SANTA CLARA VALLEY HEALTHCARE

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April 27, 2026

Health Resources and Services Administration
U.S. Department of Health and Human Services
HRSA Information Collection Clearance Officer
5600 Fishers Lane, Room 13N82
Rockville, MD 20852

RE: Information Collection Request (ICR) Title 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

Dear HRSA Information Collection Clearance Officer,

Santa Clara Valley Healthcare ("SCVH"), which is the division of the County of Santa Clara that operates the County's health care system, submits this letter in response to the Information Collection Request (ICR) notice issued by the Health Resources and Services Administration ("HRSA") on February 26, 2026 concerning the 340B Rebate Model Pilot Program Application. SCVH is the largest safety net health care provider in the County of Santa Clara and includes essential hospitals, as well as a network of community clinics. SCVH participates in the federal 340B Drug Discount Program as a "covered entity" in multiple covered entity categories and depends on the 340B program to advance the program's statutory goals of expanding access to comprehensive services to our community. SCVH appreciates the opportunity to submit information in response to the ICR related to HRSA's proposed 340B Rebate Model Pilot Program.

Before addressing the ICR specifically, SCVH reiterates its general opposition to HRSA moving forward with any form of 340B Rebate Model Pilot Program. SCVH's views on the problems that will result from 340B discount drug prices being offered through post-purchase rebates as opposed to at the time of purchase are set forth in detail in the comment letter SCVH submitted to HRSA on April 20, 2026 in response the agency's Request for Information on the 340B Rebate Model Pilot Program (HHS Docket No.: HRSA 2026-03042) (copy attached hereto). As explained in SCVH's comment letter, implementation of a 340B rebate model will create significant new burdens for covered entities in multiple ways.

> Regarding the ICR specifically, HRSA seeks feedback from covered entities concerning the burden entailed in providing documentation to drug manufacturers to obtain discounted pricing on covered outpatient drugs through after-purchase rebates. HRSA states in the ICR notice that the agency's Office of Pharmacy Affairs (OPA):
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> > [E]xpects that data submitted by covered entities to manufacturers [under a 340B rebate model] will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claim requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data request may not be significant.

91 Fed. Reg. 9632, 9633. The ICR then goes on to indicate in a table that HRSA is anticipating that covered entities will, on average, spend only five (5) additional hours per year submitting data to manufacturers to secure 340B discount pricing through rebates.

SCVH respectfully contends that HRSA's analysis of the documentation burden that will derive from a 340B rebate model program is incorrect. SCVH has engaged in efforts to project the additional time and resources that will be required of the organization to participate in a 340B rebate model program, and the burden will be, in fact, very significant. Pursuing 340B discounts from manufacturers through after-purchase rebates will require hours of additional work on a weekly basis for SCVH Pharmacy Department staff and that projection relates just to the initial submission of rebate requests. SCVH is anticipating that, under a 340B rebate model, manufacturers will routinely reject or deny initial rebate requests, which will thereby require follow-up efforts from covered entities that require even more time and resources. HRSA's estimate that covered entities will experience only a burden of 5 additional hours per year in providing drug data to manufacturers under a rebate model is exponentially too low.

SCVH also takes issue with HRSA relying on the concept that covered entities are already required to submit claims data to some drug manufactures in connection with contract pharmacy policies, etc. for purposes of estimating the additional burden that will be created by a 340B rebate model. HRSA's burden analysis necessarily assumes the manufacturer data collection demands from drug manufacturers referenced from manufacturers are valid and appropriate under the 340B statute. SCVH does not believe that to be the case and, to the contrary, believes some claims data submission requirements manufacturers are seeking to impose on covered entities are inappropriate under the 340B statute. The fact that drug manufacturers are already imposing improper data submission requirements on covered entities should not be a reason for HRSA to discount the even greater burden on covered entities that will arise

from participating in a 340B rebate model program.

SCVH respectfully requests that HRSA use the information provided in this letter, as well as additional similar data that will be furnished by other covered entities in response to the ICR, to reevaluate its estimate for the burden that will be created for covered entities in meeting the requirements of the 340B Rebate Model Pilot Program.

Sincerely,

DocuSigned by:
Phoebe Li
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Phoebe Li, PharmD
Director of Pharmacy
Santa Clara Valley Healthcare