Ryan White Clinics for 340B Access

February 13, 2018

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 Gregg Harper
Chairman, Subcommittee on Oversight and Investigations
2125 Rayburn House Office Building
Washington, DC 20515

Re: Recent Committee Report on 340B Drug Pricing Program

Dear Chairmen Walden, Burgess, and Harper:

Ryan White Clinics for 340B Access (RWC-340B) is a coalition of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act and participate as "covered entities" in the federal 340B drug discount program (340B program). RWC-340B writes to share its views on the Energy and Commerce Committee majority's January 10, 2018 report, "Review of the 340B Drug Pricing Program."

We strongly agree that the 340B program "enjoys strong bipartisan support in Congress" and is a "vital lifeline to health care providers." We appreciate that the report recommends that HRSA be given the resources it needs to implement integrity provisions including the establishment of an administrative dispute resolution process, the imposition of civil monetary penalties against manufacturers, and creation of covered entity access to manufacturer ceiling prices. We also appreciate the report's restatement of the program's intent – "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

However, we are troubled by several recommendations in the report that reflect an apparent effort to reinterpret the program's intent. If implemented, these recommendations could lead to future policies and practices that would seriously diminish our ability to comprehensively serve our communities. We are also concerned that the report recommends new, intrusive billing and reporting requirements that, if adopted, could adversely affect the 340B market in a manner that would ultimately limit program use to only those who are uninsured or low income. And, we are disappointed that the report fails to recognize threats from for-profit pharmacy benefit managers (PBMs), insurance companies and other payers that are increasingly misappropriating 340B savings through discriminatory reimbursement. Our views on each issue are detailed below. We firmly believe that the report's recommendations in these areas would inevitably lead to an evisceration of the 340B program, leaving the states and federal government responsible to do the job we are now doing very well with the critically important support of the 340B program.

The 340B program, as structured and functioning for the last two decades, works for RWCs because it allows us to care for the comprehensive needs of our communities and is not limited to providing drugs to only the uninsured or low income patients.

RWC-340B strongly disagrees with the report's repeated assertions that the program's intent is unclear or should be narrowed or limited. The report states that the original intent of the 340B program may no longer be relevant given changes in the health care industry.[1] For RWCs, the 340B program is more relevant than ever in the fight against HIV/AIDS. The 340B model works because of the flexibility in how we are permitted to use our savings. The 340B program must be understood against the backdrop of the National HIV/AIDS Strategy. To be successful in the fight against HIV/AIDS, persons living with the disease need much more than prescription drugs. The 340B program allows us to stretch our resources to support the full continuum of care that our patients need – from testing, to linkage to care, to medication adherence and viral suppression. Many of these services are not reimbursed by any payer, though these are the services that most directly help people living with HIV/AIDS access and remain in care.

We are alarmed by the report's claim that it is unclear "whether Congress intended low-income and uninsured individuals to directly benefit from the reduced drug prices offered under the 340B program." The statement reflects an apparent motive to redefine and narrow the purpose of the program by suggesting that it should only be used to reduce the cost of medications for low-income and uninsured patients, rather than providing comprehensive care to our patients. Such a dramatic policy shift would inevitably and substantially diminish our ability to serve the HIV/AIDS population and to protect against the spread of the epidemic. RWCs are experienced in providing holistic care to vulnerable individuals who are routinely stigmatized, particularly those with the dual stigmas of HIV/AIDS and opioid misuse. Early and consistent treatment means that an HIV/AIDS patient, including a patient with an opioid addiction, is less likely to infect others, thereby curbing the high costs associated with HIV/AIDS treatment. If the 340B program was limited to certain populations or the ways in which we could use our savings to help our communities, we would be unable to care for our communities as we now do.

While the 340B program serves the important function of allowing us to provide high-cost drugs to uninsured and underinsured patients, this is not the only function of the program. Significantly, the cost of some new HIV/AIDS medications is so high even with a 340B discount (approximately $1,900 per month) that we have to subsidize the drug costs for our underinsured and uninsured patients. Stated differently, passing along the 340B discount alone does not make the drug affordable for many of our patients. It is essential that we be able to continue to derive revenue from the program by serving fully insured patients because we rely on such revenue to assist the uninsured and underinsured, thereby fulfilling our public health mission. Covered entities are highly dependent on 340B revenue to treat more vulnerable patient populations and to improve services for those populations. Changes to that construct would mean fewer savings to care for fewer patients, a complete contradiction of the program's stated intention and how the program has worked over the past 25 years to support covered entities that, by definition, serve vulnerable populations.

The report's new reporting and billing recommendations are an unnecessary and harmful reformulation of the program, leading to less care for fewer patients.

[1] Energy and Commerce Committee, *Review of the 340B Drug Pricing Program*, at 48 - 50.

RWC-340B is greatly concerned that the report's recommendations for new billing and reporting requirements for covered entities reflect a clear path toward redefining and narrowing the 340B program. The recommendations set a troubling precedent of extracting and publicizing private information that goes well beyond the reporting requirements applicable to RWCs under our grants and sub-grants. Examples of these recommendations include a call for new mechanisms to "monitor the level of charity care provided by covered entities" and to "track program use, and ensure that low-income and uninsured patients directly benefit from the 340B program."

Tracking and monitoring charity care and tracking program use for low-income and uninsured patients can only mean one thing – a path toward limiting which populations can be eligible for 340B savings and therefore a reduction in 340B savings or use of those savings for 340B safety net providers. The report evidences an apparent interest in remaking the 340B program into a direct drug discount program for certain populations which, in our view, reflects a different and improper understanding of how the 340B program should work. We strongly believe that such a reformulation of the program would lead to covered entities serving fewer patients and providing fewer services since they would receive little to no 340B revenue to help pay for those patients and services. Covered entities would be unable to provide more patients with more comprehensive services, as originally envisioned by Congress.

Further, the intrusive nature of the billing and reporting recommendations stand in stark contrast to the complete lack of reporting requirements for manufacturers. While we applaud the report's authors for noting the need for manufacturer transparency, we wish they had taken aim at manufacturers' complete freedom to hide from the public their pricing information – specifically their drugs' average price and best price in the marketplace – as a result of a unique industry-specific confidentiality law that they convinced Congress to adopt in 1990. The blatant imbalance in transparency requirements applicable to covered entities versus manufacturers is patently unfair and must be rectified. Instead of tackling this serious problem, most of the report's recommendations would undermine the purpose, goals, and mechanisms that currently make 340B work for those it serves.

The report creates a path toward discriminatory reimbursement and misappropriation of 340B savings away from safety net providers to payers.

PBMs, managed care plans, and other third party payers are increasingly usurping the benefit of the 340B program from covered entities by reimbursing 340B drugs well below the payers' non-340B rates and by establishing other discriminatory terms in their pharmacy participation agreements. RWC-340B is concerned that the report fails to acknowledge and denounce these discriminatory practices. Left unchecked, discriminatory reimbursement will greatly reduce, if not eliminate, the benefit of the discount for covered entities, thereby undermining the purpose of the 340B program.

Congress intended the benefits of the 340B program to accrue to 340B covered entities, not to payers that do not have the same safety-net mission or not-for-profit status. HRSA has expressed concerns that providers would have no reason to participate in the 340B program if insurers take the benefit of 340B savings. HRSA explains that "if covered entities were not able to access resources freed up by the drug discounts when they… bill private health insurance, their

programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities."[2]

Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers including Ryan White clinics. The Government Accountability Office has found that providers use 340B to offset losses incurred from treating some patients, support existing pharmaceutical and clinical services, lower drug costs for low-income patients, serve more patients, and to provide additional services, such as case management, which facilitate access to appropriate care.[3] Reducing reimbursement to 340B covered entities will jeopardize our ability to provide these important services.

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For the above reasons, RWC-340B strongly urges the Committee to focus on shoring up this vital program for America's safety-net program rather than reformulating it in ways that would narrow patient eligibility, complicate how the program works through onerous and ultimately harmful reporting requirements, or allow payers to misappropriate 340B savings away from safety net providers.

For further information, please contact Peggy Tighe at Peggy.Tighe@PowersLaw.com or see RWC340B.org.

Sincerely,

MEMBERS OF RWC-340B

AIDS Center of Queens County
AID Atlanta
AIDS Care Group
AIDS Healthcare Foundation
AIDS Outreach Center
AIDS Resource Center of Wisconsin
AIDS Taskforce of Greater Cleveland
Alamo Area Resource Center
Allies for Health + Wellbeing
Big Bend Cares
CAN Community Health
Chattanooga CARES
Christie's Place
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Damien Cares
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Fenway Health
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Heartland CARES, Inc.
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MetroHealth
Northern Nevada HOPES
North Jersey Community Research Initiative
Northland Cares
Nuestra Clinica
One Community Health
Open Door Health Center of Illinois
Positive Health Clinic
Positively U
Prism Health North Texas
South Carolina HIV/AIDS Council
Southwest CARE Center
Thrive Alabama
Trillium Health
Urban Solutions Inc.
Whole Family Health Center

cc: Ranking Members Pallone, Green, and DeGette

[2] HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act* (July 2005), https://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.

[3] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 17 (Sept. 2011), http://www.gao.gov/products/GAO-11-836.