COUNTY OF SANTA CLARA
Health System

Pharmacy Department
2325 Enborg Lane Suite 3H320
San Jose, CA 95128
(408) 885-2300

October 6, 2025

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: Information Collection Request: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, OMB No. 0915-0327 Revision
(HHS Document No.: HRSA-2025-14955)

Dear Administrator Engles,

Santa Clara Valley Healthcare (SCVH) provides these comments on the Health Resources and Services Administration's (HRSA's) Public Comment and Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program, issued on August 7, 2025 [hereinafter "Enrollment and Re-Certification ICR"]. SCVH is the division of the County of Santa Clara that operates the County's health care system, including Santa Clara Valley Medical Center (SCVMC). SCVMC participates in the 340B Durg Pricing Program ("340B") as a disproportionate share hospital ("DSH") covered entity. SCVH appreciates the opportunity to submit feedback to HRSA concerning the contents of the Enrollment and Re-Certification ICR.

SCVH is specifically concerned with the language in the Enrollment and Re-Certification ICR stating that HRSA intends to update its registration form "to clarify that entities should submit a trial balance that clearly indicates unique and separate reimbursable outpatient costs and charges for each service being requested." SVCH believes that tying access to 340B drugs to only those outpatient hospital services reflected by a unique and separate costs and charges will result in inappropriate termination or modification of exiting 340B child sites, despite those child sites being important delivery sites for hospital services. Nowhere in the 340B Statute is there any reference to the "trial balance" nor is there any statutory requirement that defines a 340B covered entity by "unique and separate costs

and charges." HRSA's policies concerning eligibility and registration of hospital child sites for 340B participation are already overly restrictive and the changes proposed in the Enrollment and Re-Certification ICR will exacerbate the issue.

Background on SCVH

SCVH serves as the safety net health care system for Santa Clara County, by operating the four general acute care hospital campuses of SCVMC, a network of community clinics and other providers, such as pharmacies to the 1.9 million residents of Santa Clara County, with over 137,000 low-income and 76,700 uninsured residents.[1] The drug discounts available to SCVMC under the 340B program helps SCVH provide comprehensive care to County residents, while expanding access to much needed services for these low-income and uninsured patients.

Like many other safety net hospitals, SCVMC operates certain hospital-based outpatient clinics throughout the community to ensure that care is accessible to patients near their homes and workplaces. These outpatient locations are very much part of SCVMC and by making drugs available to patients these locations, SCVMC is able to ensure that its patients are maintaining their drug regimens and that the location of services is not a barrier to managing and maintaining their health status. .

HRSA's Intended Changes to 340B Registration Requirements At Hospitals Are Not Authorized by the 340B Statute and Are Not Consistent With Medicare Enrollment Standards

SCVH is submitting this comment to express its opposition to HRSA's plan to modify 340B hospital registration form instructions to establish that any service for which 340B participation is sough must correspond to "unique and separate reimbursable outpatient costs and charges," as reflected on the hospital's trial balance and as correspondingly reported on the hospital's Medicare cost report. This new policy may potentially result in some long-existing outpatient locations of SCVMC that are currently registered as "340B child sites" of SCVMC and that indisputably provide services to SCVMC patients potentially losing eligibility to dispense 340B drugs- solely because of technical accounting and cost reporting structure decisions wholly unrelated to the 340B Program. Such a result is at odds with the clear intent of the 340B Program.

The 340B statute establishes broadly that drugs acquired through the 340B Program are available to "patients" of the covered entity eligible to purchase the drugs.[2] The statute

---

[1] United States Census Bureau. Santa Clara County, California Profile. Accessed 3 Sept. 2025. https://data.census.gov/profile/Santa_Clara_County,_California?g=050XX00US0608

[2] *See* 42 United States Code (U.S.C.) Section 256b(a)(5)(B).

does not in any way indicate that a "patient" of a covered entity must be an individual treated on the main campus of a hospital and indeed, HRSA has through long-standing policies generally agreed that patients at child sites do qualify to receive 340B drugs as covered entity patients. Tying child site eligibility to the Medicare cost report treatment of a particular outpatient department or service line has no basis in the 340B Statute.

In addition to being unsupported by controlling statutory text, HRSA's proposal to limit 340B registration to only sites with "unique and separate" cost centers on the hospital's trial balance is also unreasonable and arbitrary. Although HRSA is relying on Medicare cost report information to evaluate child site eligibility for 340B participation, the standard HRSA is imposing is considerably more restrictive than Medicare enrollment rules. Outpatient locations can bill Medicare as part of hospital as soon as they meet the criteria for eligibility, none of which require that the outpatient location be identified by "unique and separate" trial balance accounts with Medicare reimbursable outpatient costs and charges.[3]

So long as an outpatient facility is an integrated component of a covered entity, subject to the same ownership and control of a covered entity, and with an integrated medical staff, service furnished at that facility may be billed to Medicare as hospital services, irrespective of how exactly the outpatient unit is reflected on the hospital's trial balance or Medicare cost report. It is understandable for HRSA to require covered entities to provide information necessary to demonstrate that a prospective child site is in fact part of the covered entity, but if HRSA is going to rely on Medicare participation status as a proxy for evaluating 340B eligibility, HRSA should actually follow the same rules as Medicare; not create its own arbitrary process that does not provide any additional benefit as related to identifying locations of a hospital.

Medicare participation criteria for outpatient locations are not conditioned at all on how a hospital has elected to set up trial balance accounts or Medicare cost reporting cost centers. Further, even Medicare reimbursement policy has long afforded providers with a level of discretion in how they elect to set up departments and cost centers on a cost report.[4] In this regard, Medicare rules allow for costs for multiple outpatient locations to be reported in a single trial balance account and Medicare cost report cost center, and a single outpatient location to be reported across multiple trial balance accounts and Medicare cost report cost centers, if an organization has an accounting rationale for doing so. HRSA's proposed modification to the 340B registration criteria interferes with covered

[3] 67 Federal Register 49,982, 50,084-05 (Aug. 1, 2002).
[4] *See generally* Centers for Medicare and Medicaid Services, Medicare Provider Reimbursement Manual, Part 1 (CMS Pub. 15-1), Chapter 23.

entity discretion on Medicare cost reporting decisions to the extent HRSA will only allow outpatient department's with "unique and separate" trial balance accounts and Medicare cost report cost centers reflecting Medicare reimbursable outpatient costs and charges to participate in the 340B Program as child sites. There is no reasonable basis for such a policy when it is not at all necessary to ensure an outpatient department is treating patients of a covered entity. Further, there is an extremely straight forward and long-established source of information to identify the locations of a 340B hospital that qualify as child sites- the hospital's Medicare Enrollment Record. The proposed change to the current 340B registration policy, if implemented, will create otherwise unnecessary challenges and administrative burden for safety net providers with respect to getting access to 340B drugs at a time these providers, like SCVMC, are facing the prospect of significantly reduced Medicaid revenue to the cuts called for by H.R. 1.

The goal of the 340B program is to "to stretch scarce federal resources" to serve more eligible patients and provide more comprehensive care.[3] Covered entities being able to dispense 340B drugs to patients at off-campus, outpatient sites has become a key method of stretching resources and expanding patient access to care. In that regard, for the reasons stated above, HRSA's intention to adopt a child-site eligibility standard limited to locations with a "unique and separate" reimbursable outpatient costs and charges for each service being registered as a child site is directly contrary to purpose of the 340B program. The County therefore respectfully requests that HRSA does not move forward with change to the registration instructions for hospitals set forth in the Enrollment and Re-Certification ICR.

Sincerely,

DocuSigned by:
Jennefer Yoon
CDEB420EFAC04C4...

Jennefer Yoon, PharmD
Assistant Director of Pharmacy Services
Santa Clara Valley Healthcare