Ryan White Clinics for 340B Access

Response to Request for Input Regarding the 340B Program submitted to House Energy and Commerce Committee Ranking Member Greg Walden (R-OR) and Senate Health, Education, Labor and Pensions (HELP) Chairman Lamar Alexander's (R-TN)

October 30, 2020

Ryan White Clinics for 340B Access (RWC-340B) is a national association of HIV/AIDS health care clinics and service providers receiving support under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Ryan White clinics are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and are serving on the frontlines of both the AIDS epidemic and the COVID-19 pandemic, supporting high risk clients and communities. Our members provide primary care, case management, and other support services for persons living with HIV/AIDS (PLWHA).

The 340B Drug Pricing Program allows RWC-340B members to leverage their 340B savings to support the full HIV/AIDS care continuum, from diagnosis, to linkage to care, to medication adherence and viral suppression. Ryan White clinics achieve viral suppression rates far above the average national viral suppression rate. This success in viral suppression rates results in fewer transmissions of the HIV/AIDS virus and is instrumental in helping to achieve the goal of the Trump Administration to end the HIV/AIDS epidemic by 2030. Safety net providers like our members rely on the savings generated from the 340B program to help achieve these health outcomes and to finance their mission of serving low-income patients.

We submit this document in response to the Ranking Member and Chairman's statement calling for "input on how to improve the 340B Drug Pricing Program." RWC-340B outlines below five separate but interconnected comments about the request for input and asks that members of the House Energy and Commerce and Senate HELP committees take the following steps in addressing the 340B program:

- work in a bipartisan, collaborative fashion in any further discussions about the 340B program;
- consider a recently released analysis of Ryan White clinics, the services they provide and the outcomes they achieve, to fully understand the harm to public health, including the fight to end the AIDS epidemic, that would result from any 340B program reforms causing resource reductions among Ryan White clinics;
- change the conversation about the 340B program to support frontline safety net providers and focus on protecting the program;
- use your authority to stop recent manufacturer actions that represent the greatest threat to the 340B program since its inception, reasserting Congress' 340B oversight responsibility and HHS' existing authority to regulate the program; and

- advance legislation to prevent duplicate discounts involving Medicaid managed care plans and to prohibit discriminatory reimbursement against 340B covered entities by all payers.

1. The partisan nature of the request for input stands in stark contrast to long-standing bipartisan support for the 340B program.

We appreciate that your statement begins with the acknowledgement that "(S)trong bipartisan support for 340B has spanned almost three decades." As you know, the 340B program was the result of a bipartisan effort, advanced by Senators Hatch (R-UT) and Kennedy (D-MA) and signed into law by President George H.W. Bush in 1992. In the 109th Congress, several Senate Republicans introduced S.4 - Healthy America Act, legislation that would have, among other policy changes, expanded the 340B program and permitted the use of multiple contract pharmacies. The Affordable Care Act (ACA) also included provisions that expanded the 340B program and, while the ACA was not supported by most Republicans in Congress, it was supported by PhRMA.

In the 115th Congress, the bipartisan spirit of the 340B program was seriously threatened when PhRMA and BIO, trade associations representing pharmaceutical manufacturers, waged a multi-tiered campaign attacking the 340B program. We worked closely with House Energy and Commerce and Senate HELP committee staff and members to assist in their evaluation and assessment of the 340B program but were disappointed that many of those discussions devolved along partisan lines and resulted in "340B-unfriendly" legislation. Several of these "reform" proposals advanced by Republican committee members would have fundamentally altered the 340B program. Examples include partisan proposals that would have narrowed the size and the scope of the program by reducing manufacturers' responsibility to provide discounts to the safety net; turned 340B into a "pass-through" program robbing safety net providers of their ability to use program savings to increase patient care; restricted which patients meet the long-established regulatory definition of patient; and under the auspices of transparency, would have established intrusive and unfair reporting requirements for covered entities that were not mirrored for manufacturers. We did not consider that kind of "reform" as protective of the 340B program, the safety net, or the patients and communities served by the program.

We were pleased, however, that those efforts culminated in one especially important bipartisan, bicameral letter to the Health Resources and Services Administration (HRSA) that you both signed with Ranking Member Frank Pallone, Jr. (D-NJ) and Senate HELP Committee Ranking Member Patty Murray (D-WA). The letter responded to HRSA's requests for additional regulatory authority under the 340B program by stating that Congress should not approve new regulatory authority for HRSA until HRSA acted to implement its existing regulatory authority.

**RWC-340B urges that, given this rich bipartisan history, both the House Energy and Commerce and Senate HELP committees work in a bipartisan, collaborative fashion in any further discussions about the 340B program.**

2. A recent study provides indisputable evidence of the vital role that Ryan White clinics play in the safety net and confirms that any "resource reductions" – including any reductions in

340B savings – could have long-term, harmful consequences for both Ryan White patients and the fight against HIV/AIDS.

RWC-340B recently commissioned a pivotal white paper and fact sheet about Ryan White clinics. The analysis examines access to HIV care and the important role of both the Ryan White HIV/AIDS Program (RWHAP) and 340B Drug Pricing Program for clients of RWHAP clinics and viral suppression. The analysis reviews funding sources and policies related to program income for RWHAP clinic grantees, and how, according to modeling by HRSA and the Centers for Disease Control and Prevention (CDC), elimination of the RWHAP program would undermine progress in controlling the spread of HIV. Key findings from the study include the following:

KEY DEMOGRAPHICS

- 50% of all PLWHA in the United States receive medical care through the RWHAP.
- 87.1% of RWHAP clients receiving HIV care are virally suppressed, exceeding the national average 62.7% of PLWHA.
- Of RWHAP clients, 73.7% are racial/ethnic minorities; 61.3% live at or below the federal poverty level; 71.6% are cis male, 26.5% are cis female, 1.9% are transgender; and 41.6% are 50 years of age or older.
- RWHAP clinics have also shown a reduction in disparities in viral suppression rates between demographic groups.

IMPLICATIONS OF RESOURCE REDUCTION

- If RWHAP grantee clinics were to lose any sources of funding or reduction in 340B savings, these providers may be compelled to eliminate other services in order to manage costs.
- Losing stable access to care, medications, and services could result in a heightened risk for severe illness in PLWHA.
- These clinical and non-clinical outcomes suggest that program clients could have negative clinical and non-clinical effects if funding for RWHAP clinics were reduced.
- Reduction in resources, including 340B Drug Pricing Program savings, could have long-term consequences for patients served through RWHAP-funded clinics, including disruptions in care and treatment, adverse health outcomes, or increased healthcare expenses.
- In addition to the effects on clinics and patients, state and local governments could also see detrimental financial effects.

These findings strongly suggest that resource reduction to Ryan White clinics resulting from 340B reform efforts, whether intentional or not, could undermine this nation's fight to end HIV/AIDS by 2030.

**RWC-340B urges that Congress consider this important new analysis about Ryan White clinics when reviewing the 340B program and note that any reduction in resources, including a reduction in 340B savings, could seriously harm both Ryan White clinic patients and the fight to eliminate HIV/AIDS.**

3. The request for input overstates the need for "modernization" and understates the need for Congress and HHS to oppose the recent, unilateral manufacturer actions regarding 340B

contract pharmacies at a time when frontline providers are fighting an unprecedented public health crisis.

While we agree that oversight and review of any federal program is beneficial, we strongly disagree with several reasons stated in the information request for "modernization." The statement reaches two unfair and inaccurate conclusions – that "(p)rogram changes are needed and long overdue" and there is a "lack of data necessary for effective oversight to maintain the integrity of the program." We believe that these statements overstate and mischaracterize the 340B program. The conversation we should be having is how we can all work together to protect the 340B program. We enumerate ways to so in the next section. The 340B program has been very successful in lowering drug prices for safety net providers, allowing them to expand services and care for more patients in our most vulnerable communities. These successes are directly in line with the stated intention of the program: to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

Ryan White clinics and other grantees are fully transparent in their reporting of 340B data. Characterizing the 340B program as in dire need of oversight and transparency and giving passing reference to being in support of the program without talking about the specific and very real benefits and value provided by the program is akin to pulling a fire alarm when there isn't a fire.

It is particularly frustrating that this information request comes at a time when Ryan White clinics and other safety net providers are facing the greatest challenge to the 340B program – manufacturer unilateral actions to self-regulate the program – and when our clinics are on the frontlines of fighting the COVID pandemic and HIV/AIDS epidemic. The function of the 340B program – to facilitate the ability of safety-net providers to care for our nation's most vulnerable patients – is now more important than ever.

As you know, over the last few months, four pharmaceutical manufacturers – Eli Lilly and Co., Sanofi-Aventis US LLC, AstraZeneca PLC, and Novartis Pharmaceuticals – flouted the 340B statute and regulations by refusing to sell 340B discounted drugs to covered entities when ordered via contract pharmacy arrangements. We believe that these manufacturers' actions violate the 340B statute and need to be stopped now. We were pleased by your statement that "allowing program participants to continue playing by their own rules leaves the most important 340B stakeholder on the sideline – the patient" and trust that you are referencing the above manufacturers that are writing new rules for the 340B program. We also appreciate the acknowledgement that "(c)ontract pharmacies serve an important role in improving access to prescription drugs."

One especially troubling model advanced by Kalderos, a third-party vendor working on behalf of manufacturers, would unilaterally change 340B from an up-front discount program to a rebate model without HRSA's approval or Congress' direction to make such a dramatic change. Under the Kalderos model, called 340B Pay, participants would be forced to purchase drugs at list price and then request rebates, giving drug manufacturers extraordinary and incredibly unfair leverage over safety net providers. Ultimately, the model threatens the ability of the

safety net to access 340B savings and provide accessible, affordable prescription drugs and critical health care to vulnerable communities.

Ryan White providers are especially dependent on their 340B contract pharmacy arrangements to meet the pharmacy needs of their patients and to help finance their fight to end the HIV/AIDS epidemic in this country. The manufacturer actions described above will cripple the ability of Ryan White clinics to care for vulnerable patients, undermining their use of the 340B program to protect public health and exacerbating the current public health emergency. Further, these manufacturers' self-serving policies thwart HHS's right and responsibility to oversee the program and, if left unaddressed, set a dangerous precedent of allowing manufacturers to self-regulate any other aspect of the 340B program.

**RWC-340B urges you to change the conversation about the need to reform the 340B program to one that supports frontline safety net providers and focuses on protecting the program.**

4. We are deeply troubled by the statement's legal determination that "such pharmacies are not referenced in law," the characterization of recent manufacturer actions as mere "alterations in business practices," and the absence of any concern over manufacturers' unilateral withdrawal from the contract pharmacy program and any call for HHS to take action against these companies.

While the 340B statute does not specifically mention contract pharmacies, HRSA adopted contract pharmacy guidance 24 years ago that elucidates the rights of 340B covered entities and obligations of manufacturers under both the 340B statute and state agency law. As stated by HRSA in its 1996 guidance, many covered entities do not operate their own retail pharmacies and "it would defeat the purpose of the 340B program" if they could not use affiliated pharmacies to distribute 340B drugs. Since 1996, both the HRSA and HRSA's Office of Pharmacy Affairs have allowed 340B covered entities to dispense 340B drugs to their patients through pharmacies contracted to act on the covered entity's behalf.

We are buoyed by the widespread bipartisan congressional responses opposing these manufacturer actions, with nearly 300 Members of Congress signing letters to Secretary Azar to object to the actions in the last few months. The House letter has 243 signers (174 Democrats and 69 Republicans). The Senate letter has 28 Senators (15 Democrat; 12 Republican; 1 Independent). We also understand that many members, both Republicans and Democrats, have written or communicated directly with Secretary Azar to oppose these manufacturer actions, most notably Senate Finance committee chairman Grassley's recent communication that he and Senator Ernst spoke with HHS officials, noting that many rural providers rely on 340B savings and drug manufacturers' so that patients have access to medications. "Cutting back" on the discounts during the pandemic would be especially harmful for rural providers serving low income people.

As you may know, RWC-340B and two 340B grantee clinics filed a complaint in the United States District Court for the District of Columbia to protect 340B entities' longstanding right to dispense their drugs through contract pharmacies as mandated by statute and regulation (see our press release and Letter to HHS Secretary Alex Azar). Our complaint seeks a declaratory judgment that covered entities are entitled to purchase covered outpatient drugs through

contract pharmacies at 340B discounts. It also asks the U.S. District Court to direct HHS Secretary Azar to:

- promulgate dispute resolution regulations within 60 days of the Court's order;
- enforce the covered entities' rights to purchase covered outpatient drugs via contract pharmacies at 340B discounts by ordering them to refund overpayments owed to the covered entities;
- use his authority to impose civil monetary penalties upon the named drug manufacturers;
- revoke the pharmaceutical pricing agreement (PPA) of any pharmaceutical manufacturer that does not offer drugs at 340B discounts when ordered via contract pharmacy arrangements; and
- exclude such manufacturer from the Medicaid and Medicare Part B programs.

**RWC-340B urges you to work in a bipartisan fashion to enforce the requirements of the 340B statute against manufacturers that overcharge covered entities for drugs dispensed by contract pharmacies.**

5. Congress should act to make improvements to the 340B program – preventing duplicate discounts in the area of Medicaid managed care and prohibiting discriminatory reimbursement by all payers.

Rather than giving credence or acquiescence to manufacturers' or pharmaceutical benefit managers' efforts t to eliminate or shrink the benefit of the 340B program for safety net providers, Congress should address two issues that we believe require immediate congressional action and/or intervention.

- **Advance legislation to prevent duplicate discounts through a neutral, third party clearinghouse that would compile, track, and remove duplicate discounts from the rebate file, all in a confidential manner.**

RWC-340B has shared draft language with relevant committee staffers for the House Energy and Commerce committee and the Senate Finance committee that would create a process led by a third party neutral (rather than any type of 340B stakeholder) to introduce fairness and protection of sensitive information to the end goal of reducing the risk of duplicate discounts on Medicaid managed care claims.

The language should be welcomed by manufacturers, states, and covered entities – all of whom have recognized that preventing Medicaid duplicate discounts is a shared stakeholder goal. Because the neutral third party would protect the confidentiality of the information, all stakeholders would be protected from any potential misuse of their information. The idea of such a federal structure and oversight of duplicate discounts is not a new one, it simply takes on new significance considering that manufacturers have stated that their unilateral actions are intended to prevent duplicate discounts.

- **Advance legislation to prohibit discriminatory reimbursement against 340B covered entities by third-party for-profit entities that are unregulated in the 340B stakeholder program and were never the intended beneficiaries of the program.**

Pharmacy benefit managers (PBMs) and other third-party payers are attempting to usurp the benefit of the 340B drug discount program by offering 340B covered entities lower reimbursement rates than those offered to non-340B entities. These discriminatory practices are viewed by safety net providers as a direct attack on the 340B program and leave the 340B provider community with no choice but to fight them.

There is no dispute that 340B program was not intended to benefit private insurers and PBMs, especially those that are for-profit. HRSA views discriminatory reimbursement as a threat to the 340B program and has noted in a 340B manual for hemophilia treatment centers that "(I)f 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." According to HRSA, the 340B program was established to provide additional financial resources to covered entities without increasing the federal budget. The difference between a 340B drug's lower acquisition cost and standard non-340B reimbursement represents the very benefit that Congress intended to give covered entities when it established the 340B program. Covered entities use these savings to treat more vulnerable patient populations or to improve services for them.

Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers. Covered entities use 340B savings in a variety of ways to benefit the vulnerable patients they serve. The Government Accountability Office has found that providers use 340B to: offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management to facilitate access to appropriate care.

This unfair practice is well documented. Apexus, which is under contract with HRSA to provide 340B technical assistance and other services, has issued an informational paper that cautions that some private payers have been issuing contracts to 340B covered entities with significantly lower reimbursement than they would offer other retail pharmacies.

**RWC-340B urges Congress to adopt legislation to create a national clearinghouse to prevent Medicaid managed care duplicate discounts and to prohibit discriminatory reimbursement against 340B covered entities by third-party payers.**

To restate our requests, we ask that you: work in a bipartisan, collaborative fashion in any further discussions about the 340B program; review our recently released analysis of Ryan White clinics to fully understand the harm to public health that would result from any resource reductions to the 340B program; change the conversation about the 340B program to support frontline safety net providers and focus on protecting the program; use your authority to stop recent manufacturer actions that represent the greatest threat to the 340B program since its inception; reassert Congress' responsibility and HHS' authority to regulate the 340B program;

and advance legislation to prevent Medicaid managed care duplicate discounts and to prohibit discriminatory reimbursement against covered entities in the 340B program.

Thank you for your consideration.