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Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington, DC 20201

Re: RIN: 0991-ZA49 - Comments on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (submitted via Federal eRulemaking Portal: <http://www.regulations.gov>)

Ryan White Clinics for 340B Access (RWC-340B) is a national association 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 appreciates this opportunity to comment on a Department of Health and Human Services (HHS) policy statement and request for information (RFI) published on May 16, 2018 entitled “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”¹ While we share the objectives of lowering drug prices and reducing out of pocket costs, we do not agree with the implied assumptions included in many of the questions that the 340B program is a cause for rising drug prices. We also believe the 340B program is working as Congress intended and does not need the kind of “wholesale reform” advocated by some within the pharmaceutical industry.

The 340B program is critically important to Ryan White Clinics (RWCs) and their patients, allowing them to stretch their scarce resources to support the full continuum of care that their patients need including testing, linkage to care, treatment, retention, case management, and medication adherence. The program allows these services to be provided at little or no cost to needy patients. Many of these services are not reimbursed by any payer, though these services directly enable people living with HIV/AIDS to access and remain in care and, most importantly, to become virally suppressed so they cannot transmit the virus to others. 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 and RWC’s access to 340B savings. Such progress means HIV-infected patients are living longer, but are often facing age-related diseases

¹ HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,692 (May 16, 2018), <https://www.federalregister.gov/documents/2018/05/16/2018-10435/hhs-blueprint-to-lower-drug-prices-and-reduce-out-of-pocket-costs#addresses>.

that set in earlier and require continued intensive and comprehensive services. The 340B program is helping RWCs win the battle against the HIV/AIDS epidemic and any narrowing of 340B utilization will undermine that battle.

The 340B program has become an important program for RWCs and other safety net providers to maintain existing services or provide new services that are needed in the community but that are not reimbursed. The program generates both savings and revenue that help underwrite these services at no cost to taxpayers and at relatively low cost to pharmaceutical manufacturers. While some sectors of the pharmaceutical industry are waging attacks on the 340B program, it is important to note that the program is voluntary for manufacturers. It is the “price of admission” for manufacturer participation in the quite lucrative Medicaid and Medicare Part B markets. Importantly, the 340B program is a total of approximately 2-4% of overall drug spending, a relatively small price to pay to sell pharmaceuticals to Medicare and Medicaid patients. The Government Accountability Office (GAO) found that in 2015 the average profit margin for the 25 largest pharmaceutical companies was three times the average profit margin of the 500 largest companies in the world.²

In summary, the 340B program is working as it was intended for RWCs and their patients. Calls from the pharmaceutical industry to overhaul the program are unfounded and intended to shrink the program. There is no credible evidence that the 340B program is a driver of rapidly increasing drug prices. Instead, the 340B program is an important tool for safety net providers like RWCs to access discounts on drugs so that they may provide not only lower cost drugs to their patients but other vitally important services that would be unaffordable without the program. If the size or scope of the 340B program were diminished, the burden of providing these necessary services would likely fall to the states or the federal government.

RWC-340B’s comments are separated into two parts. We first address questions and issues in the RFI related specifically to RWCs in the 340B program. We then address other questions of interest to RWC-340B that are related to the 340B program or to the issue of rising drug prices in general.

Response to Questions on the 340B Drug Discount Program

As an initial matter, RWC-340B objects to the RFI’s focus on list prices and on the inclusion of questions about the 340B program under the heading “Create Incentives to Lower List Prices”. (p. 22697 of RFI). List prices are neither the price that manufacturers receive for their drugs nor the price that patients pay for drugs. The RFI’s focus should be on the cost of drugs to patients and their insurers (including Medicare, Medicaid and other government insurance programs) rather than list prices. There is no concrete evidence that the 340B program causes an increase in list prices, but there is evidence that the 340B program allows covered entities to lower the prices that patients and their insurers pay for drugs.

The RFI’s implication that the 340B program is even partially responsible for rising drug prices reflects a disturbing misunderstanding about how the 340B program works. The 340B

² U.S. Gov. Accountability Office, GAO-18-40, *Drug Industry Profits, Research and Development Spending, and Merger and Acquisition Deals*, at 18-19 (Nov. 2017), <https://www.gao.gov/assets/690/688472.pdf>.

program affords covered entities the freedom and flexibility to use the savings generated from the program to provide more services and more comprehensive care to more patients. It is no coincidence that RWCs are winning the war against the HIV/AIDS epidemic by keeping their patients on their drug regimens and helping them to achieve viral suppression. An individual with HIV/AIDS that achieves viral suppression does not spread the disease. Keeping an HIV patient's viral load suppressed protects against others contracting the disease which, in turn, lowers overall health costs in the U.S. That success is due, in large part, to 340B savings that RWCs use to provide a variety of patient services, including prevention, education, medication adherence, and social services. A fact that is often lost in discussions about the 340B program is that the health care providers that receive the savings are nonprofit, safety net providers that are restricted under the tax code from using funds for any purpose other than their safety net mission. Proposing increased federal oversight of the 340B program is anathema to the best feature of the 340B program – communities and health care professionals, rather than the federal government, determining how to use the resources afforded by 340B at the local level.

“How has the growth of the 340B drug discount program affected list prices?” (p. 22699 of RFI)

Critics complain about the “explosive” growth in the 340B program, but the growth in eligible hospitals stems largely from very deliberate actions by Congress and HRSA. There is no doubt that the 340B program has grown in recent years, but critics fail to note that the growth, in large part, is due to deliberate Congressional actions. And, the “growth” in eligible outpatient clinics is, for the most part, not growth at all, but simply reflects the fact that the agency charged with administering the 340B program – the Health Resources and Services Administration (HRSA) – implemented a policy that requires hospitals to register each clinic that participates in the program.

Congress expanded the number of hospitals eligible for the program on three separate occasions – in the Medicare Modernization Act of 2003, the Deficit Reduction Act of 2005 and the Affordable Care Act of 2010 (ACA). In particular, Congress added children's hospitals, cancer hospitals and hospitals located in rural areas. Congress added these hospitals because of their vital safety net role in America, especially in rural areas. Therefore, while the number of hospitals qualifying for the 340B program has increased since the program's inception in 1992, such growth is the result of deliberate, policy-oriented actions taken by Congress to add new providers as eligible entities.

About six years ago, HRSA implemented a change to the 340B registration database that gave the appearance of program growth. HRSA began requiring 340B hospitals to register every outpatient clinic located outside the hospital's main facility. Presumably, HRSA initiated this policy to increase transparency about the clinics where 340B drugs were being used. The HRSA policy states that a hospital that operates an outpatient medical office building with several clinics in the building must register each clinic. HRSA's policy also requires that a hospital with two campuses providing inpatient services to register all of the outpatient clinics at the second campus. It is no secret that hospitals are providing a greater number of services on an outpatient basis and are often furnishing those services in outpatient clinics outside the main facility to relieve congestion at the main facility and to offer services closer to patient homes. HRSA's policy resulted in some hospitals registering hundreds of outpatient clinics, even though the

clinics had already been participating in the 340B program for years. Further, HRSA makes a careful determination of eligibility for each hospital and outpatient site that applies for the program, and there is no evidence that ineligible facilities or sites are being admitted.

It is illogical to suggest that growth in the 340B program is a contributing factor to rising drug prices. The 340B program makes up a very small portion of the total discounts and rebates provided by drug manufacturers. In 2015, 340B program discounts totaled \$6.1 billion, which accounted for only 1.3 percent of the \$457 billion in net drug spending and 3.6 percent of total industry discounts and rebates in the United States.³ This amount is much smaller than the rebates and fees negotiated by insurers, managed care plans and pharmacy benefit managers (PBMs), which totaled \$57.7 billion and made up 33.9 percent of total industry discounts and rebates in the United States.⁴ In addition, list prices are set by manufacturers and there are absolutely no federal constraints on what manufacturers set as their list price for a drug. Speculation that the 340B program could be an important reason for rapidly increasing list prices or manufacturers' cross-subsidization of costs, is not an economically sound argument. The research by the pharmaceutical industry is that 340B discounts represent less than 5% of drug spending and of overall manufacturer discounts. Any review of the 340B program in the context of rising drug prices should conclude that the 340B program is not the cause of increasing drug prices. To the contrary, because of increasing drug prices, the 340B program is even more important to safety net providers than it was at the program's inception.

“Has it caused cross-subsidization by increasing list prices applicable in the commercial sector?”(p. 22699 of RFI)

The idea that manufacturer discounts to 340B entities force manufacturers to charge more in the commercial sector is based on a misunderstanding of the elasticity of manufacturing costs in the U.S. pharmaceutical market. The costs associated with developing and commercializing pharmaceuticals in the U.S. are not inelastic. Manufacturers have many choices for offsetting 340B discounts (or any other discount or rebate) with a decrease in spending in other areas. In November 2017, the GAO released a report analyzing the reasons for drug price increases based on a study of the pharmaceutical industry from 2006 to 2015.⁵ The GAO reported that 67 percent of all pharmaceutical companies saw an increase in their annual average profit margins from 2006 to 2015.⁶ Among the largest 25 companies, annual average profit margin was between 15 and 20 percent, as compared to the annual average profit margin across non-pharmaceutical companies which was between 4 and 9 percent.⁷ The only conclusion that can be drawn from these studies is that pharmaceutical companies charge high prices to maximize profits. RWC-340B does not object to private sector profits, but the idea that pharmaceutical companies have to raise their prices because of the 340B discounts that they provide to safety net providers is patently absurd.

³ 340B Health, *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers*, at 15, 20 (July 2017), https://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf.

⁴ *Id* at 21.

⁵ U.S. Gov. Accountability Office, GAO-18-40, *Drug Industry Profits, Research and Development Spending, and Merger and Acquisition Deals* (Nov. 2017), <https://www.gao.gov/assets/690/688472.pdf>.

⁶ *Id* at 17.

⁷ *Id* at 18.

The amount of money that drug manufacturers have spent on advertising and marketing makes up a significant portion of their overall spending, and exceeds the amount of discounts they provided to 340B covered entities by a wide margin. In 2012, the U.S. pharmaceutical industry spent \$27.3 billion in marketing to consumers and healthcare professionals, including \$3.1 billion in direct-to-consumer advertising.⁸ The pharmaceutical industry also collectively spent more than \$150 million annually lobbying Congress in recent years.⁹ CEOs of the 14 biotech and pharmaceutical companies in the S&P 500 each received a median compensation package valued at \$18.5 million in 2015.¹⁰

As evidenced by these numbers, 340B discounts make up a small portion of the total expenditures by pharmaceutical companies and pale in comparison to the amount of money spent on marketing, executive compensation, and lobbying, over which the industry has complete control. Additionally, pharmaceutical companies have some of the highest profits of any industry. Any claims that 340B causes pharmaceutical companies to cross-subsidize by increasing list prices in the commercial sector to account for 340B rebates is unfounded, unfair, and a dangerous diversion by those who do control prices in the market – the pharmaceutical industry.

“What impact has this had on insurers and payers, including Part D plans?” (p. 22699 of RFI)

RWC-340B strongly disagree that there is any relationship between the 340B program and prices paid for drugs by insurers and payers. Payers are paying no more than fair market rates, and sometimes even less than fair market rates. Conversely, services provided by covered entities are often uncompensated or undercompensated.

One disturbing trend that RWCs have experienced in their recent contract negotiations with PBMs, managed care plans, and other third party payers is that these payers are trying to usurp the benefit of the 340B program by reimbursing 340B drugs well below the payers’ non-340B rates and by establishing other discriminatory terms in their pharmacy participation agreements. 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 nonprofit status. Covered entities use 340B revenue to treat more vulnerable patient populations and to improve services for those populations. Increasing efforts by payers to transfer the intended benefit of the 340B program to themselves is reducing the ability of RWCs and other safety net providers to provide essential services, thereby increasing overall health care costs.

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 340B 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.” RWC-340B strongly urges HHS to focus on shoring

⁸ *Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers* at 22.

⁹ Center for Responsive Politics, *Pharmaceutical Industry Lobbying and Political Spending Data*, www.opensecrets.org/lobby/induscode.php?id=H4300 (last visited July 1, 2018).

¹⁰ Matt Krantz, *Drug Prices Are High. So Are the CEOs' Pay*, USA TODAY (Aug. 26, 2016), <https://www.usatoday.com/story/money/markets/2016/08/26/drug-money-pharma-ceos-paid-71-more/89369152/>.

up this vital program for America's safety-net providers rather than allowing payers to misappropriate 340B savings away from safety net providers.

“Does the Group Purchasing Organization (GPO) exclusion, the establishment of the Prime Vendor Program, and the current inventory models for tracking 340B drugs increase or decrease prices?” (p. 22699 of RFI)

The 340B statute states that certain hospitals may not purchase covered outpatient drugs through a GPO or other group purchasing arrangement. RWCs are not subject to the GPO exclusion so the statutory provision does not affect them directly. The GPO exclusion does, however, drive up costs for hospitals subject to the exclusion. It forces them to maintain multiple drug inventories and to purchase many of their drugs at non-340B, non-GPO prices that no one else in the market is paying. More rigorous tracking requirements in inventory models associated with the GPO exclusion result in higher software, labor and vendor costs to comply with the program. The GPO exclusion therefore increases prices paid by affected hospitals and adds to the administrative costs of complying with 340B program requirements. For RWCs that are owned by or affiliated with hospitals subject to the GPO prohibition, these additional costs and administrative complexities have a negative impact on the efficiency of the delivery systems in which RWCs operate.

“What are the unintended consequences of this program?”(p. 22699 of RFI)

We do not agree that there are unintended negative consequences, economic or otherwise, that arise from the 340B program for the pharmaceutical industry or payers. Any suggestion otherwise is a patently unfair attempt by critics of the program to malign the 340B program by suggesting that the industry has no control over its costs and that 340B must therefore be realigned, reinterpreted, and reformed. The one unintended consequence for 340B providers is the one described in response to the last question, *i.e.*, PBMs, managed care plans, and other third party payers 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. 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.

RWCs can attest firsthand to the very positive patient outcomes that are a result of this program, which RWC-340B suspects is the very type of “consequence” that Congress intended when it enacted the program. The 340B program, as structured and functioning for the last two decades, works for RWCs because it allows them to care for the comprehensive needs of their communities and is not limited to providing drugs to only the uninsured or low income patients. While the 340B program serves the important function of allowing RWCs 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 RWCs have to subsidize the drug costs for their underinsured and uninsured patients. In short, passing along the 340B discount alone does not make the drug affordable for patients.

The 340B program is more relevant than ever in the fight against HIV/AIDS. By serving fully insured patients, RWCs are able to derive revenue from the program that they then invest in programs to assist the uninsured and underinsured, thereby fulfilling the public health mission of the Ryan White program. 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.

The 340B model works because of the flexibility in how RWCs and other 340B covered entities are permitted to use their savings. To be successful in the fight against HIV/AIDS, persons living with the disease need much more than prescription drugs. The 340B program allows RWC-340B members to stretch their 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. Importantly, program savings help underwrite the cost of these services at no cost to taxpayers. The inherent flexibility and local focus of the 340B program allows us to care for our communities as we now do.

In terms of unintended negative consequences, Congress intended the benefits of the 340B program to accrue to 340B covered entities, not to PBMs and other payers that do not have the same safety-net mission or nonprofit status. This unintended usurpation of the 340B discount runs directly contrary to Congressional intent. We urge the Administration to address threats from for-profit PBMs, insurance companies and other payers that are increasingly misappropriating 340B savings through discriminatory reimbursement.

“Would explicit general regulatory authority over all elements of the 340B Program materially affect the elements of the program affecting drug pricing?” (p. 22699 of RFI)

Explicit, general regulatory authority over all elements of the 340B program would run directly contrary to the Administration’s goals of reducing regulatory burden¹¹ and could significantly increase drug costs, while reducing the availability of effective services, where covered entities’ ability to utilize the program is narrowed. In addition, increasing the administrative costs of the program would undermine Congress’s intent “to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹² For RWCs, any change to the 340B program that reduces the number of patients who can receive 340B drugs or undermines the flexibility of the 340B program has a direct and negative impact on the fight against the HIV/AIDS epidemic.

Statements that covered entities require greater regulation over their use of 340B program savings represent an unwelcome and unnecessary government intrusion into a program that is

¹¹ HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22,692, 22,699 (May 16, 2018) (“HHS is actively working to reduce regulatory burdens.”); Reducing Regulation and Controlling Regulatory Costs, Exec. Order No. 13,771, 82 Fed. Reg. 9,339 (Feb. 3, 2017).

¹² H.R. REP. 102-384, pt. 2, at 12 (1992).

working effectively for RWC patients. RWCs are on the front lines of caring for low-income and vulnerable patients. Locally controlled RWCs are in a better position than federal bureaucrats 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. 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 covered entities were forced to spend funds on complying with additional burdensome regulations. Therefore, RWC-340B strongly opposes any efforts to limit that flexibility and strongly rejects a one-size-fits-all approach to regulation.

Concerns about HRSA's regulatory authority would be more understandable if directed at requirements applied to manufacturers. Unlike manufacturers, RWCs receive federal grant funding and, like other federal grantees and sub-grantees, are subject to detailed reporting requirements as a condition of receiving such funds. In addition, participating 340B hospitals must submit reams of financial information to the Internal Revenue Service (IRS) to support their non-profit status and to HHS as part of their annual filing of their Medicare cost reports. However, to date, HRSA has only audited twelve manufacturers and has utilized a process that, compared to the covered entity audit 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. We urge the Administration to enforce the law as it is written and implement the current program integrity provisions enacted by Congress, such as the development of a system to enable HHS to verify the accuracy of ceiling prices calculated by manufacturers, as opposed to imposing additional regulatory burdens on covered entities.

“Program Eligibility. Would changing the definition of “patient” or changing the requirements governing covered entities contracting with pharmacies or registering off-site outpatient facilities (i.e., child sites) help refocus the program towards its intended purpose?”(p. 22699 of RFI)

There is no actionable evidence that the 340B program needs to be refocused or that it is being used extraneous to its original intended purpose. Narrowing current uses of the program – whether by shrinking the “patient” definition, restricting the use of contract pharmacies or disqualifying off-site facilities – would make it more difficult for covered entities to fulfill the program's purpose. Simply put, these measures would increase prices paid for drugs, decrease resources for the safety-net, and reduce patient access and choice. Additional restrictions would also increase the administrative costs of administering the 340B program, while increasing regulatory burden.

Like other covered entities, RWCs benefit from the 340B program when discounted drugs 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.”¹³ The word “patient” has a well-understood meaning in the RWC

¹³ 42 U.S.C. § 256b(a)(5)(B) (2012).

community, and based on the plain, statutory meaning, a patient is “a person who receives medical care or treatment.”¹⁴ Based on guidance from HRSA, which has been relied on for over twenty years, an individual is a patient of a covered entity if the individual receives health care services from a health care professional affiliated with the covered entity and the covered entity maintains medical records for those services. 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. RWC-340B and other covered entities support efforts in Congress to codify this current definition of “patient”.¹⁵ We urge HHS to maintain the 1996 patient definition guidelines, which have worked well for over twenty years.

Limiting contract pharmacies or registration of outpatient facilities would reduce patient access and diminish the positive impact of the 340B program, while increasing overall drug expenditures by participating safety-net providers. HRSA first issued contract pharmacy guidelines in 1996 to allow covered entities without in-house pharmacy services to contract with a pharmacy to provide 340B pharmacy services. In 2010, HRSA updated the guidelines to allow covered entities to provide 340B pharmacy services by utilizing both in-house and contract pharmacies. This update also allowed covered entities to contract with multiple contract pharmacies.¹⁶ Contract pharmacies improve access to affordable medications, so allowing covered entities to enter into multiple contract pharmacy arrangements furthers this goal. Allowing for multiple pharmacy options enhances patient choice as well.

In regards to the registration of “child sites”, HIV/AIDS is a difficult disease to treat, and being allowed to operate in multiple sites affords greater access to underserved patients. RWC-340B does not object to reasonable registration requirements for child sites, but such requirements must be sufficiently flexible to allow RWCs to treat and/or manage patients in non-clinical settings such as patient homes, correctional institutions and on the streets.

In sum, 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, including patients with HIV/AIDS, which would take away from the intended purpose of the program. RWC-340B does not object to reasonable federal oversight, but any increased regulatory authority should come with a directive to maintain the program as it is currently operating.

“Duplicate Discounts. The 340B statute prohibits duplicate discounts. Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Are the current mechanisms for identifying and preventing duplicate discounts effective?” (p. 22699 of RFI)

Evidence supports the conclusion that current mechanisms to prevent duplicate discounts are relatively effective. The systems used to prevent duplicate discounts continue to adapt and improve over time. RWC-340B supports the use of retrospective claims identification models (such as the model currently in place in Oregon) or use of a separate BIN-PCN for Medicaid managed care organization (MCO) plans to avoid duplicate discounts on Medicaid MCO claims.

¹⁴ *Patient*, Merriam-Webster Online Dictionary (2018), <http://www.merriam-webster.com/dictionary/patient>.

¹⁵ Stretching Entity Resources for Vulnerable (SERV) Communities Act, H.R. 6071, 115th Cong. (2018).

¹⁶ 61 Fed. Reg. 43,550, 43,554 (Aug. 23, 2016).

As noted in a 2016 HHS Office of Inspector General’s report, claims level identification improves accuracy in identifying 340B claims and thereby helps states correctly collect rebates.¹⁷

Some states have proposed restrictions on the use of 340B drugs for Medicaid beneficiaries in certain circumstances, i.e., when the covered entity uses a contract pharmacy or for Medicaid MCO beneficiaries. Such models are unrealistic and would have disastrous consequences for RWCs. Many RWCs lack pharmacies of their own, and rely upon contract pharmacies to access 340B program benefits. In addition, RWCs treat the indigent and underinsured and Medicaid MCOs make up a significant portion of the payer mix. 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 states should be empowered to find the best solution for their state.

“Are drug companies paying additional rebates over the statutory 340B discounts for drugs that have been dispensed to 340B patients covered by commercial insurance?” (p. 22699 of RFI)

HRSA specifically recognized that covered entities are permitted to “work within the reimbursement policies of the public and private health insurance plans they work with” to exercise “billing flexibility” and generate the “income that 340B was enacted to create.”¹⁸ Any additional rebate depends on private contracts and only exists if the parties have voluntarily negotiated and contracted to do so. In contrast, the rebates manufacturers pay to PBMs have been criticized as anticompetitive and inappropriately limiting patient choice. The lack of transparency in these arrangements makes it impossible to know what portion of high drug prices is the result of these rebates—in other words, there is no way to know what “chunk” PBMs take out of the soaring cost of drugs. In addition, PBMs design their drug benefits to maximize these rebates (i.e., covering drugs that generate more rebates and discouraging patients from taking necessary drugs that may generate less profit), thereby limiting patient choice and typically impacting the sickest patients. These rebate arrangements hardly deserve to be protected at the expense of helping safety net providers with their outpatient drug costs.

“What is the impact on drug pricing given that private insurers oftentimes pay commercial rates for drugs purchased at 340B discounts?” (p. 22699 of RFI)

There is no actionable evidence of any impact on overall drug pricing from such a practice. “Commercial rates” are nothing more than the fair market rates that the market supports. In fact, this practice is critically important for the survival of the 340B program. If the safety net providers participating in the 340B program were not receiving commercial reimbursement rates for providing 340B drugs, and instead passed along the discount to insurers, they would not be realizing any savings and would not be able to stretch scarce federal resources

¹⁷ U.S. Dept. of Health and Human Services, Office of Inspector Gen., OEI-05-14-00430, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, at 16 (June 2016), <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf>.

¹⁸ U.S. Dept. of Health and Human Services, Health Resources and Services Admin., *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act*, II.K at 28 (July 2005), <https://ecitydoc.com/download/document-6478972.pdf>.

in order to meet the needs of the underserved and other vulnerable patient populations. Nor would they be able to provide essential services that are often uncompensated or undercompensated—the exact impact that Congress intended. Again, the 340B program was not intended to benefit private, often for-profit, insurers.

Safety net providers use the pharmacy-related revenue derived from fully insured patients to assist all patients, especially the uninsured and underinsured, thereby fulfilling their public health mission. Program savings help underwrite the cost of these services at no cost to taxpayers. 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 twenty-five years to support covered entities that, by definition, serve vulnerable populations.

Any attempt by PBMs, managed care plans, and other third party payers to usurp 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 is harmful to the 340B program. Discriminatory reimbursement ultimately harms the low income and medically vulnerable patients served by 340B providers, including RWCs. The GAO has found that providers use 340B savings 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.¹⁹ Reducing reimbursement to 340B covered entities will jeopardize the ability of RWCs and other 340B covered entities to provide these important services.

“Do insurers, pharmacy, PBM, or manufacturer contracts consider, address, or otherwise include language regarding drugs purchased at 340B discounts?” (p. 22699 of RFI)

These contracts can, and sometimes do, address drugs purchased with 340B discounts. As noted above, 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. 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.

“What should be considered to improve the management and the integrity of claims for drugs provided to 340B patients in the overall insured market?” (p. 22699 of RFI)

In order to improve the drug market, there should be significant improvements regarding manufacturer integrity and transparency. HHS should implement the manufacturer integrity

¹⁹ U.S. Gov. Accountability Office, GAO-11-836, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 17 (Sept. 2011), <https://www.gao.gov/assets/330/323702.pdf>.

provisions in the 340B statute, which require access by covered entities to the 340B price in an on-line database, definition of the 340B price (often referred to as the “ceiling” price) and civil monetary penalties for manufacturer overcharges. Unintended consequences on all categories of 340B providers should also be considered before making any substantial changes to the 340B program. As discussed in the previous question on unintended consequences, the 340B program provides a number of benefits for unserved and vulnerable populations served by RWCs. RWC-340B supports transparency within the 340B program but does not support covered entity reporting requirements that are intrusive and unfair compared to the meager disclosure requirements applicable to manufacturers.

“What additional oversight or claims standards are necessary to prevent duplicate discounts in Medicaid and other programs?” (22699 of RFI)

As stated in the response to a prior question (*“Are the current mechanisms for identifying and preventing duplicate discounts effective?”*), the systems that are in place to prevent duplicate discounts are generally effective and continue to evolve and improve over time. We support the use of retrospective claims identification models (*i.e.*, the model currently in place in Oregon) or use of a separate BIN-PCN for Medicaid MCO plans to avoid duplicate discounts in Medicaid MCO claims so long as the PBM industry is prohibited from discriminatory reimbursement practices. For additional discussion of duplicate discounts, please see our response to the prior question.

Request for Comments Not Specific to the 340B Drug Discount Program

Increasing Competition (p. 22695 of RFI)

“Does the Best Price reporting requirement of the Medicaid Drug Rebate Program pose a barrier to price negotiation and certain value based agreements in other markets, or otherwise shift costs to other markets?” (p. 22695 of RFI)

No. The “best price” reporting requirement of the Medicaid Drug Rebate Program is an essential element in the calculation for manufacturer discounts in the 340B program. Moreover, it protects tax payers by ensuring that Medicaid programs do not pay inflated prices for drugs and is therefore essential for the sustainability of Medicaid.

Better Negotiation (p. 22696 of RFI)

“What steps can be taken to improve price transparency in Medicare, Medicaid, and other forms of health coverage so that consumers can seek value when choosing and using their benefits?” (p. 22696 of RFI)

RWC-340B is all in favor of transparency in the 340B program but the reality is that manufacturers are far less transparent than covered entities when it comes to sharing data with HRSA and the public. When covered entities are selected for a 340B audit, they provide access to patient medical charts, medication purchase records, claims-level billing information and other

raw data relevant to their compliance with 340B requirements. This is in addition to all the cost, charge, reimbursement and patient information they must provide when submitting their federal grant applications, their Medicare and Medicaid cost reports and the various documents in support of their IRS non-profit status. Drug companies, by contrast, enjoy a unique industry-specific confidentiality law that protects them from having to share their drugs' average manufacturer price (AMP) and best price in the marketplace, as well as how much a drug's AMP has increased relative to the rate of inflation, even though this is the very information on which their 340B ceiling price calculations are based. They must report their drugs' AMP and best price to the Centers for Medicare & Medicaid Services but rarely does the government ever audit the raw data underlying those calculations. More importantly, such data is never submitted and reviewed by HRSA as part of a 340B audit. The current lack of parity in transparency requirements applicable to manufacturers and covered entities needs to be rectified.

Increased manufacturer price transparency would greatly improve consumers' ability to see value in their drug purchases. Elimination of the current confidentiality protections enjoyed by drug companies regarding their drugs' "best price" and AMP would bring fundamental transparency in a system that is crying out for reform. No other industry in the U.S. is protected under federal law from disclosing its pricing to purchasers, payers, competitors and the general public. Public access to a drug's best price or AMP would go a long way in allowing consumers to seek value when choosing and using their pharmacy benefits. The confidentiality provisions shielding access to such information serves no other purpose than to obfuscate informed consumer decision-making.

RWC-340B is aware that Medicare, Medicaid and other payers would like greater transparency when they are asked to pay for 340B drugs. For reasons already discussed above, RWCs are concerned that this information would simply be used by payers to cut reimbursement to covered entities and their pharmacies. RWC-340B would support increased transparency into 340B claims identification if paired with federal protection against discriminatory reimbursement and other misuses of such information.

"Value-Based Arrangements and Price Reporting. What benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value based arrangements?" (p. 22696 of RFI)

Value-based purchasing is a laudable goal; however, allowing manufacturers to increase their prices further through exclusions described in this question appears completely contradictory to lowering drug prices, especially for safety net providers, and also to the stated goal of price transparency. Further, any efforts to dismantle the 340B program or undermine its efficacy could bring serious, unintended consequences to the patients that RWCs serve.

"How should Medicare or Medicaid account for the cost of disease averted by a curative therapy paid for by another payer? (p. 22697 of RFI)

While much progress has been made in the fight against HIV/AIDS, and patients are living longer and healthier lives, we anxiously wait for the day that there is a cure. In the

meantime, the 340B program has proven to be an invaluable tool for reducing the scourge of HIV/AIDS. Payers are not the only ones that can avert the cost of disease; providers in the 340B program play a crucial role. As stated in our previous answers, RWCs provide an excellent example of how providers can use 340B savings to avert not only the cost of a disease but also help prevent its transmission, resulting in lower overall health costs. Such an approach will become increasingly more important as the population with HIV/AIDS ages and become Medicare beneficiaries.

Create Incentives to Lower List Prices (p. 22697 of RFI)

“CMS regulations presently exclude manufacturer sponsored drug discount card programs from the determination of average manufacturer price and the determination of best price. What effect would eliminating the exclusion have on drug prices?” (p. 22698 of RFI)

In general, exclusions from “best price” and AMP calculations increase drug costs within the Medicaid and 340B programs which increases drug costs for tax payers. Combined with increased transparency, eliminating these exclusions could result in overall lower prices.

Additional Feedback (p. 22699 of RFI)

“What other regulations or government policies may be increasing list prices, net prices, and out-of-pocket drug spending?” (p. 22699 of RFI)

Encouraging HRSA to adopt its proposed CMP and penny pricing regulation (HRSA has postponed implementation multiple times) would help reduce list prices, net prices and out-of-pocket drug spending. HRSA could also move forward with the statutorily required website to provide access to the 340B price for covered entities, improving program and price transparency.

“To what extent do current regulations or government policies related to prescription drug pricing impose burden on providers, payers, or others?” (p. 22699 of RFI)

340B safety-net providers abide by a variety of program requirements and are subject to routine HRSA audits. Complying with 340B eligibility and program compliance rules is a significant administrative burden on providers. Despite this increased scrutiny, HRSA has yet to remove a covered entity from the 340B program for misuse or abuse. In fact, most audits of covered entities find inadvertent errors and simple errors that are readily corrected. Entities in the 340B program are more than twice as likely to be audited as a tax filer in the United States. To date, while almost 1000 covered entities have been subject to audit, only a dozen manufacturers have been audited.

“To what extent do the planned actions described in this document impose burden, and do these burdens outweigh the benefits?” (p. 22699 of RFI)

The RFI’s questions are nearly all slanted in a way to prompt answers that would benefit pharmaceutical manufacturers. They present a clear path toward thwarting the benefits of the 340B program, dismantling it to the benefit of pharmaceutical manufacturers at the expense of

patients served by the safety net through the 340B program. Most questions are based on the faulty assumptions posited by the pharmaceutical industry that there is “explosive growth” in the 340B program, that manufacturers are suffering from their voluntary participation in this program, and that drug prices are rising as a direct result of the 340B program. None of these contentions are true or based on objective, unbiased, statistical research or fact.

Program savings from 340B help to underwrite services to vulnerable patient populations at no cost to taxpayers. The 340B program is a vital program for RWCs and is working exactly as Congress intended it to work. Narrowing and burdening the 340B program threatens the widespread benefits supported by program savings.

Concluding Comments

In conclusion, there is little evidence to support the dubious claim that the 340B program has a material impact on list prices, which are set at the discretion of pharmaceutical manufacturers seeking to maximize profits. The 340B program continues to permit participating entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Government measures that would limit the 340B program would have potentially far reaching negative consequences and would undermine a system that allows RWCs to provide necessary services, without which our nation’s health and health costs would suffer substantially.

Our nation is winning the war against the HIV/AIDS epidemic in large part because of the hard work of RWCs and the fiscal support provided by the 340B program. RWCs have demonstrably increased viral suppression rates which, in turn, have reduced the spread of this highly contagious disease. If the 340B program is narrowed, burdened, or if RWCs or other covered entities are subject to less flexibility in how they use their savings, it is possible that another HIV/AIDS public health crisis could be triggered and the federal government and/or the states would bear extremely burdensome costs. We ask the Administration to ensure that the 340B program remains strong to allow covered entities to continue to serve vulnerable populations, rather than undermine it with more regulation or bureaucracy.

For further information please contact Peggy Tighe at Peggy.Tighe@powerslaw.com, Barbara Straub Williams at Barbara.Williams@powerslaw.com or Bill von Oehsen at William.vonOehsen@powerslaw.com or see www.RWC340B.org.

Sincerely,

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AIDS Care Group – *Philadelphia, Pennsylvania*
AIDS Center of Queens County – *Queens, New York*
AIDS Healthcare Foundation – *Los Angeles, California*
AIDS Outreach Center – *Fort Worth, Texas*
AIDS Project of the Ozarks – *Springfield, Missouri*

AIDS Resource Center of Wisconsin – *Milwaukee, Wisconsin*
AIDS Taskforce of Greater Cleveland – *Cleveland, Ohio*
Alamo Area Resources Center – *San Antonio, Texas*
Allies for Health + Wellbeing – *Pittsburgh, Pennsylvania*
Big Bend Cares – *Tallahassee, Florida*
CAN Community Health – *Sarasota, Florida*
Cempa Community Care – *Chattanooga, Tennessee*
Christie’s Place – *San Diego, California*
Conemaugh Health System – *Johnstown, Pennsylvania*
Damien Cares – *Indianapolis, Indiana*
Equitas Health – *Columbus, Ohio*
Evergreen Health Services – *Buffalo, New York*
Fenway Health – *Boston, Massachusetts*
Foothill AIDS Project – *Claremont, California*
Heartland CARES – *Paducah, Kentucky*
Hyacinth AIDS Foundation – *Elizabeth, New Jersey*
Men’s Health Foundation – *Los Angeles, California*
MetroHealth – *Washington, DC*
North Jersey Community Research Initiative – *Newark, New Jersey*
Northern Nevada HOPES – *Reno, Nevada*
Northland Cares – *Prescott, Arizona*
Nuestra Clinica – *Lancaster, Pennsylvania*
One Community Health – *Sacramento, California*
Open Door Health Center – *Elgin, Illinois*
Positive Health Clinic – *Pittsburgh, Pennsylvania*
Positively U – *Davenport, Florida*
Prism Health North Texas – *Dallas, Texas*
South Carolina HIV/AIDS Council – *Columbia, South Carolina*
Southwest CARE Center – *Santa Fe, New Mexico*
Thrive Alabama – *Huntsville, Alabama*
Trillium Health – *Rochester, New York*
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CARES of Southwest Michigan – *Kalamazoo, Michigan*
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Wellness AIDS Services – *Flint, Michigan*
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