ATTACHMENT

SANTA CLARA VALLEY HEALTHCARE

SCVH Administration
777 Turner Drive,
Suite 220
San Jose, CA 95128

April 20, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

RE: Request for Information: 340B Rebate Model Pilot Program
(HHS Docket No.: HRSA-2026-03042)

Dear Administrator Engels,

Santa Clara Valley Healthcare (SCVH), which is the division of the County of Santa Clara that operates the County's health care system, appreciates the opportunity to comment on the request for information (RFI) from the Health Resources and Services Administration (HRSA) regarding a 340B Rebate Model Pilot Program. SCVH is the largest safety net health care provider in Northern California and includes essential hospitals, as well as a comprehensive network of community clinics. SCVH depends on the 340B program to advance the County's missions of expanding access to comprehensive services to our community, which aligns directly with the statutory intent behind the 340B program. We urge HRSA to consider the costs of rebate models on safety net systems like ours and not move forward with the proposed rebate model or related pilot program.

SCVH strongly opposes any shift to a rebate model for discounted 340B drug pricing and urges HRSA to continue implementing 340B pricing as an upfront discount. Rebates, under the proposed model, will increase 340B participation costs significantly, redirecting funds to manufacturers that would otherwise go to patient care or other initiatives to expand access to patient care for needy populations. Not only is this contrary to 340B's intent, but HRSA has not provided a policy rationale explaining this proposal to change decades of established practice under which the 340B program has operated successfully.

As mentioned, SCVH is the biggest safety net health care system in Northern California, with 4 general acute care hospital campuses, a comprehensive network of community clinics, with ancillary departments that support the hospitals and clinics like pharmacy, laboratory

and diagnostic imaging services. According to the United States Census Bureau, our county has 1.9 million residents, with over 137,000 who meet the definition of low-income and another 76,700 who do not have any form of health insurance coverage. SCVH participates in the 340B program as a covered entity. The discounts on drugs available under the 340 program helps SCVH immensely in furnishing a comprehensive array of health care services to county residents and expanding access to much needed services for these low-income and uninsured patients.

SCVH appreciates the opportunity to respond to HRSA's RFI and share specific details on how the proposed rebate models would impact our ability to serve patients based on our experience with preparing for the implementation of the 340B rebate pilot program that was halted by the federal courts. Although the purpose of this letter is to respond to the specific inquiries posed by HRSA in the RFI, SCVH notes that we continue to also dispute the overall legal validity of 340B discounts being made available via after-purchase rebates and not up front at the point of sale. SCVH therefore respectfully refers HRSA to comments submitted by America's Essential Hospitals for a detailed discussion of some significant legal concerns with rebate models. With that said, information that is directly responsive to the RFI follows below.

The Financial and Operational Costs of Rebate Models Are Unsustainable

Safety Net Healthcare Providers Are Facing a Dire Financial Landscape and 340B Rebate Models Will Only Make the Situation Worse

As a safety net healthcare system, SCVH operates on thin financial margins even at the best of times. These are not the best of times for safety net health care. Safety net providers already are facing unprecedented financial challenges due to the sweeping federal Medicaid policy changes that were enacted through H.R. 1 in July 2025. Moreover, in addition to the impact of H.R. 1, SCVH is already experiencing significant, new monetary losses due to the Centers for Medicare and Medicaid Services' (CMS) implementation of the "maximum fair price" program for Medicare reimbursement on certain medications, which took effect at the start of 2026. With these other potentially devastating financial challenges already in place, SCVH simply cannot afford the massive disruptions to our finances that would result from imposition of a 340B rebate model.

Even if rebate models work as intended, they would disrupt our health system's finances by causing substantial increases in our administrative costs, limiting our health system's access to 340B subprime discounts, and by requiring our health system to make advance payments on impacted pharmaceuticals to boost the profits of pharmaceutical companies. If pharmaceutical companies deny rebates for our 340B eligible patients, SCVH will be left with substantial additional costs. Overall, we estimate that the implementation of a rebate model will cost our health system tens of millions of dollars between additional costs necessary to seek post-purchase

rebates and anticipated cash flow delays that will necessarily result from a rebate methodology for 340B discount pricing.

Complying with a 340B Rebate Model Entails Significant Additional Administrative Burden for Covered Entities

New 340B requirements added by manufacturers are adding substantial administrative costs to the program that divert funding from patient care. SCVH believes it is fair to assume that some percentage of rebate claims will be denied and, as such, will need to be appealed. Fighting and resolving such rebate denials will involve significant capital outlay. Since the County has not been confronted with a similar situation previously, it is difficult for the SCVH Pharmacy Department to the additional costs of challenging rebate delays and denials. However, we note that SCVH Pharmacy Department has already experienced difficulties with Medicare drug claims during the 3 months the MDPNP has been existence and we have serious concerns that navigating 340B discount rebate programs from different drug manufacturers will be similarly fraught.

SCVH is concerned about rebate delays as well as outright rebate denials. The concerns about delays are especially pressing for drugs administered to patients in outpatient hospital departments. Standard hospital operations do not allow for immediate submission of claims data for physician-administered drugs, which hospitals maintain separately from pharmacy claims due to different filling requirements and which may not be available for weeks or longer after the drug is administered to a patient due to how the bills are created by the hospital in accordance with billing rules. Delayed rebates will interfere with the billing workflow for physician-administered drugs in outpatient hospital departments.

HRSA has previously acknowledged the likely challenge of delayed or denied rebates but has failed to propose efficient and enforceable methods to address these issues. HRSA's previously issued FAQs indicate that in the event of a dispute, "covered entities [or the IT platform vendor] and manufacturers should work to resolve the issue," and only once the parties have failed to find a consensus should the covered entity contact a generic HRSA email. Such a system is inadequate and would force covered entities to pay for the time and resources to negotiate payment when manufacturers are responsible for the failures.

While SCVH is particularly concerned about dealing with rebate denials and delays, the fact is that the County is going to incur significant additional costs just to be in a position to submit rebate requests to drug manufacturers. If HRSA permanently adopts a rebate model that covers the same drugs as the Medicare Drug Price Negotiation Program (MDPNP), the SCVH Pharmacy Department is anticipating having to add FTEs to manage tasks entailed in complying with a rebate model, including claims level tracking and submission as well as reconciliation and dispute

management. Moreover, the additional burden created by a 340B rebate model will impact more than just SCVH Pharmacy Department Staff. Managing different manufacturer requirements will create significant operational complexity beyond the current 340B system. Preparing to implement a proposed rebate program involved will necessitate staff coordination across multiple departments, including pharmacy, operations, accounting, information technology, and legal.

Costs Associated with Having to Make Advanced Payments to Drug Manufacturers

By fundamentally changing the nature of the 340B rebate program from a point-of-sale discount to a post-purchase reimbursement system, rebate models would require covered entities to pay substantial sums of money to manufacturers before receiving discount drug pricing, which here, will reduce the cash on hand for covered entities like those operated by SCVH, as well as any interest that could have generated from that funding. 340B rebate model policies thereby allows manufacturers to generate interest from money owed to safety-net providers, rather than allowing those monies to be held by our health system and used for patient care activity or access expansion initiatives. Projecting for implementation, we estimate that having to pursue after-purchase rebates to secure discount pricing on 340B drugs would reduce SCVH's cash on hand by approximately $3.9 million for a 30-day period, $7.9 million for a 60-day period and by roughly $11.8 million after 90 days. This significant reduction in available cash will create significant operational difficulties for our health system.

Challenges in Maintaining an Adequate Supply of Drugs

The 340B program is currently designed to provide upfront discounts, which helps covered entities ensure that an adequate supply of drugs to meet patient's needs remains available. Ensuring an adequate supply of drugs is important for responding to emergencies and meeting the needs of patients with complex care needs. However, under the proposed rebate model, covered entities would lose access to 340B pricing for stockpiled drugs that are not able to be used because of the everyday realities of patient care. The costs of this policy will fall on patients, particularly those with rare diseases and complex care needs who already have challenges accessing the care they need.

The Proposed Rebate Models Are Not Necessary to Address Drug Manufacturers Purported Program Integrity Concerns

SCVH has described above the significant financial and administrative burdens covered entities will have to endure if forced to seek 340B pricing through after-purchase rebate requests. We believe it is important to contrast those burdens with the fact that there is little evidence to believe that the proposed rebate models will create any significant benefits in terms of protecting the integrity of the 340B program.

Making 340B discount pricing available only through rebates would not improve 340B program integrity. HRSA already conducts routine audits of covered entities that show minimal compliance issues, and manufacturers have not demonstrated systemic integrity issues in 340B. Nevertheless, even assuming there is room for improvement with program integrity, there are significantly less burdensome alternatives to rebates that are available to HRSA. For example, the Department of Health & Human Services could require other state Medicaid agencies to adopt Oregon Medicaid's process of preventing Medicaid duplicate discounts by collecting covered entity data retrospectively, allowing the agency to exclude 340B claims from rebate requests.

If there are legitimate program integrity concerns with the 340B program—which is not supported by any actual data or other evidence that has been proffered by manufacturers to date—those issues should be addressed by HRSA (and/or CMS with respect to duplicate discounts) through targeted modifications to the program rather than a disruptive overhaul of 340B by implementation of a rebate model.

Additional Comments

SCVH is concerned that the proposed rebate model would ultimately hinder rather than help covered entities achieve the goal of the 340B program: "to stretch scarce federal resources" to eligible patients and provide comprehensive care.[3] SCVH therefore believes HRSA should withdraw the proposed 340B Rebate Pilot in its entirety and limit drug manufactures to making 340B pricing available only through up-front discounts for covered entities. If the rebate program serves to delay or prevent covered entities from doing so, then there is no need to make such a fundamental change to the 340B program.

SCVH understands the need for further transparency and compliance within the 340B program. However, we believe that the proposed rebate program would not help in that regard. The proposed rebate model for access to 340B discount drug pricing only serves to increase administrative burden for covered entities while delaying the savings needed to help fund much needed care in the community. SCVH implores HRSA not to move forward with any form of 340B rebate model and allow the program to continue with point-of-purchase discounts only, consistent with the entire history of 340B and the intent behind creating a drug discount program for safety net providers.

We thank HRSA for its consideration of the information provided in this letter.

Sincerely,

DocuSigned by:
Paul Lorenz
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Paul E. Lorenz
Chief Executive Officer
Santa Clara Valley Healthcare