Ryan White Clinics for 340B Access

July 7, 2017

The Honorable Greg Walden
Chairman, Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Michael Burgess, M.D.
Chairman, Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Tim Murphy
Chairman, Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Re: LETTER TO HRSA REGARDING 340B DRUG PRICING PROGRAM

Chairmen Walden, Burgess and Murphy,

Ryan White Clinics for 340B Access (RWC-340B) would like to take this opportunity to share its views on the 340B drug pricing program (340B program) in light of your recent letter to the Health Resources and Services Administration (HRSA). RWC-340B is a coalition of Ryan White clinics (RWCs) that participate in the 340B program and organized several years ago to preserve access to this critically important program. Members of RWC-340B provide primary care and many other services to persons living with HIV/AIDS.

While we greatly respect the committee's role in overseeing the 340B program, we were alarmed by several statements in the letter. We are writing to express our strong support for the 340B program and to share our views on the specific issues you raise. As described in more detail below, we disagree that the 340B program should have more federal government oversight to address so-called "rapid growth" in the program or to subject covered entities to new reporting requirements on how they use their 340B savings. We also believe that allegations of covered entities diverting savings away from patients are unfounded. RWC-340B therefore asks that the committee not take any actions that would mire the program in excess bureaucracy or otherwise undermine its effectiveness in supporting the services that RWCs provide to the HIV population.

By Establishing the 340B Program, Congress Intended to Strengthen the Nation's Health Care Safety Net at No Cost to Taxpayers, Not to Create a Patient Assistance Program

The 340B program has become an important tool for RWCs and other safety net institutions to maintain existing services or provide new services that are needed in the community but that are not reimbursed. Program savings help underwrite the cost of these services ***at no cost to taxpayers***. We are aware, however, that some in the pharmaceutical industry are waging

attacks on the 340B program. Their claims should be viewed with a healthy dose of skepticism, and some are just plain wrong. It is important to bear in mind that manufacturers' participation in the program is voluntary. They participate as a condition of their drugs being covered by the Medicaid and Medicare Part B programs. As you know, the program was established as part of the Veterans Health Care Act of 1992 at a time when our nation was facing rapidly increasing drug prices, similar to the challenges we face today. The financial impact on the pharmaceutical industry represents only 2% to 4.5% of the total drug spend in this country, a small price to pay for these companies to gain access to the lucrative Medicaid and Medicare Part B markets.

The 340B program was never intended for pharmaceutical manufacturers to provide individual drug discounts to select patients. Rather, it was established as a result of a bipartisan compromise intended to address rapidly increasing drug costs by lowering those costs for safety net providers best positioned to know their patients' needs. Twenty-five years later, the cost of drugs is again of great public concern. We see no reason for Congress to default on its promise to lower the cost of drugs for safety net providers and their patients when it established the 340B program in 1992.

The Program Is Helping RWCs Win the Battle Against the AIDS Epidemic and Any Change That Reduces 340B Utilization Will Undermine Those Efforts

The 340B program 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.[1]

RWCs implement the continuum of care model better than anyone, and the results are demonstrable. According to 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.[2] These success rates are much higher for RWCs. Among HIV-infected persons 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.[3]

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[1] *See, e.g.,* Viral Load, *at* https://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/understand-your-test-results/viral-load/.

[2] 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/.

[3] 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.

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 people diagnosed with HIV/AIDS 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 the HIV population 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.

Claims About "Rapid Expansion" of the Program Are Overstated

While the number of hospitals qualifying for the 340B program has increased significantly since the program's inception in 1992, such growth is the result of deliberate, policy-oriented actions taken by Congress. The only hospitals that participate are those that satisfy the eligibility criteria established by Congress. HRSA makes a careful determination of eligibility for each hospital that applies for the program, and there is no evidence that ineligible hospitals are being admitted. Congress supported the expansion of hospital participation in the 340B program as evidenced by enactment of the following laws: the Medicare Modernization Act of 2003, Deficit Reduction Act of 2005 and Affordable Care Act of 2010.

Concerns about inappropriate growth in the 340B program should not be based on Congress' decision to add new hospitals under the above laws. Congress intentionally added these hospitals because of their vital safety net role in America, especially in rural areas. Congress, under the control of both parties, would not have repeatedly expanded 340B hospital eligibility criteria, if it did not believe that the 340B program was a success and fulfilling its intent.

Concerns About HRSA's Audit Process and Reporting Requirements Should Be Directed at Those Being Applied to Manufacturers, Not Covered Entities

Your letter to HRSA expressed concerns with both the audit process and reporting requirements applicable to covered entities. Yet, over the past few years, HRSA has performed more than 600 audits of covered entities, relying on an audit process that has become increasingly rigorous and detailed-oriented. RWCs receive federal grant funding and, like other federal grantees and subgrantees, are subject to detailed reporting requirements as a condition of receiving such funds. Participating 340B hospitals meanwhile must submit reams of financial information to the IRS in support of their non-profit status and to HHS as part of their annual filing of Medicare and Medicaid cost reports. Your concerns about HRSA's audit process and reporting requirements would be more understandable if directed at those being applied to manufacturers. To date, HRSA has only audited six manufacturers and has utilized a process that, compared to the covered entity protocol, is still in its infancy. And until HRSA operationalizes a password-protected website for covered entities to access 340B pricing, there will continue to be no transparency into the discounts that manufacturers are required by law to give covered entities.

Citing the results of HRSA's audits, you also allege that covered entities commonly violate program requirements by subjecting manufacturers to duplicate discounts and diverting 340B drugs to ineligible patients. These problems are significantly overstated. In many instances, the

duplicate discount findings rest on mere technical errors in the information provided to HRSA by the covered entity and have no bearing on whether duplicate discounts actually occurred or ever could occur based on a state's policy for seeking Medicaid rebates. For example, many states have developed their own mechanisms for excluding 340B drugs from their Medicaid rebate requests, rendering compliance with HRSA's database requirements inconsequential.

In addition, the suggestion in the letter that covered entities get the benefit of both a 340B discount and the Medicaid rebate is simply false. Medicaid rebates go to the State Medicaid agency. Furthermore HRSA will find a covered entity in violation of the duplication discount prohibition even if only one error is found out of thousands of prescriptions filled. With respect to HRSA's diversion findings, HRSA has abandoned its longstanding interpretations of when an individual is eligible to receive 340B drugs and replaced them with a much narrower definition of "patient" that is inconsistent with its prior guidance. The agency's new interpretation, which forms the basis for the large majority of its diversion findings, has never been subject to notice-and-comment rulemaking. The diversion findings therefore serve as evidence of covered entity confusion over the scope of the patient definition, not of covered entities commonly and recklessly diverting 340B drugs to ineligible patients, as the letter seems to suggest.

Industry Allegations That Covered Entities Are Diverting Program Savings from Patients Are Unfounded

We are especially dismayed by the contention in your letter that underinsured and uninsured patients are paying full price for drugs that should have been provided at a discount. We do not see evidence to support this claim. RWCs are driven by both a mission and legal mandate to care for individuals regardless of their ability to pay. We routinely reduce co-payment obligations for patients who meet low-income eligibility standards. The discounts we receive through the 340B program allow us to continue and expand this practice, so we wholeheartedly agree that providing free or discounted drugs to low-income patients is one of the goals of the program. And this is exactly how the program is being used. The 340B program is critically important to the ability of safety net organizations to provide cost-effective medications to their underinsured and uninsured patients. We strongly believe that RWCs and other covered entities have been excellent stewards of the 340B program and are using 340B program savings to serve their communities.

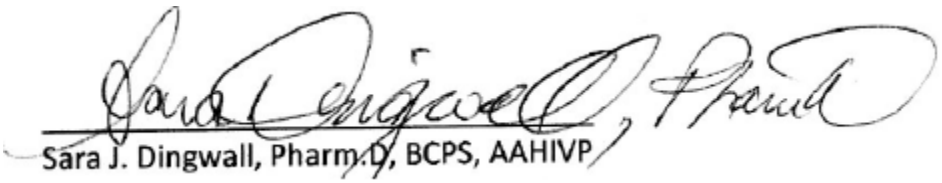
We understand why some in the pharmaceutical industry would like to shoulder less of their responsibility to care for uninsured and underinsured patients. Their messaging that patients don't receive discounts appears intended to reduce their twenty-five-year-old responsibility to give discounts on their products, some of which can be quite expensive. We do not see evidence of covered entities diverting savings away from patients. In fact, RWCs regularly use their 340B savings to provide free or discounted drugs to low-income patients. They also use the savings to provide other necessary treatment and services to these vulnerable populations, consistent with the program's purpose to allow covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Notwithstanding the industry's talking points, the reality is that any efforts to scale back the 340B program would significantly increase drug costs and reduce the availability of effective services for under and uninsured patients.

Additional Government Bureaucracy Is Unnecessary and Would Be Harmful

RWCs qualify for 340B because of their eligibility under the Ryan White Care Act. RWCs are required by the nature of their grants to be fully transparent and accountable for the funding they receive and the services they provide. Statements that covered entities require greater accountability for their use of program savings represent an unwelcome and unnecessary government intrusion into a program that is working well for RWC patients. We view any new regulatory burdens on covered entities as threatening to all covered entities and their patients.

RWCs are on the front lines of caring for low-income and vulnerable patients. They are in a better position than federal bureaucrats and drug company executives to assess how best to use 340B savings to meet the health care needs of their communities. The strength of the 340B program is the flexibility it affords covered entities to use program savings where they are already held accountable, in their communities. RWC-340B would therefore strongly oppose any efforts to limit that flexibility. Second guessing RWCs' 340B patient care initiatives would diminish their effectiveness and shift responsibility away from them and on to the backs of taxpayers. There is simply no question that the federal government and/or the states would bear the costs of serving these vulnerable populations if the 340B program were scaled back or eliminated.

Our nation is winning the war against the HIV/AIDS epidemic in large part because of the hard work of RWCs and the support provided by the 340B program. Our 340B clinics have demonstrably increased viral suppression which, in turn, has reduced the spread of this highly contagious disease. If manufacturers are permitted to dial back their 340B program commitments, or if RWCs and other covered entities are subject to less flexibility in how they use 340B savings for their patients, Congress could inadvertently trigger another HIV public health crisis. As such, we ask that the committee use its oversight authority to ensure that the 340B program remains strong for those we serve, rather than cripple it with more regulation and bureaucracy. For further information, please contact Peggy Tighe at Peggy.Tighe@PowersLaw.com or see RWC340B.org.



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RWC-340B President

cc: Ranking Members Pallone, Green, and DeGette