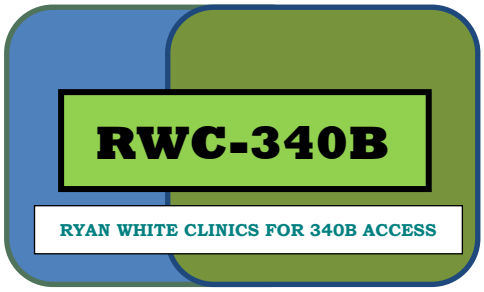

October 27, 2015

Captain Krista Pedley
Director, OPA, HRSA
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: Regulatory Information Number 0906-AB08
Comments on 340B Drug Pricing Program Omnibus Guidance

Captain Pedley,

Ryan White Clinics for 340B Access (RWC-340B) appreciates the opportunity to respond to the 340B Drug Pricing Program Omnibus Guidance (Proposed Guidance) published by the Health Resources and Services Administration (HRSA) in the August 28, 2015 edition of the Federal Register.[1] RWC-340B is a coalition of primary care providers that focus on the treatment of HIV and AIDS, receive funding under the Ryan White CARE Act, and participate in the federal 340B drug discount program (340B program) as "covered entities." The 340B program is critically important to Ryan White clinics (RWCs) and their patients, serving as a lifeline that allows the RWCs to offer a wide range of services and improve the quality of care delivered to people living with HIV/AIDS (PLWHA).

While we believe that HRSA's proposed 340B Drug Pricing Program Omnibus Guidance contains some helpful clarifications, it also would make a number of dramatic changes to the program that would significantly harm RWC safety net providers and the valuable work they do to protect the public health. As discussed below, key changes in the proposed Guidance are at odds with the goals of HRSA's own Ryan White program and the language and purposes of the 340B statute itself. In the area of the patient definition in particular, HRSA attempts to find a solution to a problem that does not exist, as the long-standing current definition has served the program well for over twenty years to help RWCs stretch scarce federal resources and provide more services to more patients.

The potential impact of the Proposed Guidance is magnified as pharmacy benefit managers (PBMs), private payers, and others are putting constant reimbursement pressure on RWCs and other covered entities. Rather than taking steps to preserve covered entities' access to 340B savings, the Proposed Guidance seems intent on shrinking the program and limit RWCs' access to it. The program is not broken for RWCs, and does not need to be fixed.

[1] 80 Fed. Reg. 52,300.

RWC-340B urges HRSA to retract the Proposed Guidance or modify it in the problematic areas to avoid destabilizing two critical programs: Ryan White and the 340B Drug Pricing Program. In particular, RWC-340B asks HRSA to:

- Ensure that any guidance implements the continuum of care model that is a major focus of the National HIV/AIDS Strategy;
- Retract the proposed patient definition until and unless it can be reformed to:
  - Interpret the word "patient" in a way that matches its plain meaning,
  - Reaffirm that the proper focus is on whether an individual is a patient of an RWC, and not whether a particular prescription fulfills a convoluted multi-part test, and
  - Reflect the full spectrum of core medical services that RWCs are tasked with providing under the law, including medical case management;
- Eliminate provisions that improperly shift the burden of preventing Medicaid managed care organization (MCO) duplicate discounts onto covered entities;
- Prevent discrimination against 340B covered entities in limited distribution networks; and
- Reform the audit process to provide appropriate due process safeguards.

After discussing the role of RWCs, the importance of the 340B program, and the role of the continuum of care model, this comment discusses these requests and others in greater detail.

I. BACKGROUND ON RWCS, THE 340B PROGRAM, AND THE CONTINUUM OF CARE MODEL

The Proposed Guidance must be understood against the backdrop of the National HIV/AIDS Strategy, the continuum of care model, and the success of RWCs in using the 340B program to fund the continuum of care model and achieve measurable results. Experts recognize that, to be successful in the fight against HIV/AIDS, persons living with the disease need more than medical care. RWCs often serve as a gateway to a broader range of services. The 340B program allows them to stretch their resources to support the full continuum of care that their patients need, from testing, to linkage to care, to medication adherence and viral suppression. Patients with a suppressed viral load are virtually non-infectious – a major step toward eradicating the disease.[2]

The continuum of care model, also called the treatment cascade model, is a critical feature of the National HIV/AIDS Strategy.[3] President Barack Obama issued Executive Order 13649 on July 15, 2013, which created the HIV Care Continuum Initiative and HIV Care Continuum Working Group to study how the continuum of care model can be employed and strengthened in all federal efforts to address HIV/AIDS.[4] The working group released a report containing recommendations, including some to be addressed by HRSA, for leveraging the continuum of care model in the federal fight against HIV/AIDS.[5] The recommendations include increasing the percentage of Ryan White program clients in continuous

[2] *See, e.g.,* Viral Load, *at* https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/viral-load/.
[3] The White House Office of National AIDS Policy, National HIV/AIDS Strategy for the United States (July 2010).
[4] Accelerating Improvements in HIV Prevention and Care in the United States Through the HIV Care Continuum Initiative, 78 Fed. Reg. 43,057 (July 18, 2013).
[5] The White House Office of National AIDS Policy, National HIV/AIDS Strategy – Improving Outcomes: Accelerating Progress Along the HIV Care Continuum (Dec. 2013).

care and supporting, implementing, and assessing models of care that more effectively deliver services along the care continuum.[6]

RWCs execute on the continuum of care model better than anyone, and the results are demonstrable. According to the latest data from the Centers for Disease Control (CDC), 40% of Americans living with HIV/AIDS are engaged in care, 37% are receiving antiretroviral therapy, and 30% have a suppressed viral load.[7] Among diagnosed PLWHA who receive care or case management services funded by the Ryan White program, 76% are retained in medical care, 80% are receiving antiretroviral therapy, and 70% have a suppressed viral load.[8]

These demonstrable results are due in large part to the 340B program, which allows RWCs to plug the gaps in the continuum of care that prevent diagnosed PLWHA from achieving viral suppression. Many of these services – including testing, linkage to care, retention in care, medication adherence, case management, and arranging for transportation and housing – are not reimbursed by any payer, though these are the services that most directly allow PLWHA to access and remain in care.

Only one conclusion is possible – **any change to the 340B program that reduces the number of patients who can receive 340B drugs or reduces the reimbursement received from payers for 340B drugs has a direct and negative impact on the fight against HIV/AIDS.**

RWC-340B urges HRSA to remember its commitments to the continuum of care model when reviewing comments on the Proposed Guidance. The mission of HRSA is "[t]o improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs." HRSA has played a critical role in elevating RWCs to the forefront of the fight against HIV/AIDS, but much of that progress would be threatened by the effects of the Proposed Guidance on RWCs.

II. THE PROPOSED PATIENT DEFINTION WOULD DO SIGNIFICANT HARM TO RWCS AND THEIR PATIENTS

Like other covered entities, RWCs benefit from the 340B program when discounted drugs purchased through the 340B program are dispensed or administered to individuals eligible to receive them. The 340B statute states that "a covered entity shall not resell or otherwise transfer a [340B] drug to a person who is not a patient of the entity."[9] This limitation is often called the prohibition against diversion.

A. The Word "Patient" Has a Well-Understood Meaning in the RWC Community That Is Not Reflected in the Proposed Guidance

In the absence of guidance, RWCs and other 340B program stakeholders would interpret the language of the statute in accordance with its plain, statutory meaning. A patient is "a person who

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[6] *Id.* at 8-9, 12.
[7] CDC, Vital Signs: HIV Diagnosis, Care, and Treatment among Persons Living with HIV – United States, 2011 (Nov. 28, 2014), *at* https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/viral-load/.
[8] Rupali Doshi *et al* (HRSA HAB), Continuum of HIV Care Among Ryan White HIV/AIDS Program Clients, United States, 2010, *at* http://hab.hrsa.gov/data/reports/continuumofcare/index.html.
[9] 42 U.S.C. § 256b(a)(5)(B).

receives medical care or treatment."[10] Guidance interpreting the word "patient" should describe the circumstances in which a person will be deemed to have received medical care or treatment. For nearly 20 years, HRSA has published the following definition, centered on the provider-patient care relation, which has been relied upon by covered entities in establishing and growing their programs:

> An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
>
> > 1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
> >
> > 2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
> >
> > 3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
>
> An individual will not be considered a ''patient'' of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
>
> An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a ''patient'' of the covered entity for purposes of this definition if so registered as eligible by the State program.[11]

Paraphrased, an individual is a patient of a covered entity if the covered entity has an ongoing relationship with an individual who has received health care services from a health care professional affiliated with the covered entity. The existing patient definition is consistent with the plain meaning of the word "patient" using objective standards – the maintenance of records and the provision of health care services. The Proposed Guidance does not describe any fault with the statutory meaning or the 1996 guidelines.

The Proposed Guidance contains a six-part test that shifts the focus away from the relationship between an individual and his or her care provider. Instead, the proposed tests would examine individual prescriptions and orders, largely reducing the provider-patient relationship to a transaction. The patient definition proposed by HRSA is the following:

> (a) Criteria. Section 340B(a)(5)(B) of the PHSA prohibits covered entities from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity. HHS interprets

[10] Merriam-Webster, *at* http://www.merriam-webster.com/dictionary/patient.
[11] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156, 55,157-58 (Oct. 24, 1996).

this section to include all patients that meet all of the following criteria on a prescription-by-prescription or order-by-order basis:

> (1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B database;
>
> (2) The individual receives a 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 may bill for services on behalf of the provider.
>
> (3) An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.
>
> (4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract;
>
> (5) The individual is classified as an outpatient when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and
>
> (6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.[12]

While each of the six proposed prongs of the patient definition describes "the individual," the test proposed actually determines whether a given ***prescription or order*** fulfills the six criteria. HRSA has not proposed a patient definition, but rather an eligible prescription test. Such a test does not determine whether a "***person"*** receiving a 340B drug is someone ***"who is not a patient of the entity***."[13] A prescription-based test cannot be reconciled with the language or intent of the statute and is legally invalid.

RWC-340B urges HRSA to maintain the 1996 patient definition guidelines, which have worked well for nearly twenty years. If it finds fault in them, HRSA should publish a proposed patient definition that describes any faults in the current guidance and explains how any proposed changes fit the concept of a "patient."

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[12] Proposed Guidance at 52,319. The use of the word "provider" to describe an individual health care professional is confusing. The word "provider" has different meanings in different contexts (Medicare, Medicaid, Ryan White, and general lay definition). Throughout this comment, "health care professional" is used in lieu of "provider."

[13] 42 U.S.C. § 256b(a)(5)(B).

B. Every Prescription Filled for an Individual Under the Care of an RWC Should Continue to Be 340B Eligible

The distinction between an eligible patient and an eligible prescription is not supported by the 340B statute, which only prohibits the dispensing or administration of drugs to a person who is not a patient of a covered entity. A person's status with respect to his or her health care provider cannot change from moment to moment and back again depending on which prescription is presented. The proposed patient definition would create just that result.

Each relevant part of the Ryan White statute describes the types of core medical services that a funded entity can provide. The core medical services include:

- Outpatient and ambulatory health services
- AIDS Drug Assistance Program treatments
- AIDS pharmaceutical assistance
- Oral health care
- Early intervention services
- Health insurance premium and cost sharing assistance for low-income individuals
- Home health care
- Medical nutrition therapy
- Hospice services
- Home and community-based health services
- Mental health services
- Substance abuse outpatient care
- Medical case management, including treatment adherence services[14]

Under the common sense and dictionary definition of a patient, at a minimum, an individual would be a patient of an RWC if he or she received any of the core medical services from the RWC. Such a person would have "receive[d] medical care or treatment." Each of these services is within the scope of an RWC's grant within the meaning of the fourth prong of the proposed new patient definition unless the grant dictates otherwise, and is a health care service within the meaning of the first prong of the new patient definition. Yet, under the proposed test, a patient who receives one or more of these medical services from an RWC could nevertheless not be its "patient" for 340B program purposes. This is a significant restrictive change from the current definition, and is an unauthorized alteration of the duties and obligations of providers in the program.

1. Prong One – Site of Service

The focus on registered child sites in the first prong is unnecessarily restrictive. HIV/AIDS is a difficult disease to treat, and providers often must venture wherever the patient is located. That might be at a home, on the streets, or in a custodial facility. Individuals treated where they are residing are no less patients than individuals treated within a clinic.

Many RWCs provide services in non-traditional settings. The proper treatment of HIV/AIDS requires patients to stay in care, which means care must be provided through as many access points as

[14] 42 U.S.C. §§ 300ff-14(c)(3)(A-M); 300ff-22(b)(3)(A-M); 300ff-51(c)(3)(A-M).

possible, whether the care must be brought to the patient or the patient is brought to the care. Some may use mobile units. Some may share clinic space with other providers and operate part-time clinics. Some might operate clinics in non-medical space, like community centers. HRSA should recognize these non-traditional sites and either permit them to be registered or clarify that 340B drugs may be used to fill prescriptions written in them. The Electronic Handbook used by HRSA to verify child site registrations might not be an appropriate tool.[15] If HRSA does not retract the patient definition, it should clarify that services provided ***through*** a registered site can qualify under prong one.

2. Prongs Two and Three – Health Care Service Related to Drug

Under the second and third prongs of the proposed patient definition, however, the covered entity could only use its 340B drugs for its patient if the prescription itself was written by a prescriber employed by or in an independent contractor relationship with the covered entity.[16] This is a major restrictive change to HRSA's current guidance, and one that is fundamentally at odds with the Ryan White care model. An RWC often acts as the medical home for its patients, serving as the primary care provider, but also arranging for an array of specialty and other ancillary provider services needed to keep HIV-positive patients healthy. HIV is a complex disease frequently accompanied by many comorbidities. As a condition of participation in the Ryan White program, RWCs are required to form linkage relations with specialty and other ancillary providers, and to refer patients to needed specialty services like urology, cardiology, pulmonology (to name a few) and follow that care, ensuring that the patient is treated as a whole. Under the proposed guidance, RWCs would no longer be able to use 340B drugs when filling prescriptions resulting from their patients' referral visits, even though neither the statute nor current guidance imposes such a limitation. Depriving RWCs of the benefit of the 340B program in the referral context harms the purposes of the Ryan White program, which is to promote an integrated, coordinated care model.

Similarly, the Proposed Guidance would destroy the ability of an RWC to avail itself of 340B benefits when it receives a Ryan White grant for medical case management (MCM) – a core medical service under the Ryan White CARE Act.[17] MCM involves the coordination of healthcare services for the patient by a healthcare professional. Although MCM is not paid for by private insurance, it is essential to the Ryan White care model, which has proven result in better patient healthcare outcomes. But under HRSA's Proposed Guidance, because the MCM provider doesn't generally write a prescription, but rather coordinates care, a Ryan White MCM grantee would be ineligible to fill its patient's prescription using 340B, even though its grant makes it an eligible covered entity under the statute. This interpretation of the word "patient" is clearly at odds with the Ryan White statutory framework.

HRSA recognizes the importance of coordinating care for PLWHA, much as Congress did when it named MCM a core medical service. The April 2014 Guide for HIV/AIDS Clinical Care published by HRSA's HIV/AIDS Bureau (HAB) contains entire chapters dedicated to systemic issues that affect PLWHA, including neurologic issues and pulmonary issues, and comorbidities, coinfections, and complications,

[15] The Electronic Handbook is actually a HRSA-maintained database of grantee information rather than a handbook in the traditional sense.
[16] RWC-340B is not certain which professionals would meet the "independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider" description. The test could mean too many different things. HRSA should rephrase that prong and re-propose it for public comment.
[17] 42 U.S.C. §§ 300ff-14(c)(3)(M); 300ff-22(a)(3)(M); 300ff-51(c)(3)(M).

including hepatitis C virus and renal disease.[18] HIV/AIDS is a complicated disease, and its treatment requires the coordination of multiple specialties to keep the patient as a whole healthy. The RWC is the hub of care for PLWHA, and should be able to use 340B drugs to fill all prescriptions written for its patients, including those written for its MCM patients.

The second and third prongs also effectively would eliminate a type of eligible covered entity – the pharmacy grantee. HRSA should recognize that pharmacies can receive Ryan White program funding and thus can qualify as a covered entity. In many states, including California, pharmacists are recognized as clinical health care providers, and who therefore can have their own patients who should be eligible to receive 340B drugs.[19] Pharmacists provide two core medical services – outpatient and ambulatory health services and AIDS pharmaceutical assistance. The 340B statute indicates that entities receiving "assistance" or a "grant" through the Ryan White program may purchase covered outpatient drugs at or below the 340B ceiling price.[20] The statute does not distinguish between types of providers, and instead uses the broader term "entity." As pharmacists are increasingly taking clinical responsibility for treatments, they are becoming more and more responsible for the drug therapies of their patients. HRSA should recognize that pharmacies can be eligible covered entities and that pharmacists can have clinical responsibility for patients.

Congress did not include any limitation on the types of prescriptions a covered entity may fill on behalf of its patients. The proposed guidance reads a limitation into the word "patient" that is neither apparent nor logical. If HRSA does not retract and re-propose the patient definition guidance, the second and third prongs should be eliminated, at least as they would apply to RWCs.

3. Prong Four – Scope of Grant

Likewise, the fourth prong, which requires the individual to receive a service that is consistent with the covered entity's scope of grant, could cause confusion when applied on a prescription-by-prescription basis. PLWHA often select an RWC to be their primary care medical home, and RWCs generate individual prescriptions that are not always directly related to the HIV disease itself, but are related to the overall health of the patient. As noted above, HRSA has recognized the importance of treating these conditions. The overall health of a patient affects the patient's ability to stay adherent to his or her treatment and keep the virus under control. For example, an individual might present to an RWC with a sinus infection. His or her health care professional might write a prescription for the individual's antiretroviral therapy and for antibiotics to treat the infection. Both prescriptions are within the scope of a typical RWC grant, because both are issued for the treatment of a PWLHA. If the prescription for antibiotics were examined outside the context of the patient's overall treatment regimen, one might question whether the treatment is consistent with the RWC's grant. It is unclear whether HRSA intends for the exact same individual with the exact same condition to be the RWC's patient for one prescription but not for the other. Some conditions are clearly related to HIV/AIDS, like thrush, or are high-incidence co-morbidities, like hepatitis C. HRSA should clarify that all of the above situations would be "consistent with" an RWC's scope of grant if the individual receiving the treatment is HIV-positive or otherwise eligible under the grant.

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[18] HRSA, HAB, Guide for HIV/AIDS Clinical Care (Apr. 2014), *at* http://hab.hrsa.gov/deliverhivaidscare/2014guide.pdf.
[19] CAL. BUS. & PROF. CODE §§ 4050 (pharmacy as profession); 4052.6 (powers of advanced practice pharmacists)
[20] 42 U.S.C. § 256b(a)(4)(D), (J).

Congress has not given any indication that it intended for RWCs to use the scope of their grants and sub-grants to assess 340B eligibility on a prescription by prescription basis. Such an approach is inconsistent with a program designed to help safety net providers stretch scarce resources as far as possible. HRSA, which is the agency that administers the 340B program through its Office of Pharmacy Affairs and the Ryan White program through HAB, should be striving to coordinate and implement strategies using the 340B program that are designed to improve the health of patients while also maximizing the program's benefit for its grantees. With articles about rising drug prices filling the news, the Proposed Guidance seems intent on shrinking a low-cost drug benefit that operates ***without any subsidization from the government or taxpayers***. HRSA should withdraw the patient definition guidance and re-propose guidance that focuses on the provider-patient relationship.

C. The Proposed Patient Definition Undermines the Continuum of Care Model

As discussed above, the continuum of care model is the best recognized approach to identifying PLWHA and treating them. HRSA has noted that RWCs achieve significant results when treating PLWHA with the continuum of care model in mind. The proposed patient definition, though, would ***create large gaps*** in the continuum rather than ***close them*** as the President directed. HRSA should consider how it can ensure that RWCs can continue to employ the continuum of care model. Any patient definition applicable to the grantee covered entities must be broad enough to include any patient that the grantee will serve in a manner that is consistent with the scope of its grant and the underlying legal authority for the grant.

III. THE PROPOSED GUIDANCE IMPROPERLY PLACES THE BURDEN ON COVERED ENTITIES TO PREVENT MEDICAID MANAGED CARE DUPLICATE DISCOUNTS IN CLINIC AND CONTRACT PHARMACY SETTINGS

The Proposed Guidance makes two significant changes with regard to how 340B drugs are billed to Medicaid that would shift the burden to prevent duplicate discounts caused by Medicaid managed care rebates onto RWCs. The Proposed Guidance implies that the 340B statutory duplicate discount prohibition applies to drugs billed to an MCO, and would improperly expand the Medicaid Exclusion File (MEF) to include elections related to Medicaid MCOs.[21] The Proposed Guidance would also create a presumption that contract pharmacies will not bill MCOs for claims involving drugs purchased through the 340B program. RWC-340B feels very strongly that both changes contradict very clear legislative language, are outside HRSA's authority, and must be rescinded.

A. HRSA Does Not Have the Authority to Regulate MCO Billing

Grantee covered entities participating in the 340B program are subject to two restrictions – they may not resell or otherwise transfer 340B drugs to a person other than a patient and they may not bill Medicaid for drugs subject to a Medicaid drug rebate if doing so would subject a manufacturer to providing the 340B discount and a Medicaid drug rebate on the same drug. The latter provision is known as the duplicate discount prohibition. Section 2501(c) of the Affordable Care Act expanded the universe of drugs that were eligible for a Medicaid rebate to include those that are covered by an MCO, unless the drug was purchased by a 340B covered entity.[22] The duplicate discount prohibition was not

[21] Throughout this comment, the term MCO only refers to Medicaid MCOs.
[22] Patient Protection and Affordable Care Act, Pub. L. 111-148, §2501(c), 124 Stat. 119, 308-09 (2010), codified at 42 U.S.C. § 1396r-8(b)(1)(A), (j)(1).

altered. Because 340B drugs billed to MCOs are not rebatable, covered entities may choose whether or not to use 340B drugs when billing an MCO in the same manner they choose whether or not to use 340B drugs when billing any other private payer.[23] Since the duplicate discount prohibition is not triggered by MCO billing, HRSA cannot require covered entities to declare their MCO billing preferences.

The 340B statute states that a covered entity "shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under [the 340B statute] **if the drug is subject to the payment of a rebate** under [the Medicaid drug rebate statute]."[24] Section 2501(c) of the Affordable Care Act added language to the Medicaid drug rebate statute that permitted states to seek rebates on drugs covered by an MCO, but with one important caveat: "[c]overed outpatient drugs **are not subject to the requirements of this section** [i.e., not subject to a rebate] if such drugs are … (A) dispensed by health maintenance organizations including Medicaid managed care organizations … and (B) subject to discounts under section 340B of the Public Health Service Act."[25] If a drug bought by a 340B covered entity is paid for by an MCO, the drug is not subject to the payment of a rebate, and therefore not subject to the 340B statute's duplicate discount prohibition.

In case there was any doubt that Congress intended to exclude 340B drugs from the MCO-covered drugs for which a state could seek a Medicaid rebate, the Affordable Care Act also required states to require their MCOs to cull 340B utilization data from prescription drug data reported to the state.[26] The Centers for Medicare and Medicaid Services (CMS) recently proposed regulations with the force of law to implement that provision, stating in relevant part that:

> Section 340B of the PHS Act prohibits covered entities from billing Medicaid for covered outpatient drugs purchased at discounted 340B prices **if the drugs are subject to a Medicaid rebate**. Section 1903(m)(2)(A)(xiii)(III) of the Act provides that **the reporting standard for MCOs does not include information about drugs that are not subject to the rebates under section 1927 of the Act.** As we propose in paragraph (s)(2), that MCOs, PIHPs, and PAHPs must report utilization data, **it would follow that covered outpatient drugs purchased at 340B prices need to be excluded from the utilization reports** to the state to avoid duplicate discounts for rebates paid by manufacturers. To ensure that drug manufacturers will not be billed for rebates for drugs purchased and dispensed under the 340B Drug Pricing Program, MCOs, PIHPs, or PAHPs must have mechanisms in place to identify these drugs and exclude the reporting of this utilization data to the state as to avoid the manufacturer from incurring a duplicate discount on these products.[27]

The CMS regulatory proposal conflicts with the interpretation implied by HRSA in the Proposed Guidance. Both are agencies within the Department of Health and Human Services. The interpretation

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[23] RWC-340B appreciates that the Proposed Guidance states that a covered entity may choose whether or not to use 340B drugs when billing an MCO.

[24] 42 U.S.C. § 256(a)(5)(A) (emphasis added).

[25] 42 U.S.C. § 1396r-8(j)(1) (emphasis added).

[26] Patient Protection and Affordable Care Act, Pub. L. 111-148, § 2501(c), 124 Stat. 119, 308 (2010), codified at 42 U.S.C. § 1396b(m)(2)(A)(xiii).

[27] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability, 80 Fed. Reg. 31,098, 31,115 (June 1, 2015). PIHP and PAHP refer to Prepaid Inpatient Health Plans and Prepaid Ambulatory Health Plans respectively.

proposed as part of regulatory rulemaking should control, even if there were no compelling statutory reasons that require it.

The Proposed Guidance misstates a critical point when it says that the 340B statute "prohibits duplicate discounts whereby a State obtains a rebate on a drug provided to a Medicaid fee-for-service ***or managed care organization patient*** when the same drug was discounted under the 340B Program."[28] The 340B statute does not prohibit duplicate discounts related to MCO enrollees. The Medicaid drug rebate statute does, and it very clearly preserves a covered entity's right to choose to use 340B drugs when billing the MCO. The proposed changes are impermissible.

B. The MEF Is Not an Appropriate Tool to Prevent MCO Duplicate Discounts

The Proposed Guidance would expand the MEF to include information regarding how covered entities bill MCOs. The MEF is not an appropriate tool for preventing MCO duplicate discounts. Because HRSA lacks the authority to require covered entities to report MCO billing decisions in the MEF, any information available to the public would be misleading and incomplete. Manufacturers, MCOs, and state Medicaid agencies might reach dangerous conclusions regarding the completeness of the information, actually increasing the duplicate discount risk to manufacturers.

The MEF would also become incredibly complicated if the Proposed Guidance were put into effect. There were 275 MCOs in the United States as of March 2015.[29] There are over 33,000 registered sites as of October 2015. The MEF would have to accommodate thousands of combinations. California alone has 22 MCOs and 3,035 registered sites.[30] Each site could conceivably have 4,194,304 (2 to the 22nd power) variations on which MCOs they choose to bill using 340B drugs and which they "carve out." In addition, the MEF would need to be able to accommodate drug-by-drug decisions. Most importantly, changes would have to be nearly instantaneous and the MEF would have to be able to handle a massive increase in volume.

The only parties that can prevent duplicate discounts on drugs covered by MCOs are the MCOs themselves in coordination with the relevant state Medicaid agencies. The relationship between each provider and an MCO is a private relationship governed by a private contract. Many possible solutions are being examined and tested across the country, including retrospective claims-based approaches and private-public partnerships that would feature a nationwide duplicate discount clearinghouse. In the absence of federal authority to intervene, though, the stakeholders involved and the states should be permitted to find the best solution.

C. The Proposed Presumption Against MCO Billing in Contract Pharmacies Is Unsupported by the 340B Statute and an Unauthorized Intrusion on Private Contracts

The Proposed Guidance creates a presumption that a contract pharmacy will not bill a covered entity's 340B drugs to MCOs. As explained in Section III.A, HRSA lacks the authority to regulate MCO billing. HRSA must remove the presumption from its final guidance.

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[28] Proposed Guidance at 52,319.
[29] Kaiser Family Foundation, Total Medicaid MCOs, *at* http://kff.org/other/state-indicator/total-medicaid-mcos/.
[30] *Id.*

Even if the presumption were permissible, it would have unintended disastrous consequences for RWCs, and on that basis should be retracted. Many RWCs lack pharmacies of their own, and rely upon contract pharmacies to access 340B program benefits. Many RWCs treat the indigent and underinsured, and MCOs make up a significant portion of the payer mix. HRSA proposes that an RWC that uses a contract pharmacy and wishes to use 340B for its Medicaid MCO patients may not do so until it has in place a written agreement, approved by HRSA, with its contract pharmacy and the state Medicaid agency or MCO that describes a system to prevent duplicate discounts. Such a model is not realistic. RWCs would rarely have the contracting leverage to reach the type of written agreement described in the Proposed Guidance. In fact, the MCO would hold undue bargaining power due to the knowledge that the RWC must reach an agreement. Entering into an agreement with a state Medicaid agency could take years, during which time the covered entity would be foregoing critical 340B program benefits. Private payers and PBMs are already forcing covered entities to give up their 340B savings or share them, and this mandated negotiation would make that predation even easier and more prevalent. Rather than seeking to restrict RWCs' ability to use 340B drugs for their Medicaid MCO patients, HRSA should be taking steps to stop commercial entities from usurping 340B savings.

If the presumption became part of the fabric of the 340B program, the RWCs would be forced to choose between excluding MCOs from their contract pharmacy arrangements or accepting uneven bargaining terms. This would have a huge, even devastating, impact on some RWCs that rely on the resources generated from billing Medicaid managed care plans.

IV. THE PROPOSED GUIDANCE DOES NOT GO FAR ENOUGH TO PREVENT DISCRIMINATION AGAINST 340B COVERED ENTITIES PURCHASING SPECIALTY DRUGS

RWC-340B supports the proposed processes that manufacturers will follow when offering drugs through a limited distribution plan. The language in the Proposed Guidelines should be strengthened to clarify that manufacturers ***must*** submit for HRSA review and approval a limited distribution plan as soon as the need for one is reasonably apparent. Covered entities have a statutory right to purchase covered outpatient drugs at or below the 340B ceiling price, and manufacturers cannot circumvent their responsibilities under the statute and their Pharmaceutical Pricing Agreements (PPAs) by favoring non-340B purchasers over 340B purchasers. This issue is of critical importance to RWCs, as novel and useful therapies are increasingly placed into limited distribution networks and subject to other distribution related barriers.

With regard to specialty drugs, though, the Proposed Guidance does not address an important and increasingly common form of discrimination against RWCs and their contract pharmacies. The Proposed Guidance notes that certain drugs are approved by the Food and Drug Administration (FDA) subject to the manufacturer's compliance with a Risk Evaluation and Mitigation Strategy (REMS), and states that "[a]s a result, certain manufacturers may use a restricted network of certified specialty pharmacies, which do not fall under the terms of a contract pharmacy agreement or wholesaler contract for the distribution of drugs to a covered entity."[31] Under the Proposed Guidance, manufacturers "may develop a limited distribution plan when a covered outpatient drug must be handed in a special manner."[32]

[31] Proposed Guidance at 52,312.
[32] *Id.*

RWCs are increasingly encountering situations in which a manufacturer will refuse to ship a specialty drug to a contract pharmacy when the drug is purchased on the RWC's account, though it will ship the same drug to the pharmacy when the drug is purchased on the pharmacy's account. Since the contract pharmacy will have physical custody of the drugs (and in a replenishment model, will also have title to the drugs once received) the distinction between drugs purchased on the pharmacy's account and those purchased on the covered entity's account is inconsequential. HRSA should clarify that if all patient safety concerns are adequately addressed, the manufacturer must offer drugs at 340B pricing to any covered entity if it offers the drugs at non-340B pricing in the same circumstances.

HRSA should also clarify that a manufacturer may not use a 340B-specific distribution mechanism. For example, if a drug is offered in a limited distribution network for 340B accounts, it must also be offered in a limited distribution network for non-340B accounts. If a drug is offered without restrictions on non-340B accounts, it must be offered without restrictions on 340B accounts.

V. RWC-340B SUPPORTS THE BALANCE STRUCK BETWEEN RWCS AND AIDS DRUG ASSISTANCE PROGRAMS

RWC-340B supports the clarification in the Proposed Guidance that an AIDS Drug Assistance Program (ADAP) cannot seek a 340B rebate for a drug that was already purchased by a 340B covered entity.[33] Though there is no duplicate discount prohibition applicable to the ADAP rebates, a single covered outpatient drug can only logically be purchased by one end user. If a non-ADAP covered entity has purchased a drug for a price at or below the 340B ceiling price, the manufacturer has fulfilled its obligations.

RWC-340B urges HRSA – as the steward of both the RWCs and the ADAPs – to encourage RWCs (and other covered entities that treat PLWHA) and ADAPs to work together to identify ways in which both types of covered entities can access the benefits of 340B program participation. HRSA should discourage ADAPs that serve as payers from offering unreasonably low reimbursement rates to their RWC partners. Below-market reimbursement rates can be designed to approximate the actual acquisition cost of the drug purchased at or below the 340B ceiling price. As a result, the RWC might decide not to use 340B drugs to treat ADAP enrollees. HRSA should encourage ADAPs and RWCs to enter into shared savings arrangements that allow both parties to benefit from the lower cost drugs.

In the event that an ADAP and non-ADAP covered entity determine that the non-ADAP covered entity will not use 340B drugs so that the ADAP may seek rebates, HRSA should encourage ADAPs to communicate to other covered entities once the ADAP can no longer make a "qualified payment" for a drug. That might occur because the annual out-of-pocket limits of the insurance policy (if any) have been reached and there is no cost-sharing to be paid, or because the individual obtains insurance from another source. At that point, the ADAP should inform other covered entities that they should use 340B drugs when treating the individual.

VI. HRSA SHOULD REFORM THE COVERED ENTITY AUDIT AND HEARING PROCESS

The covered entity audits performed by HRSA to date have not employed sufficient due process and fairness safeguards. At a minimum, HRSA should:

[33] *Id.* at 52,322.

1. Release its audit protocol so that covered entities can perform meaningful self-audits and have assurances that HRSA is conducting audits uniformly and fairly, and conform the audit protocol to the most recent edition of the Government Auditing Standards published by the Government Accountability Office;[34]

2. Ensure that all audited covered entities have an exit interview with the audit team that allows for a dialogue regarding potential findings, provide the covered entity with access and an opportunity to comment on the auditors' draft report prior to submission to HRSA, and incorporate the auditors' report to HRSA in audit findings provided to the covered entity;

3. Reinstate the preliminary audit report, or otherwise create a second layer of administrative review that would permit covered entity and HRSA to discuss issues;

4. Allow covered entities at least ninety days to respond to any adverse audit findings or to submit a corrective action plan;

5. Clearly explain the covered entity's appeal rights and whether the audit report constitutes a final agency action; and

6. Arrange for live hearings on disputed audit findings.

On the last point, the 340B statute requires a hearing before HRSA may order repayment.[35] HRSA asserts that a written hearing is sufficient. Covered entities that allege a dispute in the material facts raised in an audit report should be permitted to attend an in-person or live hearing on the issues. A written hearing cannot fulfill the statutory requirement in that situation.

In addition, a live hearing is required under the Constitution, if not also by the 340B statute, when HRSA is seeking to deprive a covered entity of participation in the program or a significant financial repayment. When determining whether the constitutional guarantee of due process requires an agency to hold a hearing, the agency should consider "the private interest that will be affected by the official action," "the risk of erroneous deprivation of such interest through the procedures used," "the probable value, if any, of any additional or substitute procedural safeguards," and "the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail."[36] The factors must be considered against the backdrop of due process generally, which "negates any concept of inflexible procedures universally applicable to every imaginable situation."[37] When program participation or a major financial impact is contemplated, an RWC's survival may well be at stake, and thus these factors require a live evidentiary hearing.

VII. RWC-340B URGES ADDITIONAL CLARIFICATIONS AND GUIDANCE

The Proposed Guidance addresses many topics and encompasses nearly every aspect of 340B program compliance. HRSA should clarify some of its proposals. Additionally, HRSA should add

[34] Government Accountability Office, GOVERNMENT AUDITING STANDARDS, GAO-12-331G (2011 rev.).
[35] 42 U.S.C. § 256b(a)(5)(C), (D).
[36] *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).
[37] *Cafeteria & Rest. Workers Union v. McElroy*, 367 U.S. 886, 895 (1961).

elements when it finalizes the guidance. With respect to all of the changes proposed, RWC-340B asks that HRSA provide a clear timeline as to when the final guidance will go into effect and when HRSA's interpretations will be applied and enforced through audits.

A. HRSA Should Clarify That Only Material Program Violations Must Be Disclosed

The Proposed Guidance would require or expect covered entities to report instances of diversion, duplicate discounts, and other compliance issues to HRSA. RWC-340B believes that such disclosures should be subject to a materiality threshold, in line with other federal programs. Many errors (i.e., "fat finger" errors) can be corrected quickly and easily, and the time needed to prepare and submit a self-disclosure to HRSA would be inefficient for both the covered entity and the agency.

B. The Requirement That Covered Entities Must Request the 340B Discount at the Time of Purchase Is Arbitrary and Unsupported by the Statute

The 340B statute requires participating drug manufacturers to sell covered outpatient drugs at a price that does not exceed the 340B ceiling price. In the Proposed Guidance, HRSA states that "[c]overed entities are responsible for requesting 340B pricing at the time of the original purchase."[38] There is no basis for such a requirement. The statute gives covered entities a right to the discounted price and does not place any restrictions on that right. HRSA should remove any language that suggests otherwise, as such language could inadvertently cause manufacturers to set arbitrarily short time limits for honoring legitimate credit-and-rebill requests. Likewise, HRSA should remove any language suggesting that credit-and-rebills initiated to correct any errors in purchasing must be initiated within some time frame.

C. HRSA Should Permit Covered Entities More Time to Offer Repayment

HRSA should also allow up to 180 days for covered entities to work with manufacturers regarding repayments after identifying a diversion or duplicate discount violation. HRSA should clarify that the 180-day window is the time period during which the covered entity should notify the manufacturer and offer repayment. The repayment might not be completed during the 180-day window if the manufacturer is slow to respond or the parties engage in a discussion. If a manufacturer does not respond to a written repayment offer tendered to the person and address listed in the HRSA public database within 45 days, HRSA should clarify that the covered entity has no obligation to make a second offer.

D. HRSA Should Update the MEF More Frequently Than Quarterly

The MEF would continue to be a significant tool for fee-for-service Medicaid duplicate discount prevention under the proposed guidance. HRSA should endeavor to ensure that the file can be updated more frequently than quarterly. Changes in law or billing practices are difficult enough to coordinate without trying to also hit a hard calendar deadline.

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[38] Proposed Guidance at 52,308.

RWC-340B appreciates this opportunity to comment on the 340B Drug Pricing Program Omnibus Guidance proposed by HRSA. The coalition recognizes the difficult task faced by HRSA in crafting guidance that can be applied fairly to a diverse set of health care providers. The Proposed Guidance includes a number of helpful clarifications that will assist RWCs as the program moves into the future. In many key areas, however, the proposals are contrary to the statute, frustrate the program's purpose, and/or exceed HRSA's authority. RWC-340B asks HRSA to:

- Ensure that any guidance implements the continuum of care model that is a major focus of the National HIV/AIDS Strategy;
- Retract the proposed patient definition until and unless it can be reformed;
- Eliminate provisions that improperly shift the burden of preventing MCO duplicate discounts onto covered entities;
- Prevent discrimination against 340B covered entities in limited distribution networks; and
- Reform the audit process to provide appropriate due process safeguards.

When preparing final guidance, RWC-340B asks HRSA to remain mindful of RWCs and ensure that any proposed changes would not negatively impact the mission of RWCs to treat PLWHA and incorporate the continuum of care model of the National HIV/AIDS Strategy. HRSA and RWCs have made great progress in the fight against HIV/AIDS, but that progress is fragile and highly dependent on the continued viability and health of the 340B program.

Sincerely,

MEMBERS OF RWC-340B

AIDS Care Group (PA)
AIDS Healthcare Foundation (Throughout US)
Cares Community Health (CA)
Evergreen Health Services (NY)
Midway Specialty Care Center (FL)
Southwest Care Center (NM)
Thrive Alabama (AL)
Trillium Health (NY)
Whole Family Health Center (FL)

ALLIES OF RWC-340B

ActionAIDS (PA)
African American Health Alliance (MD)
AIDS Alabama (AL)
AIDS Arms (TX)
AIDS Resource Center of Wisconsin (WI)
Big Country AIDS Resources (TX)
Boulder Community Health (CO)
Colorado Organizations Responding to AIDS (CO)

Empath Health (FL)
Family and Medical Counseling Service (DC)
Foothill AIDS Project (CA)
Health Services of North Texas (TX)
Legacy Community Health (TX)
McGregor Clinic (FL)
Northern Nevada HOPES (NV)
Positive Health Clinic of the Allegheny Health Network (PA)
Positive Women's Network – USA (CA)
Prevention Point Philadelphia (PA)
Project Inform (CA)
Racial and Ethnic Health Disparities Coalition (MD)
San Francisco Community Clinic Consortium (CA)
Southern HIV/AIDS Strategy Initiative (NC)
The Access Network (SC)
THRIVE! The Persons Living With HIV/AIDS Initiative of Colorado (CO)