STATE OF WASHINGTON

DEPARTMENT OF HEALTH

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Samantha Miller
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U.S. Department of Health and Human Services
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Rockville, MD 20857

RE: Agency Information Collection Activities: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation; OMB Control No. 0906-NEW; 91 Fed. Reg. 35989 (June 15, 2026)[1]

Dear Ms. Miller:

The Washington State Department of Health (DOH) submits these comments on the Health Resources and Services Administration's (HRSA) information collection request (ICR) for the 340B Rebate Model Pilot Program. DOH's mission is to protect and improve the health of all people in Washington State. DOH is itself a 340B covered entity. Through its Division of Disease Control & Health Statistics, DOH operates the Washington AIDS Drug Assistance Program (ADAP), the state Sexually Transmitted Infection (STI) prevention and treatment program, and the state Tuberculosis (TB) program. Under Washington statute, governmental public health is required to ensure treatment for people who can't afford it[2]. These medication assistance programs depend on 340B pricing to deliver life-saving medications to uninsured and underinsured Washingtonians.[3]

DOH opposes the rebate model with serious concerns and submits these comments for two purposes. First, within the scope of the Paperwork Reduction Act (PRA), DOH demonstrates that

[1]Health Resources and Services Administration, "Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW," 91 Fed. Reg. 35989 (June 15, 2026) (hereinafter "ICR Notice"). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

[2] https://app.leg.wa.gov/rcw/default.aspx?cite=43.70, https://apps.leg.wa.gov/wac/default.aspx?cite=246-100-036, https://app.leg.wa.gov/rcw/default.aspx?cite=70.28.031

[3]Washington State Department of Health, AIDS Drug Assistance Program (ADAP) (providing access to HIV medications for low-income Washingtonians living with HIV who are uninsured or underinsured). https://doh.wa.gov/you-and-your-family/illness-and-disease/hiv/getting-help-paying-hiv-caretreatment/aids-drug-assistance-program-adap (last accessed 06/29/26)

HRSA's estimate of 5 hours per response substantially understates the true reporting burden the Pilot would impose on covered entities like DOH, and that the collection lacks practical utility for governmental public health covered entities.[4] Second, DOH places on the record the public health harms the rebate model would cause in Washington, so that HRSA has a complete picture as it evaluates whether to proceed. DOH recognizes that HRSA has stated it will treat comments on the merits of the rebate model as outside the scope of this PRA notice;[5] DOH respectfully submits that the burden and practical-utility questions the PRA squarely presents cannot be answered without understanding how this collection would function for the governmental public health programs required to comply with it.

DOH as a 340B Covered Entity

The 340B Drug Pricing Program allows covered entities to purchase outpatient drugs at discounted prices, stretching scarce federal and state public health dollars to reach more patients.[6] DOH uses 340B pricing to operate three programs that serve as the public health safety net for infectious disease in Washington:

- **Washington ADAP** provides free HIV medications to low-income Washingtonians living with HIV. ADAP already operates through a rebate mechanism and is the only DOH program that would fall within the initial scope of the Pilot as currently described.
- **The STI program** purchases and distributes free medications—most critically Bicillin L-A, the only acceptable treatment for syphilis in pregnant patients—at no cost to local health jurisdictions, providers, and patients, with an explicit prohibition on billing to avoid duplicate discounts.
- **The TB program** provides free tuberculosis medications to uninsured and underinsured patients statewide and supplies local health jurisdictions operating under DOH's grantee number without cost to the LHJ or the patient. In 2025 the program shipped 81 orders totaling roughly 61,000 pills.

These medication assistance programs operate on small, fixed federal and state grant budgets with minimal administrative staffing. The 340B discount is what allows these medication programs to function. In the interest of public health and safety, treating HIV, STIs and TB as quickly after exposure and diagnosis protects the public's health by interrupting disease transmission, reducing illness and death, and preventing the emergence of drug-resistant strains. To maintain these critical public services, it is essential to exclude governmental public health programs from the Pilot.

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[4] Paperwork Reduction Act of 1995, 44 U.S.C. § 3506(c)(2)(A) (requiring agencies to evaluate whether a proposed collection is necessary for the proper performance of agency functions, including whether the information will have practical utility, and to estimate the burden of the collection); 5 CFR 1320.8(b). https://www.govinfo.gov/link/uscode/44/3506 (last accessed 06/29/26)

[5] ICR Notice, 91 Fed. Reg. at 35990 (HRSA stating that comments received during the 60-day comment period reflecting general opposition, financial impacts, patient-care effects, and legal arguments "do not directly address the necessity, practical utility, or burden of the information collection under the PRA and therefore were not considered in revising burden estimates or data collection requirements"). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

[6] 42 U.S.C. § 256b (section 340B of the Public Health Service Act, establishing the 340B Drug Pricing Program). https://www.govinfo.gov/link/uscode/42/256b (last accessed 06/29/26)

The Collection Lacks Practical Utility for Governmental Public Health Covered Entities and Conflicts with Washington Law

The PRA directs HRSA to evaluate whether the collection is necessary for the proper performance of agency functions and whether it will have practical utility.[7] For DOH's governmental public health programs, the covered-entity data collection has little practical utility and presents a direct legal conflict.

The required reporting fields include patient-level and claims-level data elements, including prescriber and dispenser identifiers, prescription numbers, and fill data, submitted to participating manufacturers. In 2026, Washington enacted Engrossed Second Substitute Senate Bill 5981, which prohibits drug manufacturers from requiring 340B covered entities to submit patient-level data as a condition of 340B program participation.[8] The Pilot's data-submission design, as described, would require DOH to transmit exactly the category of data that Washington law protects. A federal collection that cannot lawfully be completed by covered entities in Washington as designed does not satisfy the practical-utility standard, and DOH urges HRSA to exclude governmental public health covered entities or reconcile the Pilot's data requirements with state patient-privacy laws before proceeding.

Separately, the collection presents an operational barrier unrelated to patient privacy: the Pilot would require covered entities to submit bank account information directly to a third-party vendor to receive rebate payments by electronic transfer. DOH cannot provide a private vendor with state banking information in this manner, and the rebate-payment mechanism as described is incompatible with the financial controls under which a state agency operates. This further limits the practical utility of the collection as applied to governmental public health covered entities.

HRSA's Burden Estimate Substantially Understates the True Reporting Burden

HRSA estimates that covered-entity reporting under the rebate model will require 5 hours per response or per week, yielding roughly 3.96 million total annual burden hours across 15,249 covered entities.[9] HRSA characterizes 5 hours as "a reasonable median burden."[10] DOH's experience as a covered entity indicates that this figure does not reflect the operational reality for governmental public health programs, for the following reasons.

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[8]Engrossed Second Substitute Senate Bill 5981, Chapter __, Laws of 2026 (Wash. 2026) (prohibiting drug manufacturers from requiring 340B covered entities to submit patient-level data as a condition of eligibility for 340B program pricing). https://app.leg.wa.gov/billsummary?Year=2025&BillNumber=5981 (last accessed 06/29/26)

[9]ICR Notice, 91 Fed. Reg. at 35990–35991 (Table 1, Total Estimated Annualized Burden Hours: 15,249 covered entities × 52 responses × 5 hours = 3,964,740 burden hours for covered-entity reporting). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

[10]ICR Notice, 91 Fed. Reg. at 35990 (estimating 5 hours per response for covered-entity claims data reporting, described as "a reasonable median burden"). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

First, the estimate counts only the per-response transmission of data and omits the standing infrastructure each covered entity must build before it can submit a single compliant response. HRSA's own description of the reporting process lists claims identification, extraction, validation, formatting, submission, reconciliation, denial management, and ongoing auditing.[11] For DOH, building that capacity is not a rounding error. DOH's TB program estimates that converting from the upfront discount to a rebate model would require an additional 0.15 full-time-equivalent (FTE) staff in the first year, which is roughly $16,800 in incremental personnel cost, and a sustained increase from 0.25 FTE to 0.35 FTE thereafter, on top of existing program coordinator and authorizing-official time. For the STI and HIV programs combined, FTE and contractual fees estimates are much higher, and involve a full-time, 40 hour per week, coordinator, plus 0.20 FTE support from a mid-range epidemiologist, totaling $190,000 per year in total FTE costs. These are real hours that the per-response estimate does not capture. Based on existing details for the rebate model, anticipated roles, responsibilities, and resources needed to implement and operationalize the Pilot elements include:

- Staffing to collect, aggregate, and report purchasing, cost, and utilization data on a DOH-provided form. Specifically, it would require an additional mid-level public health specialists and minimal support from an Epidemiologist 2.
    - Mid-level public health specialist – Startup year would require 1.35 FTE ongoing for supporting all DOH 340B covered entity programs and contractors and would include development and implementation of contract guidance and monitoring responsibilities, compliance management policy development and training, and cross program coordination data collection, quality assurance, data entry, and submission of the required files and reporting, both incoming from programs and contractors and to the rebate model vendor.
    - Mid-level epidemiologist – Startup year would require 0.2 FTE ongoing for supporting 340B program staff with data analysis and reporting responsibilities.
- Contract cost increase for pharmacy benefit management- ADAP contracts with a pharmacy benefit manager (PBM) to invoice drug manufacturers quarterly to collect rebates for 340B eligible medications purchased by ADAP. These duties include, but are not limited to, data collection, reporting, invoice development and management, rebate reimbursement collections on behalf of ADAP. Estimated on-going contractual costs to add rebate model-related elements and deliverables: $5,000/year.

Second, the estimate assumes covered entities can readily generate the required claims-level data elements. For DOH that assumption does not hold. DOH's STI surveillance system would require modification to produce the required data, and the state IT staffing model dedicates roughly one person to that system; the staff time needed to generate and transmit rebate data sets to multiple manufacturers does not exist within the current model. Denial-management capacity

[11] ICR Notice, 91 Fed. Reg. at 35990 (HRSA acknowledging that covered-entity reporting involves "claims identification, extraction, validation, formatting, submission, reconciliation, denial management, and ongoing auditing"). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

– staff to track, dispute, and re-submit denied rebate claims – does not exist within DOH's Office of Infectious Disease at all. The burden estimate treats this capacity as already in place.

Third, the estimate does not reflect the variation HRSA itself acknowledges among covered entities of different sizes, patient volume, and technical infrastructure. A single 5-hour median applied uniformly across 15,249 entities obscures the fact that small, grant-funded governmental programs, which cannot spread fixed compliance costs across a large commercial dispensing volume, will experience a far higher effective burden per dollar of medication delivered. DOH urges HRSA to exempt governmental public health covered entities from the pilot or develop burden estimates that separately account for small governmental public health covered entities rather than collapsing the full range into one median.

HRSA also relies on the premise that the required data "is comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships."[12] For DOH's governmental public health programs this premise is inaccurate. DOH does not maintain commercial pharmacy-benefit data infrastructure of the kind the estimate assumes; its data systems are public health surveillance systems built for disease control, not rebate adjudication. The burden of bridging that gap is omitted from the estimate.

Public Health Consequences for Washington (Submitted for the Record)

Although HRSA has stated it will treat merits comments as outside the scope of this notice, DOH submits the following so that the agency understands what the reporting burden purchases and what it threatens. The rebate model replaces an upfront discount with a requirement that covered entities first purchase medications at full price and recover the difference later through rebates. For DOH's fixed-budget programs, the cash-flow consequences directly reduce the number of patients served, therefore increasing risk of transmission, serious illness, or death.

We are in a time of rising cases and medication costs[13], and challenges with medication supply specifically for Bicillin L-A. Requiring governmental public health entities to focus attention on the possibilities and impact from the rebate pilot, takes staff time and administrative burden instead of evidence-based public health practices and activities.

The STI program offers the clearest illustration. With the 340B discount, one box of five doses of Bicillin L-A costs DOH approximately nineteen cents; the most recent non-340B quoted price for the same box was roughly $3,750. Across DOH's purchases of this medication over the last two years, the same volume would have cost approximately $1,683,750 at the non-340B price—roughly 47 percent of Washington's entire annual federal STI grant award of about $1.8 million, for a single medication. Bicillin L-A is the only acceptable treatment for syphilis in pregnant patients; the second-line alternative, doxycycline, causes birth defects and cannot be used. Reduced availability of Bicillin L-A would lead directly to treatment delays, increased

[12] ICR Notice, 91 Fed. Reg. at 35990 (HRSA stating that the data submitted by covered entities to manufacturers "is comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships"). https://www.federalregister.gov/documents/2026/06/15/2026-11989/agency-information-collection-activities-proposed-collection-public-comment-request-information (last accessed 06/29/26)

[13] Washington State STI Epidemiological Profile 2024 , Tuberculosis Cases Statewide by Year, 2021-2025

congenital syphilis, and preventable neonatal deaths at a time when syphilis morbidity is at or near record levels.[14]

The TB program faces a parallel problem. Tuberculosis treatment requires a minimum of six months of continuous, multi-drug therapy, and the national drug-supply infrastructure is unreliable, so DOH and local health jurisdictions maintain small medication caches to start treatment promptly. Under a rebate model, DOH would pay full price upfront and wait for rebates that are neither guaranteed nor timely, while medication that expires before it is dispensed cannot generate a recoverable rebate at all. The result would be smaller caches, slower treatment initiation, and missed national treatment-timeliness targets, with every delayed or interrupted course of treatment raising the risk of disease progression and onward transmission.[15]

Across all three programs, the pattern is the same: higher upfront costs against fixed budgets mean fewer patients treated, slower treatment, and greater disease spread, with the heaviest impact falling on uninsured, low-income, and rural Washingtonians who depend on public health programs precisely because they have no other source of care. Each of these programs has reported that it sees no benefit from the rebate model for the medications it purchases and the communities it serves.

Recommendations

DOH respectfully recommends that HRSA:

1. **Exempt governmental public health covered entities from the rebate model.** HIV/ADAP, STI, and TB programs operated by governmental public health authorities should be exempted from the rebate model and from any future 340B model that requires full-cost upfront purchasing or patient-level data reporting, because the collection has minimal practical utility for these programs and disrupts essential disease-control functions.
2. **Revise the burden estimate to reflect true operational cost.** The 5-hour-per-response estimate should be revised upward to account for one-time infrastructure build-out, denial management, system modification, and the disproportionate per-entity burden on small governmental public health covered entities. Estimated administrative and financial burden total for all programs would be $211,800 and 1.55 FTE per year.
3. **Reconcile the collection with state patient-privacy law.** HRSA should confirm that no covered entity will be required to submit patient-level data where state law prohibits manufacturers from conditioning 340B pricing on that data.

[14] Centers for Disease Control and Prevention, Sexually Transmitted Infections Surveillance (documenting record or near-record syphilis and congenital syphilis morbidity in recent years). https://www.cdc.gov/sti-statistics/ (last accessed 06/29/26)

[15] Centers for Disease Control and Prevention, National Tuberculosis Indicators Project (NTIP) (establishing national targets for timely tuberculosis treatment initiation and completion). https://www.cdc.gov/tb-program-evaluation/php/ntip/ (last accessed 06/29/26)

4. **Remove the direct bank-account-submission requirement.** The rebate-payment mechanism should accommodate the financial controls of governmental covered entities rather than requiring direct submission of banking information to a private vendor.
5. **Demonstrate practical utility for all Grantee entity types before implementation.** HRSA should not proceed with the collection until it can show that the data it would gather has practical utility commensurate with the burden imposed, consistent with the PRA.

DOH shares HRSA's interest in a 340B Program with strong integrity and reliable data. The information collection as designed, however, rests on a burden estimate that does not reflect what compliance actually requires of small governmental public health programs, and it would impose that burden in service of a model that reduces the number of Washingtonians who can be treated for HIV, syphilis, and tuberculosis. DOH urges HRSA to revise the burden estimate, exempt governmental public health covered entities, and resolve the conflicts with state law and state financial controls before moving forward. Thank you for the opportunity to comment.

Sincerely,

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