Submitted to paperwork@hrsa.gov

HRSA Information Collection Clearance Officer
Room 13N82
5600 Fishers Lane
Rockville, Maryland 20857

RE: ICR: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-XXXX

Dear HRSA Information Collection Clearance Officer:

UW Medicine appreciates the opportunity to comment on the Health Resources and Services Administration's (HRSA) Information Collection Request (ICR) regarding the burden associated with the collection of data by covered entities to submit to manufacturers in connection with a potential 340B Rebate Model Pilot Program. UW Medicine strongly disagrees with the ICR's statement that "the burden associated with [the] potential 340B Rebate Model Pilot Program data requests may not be significant." In fact, the burden on UW Medicine and similar covered entities would be massive, requiring a $22 million upfront drug spend annually, new staffing and infrastructure to complete data collection and claims review requiring approximately $1 million annually in salary and benefits, and the time and expense to dispute rebate denials based on the assumption that a rebate model would include a very limited subset of drug products. Additionally, the rebate model creates cash flow issues and shifts the cost and burden of operationalizing the new model onto covered entities who are meant to benefit from the program.[1]

UW Medicine operates Harborview Medical Center and UW Medical Center, two public hospitals that are critical to delivering high quality care to safety-net populations and training the next generation of physicians. UW Medicine is the leading safety-net provider of healthcare to under and uninsured across our state and region, providing over $502 million in uncompensated care including over $69 million in charitable care in FY 2025. UW Medicine employs over 33,000 staff providing approximately 1.5 million outpatient visits and nearly 47,000 inpatient admissions annually. Our system welcomes 280 incoming medical students each year across the WWAMI region (Washington, Wyoming, Alaska, Montana, and Idaho) training 68% of medical residents in Washington. UW Medicine is also Washington State's largest provider of behavioral health services and operates numerous community-based clinics, including programs serving people experiencing homelessness. UW Medicine hospitals, University of Washington Medical Center and Harborview Medical Center, are covered entities under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b ("340B Statute").

UW Medicine strongly opposes any shift to a backend rebate-based model and urges HRSA to preserve the upfront discount structure that has governed the 340B program for more than 30 years due to, among other reasons, the operational burden a rebate model puts on covered entities. As Washington State's largest safety-net health system, our 340B program is built on decades of reliance on upfront discounts,

[1] We understand that the American Hospital Association (AHA) and other trade associations further elaborated on the burden to covered entities in a response to HRSA. These projections exceed $1B annually, with figures exceeding $2B if, on average, hospitals have to dedicate 3 FTEs to manage a 340B rebate program.

including how we manage inventory, structure compliance processes, partner with vendors, and deploy resources to support and expand patient care. Transitioning to a rebate model would disrupt these well-established reliance interests and fundamentally alter our ability to deliver care to underserved and medically complex populations by cannibalizing the 340B savings, requiring them to go toward administrative overhead of submitting for and chasing down rebates. The 340B drug discounts that UW Medicine receives go to support our clinical care in our homeless health services including community level clinics that provide direct access to care. The discounts allow us to give discounted drug prescriptions to our under and uninsured patients who otherwise could not afford their treatment. Moving to a rebate model will delay and in some cases prevent this care due to a lack of safety net resources, defeating the intent of purpose of the 340B program as passed by Congress. Respectfully, HRSA's assertion that the burden of such a model "may not be significant" does not reflect the operational realities of a large, integrated health system like UW Medicine or the operational realities of how the 340B Program has functioned for decades.

A rebate model would impose significant administrative complexity and cost, diverting critical resources away from patient care in a manner that conflicts with the statutory purpose of the 340B program, which is to stretch limited resources and expand access for vulnerable populations. UW Medicine strongly urges HRSA not to implement a rebate model that would shift financial and administrative burden onto safety-net providers and undermine access to care for the patients we serve. HRSA and manufactures must be realistic about the negative impact of their attempts to change a program relied upon by safety-net hospitals for decades.

The Proposed Data Collection, and the Rebate Model Itself,
Are Not Necessary Or Useful To the Proper Performance of HRSA's Functions

UW Medicine does not agree that a backend rebate system is necessary to improve program integrity or to address nonduplication under the Medicare Drug Price Negotiation Program. HRSA already conducts routine audits demonstrating strong compliance among covered entities, and manufacturers have not established systemic integrity concerns within the program. We are also concerned that manufacturers' interest in claim level data extends beyond program integrity and into commercial rebate arrangements that are unrelated to the intent of the 340B Statute. Covered entities should not be required to finance or operate these objectives.

UW Medicine understands that HRSA's proposed rebate model would apply to at least 25 drugs, significantly expanding the scope beyond earlier proposals. For a health system of our size and complexity, this would require us to purchase these drugs at substantially higher, non-340B prices, maintain inventory across our hospitals and clinics until dispensed, which may take weeks or months, and then submit claims data and wait for rebate reconciliation and disputes to resolve. This represents a fundamental shift from the longstanding 340B model of upfront discounts and introduces significant operational and financial disruption.

Even if rebates are issued within 10 days of submission (likely longer because manufacturers will pay the rebate 10 days from when *they* deem data submission is complete) and validation of the data, UW Medicine would still be required to carry the cost of these higher priced drugs prior to receiving a rebate

or needing to dispute a denied rebate. This would tie up millions of dollars in resources that are currently used to support patient care, expand access to medications, and fund critical services for underserved and medically complex populations, resources that our system has long relied upon under the established structure of the 340B program.

Requiring us to purchase the initial 25 IRA selected drugs at higher, non-340B prices and wait for rebates, even within 10 days, would result in approximately $22M in additional upfront drug spend over an annual period. Again, this number only pertains to the initial 25 drugs. This increase in cost would limit our ability to provide immediate financial assistance and increase the risk of cost-related barriers to care. Over time, this shift would erode the effectiveness of the 340B program at UW Medicine, reducing our ability to sustain programs that expand access to medications and support underserved and complex patients across our system. Congress never intended for safety-net hospitals to float such large numbers to for-profit drug companies which is precisely why the 340B program has functioned as an upfront discount program for several decades.

UW Medicine will need to continue paying wholesaler invoices on a weekly basis to preserve critical prompt pay discounts that help offset overall drug costs. However, under a rebate model, we would be required to purchase drugs at higher wholesale acquisition cost (WAC) prices upfront, rather than 340B pricing, while awaiting delayed manufacturer rebates. This creates a significant cash flow burden, as we are effectively financing the cost differential during the rebate period. Even with a 10-day repayment window, the requirement to consistently carry higher upfront drug costs, while maintaining our prompt pay obligations, introduces substantial and ongoing financial strain on our system. Again, we cannot imagine Congress intended to have safety-net hospitals finance a rebate program that only benefits for-profit drug companies.

The ICR Significantly Underestimates the Burden Associated With the Proposed Data Collection

The ICR includes statements about the estimated burden on covered entities that do not align with UW Medicine's anticipated time, money, and effort that will be expended on a rebate model. We have identified significant operational barriers that would result under a rebate model. These challenges are particularly acute for medical claims, where data are inherently inconsistent and delayed. Claims are often not submitted to payors until several days after a drug is administered, and subsequent changes in patient insurance, claim adjustments, and reversals introduce additional complexity. There is also limited clarity on how reversed or corrected claims would be treated, leading to discrepancies and uncertainty in what constitutes a complete and accurate submission.

These barriers, identified during pilot preparation and through real world data submission processes, would result in frequent data mismatches, notifications of incomplete submissions, and a substantial need for manual reconciliation. In our experience, manufacturer's defined data requirements, such as those implemented through 340B ESP, have been inconsistent and difficult to operationalize, requiring significant IT build and staff resources. Under a rebate model, these challenges would directly translate into delays in rebate payments for a significant amount of claims, increased administrative burden, and a higher risk of disputes, all of which would divert critical resources away from patient care and create ongoing financial uncertainty for UW Medicine.

Contrary to the ICR's expectation that the data being submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities, implementation of a 340B rebate model also would require significant new staffing and infrastructure at UW Medicine, resulting in substantial and ongoing administrative costs layered on top of an already complex program. UW Medicine currently invests approximately $30 million annually to operate and maintain its 340B program, inclusive of third-party administrative fees, legal support, external auditing, split-billing software, and internal FTEs dedicated to compliance and operations. Based on our current experience supporting IRA Maximum Fair Price (MFP) processes, we estimate that the proposed rebate model targeting MFP eligible medications (CY26 and CY27) are associated with over 38,000 annual transactions requiring submission, validation, and tracking. Critically, this model would require 100% claim-level review to ensure accuracy and compliance prior to submission.

The ICR includes a chart titled "Total Estimated Annualized Burden Hours." It identifies the number of responses for each covered entity as 52, annually, with an average of 5 hours per response. "Response" is not defined in the ICR, but HRSA may mean that each week of claims information submitted to receive a rebate is one "response." If HRSA believes it will take 5 hours per week for a covered entity to complete, submit, and follow through on all claims, it severely underestimates the volume of work associated with the rebate model. We estimate that approximately 3,200 claims per month would need to be submitted for the 25 drugs, each requiring careful validation to ensure compliance.

Assuming each claim requires approximately 20 minutes to review, UW Medicine estimates an incremental increase of approximately $0.97 million annually in salary and benefits for 100% compliance review. As additional drugs are added each year, this cost would scale with the number of transactions. To operationalize this process, UW Medicine anticipates the need for seven additional FTEs in the initial year of the pilot, with an additional seven FTEs required annually as more drugs are incorporated into the 340B rebate model. These resources would support data submission, rebate tracking, payment validation, dispute management, and escalation through HRSA's Administrative Dispute Resolution (ADR) process. Then add in the time and resources required from data analysts, IT teams, and accounting staff who would be continuously engaged in supporting data extraction, reconciliation, financial tracking, and reporting associated with this process. Finally, the time and expense of internal and external resources needed to dispute rebate denials related to the 38,000 transactions will bring the hours per week well over 5. Multiple full-time positions will need to be filled to exclusively support this model.

Dispute resolution would further increase the administrative burden and cost because the systems available for a rebate program (e.g., Beacon and Truzo) absolve themselves of any liability for any issues with the rebate program, leaving ADR as the only available avenue for covered entities to try to obtain wrongfully denied rebates. HRSA's ADR process was not designed to handle the magnitude of ongoing ADR claims that will be submitted. Moreover, for a covered entity to be successful in its claim that a rebate was wrongfully denied, patient data will be required to be submitted to prove the patient was an eligible 340B patient, thus requiring another data process submission to occur. This entire process will further exacerbate the increased costs to covered entities and divert resources from patients. While imprecise because HRSA has not released a rebate model for public review and comment, we estimate disputes alone will cost our organization several millions of dollars per year.

UW Medicine has already experienced significant variability in manufacturer processes under the IRA/MFP framework, with differing submission portals, data requirements, and timelines. Some manufacturers have taken months to respond to disputes, and in certain cases, resolved claims have been re-opened by the manufacturer, requiring repeated review and resubmission on a claim-by-claim basis. Under a 340B rebate model, these challenges would be magnified by UW Medicine given the broader scope and volume of claims, resulting in sustained operational strain, delayed payments, and diversion of critical resources away from patient care.

Deficiencies To Be Addressed If the Agency Proceeds

A 340B rebate approach is not operationally feasible for covered entities and would introduce significant financial, administrative, and compliance burdens that are inconsistent with the statutory structure and intent of the 340B program. Requiring covered entities to purchase drugs at non-340B prices (at a price point higher than what non-340B hospitals pay) and subsequently seek rebates would create material cash flow strain, increase administrative complexity, and heighten the risk of delayed or disputed repayments, ultimately undermining the ability of safety-net providers to deliver timely and affordable care.

If HRSA elects to proceed with development of a 340B rebate model despite the significant concerns outlined above, UW Medicine strongly urges HRSA to establish clear and enforceable guardrails to prevent additional administrative burden and financial harm to covered entities. At a minimum, HRSA should prohibit manufacturers from denying rebates to 340B hospitals, including explicitly precluding denials based on alleged Medicaid duplicate discounts or diversion. These determinations are often complex, rely on incomplete or external data sources, and are not fully within the control of covered entities operating within payer and pharmacy network constraints. Allowing such denials would introduce substantial operational risk, cash flow disruption, and uncertainty for safety-net providers like UW Medicine, undermining the stability of the 340B program.

Permitting manufacturers to deny rebate claims would also create a significant new administrative burden, requiring covered entities to engage in disputes with manufacturer designated vendors while managing delays in reimbursement. Manufacturers would continue to receive claims level data and retain their statutory audit rights, which are sufficient to address program integrity concerns without granting unilateral denial authority.

Limitations and Costs Of Implementing Automation In the Current 340B Ecosystem

As described above, options for automation and efficiencies are limited under a rebate model. UW Medicine's claims data reside across six separate systems, each with distinct data structures and extraction processes, with no automated mechanism to aggregate and submit data in the format required by manufacturer designated platforms such as 340B ESP. This requires significant manual effort and IT resources to extract, normalize, and validate claims on an ongoing basis. Compounding this burden, rebate payments are typically made on a lump sum basis and are not tied to individual claims, making it exceptionally difficult for UW Medicine to reconcile payments, confirm accuracy, and ensure full reimbursement. This lack of transparency necessitates additional manual tracking and auditing processes to identify underpayments or missing rebates.

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For these reasons, UW Medicine strongly urges HRSA and HHS to reject a rebate-based model and instead pursue prospective or limited retrospective claims identification approaches, modeled on Oregon's Medicaid framework and aligned with CMS systems, to ensure compliance with the IRA's nonduplication provisions. These alternatives would more effectively promote program integrity, reduce administrative burden, and preserve access to care for the patients and communities the 340B program is intended to serve.

We appreciate HRSA's leadership in administering and safeguarding the integrity of the 340B program and value the opportunity to provide input through this Request for Information. UW Medicine respectfully submits these comments to share our operational experience and concerns regarding a potential rebate model and its impact on safety-net providers and the patients we serve. We hope HRSA carefully considers these perspectives as it evaluates next steps and potential policy direction. Please do not hesitate to contact us if additional information would be helpful.

Sincerely,

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