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April 20, 2026

Chantelle Britton
Director, Office of Pharmacy Affairs (OPA)
Office of Special Health Initiatives
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

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

Dear Director Britton:

The Washington State Department of Health (DOH) appreciates the opportunity to provide comments on the Health Resources and Services Administration's (HRSA) Request for Information regarding the proposed 340B Rebate Model Pilot Program.

DOH administers multiple governmental public health programs that rely on the 340B Drug Pricing Program to ensure access to lifesaving medications for uninsured and underinsured populations across Washington state. These programs include the Washington AIDS Drug Assistance Program (WA ADAP), Sexually Transmitted Infection (STI) prevention and treatment programs, and the Tuberculosis (TB) program.

Based on the information currently available, DOH has significant concerns regarding the operational, fiscal, legal, and public health impacts of transitioning governmental public health covered entities to a rebate-based model, outlined below. DOH respectfully urges HRSA to exempt governmental public health covered entities from the 340B Rebate Model Pilot Program.

I. Exemption for Governmental Public Health Covered Entities

Governmental public health programs rely on the upfront 340B discount to maintain adequate medication inventory, ensure rapid treatment initiation for communicable diseases, prevent disease transmission, and avoid financial barriers to care for uninsured and underinsured individuals.

The proposed rebate model would require full-cost purchasing of medications upfront, submission of patient-level data, and new administrative reconciliation processes. There is no clear demonstrated benefit for governmental public health programs under the proposed model, and the model shifts financial risk and administrative burden to state and local public health entities.

II. Costs to Covered Entities

The STI and TB programs rely heavily on upfront 340B discounts to purchase high-cost medications. For example, Bicillin L-A for syphilis treatment costs $0.19 under 340B pricing compared to approximately $3,750 outside of 340B. Over two years, purchasing this medication at non-340B pricing would have cost approximately $1.68 million—nearly 47% of Washington's annual federal STI grant.

For the TB program, a comparison of 30 pills of standard drug-susceptible TB medications demonstrates a 340B cost of $115.20 compared to $270.60 at retail pricing. Because TB treatment requires at least six months of therapy, upfront retail pricing would significantly increase program costs while awaiting rebate reimbursement.

Transitioning to a rebate model would require additional staffing for claims submission, tracking, reconciliation, and denial management. Hiring additional staff is not feasible under current funding levels, and existing staff would be redirected from core public health work.

III. Cash Flow and Payment Timing Impacts

The rebate model introduces significant cash flow instability. WA ADAP would be required to modify existing contracts with its pharmacy benefits manager and cannot provide bank account information directly to a private vendor. Uncertainty regarding rebate timelines would impair the Department's ability to forecast available funding.

For the TB program, even short payment delays would negatively impact cash flow and limit the ability to maintain medication caches. Accounting complications may also arise when rebate funds cross state fiscal years.

IV. Rebate Denials and Appeals

There is no clarity regarding standardization of manufacturer denial processes or appeals procedures. Programs do not currently have staffing or infrastructure to manage denial disputes. Loss or delay of rebates would directly impact medication purchasing and could interrupt patient treatment.

V. Data Collection and State Law Constraints

Washington State enacted SB 5981 (2026), which prohibits drug manufacturers from requiring patient-level data as a condition of 340B eligibility. The proposed rebate model's data-sharing requirements may conflict with state law and could preclude participation.

Additionally, existing STI and TB data systems would require significant modification to meet proposed reporting requirements, requiring additional IT resources that are not currently available.

VI. Patient Access and Public Health Impact

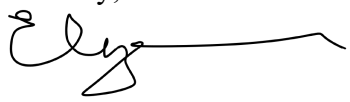
Higher upfront medication costs would likely result in reduced access, delays in treatment, increased disease transmission, and worsening health outcomes, including increased congenital syphilis, infertility, and preventable TB-related morbidity and mortality.

Programs primarily serve low-income, uninsured, and high-risk populations. Any reduction in service capacity would disproportionately impact vulnerable communities.

DOH respectfully requests that HRSA exempt governmental public health covered entities from participation in the 340B Rebate Model Pilot Program and ensure that any future reforms do not undermine access to lifesaving medications for vulnerable populations.

Thank you for the opportunity to provide these comments. DOH looks forward to continued engagement with HRSA to ensure that the 340B program supports its core mission of expanding access to care for those most in need. If you have any questions, please contact Mike Ellsworth at Michael.Ellsworth@doh.wa.gov or the Director, Federal and Inter-State Affairs for Governor Ferguson's Washington, D.C. office Rose Minor at Rose.Minor@gov.wa.gov

Sincerely,



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