October 30, 2020

House Energy and Commerce Committee
Senate Health, Education, Labor and Pensions Committee
Sent via email to: 340B@help.senate.gov and 340B@mail.house.gov

Dear Ranking Member Walden and Chairman Alexander,

The following response is in regard to your October 9, 2020 request for information on improving and modernizing the 340B Program. The information shared is from Ms. Suzanne Herzog and Dr. Madeline Wallack, co-founders of RxIX Consulting, an independent 340B audit and advisory services firm. Our comments are the result of two decades worth of institutional and experiential lessons from working in the 340B space in various roles. We have a unique perspective to bring on the facts and myths surrounding 340B.

We write today to tell you that despite its mischaracterizations from critics, 340B is a simple solution within a very complex industry. 340B means cheaper drugs to qualified entities at no cost to the government or taxpayers. No one pays more. To change the program's design or purpose will create a massive financial strain for hospitals and grantees of all sizes in an already difficult economic time. There are, however, issues that need attention, which are outlined herein.

If the Committee has any questions or would like to schedule time for follow up, we would be honored.

Sincerely,

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Recommendations for Modernizing the 340B Program

The 340B Program is hard to explain and often mischaracterized. It is a novel solution to the long-standing problem of the high cost of drugs that doesn't cost the government or taxpayers money. This program should be optimized, especially given the pandemic and state of the economy. It simultaneously utilizes next to no governmental resources and yet infuses money into the safety net. At the same time, a lot has happened since the program's inception almost thirty years ago and there are opportunities for modernization.

1. 340B should be modernized to better protect the savings in ways that more efficiently benefit the entities, as intended.

No one pays more for 340B drugs—not insurers, not the government, not patients. There is no "markup" to specific patients or payers. Reimbursement for drugs is the same whether the entity is 340B or not. Instead of charging more, the 340B Program lessens the impact of inadequate payment by reducing the cost of inventory.

However, as the program has evolved over time, the 340B savings available for covered entities reinvestment into their programs has diminished. Action is necessary to prevent other stakeholders from improperly benefitting off of 340B at the expense of covered entities.

<u>First, there must be reimbursement protections for 340B entities so that the savings are not appropriated to insurance companies and PBMs.</u>

Insurance companies that lower their reimbursement to known 340B entities diminish the savings that should be going to the provider. 340B was not intended to benefit insurance companies or Pharmacy Benefit Managers (PBMs). Without any protections, there is little covered entities can do about this practice.

<u>Second, covered entities need protections surrounding fair contract terms and fee schedules from pharmacies and other vendors.</u>

340B covered entities wishing to offer access to patients via a contract pharmacy must contract with the pharmacy and software vendors to manage a compliant inventory. We have increasingly seen contract terms that do not meet Fair Market Value tests for the services provided, resulting in an unreasonable portion of the savings goes to the pharmacy or vendor. While there are a range of issues across all vendors, we are seeing

more aggressive terms from specialty pharmacies, especially when the pharmacy is owned by a PBM.

While we were at the OIG, we examined fairness in determining fair reimbursement to pharmacies for Medicaid and separating the cost of the drug from the professional fees. This same concept has not been explored for 340B at contract pharmacies. Pharmacies and technical vendors play a key role in the program, yet the lack of standardization has meant less savings for the entities.

2. CMS should rescind its 30% Medicare Part B reimbursement cut to 340B entities

Policies that shift cost savings to Medicare may not actually be effective and could adversely impact patient care. Entities should be permitted maximum flexibility to collaborate on program design to keep the focus on innovation and improving health outcomes for their communities.

For years, Medicare paid for high cost cancer drugs and other biologics based on grossly inflated reference prices. After several government investigations and lawsuits, the Medicare Modernization Act revised the formula with the hopes of fair reimbursement. In 2017, faced with the ongoing issue of high drug costs, CMS issued a rule that would reduce reimbursement by 30% to 340B hospitals. Yet, this policy does not address the issue of rising drug costs and has no impact on the manufacturers. It only harms 340B hospitals.

CMS should reconsider its proposals for more changes in 2021 as entities are anticipating being underwater on cancer care for Medicare beneficiaries.

3. A real solution for the prevention of Medicaid duplicate discounts will require more leadership from CMS and HRSA and more consist policy across States.

In 2016, CMS required States to develop policies for 340B billing and the prevention of duplicate discounts. It is our experience that States' communication to entities about expectations and billing instructions are often vague and/or limited. Entities invest significant resources in billing and auditing claims, but the scope of this task keeps growing.

States' policies are inconsistent in the following ways:

- Some States require a change to the charge to actual acquisition cost while others do not. Entities typically set the charge to be the same for a drug across all payers but are reimbursed based off contracts or governmental rules.
- Some but not all States use claims level modifiers and they are not always the same modifiers.
- Medicaid uses different modifiers than Medicare, resulting in claims requirements are overly burdensome.
- Many Medicaid Managed Care plan BIN/PCN codes are the same as the commercial plan, making it difficult to distinguish which is Medicaid.

While HRSA was statutorily required to develop a mechanism to prevent duplicate discounts, its tool for communicating an entity's 340B billing strategy to the State—the Medicaid Exclusion File (MEF)—is obsolete and is an administrative burden to entities. It only applies to an entity's internal use of 340B and not to contract pharmacy, which is the often the focus of disputes. Without consistent claims level identifiers and policies, duplicate discounts may occur. CMS and HRSA must work together to develop a new tool with better technology.

<u>Manufacturer-proposed solutions to identify duplicate discounts will not work if the real issue is instead "stacked discounts" with PBMs.</u>

In addition to ratcheting down reimbursement to 340B entities on the payment side, PBMs can also "stack" the total discount by continuing to receive manufacturer rebates on 340B claims. This is particularly egregious where the PBM owns the pharmacy contracted to serve 340B entities. In these scenarios, the pharmacy typically charges a percentage of the margin on the payment they also set as the payer. They then still collect the PBM rebate. When you have double interest in a business, you can double dip.

Interestingly, when manufacturers started inquiring this summer about contract pharmacy claims data, some clients received letters from specialty pharmacies casually alerting them that certain drugs that would no longer be included in the 340B program. The PBM knew a choice would be forced and suddenly preferred its rebate. They didn't want the manufacturers to have the data. PBMs didn't want manufacturers to see that they were double dipping.

This issue of "stacked discounts" is even more exacerbated by 340B penny prices. Manufacturers set prices. If the price rises faster than the rate of inflation, they are

penalized by CMS and the resulting 340B price is set to a penny per unit. When this happens on a specialty medication, the gap between the 340B acquisition cost and the contracted rate is significant. This larger difference is part of the penalty and the 340B is the rightful beneficiary. However, if PBMs are also collecting rebates on these transactions, they are worsening the net impact on manufacturers.

A lot of attention is paid to the total number of contract pharmacies or the growth, but more should be paid to *why* 340B entities are contracting and with whom. Specialty medications are very expensive, increasing the value of the 340B discount. With PBM owned specialty pharmacies, the power is with the plan. If an entity wants access to payer contracts, they must enter into a contract pharmacy relationship with specific contract pharmacies, where they have little leverage.

PBMs have created a scenario where everyone loses but them. Manufacturers have every right to want to address this but not by stopping contract pharmacy. This is an issue with the PBMs. Contract Pharmacy has been a customary practice that manufacturers have honored for over 10 years. Covered entities have come to rely on these relationships as an extension of the price concessions made through 340B because drug prices are so high. Manufacturers are attempting to change things primarily due to the stacked discounts from PBMs.

340B entities are collateral damage to the problem of confusing payer contracts/PBM rebates. The system of stacked rebates does not benefit 340B entities or patients and is just cause for manufacturer criticism but will not be remedied through large requests for data validation. If the issue is really about PBM rebates as we suspect, it would be wise to address it directly.

4. HRSA is not acting on its legislative authority to better oversee all stakeholders.

HRSA is authorized to audit manufacturers but the number and scope of manufacturer audits are significantly less than audits of entities. HRSA should be auditing the accuracy of the 340B ceiling price, including the inputs to the calculation.

HRSA also has legislative authority under the Affordable Care Act to review the common practice of “prior period adjustments" that manufacturers make on calculations of the components of the ceiling price up to 3 years post-submission. HRSA has not acted on this in spite of having the authority to do so and the widespread belief that 340B entities would be owed a sizable amount of money.

Manufacturers have been fined for AMP and BP manipulation on the Medicaid side, but not customarily on the 340B side. HRSA should be routinely reviewing the impact of these adjustments and when the prices are lower, money should be refunded to covered entities.

5. Excluding Orphan Drugs from the 340B Program for rural providers and free-standing cancer centers must be reversed.

The orphan exception has had a significantly negative financial impact on hospitals that would greatly benefit from additional savings. As the number of orphan approvals go up, the government is losing on potential savings and paying more for these medications, many of which are some of the most widely used drugs today.

Expenditures on prescription drugs are a key concern across the entire health care system, particularly in light of rising pharmaceutical costs, the general state of the economy, the increasing age of the population, and growing use of costly specialty and infusion drugs, which are more likely to have orphan indications. When you add the variable of "rural," the situation is even more dire.

What was the point of adding rural provider types to the list of 340B eligible entities when they cannot benefit from the much-needed discount on the most expensive drugs? It is critical that these providers are able to capitalize on the savings available at the 340B price for these high-cost drugs.

Conclusion

Any efforts to modernize the 340B program should preserve the savings AND protect autonomy for use with the entity. The strong backlash and calls for program restriction compel an answer to the question at the center of all of this: What is the 340B Program's purpose? Is 340B intended for entities to better serve their patients and communities? Or is it a program limited to uninsured patients?

Fifteen years ago, our program evaluations for the OIG focused on why eligible entities were not using the program. Enrollment was low and the recommendations were for program expansion. So, the program grew alongside other significant changes in healthcare policy—the Medicare Modernization Act of 2003, The Deficit Reduction Act

of 2005 and the Affordable Care Act of 2010. Growth in the use of 340B is positive when compared against its purpose is to help entities stretch resources and benefit patients, at almost no cost to the government. Program growth can only be viewed negatively if the purpose is limited to only directly impact qualifying patients.

Our suggestions for modernization start with the premise that 340B was intended to infuse safety net providers with funding that would otherwise come from the government.

Today's version of "underserved" means people with no insurance or low-quality insurance with high deductibles that they cannot meet. It means people who are creating "GoFundMe" accounts to cover medical costs. It means individuals with certain conditions where the drug costs are simply out of reach. This ranges from patients with rare conditions and cutting-edge treatments that will cure them, but at a six or seven figure cost to diabetics caught in the middle of manufacturers' pricing games for insulin.

340B is a simple solution in the complex world of drug pricing policy. Any alternative will require a complex and costly solution. Despite its frequent mischaracterizations, 340B means cheaper drugs to qualified entities at no cost to the government. The genius of this program lies in its simplicity: manufacturers must offer a ceiling price or below based on auditable, market-based data inputs that are also used for Medicaid. This is a straightforward discount on the cost of goods and not an insurance program or a rebate program. Drastic changes to 340B will not remove the issue of high drug prices but will require a more complex solution to the problem of high drug prices.

340B was created because manufacturers were not discounting drug prices to safety net providers that serve patients with Medicare, Medicaid or no insurance. Manufacturers had stopped offering favorable discounts after the passage of the Medicaid Drug Rebate Program (MDRP). If 340B goes away, the MDRP will still be there to create market disruption.

340B doesn't cost the government or taxpayers money. In fact, it infuses money back into entities' systems without costing the government money. As we have seen with COVID and the impact on sudden loss to the health care industry, if 340B were to drastically change, we anticipate the need for a government bailout that would make the money distributed via the CARES Act look small.

With the state of the economy, we should instead be seeking ways to optimize this program.