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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “[___ Act]”.

SEC. 2. DEFINING THE TERM PATIENT FOR PURPOSES OF THE 340B DRUG DISCOUNT PROGRAM.

Section 340B(b) of the Public Health Service Act (42 U.S.C. 256b(b)) is amended by adding at the end the follow-
ing new paragraph:
“(3) PATIENT.—

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

“(i) receives a health care service at a covered entity or an outpatient hospital facility described in subsection (c)(3) which is registered for the drug discount program under this section and listed on the public Internet website of the Department of Health and Human Services relating to this section;

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

“(iii) receives a drug that is ordered or prescribed by the covered entity provider, including any renewals of existing
prescriptions, as a result of the service described in clause (ii);

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

“(v) is classified as an outpatient when the drug is ordered or prescribed, as demonstrated by how the service was reimbursed by the applicable payer, or, where the covered entity does not seek such reimbursement, how the service would have been reimbursed under title XVIII of the Social Security Act; and

“(vi) has a relationship with the covered entity such that the covered entity creates and maintains auditable health care records which demonstrate that—

“(I) the covered entity has a provider-to-patient relationship with the individual; and
“(II) responsibility for the individual’s health care service that resulted in the prescription or order for the drug described in clause (iii) is with the covered entity.

“(B) EXCLUSIONS.—For purposes of this section, an individual shall not be considered a patient of a covered entity described in subparagraph (L) or (M) of subsection (a)(4) if—

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

“(ii) the health care service described in clause (ii) of subparagraph (A) received by the individual from the covered entity consists only of the administration or infusion of a drug or drugs, or the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting, without a covered entity provider-to-patient encounter;

“(iii) the health care service described in clause (ii) of subparagraph (A) received by the individual from the covered entity is provided by a health care organization that has only an affiliation arrangement with
the covered entity, even if the covered entity has access to the affiliated organization’s records; or

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

“(C) Regulations.—Not later than 180 days after the date of enactment of the Act, the Secretary shall promulgate final regulations through notice-and-comment rulemaking to define the term ‘patient’ with respect to covered entities described in subparagraph (L) or (M) of subsection (a)(4) to reflect the requirements described in subparagraphs (A) and (B) of this paragraph.

“(D) Definition relating to other covered entities.—In this section, the term ‘patient’, with respect to a covered entity described in subparagraphs (A) through (K), (N), or (O) of subsection (a)(4), has the meaning given such term in the October 24, 1996 HRSA Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility (61 Fed Reg. 55156).
“(E) RECORD RETENTION.—A covered entity described in subparagraph (L) or (M) of subsection (a)(4) shall retain auditable health care records which demonstrate the existence of a patient relationship in accordance with this paragraph for each prescription or order for a rolling period of not less than five years, or longer to the extent required by State or Federal law.”.