August 13th, 2025

The Honorable Tom Engels
Administrator
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane Rockville, MD 20857

RE: FR Doc. 2025-14619 340B Rebate Model Pilot Program

Dear Administrator Engels:

For more than 30 years, the 340B Drug Pricing Program has provided much needed financial support to assist hospitals serving vulnerable citizens in vulnerable communities to manage the rising prescription drug costs.

As you are well versed, Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients. These organizations include federal grantee organizations and several types of hospitals, including critical access hospitals (CAH), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations.

Despite the positive impact and robust compliance audits instituted by HRSA of eligible entities, manufacturers have continually utilized lobbying efforts to diminish the intent of the program while still attempting to take advantage of the reimbursement benefits from Federal payment programs while continually inflating their own margins.

The 340B Program was never intended to work as a rebate program.

Drug manufacturers have proposed rebate models to diminish the intent of the 340B drug discount program. Rebate models will require a significant upfront financial investment from eligible entities to administer the program with the concept that drug manufacturers will reimburse the entities timely within 10 days of rebate submission. As with any rebate program, the drug manufacturers will dispute the rebate and attempt to prolong payments with the intent the entity will either accept a lower payment or, worst-case scenario, will deplete the eligible entities' resources attempting to enforce their right to payment. This model creates even greater challenges for independent pharmacies that are contracted with the covered entity where extra chargebacks and incorrect and inflated inventories will plague small business owners, ultimately

forcing them to discontinue contracts with the covered entity. The proposed rebate program is conceptually designed to diminish the use of the 340B program while allowing the manufacturers to reap the financial benefits of participating in Medicare and Medicaid payment programs.

Policy Recommendations.

As pharmacy manufacturers continue efforts to limit the scope of the 340B program through rebate models, it is critical for the future of the 340B Program, that stronger, well-defined, and timely enforcement action be enacted to reinforce the importance of expediated and prompt reimbursement to eligible entities. Throughout the last five years, manufacturers have unilaterally taken positions to limit contract pharmacies utilization and forced many healthcare organizations to exhaust financial and legal means as well as legislative initiatives to simply receive the legally qualified covered drugs to provide to the patients. This limitation of scope has led to a multimillion-dollar impact on organizations while manufacturers were able to reinvest those dollars for their financial gain at the expense of those vulnerable patient populations.

As the proposed pilot program is drafted, there is little to no guidance regarding any enforcement initiatives outside the lengthy and limited utilization of the Alternative Dispute Resolution process. The dispute and resolution process are not only expensive for healthcare entities, but also untimely in addressing these disputes compared to the financial viability risk these entities face. It is recommended that drug manufacturers face stiff compliance and enforcement action for violation of the rebate model to incentivize compliance with the program. A lack of penalties and strict enforcement action could significantly reduce the access of these important medications to patients as well as potentially lead to the financial instability of an eligible entity.

Additionally, manufacturer violations of the pilot program should also face treble damages to be utilized to fund the Federal Government's rule enforcement as well as face interest charges and statutorily compensable damages to be awarded to the eligible entities for a lack of compliance for improperly withheld rebate in addition to the intended reimbursement.

Once again, many manufacturers also proposed various interpretations of the standard patient definition set forth in the 340B statue in their first attempts at rebate proposals. It is critical that the definition remains with HRSA and the original intent protected. Manufacturers should be required to pay the rebate within the proposed 10 days and submit any disputes directly to the covered entity first then HRSA through the ADR process. The covered entity has already concluded that the prescription should be qualified and replenished, and the only dispute should be initiated by the manufacturer. The covered entity should have no reason to enter a dispute and continue to wait on a rebate.

Impact of the Rebate Policy.

In February and March of 2025, 340B Health conducted a survey of its hospital membership to assess the financial and operational impacts of these rebate proposals on 340B hospitals. If a rebate model is imposed, the average annual financial float per 340B hospital for the upfront purchasing of 340B drugs at wholesale acquisition cost (WAC) is estimated at $72.2 million for Disproportionate Share Hospitals (DSH), $3.2 million for Sold Community Hospitals (SCH) and $1.7 million for Critical Access Hospitals (CAH).[1] The projected financial impact to these hospitals negatively impacts the ability to utilize those funds to support patient care and daily operational needs to enhance patient health outcomes. The shift of financial burden to these 340B qualifying safety net providers, many of which already operate on extremely thin or negative margins, requires them to advance revenue to drug manufacturers for the proposed ten-day window. Many of these rural, safety net hospitals are already on the brink of violating debt covenants thus worsening their cash flow and increasing operational burden. Almost 45% of these rural hospitals are operating with razor-thin margins (Kaiser Family Foundation and AHA) and extremely limited reserves. These millions of dollars will tie up critical liquidity needed for immediate debt service payments, potentially lowering key financial ratios like the debt service coverage ratio (DSCR) that are critical to bond and loan covenants. Delays in rebate processing, whether due to manufacturer tactics like claim disputes or other administrative hurdles imposed on the covered entity, could extend these cash shortages for weeks or months. These could further strain profitability and risk covenant breaches that trigger penalties, accelerating payments, or restricting access to future financing of critical capital needs. The 340B Health survey also noted that 27% of hospitals anticipate that waiting even one month for rebates could prevent them from making payroll and forcing layoffs; and 28% expect a negative impact on their ability to borrow funds. Manufacturers implementation of rebate models will delay and dispute reimbursement to covered entities without significant enforcement action. This model will significantly delay repayment for unknown periods of time creating numerous downstream effects on strained healthcare systems.

In addition to the impacts of financial strain for attaining the necessary drugs for patients, the scope of data that manufacturers will require, which includes drug purchase invoices, claims data from hospital-owned retail pharmacies and hospital outpatient locations, and detailed patient encounter data from medical records, increase administrative costs that will further financially strain safety-net hospitals. These costs are an unnecessary waste of financial resources that can be invested to advance medical care for the communities these entities serve.[2]

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[1] 340B Health Manufacturer Rebate Model Report, (March 2025), www.340bhealth.org/members/research/reports/

[2] 340B Health, Restrictions on 340B Contract Pharmacy Increase Drug Company Profits But Lead to Lost Savings, Patient Harm, and Substantial Burden for Safety-Net Hospitals, (March 2023), www.340bhealth.org/files/Contract_Pharmacy_Survey Report March 2023

In 2020, manufacturers prohibited hospitals from using contract pharmacies, except when hospitals submitted claims data through a third-party vendor. The platform required by manufacturers was used to collect and verify claims data to authorize access to the 340B pricing. The survey data shows that 98% of hospitals submitting contract pharmacy claims data to the platform had to hire new staff, redeploy existing staff, and contract with third parties.[3] Through the new pilot proposal, the manufacturers will continue to use the online platforms to require data and further create financial burden and waste on safety net providers. This waste has already been avoided through HRSA audits demonstrating that non-compliant entities are held accountable with the program without the need to extend these expenses.[4] The proposed rebate program is simply an imbalanced shift to the entities that can't afford it to add unnecessary barriers and waste to enrich the manufacturers. The purpose of the 340B program is to allow affordable access to needed medications to patients who are served by non-profit entities that aid underserved populations not to create expensive and prohibitive roadblocks to those needs of the patients.

Conclusion.

Mosaic Health System appreciates the opportunity to share with HRSA our views on these proposals to improve the efficiency and accountability of the 340B program. We believe that the rebate model is a violation of the purpose and intent of the 340B program as well as imposing a considerable financial and resource strain on the ability of healthcare systems to provide the services that are needed in our communities. The lack of certainty and financial strain will challenge the viability of many rural health programs and create potential healthcare deserts in small rural communities. We encourage the agency to be mindful of the enforcement need to hold manufacturers accountable to the requirements of the program and are happy to answer any questions or discuss this policy further.

Sincerely,

Robert M Ritchey

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[3] Id.

[4] Health Resources & Services Administration Program Integrity FY24 Audit Results, (July 2025), www.hrsa.gov/opa/program-integrity/fy-24-audit-results.