cation or recertification under the system
13 described in subsection (d)(2)(B)(iv), each
14 covered entity described in subparagraph
15 (L) or (M) of subsection (a)(4) must—

16 “(I) in the case of a targeted
17 low-income patient of the covered enti-
18 ty to whom the covered entity fur-
19 nishes or dispenses a covered out-
20 patient drug that is subject to an
21 agreement under this section (directly
22 or under a contractual arrangement
23 pursuant to which a third party dis-
24 penses such drugs), charge a fee
25 amount to such patient for such drug
26 that is not more than the ceiling price

1 (as referred to under paragraph (1))
2 for such drug; and

3 “(II) provide, in accordance with
4 the regulations promulgated pursuant
5 to clause (iii), for public notification
6 of the fee amounts established for
7 purposes of this subparagraph and the
8 definition applied for purposes of this
9 subparagraph by the covered entity of
10 the term ‘low-income individual’ pur-
11 suant to clause (ii)(I).

12 “(ii) TARGETED LOW-INCOME PA-
13 TIENT.—For purposes of this subpara-
14 graph, the term ‘targeted low-income pa-
15 tient’ means, with respect to a covered en-
16 tity described in clause (i), a patient of the
17 covered entity who is—

18 “(I) a low-income individual, as
19 defined by the covered entity; and

20 “(II) not covered under minimum
21 essential coverage, as defined in sec-
22 tion 5000A(f) of the Internal Revenue
23 Code.

24 “(iii) REGULATIONS.—Not later than
25 180 days after the date of enactment of

1 this subparagraph, the Secretary shall pro-
2 mulgate final regulations through notice-
3 and-comment rulemaking, to implement
4 the requirements under this subparagraph.
5 Such regulations shall—

6 “(I) establish requirements for a
7 process for covered entities to follow
8 to provide public notifications de-
9 scribed in clause (i)(II); and

10 “(II) ensure the security and
11 protection of privileged or otherwise
12 confidential data from unauthorized
13 disclosure or re-disclosure.”.