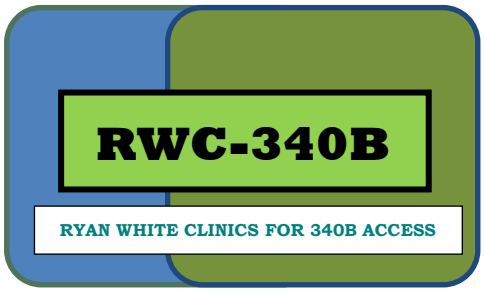

February 22, 2016

VIA EMAIL

Dr. Michael Ybarra
Senior Director of Alliance Development
Pharmaceutical Research and Manufacturers of America
950 F Street NW, Suite 300
Washington, D.C. 20004

Re: Continued Dialogue Regarding 340B Program Mega-Guidance

Dear Dr. Ybarra,

Ryan White Clinics for 340B Access (RWC-340B) appreciated meeting with you and your colleagues at the offices of the Pharmaceutical Research and Manufacturers of America (PhRMA) on November 11, 2015. With this letter we hope to outline our views, noting where we are in disagreement and where we are not, so that we can continue the valuable dialogue between our organizations regarding the federal 340B drug discount program (340B program).

Though our organizations agree on several points regarding the 340B program, we are concerned that several positions in PhRMA's public comment letter (Comment Letter) on the Proposed 340B Omnibus Guidance (Proposed Guidance) would have a significantly negative impact on our members if the Health Resources and Services Administration (HRSA) chose to implement them. We also are concerned that PhRMA's vision for the 340B program as advanced in advocacy efforts and the media frequently takes the form of pleas to shrink the 340B program or limit its current uses. On that point, our organizations appear to be in direct conflict. Our vision is to bolster and advance the 340B program while we see PhRMA's advocacy efforts taking the opposite track. We hope that this continuing dialogue can help us bring our organizations together toward a shared vision of a strong future for the 340B program.

Intent of the 340B Program

RWC-340B is appreciative of PhRMA's statement of support for the role of grantees, like Ryan White Clinics (RWCs), in our national healthcare safety net. RWCs work hard to serve their patients and rely heavily on the discounts available through the 340B program to provide "wrap-around" support services that are rarely reimbursed by any public or private payer. RWCs use the 340B program to test routinely for HIV, link HIV-positive individuals to care, retain them in care, and ensure that they adhere to a medication regimen. RWCs also use 340B program discounts to extend drug benefits to patients

who cannot afford their medications and to ensure that patients seek all forms of medical coverage for which they are eligible.

RWCs produce demonstrably better health outcomes for their patients by providing these services. According to an October 29, 2014 statement by Sylvia Burwell, Secretary of the United States Department of Health and Human Services, "[i]n 2012, 82 percent of [Ryan White] Program clients were retained in care and more than 75 percent of clients were virally suppressed."[1] Across all individuals living with HIV in the United States, only 30% were virally suppressed according to 2011 data from the Centers for Disease Control.[2] The RWCs are making great strides in the fight against HIV/AIDS.

Recognizing the value of RWCs and other grantees participating in the 340B program is, however, different from recognizing the value of the program itself. Towards that end, we are alarmed that the Comment Letter portrays a more limited view of the intent of the 340B program. The Comment Letter states that the program was enacted to make prescription drugs more accessible to uninsured or vulnerable patients.[3] It stops short of perpetuating PhRMA's prior position that only uninsured patients should be eligible to receive drugs purchased through the 340B program.[4] While RWC-340B appreciates that PhRMA has relaxed that view, we want to emphasize that the discretion afforded to each RWC in how it uses 340B savings and revenue to further the objectives of its grant has been vital to the success of the Ryan White program as a whole.

PhRMA's narrower understanding of the 340B program's purpose will make it virtually impossible for our two organizations to work together. Maintaining and enhancing access to prescription drugs is important for people living with HIV/AIDS, but it is just one of the panoply of services needed by this population to achieve viral suppression. The value of the 340B program in helping to underwrite the cost of non-pharmacy services – testing, linkage, adherence and care management – cannot be overstated. If RWC-340B members were only permitted to use their 340B savings in the pharmacy area, they would find it difficult to continue meeting the needs of their patients which, in turn, could increase HIV infection rates and undermine our hard-fought efforts to control the epidemic. We ask that PhRMA embrace what we believe is a clear statement of the program's purpose in the legislative record, namely, to help safety net providers like our members "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[5]

Eligible Patients

The definition of the word "patient" is of critical importance to the 340B program because only a "patient" of an RWC may receive its 340B drugs. The Proposed Guidance makes significant changes to existing patient definition guidelines, especially with regard to the circumstances in which a prescription

[1] http://www.hrsa.gov/about/news/pressreleases/141029ryanwhite.html.
[2] CDC, Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV – United States, 2011, at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s_cid=mm6347a5_w.
[3] Comment Letter at 1.
[4] Letter from Maya Bermingham, Senior Assistant General Counsel, PhRMA, and Lori M. Reilly, Executive Vice President – Policy and Research, PhRMA, to Commander Krista Pedley, Director, Office of Pharmacy Affairs (June 28, 2013), at http://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0906-AB04&meetingId=154&acronym=0906-HHS/HRSA.
[5] H.R. REP. NO. 102-384(II) at 12 (1992).

written outside the walls of the covered entity may be filled with 340B drugs. The Comment Letter recognizes that RWCs are often required to coordinate and manage the care that their patients receive from specialists and other providers in their community.[6] RWC-340B appreciates PhRMA's understanding of the important care coordination role provided by RWCs and how, as a result, their patients' prescriptions are typically written outside their facilities. RWCs that provide medical case management services must be allowed to use 340B drugs to fill prescriptions written by outside prescribers, so we applaud PhRMA's recommendation that such prescriptions be considered 340B eligible. PhRMA included its recommendation as an exception to the second requirement of the patient definition (prescriber be employed by or under contract with the covered entity) and we ask that in any future discussions with HRSA that PhRMA make clear that this recommendation would also be an exception to the first requirement (prescription be written at an eligible site).

But that's not all. We ask that PhRMA retract or amend its request in the Comment Letter for two changes to HRSA's Proposed Guidance that would effectively preclude the use of 340B drugs in these referral situations. First, PhRMA proposed that 340B drugs may only be used for the primary diagnosis "or a comorbidity of that diagnosis" relating to the health care service that creates the provider-patient relationship.[7] HIV/AIDS is a very complex disease because it impacts nearly every system in the body as well a patient's mental health. RWC-340B believes that the existing "consistent with the scope of the … grant" test most appropriately encompasses those who need our treatment.[8] Second, the Comment Letter asks HRSA to require that medical records be "maintained, owned, controlled and possessed by the covered entity".[9] As it could be argued that RWCs do not own the records pertaining to referral services, PhRMA's suggestion would be entirely contrary to our current use and position on this matter. It would also conflict with PhRMA's own recommendation that prescriptions based on a referral be permitted in certain circumstances. For these reasons, neither of the above recommendations should apply to RWCs or similarly situated grantees and we ask that PhRMA modify its position accordingly.[10]

Medicaid Duplicate Discounts

RWC-340B understands that the problem of duplicate discounts – when a state Medicaid agency seeks a Medicaid rebate on a drug that already was sold at a discount through the 340B program – is a concern for drug manufacturers. RWCs, as covered entities, have an affirmative duty to ensure that they do not bill fee-for-service Medicaid programs for 340B drugs unless they are certain that a duplicate discount will not result.[11] Conversely, State Medicaid agencies – and by extension their Managed Care Organizations (MCOs) – have an affirmative duty to prevent duplicate discounts on 340B drugs billed to MCOs.[12] Many states have yet to meet their obligation with regard to these managed

[6] Comment Letter at 31.
[7] *Id.* at 32.
[8] The Comment Letter requests "greater clarity" regarding the types of health care services that would be "consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract." *Id.* RWC-340B believes that any health care service provided by a Ryan White grantee to an individual living with HIV/AIDS is consistent with the Ryan White HIV/AIDS Program.
[9] *Id.* at 33.
[10] *See id.* at 32-33.
[11] 42 U.S.C. § 256b(a)(5)(A).
[12] *Id.* §§ 1396b(m)(2)(A)(xiii), 1396r-8(b)(1)(A), (j)(1).

care drugs. Though the Comment Letter contains ten recommendations to HRSA for preventing duplicate discounts in the MCO context, this letter focuses on one aspect of the recommendations that poses a unique threat to RWCs. Specifically, PhRMA's letter recommends that HRSA require covered entities to submit NCPDP information to MCOs or notify an MCO when that information is not submitted.

RWC-340B has deep concerns with providing detailed information to MCOs. An unfortunate side effect of the focus on the 340B program in the past few years has been the advent of reimbursement contracts "offered" by payers that provide substantially lower reimbursement for 340B drugs than for non-340B drugs. 340B program savings should remain with the safety net provider, and RWC-340B strongly opposes discriminatory reimbursement tactics. We hope that PhRMA shares our concerns and will support efforts to curb reimbursement cuts directed at RWCs.

Thus, RWC-340B must oppose any requirement to identify 340B claims when billing third party payers and their PBMs, other than fee-for-service Medicaid. RWC-340B believes there are other ways of addressing the duplicate discount problem and is interested in exploring these alternatives, including the creation of a state-based or national clearinghouse that would identify 340B claims using data from the covered entities, drug manufacturers and third party payers, especially Medicaid MCOs. Such a clearinghouse could protect against duplicate discounts while ensuring that the 340B program continues to benefit safety net grantees and does not become a benefit program for insurers.

Contract Pharmacies

RWCs have long appreciated HRSA's recognition of the right of RWCs to contract with retail pharmacies to serve as their agent for maintaining, dispensing, and billing payers for their 340B drug inventories. HRSA first recognized the contract pharmacy model in 1996 in large part to clarify that RWCs, federally qualified health centers, and other covered entities, which do not typically operate a retail pharmacy themselves, may still access the benefits of the 340B program as Congress intended.[13] The Comment Letter expresses a number of concerns with the contract pharmacy model, though it does exclude grantees from proposals to limit the number and types of contract pharmacy relationships that a covered entity may enter into.[14] The Comment Letter also includes a positive note regarding grantees' ability to use contract pharmacies to reduce drug costs for their patients.[15] RWC-340B is very appreciative of that recognition. Other aspects of the Comment Letter's recommendations, though, concern RWC-340B.

The Comment Letter offers suggestions on inventory management that would prove very problematic for RWCs that use contract pharmacies. The Comment Letter suggests that a covered entity must be able to identify an individual as its patient at the time a drug is dispensed or administered.[16] In practice, many RWC contract pharmacies use a "virtual" inventory wherein a single inventory is maintained and then replacement drugs are ordered on a 340B or non-340B account depending on whether or not the drug was previously dispensed to a 340B eligible patient. One of the primary

[13] *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 – Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).
[14] Comment Letter at 53-54.
[15] Comment Letter at 50, 53-54.
[16] *See, e.g., id.* at 38.

benefits of a virtual inventory system is that it spares the pharmacist the time and effort of researching whether a given prescription is 340B eligible, and allows the pharmacist to focus on dispensing medication. We predict that implementation of PhRMA's proposal would force RWCs to change their 340B inventory management practices in ways that are simply not feasible for most clinics.

For example, some covered entities would abandon altogether their virtual inventory systems in order to identify patients at the point of sale. They would establish a physically segregated 340B inventory and fill prescriptions using that inventory only when their real-time research indicates that the prescription is eligible. Unfortunately, RWCs often are not in a position to implement a physical inventory model because the up-front costs of stocking a pharmacy with both 340B and non-340B drugs would be crippling. Worse, predatory lenders sometimes offer to finance the initial inventory purchase in exchange for a substantial slice of the reimbursement obtained for the drugs. RWCs would also be disproportionately affected by the proposal because a brick-and-mortar retail pharmacy might choose to maintain one 340B physical inventory for a single significant covered entity partner because it does not have space for any additional inventories. An RWC would rarely have the negotiating leverage to be that partner.

Another possible consequence of PhRMA's proposal is that, rather than requiring pharmacists to deduce whether each customer is 340B-eligible, covered entities might start designating on the prescriptions themselves whether the individual named on the prescription is a 340B-eligible patient. However, chain retail pharmacies probably would not be willing to dedicate the resources to determining in real-time whether a customer is a patient of an RWC, though it might be able to develop the type of data sharing resources necessary to do so for a hospital. Even if some pharmacies would cooperate, RWCs would not have access to prescriptions written as a result of a referral to be able to apply a patient eligibility indicator on those prescriptions. In short, the proposal would disproportionately impact RWCs and other grantees.

With regard to billing, the Comment Letter suggests that 340B drugs must be billed with the covered entity's National Provider Identifier (NPI) when a contract pharmacy is submitting the claim.[17] This recommendation is simply not feasible. Pharmacy claims must be submitted by licensed pharmacies and many RWCs do not own or operate licensed pharmacies. This is exactly why the RWC enters into a contract pharmacy arrangement in the first place. Moreover, even if an RWC had a pharmacy NPI, the contract pharmacy filling the prescription and using another entity's NPI to submit the claim would likely violate Medicare and Medicaid billing rules and be contrary to the pharmacy's agreements with private payers.[18]

RWC-340B is also concerned by the Comment Letter's insistence that covered entities conduct an annual, **on-site**, independent audit of contract pharmacies.[19] The successful treatment of HIV/AIDS involves ensuring that patients are consistently maintained on antiretroviral therapy. Mail order pharmacies, with convenient delivery directly to patients in a timely fashion, play a significant role in

[17] *Id.* at 47.
[18] *See, e.g.,* Medicare Claims Processing Manual, CMS Pub. 100-04, ch. 1, § 30.2; Dep't of Justice, *Physical Therapy Clinics to Pay $2.78 Million to Resolve False Claims Act Allegations* (Apr. 9, 2014), *at* http://www.justice.gov/usao-dc/pr/physical-therapy-clinics-pay-278-million-resolve-false-claims-act-allegations (involving scheme in which provider whose NPI was used to bill claims had no involvement in the services rendered).
[19] Comment Letter at 54.

RWC treatment plans. RWCs do not have the resources to send audit teams across the country to audit these partners. In addition, the information needed to properly audit a contract pharmacy arrangement for compliance with the duplicate discount and diversion prohibitions (*i.e.,* wholesale orders, billing information, patient records, and copies of prescriptions) can often be obtained and viewed remotely. The proposal adds unnecessary compliance costs for RWCs.

Conclusion

RWC-340B wishes to thank PhRMA again for its willingness to engage in a dialogue regarding the future of the 340B program and its shared interest in protecting the program for RWCs. We hope this letter provides you with additional insight into how changes to the program might negatively impact grantees and RWCs in particular. If you have any questions regarding any of the concerns raised above, please contact Dr. Howell Strauss at 610-389-2301 or howellstrauss@aidscaregroup.org.

Sincerely,

MEMBERS OF RWC-340B

AIDS Arms (TX)
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)