UVA Health

April 27, 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: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906

Dear Administrator Engels:

On behalf of UVA Health and its three 340B covered entities—University Medical Center, Prince William Medical Center, and Culpeper Medical Center ("UVA Health"), we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) Information Collection Request (ICR). Among other things, this ICR asks for validation of the "accuracy of the estimated burden" of providing the information requested in a 340B Rebate Model Pilot Program.

Specifically, within the context of this ICR, HRSA estimates annual burden hours associated with the collection of data submitted by covered entities to participating drug manufacturers to request a rebate in connection with the model program. HRSA has defined burden as "the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems, if necessary, for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information." HRSA suggests that the burden associated with a potential 340B rebate model and its data requests "may not be significant." We strongly disagree. Based on our estimates below, we believe that HRSA has severely underestimated the burden that will be imposed upon covered entities.

As identified in its chart, HRSA's current estimates for covered entities include:

- 14,600 covered entities (CEs) impacted
- 52 submissions per year
- 5 hours per submission
- ~260 hours annually per entity

Whereas UVA Health's estimates include:

- 3 covered entities
- 52 submissions per year per CE (156 total submissions)
- 60-80 hours per week
- ~3,120–4,160 hours annually for all three CEs

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Our estimates are based on current 340B program operations, internal workflow analyses, and reasonable projections of increased claim volume, reconciliation requirements, and dispute activity under a rebate model. Notably, these estimates reflect the experience of only three CEs out of HRSA's projected 14,600 impacted CEs. While HRSA estimates a combined total burden of 3,796,000 hours across all entities, our projections, recognizing that each CE differs in size and scope, the estimated combined total burden for all CEs would far surpass this ambiguous estimate. This discrepancy reflects gaps in HRSA's appreciation of the operational and financial ramifications of shifting this program to a rebate model.

From an operational standpoint, implementing and maintaining even a limited 340B rebate pilot model would require an additional 1.5-2 full-time equivalents (FTEs), increasing administrative costs by approximately $200,000 annually, excluding system-related expenses such as one-time implementation and ongoing maintenance. Activities including tracking rebate eligibility, reconciling claims and purchasing data, managing manufacturer-specific requirements, addressing discrepancies, and maintaining audit readiness would require substantially more staff time on an ongoing basis. These demands would also scale with program volume, further increasing administrative burden over time. Moreover, permitting manufacturers to establish individualized rebate criteria would introduce further complexity, compounding administrative challenges and constraining providers' ability to fully realize 340B savings in support of patient care programs. Covered entities have already experienced situations in which HRSA expressed that certain manufacturer-imposed restrictions were inconsistent with the 340B statute;[1] however, manufacturers continued to implement or maintain those policies,[2] often subject to ongoing legal challenge and without uniform resolution. These manufacturer-imposed restrictions have reduced savings available to covered entities, thereby limiting resources for patient care. It is expected that for each manufacturer with specific criteria, incremental resource estimates would increase materially, further increasing the administrative burden and costs.

Expanding the 340B Rebate Model to all medications would significantly increase administrative complexity and financial risk for covered entities. For UVA Health, which had over 3 million 340B-eligible dispenses and administrations in CY2025, this model would divert substantial resources away from patient care and require major new operational investment. Assuming a conservative estimated 10% denial rate, UVA Health expects the following:

- Incremental increase of 12 FTEs required (tripling current team size) to manage ~300,000 disputed claims annually (~1,200/day) with responsibilities solely focusing on collecting and submitting data, reconciling purchases and financial statements, and submitting good faith inquiries to dispute rebate denials, as needed
- Estimated increase of $1.2M annually in staffing alone, adding to ~$25M in existing program administrative expenses, which includes third party administrator fees, dispensing fees, amongst other fees
- $52M in annual unrecoverable savings tied to rebate denials

[1] Health Resources and Services Administration, Office of Pharmacy Affairs, Program Integrity (340B Manufacturer Letters), https://www.hrsa.gov/opa/program-integrity

[2] 340B ESP, *Resources (Manufacturer Policy Materials)*, https://www.340besp.com/resources

We disagree with HRSA's assertion that a rebate model would improve 340B program integrity or is necessary to ensure deduplication under the Medicare Drug Price Negotiation Program (MDPNP). If a rebate model is advanced, UVA Health strongly urges HRSA to adopt a centralized third-party clearinghouse approach as a more efficient and transparent alternative to support deduplication, improve program integrity, and reduce administrative burden. At a minimum, HRSA should provide a clear, evidence-based explanation as to why such an approach is not operationally feasible or would be less cost-effective than a rebate mechanism.

UVA Health has significant concern with a for-profit company with ties to drug manufacturers having access to our data forever with the ability to sell it to whomever they choose and whenever they choose. Providing such an entity with ongoing access to sensitive claims and utilization data raises serious concerns regarding data privacy, security, and the potential for secondary use or commercialization of that data. Concentrating this level of control and access within a private entity may also introduce new risks to program integrity, including reduced transparency and potential conflicts of interest.

We appreciate your consideration of these comments and look forward to continued engagement with HRSA on this important issue, which has significant implications for the patients and communities served by the 340B program. Accurately accounting for the administrative and operational burden is essential to ensuring that any proposed model is both feasible and aligned with the program's intent. Please contact me if you have any questions.

Sincerely,

Danielle Griggs 4/27/2026

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