

[DISCUSSION DRAFT]

115TH CONGRESS
2^D SESSION

H. R. _____

To amend the Public Health Service Act to define the term patient for purposes of 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 define the term patient for purposes of 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. DEFINING THE TERM PATIENT FOR PURPOSES OF**
6 **THE 340B DRUG DISCOUNT PROGRAM.**

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

1 “(3) PATIENT.—

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

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

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

22 “(iii) receives a drug that is ordered
23 or prescribed by the covered entity pro-
24 vider, including any renewals of existing

1 prescriptions, as a result of the service de-
2 scribed in clause (ii);

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

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

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

23 “(I) the covered entity has a pro-
24 vider-to-patient relationship with the
25 individual; and

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

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

10 “(i) the individual is an inmate of a
11 correctional facility;

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

21 “(iii) the health care service described
22 in clause (ii) of subparagraph (A) received
23 by the individual from the covered entity is
24 provided by a health care organization that
25 has only an affiliation arrangement with

1 the covered entity, even if the covered enti-
2 ty has access to the affiliated organiza-
3 tion's records; or

4 “(iv) the primary relationship between
5 the individual and the covered entity is one
6 of employment.

7 “(C) REGULATIONS.—Not later than 180
8 days after the date of enactment of the [____
9 Act], the Secretary shall promulgate final regu-
10 lations through notice-and-comment rulemaking
11 to define the term ‘patient’ with respect to cov-
12 ered entities described in subparagraph (L) or
13 (M) of subsection (a)(4) to reflect the require-
14 ments described in subparagraphs (A) and (B)
15 of this paragraph.

16 “(D) DEFINITION RELATING TO OTHER
17 COVERED ENTITIES.—In this section, the term
18 ‘patient’, with respect to a covered entity de-
19 scribed in subparagraphs (A) through (K), (N),
20 or (O) of subsection (a)(4), has the meaning
21 given such term in the October 24, 1996 HRSA
22 Final Notice Regarding Section 602 of the Vet-
23 erans Health Care Act of 1992 Patient and En-
24 tity Eligibility (61 Fed Reg. 55156).

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