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September 8, 2025

Thomas J. Engels, Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Attention: HHS Docket No. HRSA-2025-14998
5600 Fishers Lane
Rockville, MD 20852

Re: HHS Docket No. HRSA-2025-14998 – 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, published at Vol. 90, No. 146 Federal Register 36163-36165 on August 1, 2025.

Submitted electronically via http://www.regulations.gov

Dear Administrator Engels:

UnityPoint Health appreciates this opportunity to provide comments on this 340B Program notice related to an application process for the 340B Rebate Model Pilot Program. UnityPoint Health is one of the nation's most integrated health care systems. Through more than 31,000 employees and our relationships with more than 400+ physician clinics, 34 hospitals in urban and rural communities, and 13 home care areas of service across our 8 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8 million patient visits.

The 340B Drug Pricing Program allows safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The 340B Drug Pricing Program requires drug manufacturers to provide front-end discounts on covered outpatient drugs purchased by specified government-supported facilities that serve the nation's most vulnerable patient populations.

As a large nonprofit, integrated health care system in the Midwest, the UnityPoint Health network of Disproportionate Share Hospitals, Sole Community Hospitals, Critical Access Hospitals, and Rural Health Clinics provide vital access to health care services. The 340B Drug Pricing Program has served as a critical federal resource for our safety-net providers and the patients we serve in Iowa, Illinois, and Wisconsin. ***Not including our affiliated 17 critical access hospitals, we have 12 hospitals that participate as covered entities under the 340B Drug Pricing Program***. Savings from 340B Drug Pricing Program help to provide affordable medications and support medication therapy management clinics, behavioral health outreach, preventive screenings, and other team-based and wellness initiatives.

We appreciate that HRSA is permitting stakeholders to submit feedback on the proposed 340B Rebate Model Pilot Program (Rebate Pilot). **As members of 340B Health, the American Hospital Association, the Illinois Health and Hospital Association, and the Iowa Hospital Association, we support their comment letters**. We provide additional input below.

340B REBATE MODEL PILOT PROGRAM

Background:

For over 30 years, the 340B Program has been administered by HRSA as a discount program with the exception of State AIDS Drug Assistance Programs. In August 2024, there was a proposed change, not from HRSA or Congress, but rather through the unilateral actions of a drug manufacturer. To start October 1, Johnson & Johnson (J&J) unilaterally declared its intention to establish a rebate mechanism for certain 340B-eligible drugs, including a separate claims data submission platform and third-party evaluation. J&J intended to essentially replace HRSA for determining 340B compliance and require DSH hospitals to float revenues to drug manufacturers pending self-imposed processes to approve the rebate payments. The two drugs in question, Stelara and Xarelto, contributed a combined $3.4B in J&J sales during the second quarter of 2024.[1] All UPH DSH covered entities prescribe these popular medications and would have been subject to that rebate program. For one of our DSH covered entities, these rebates comprise nearly 6% of their 340B Program benefits. Following the lead of J&J, four other drug manufacturers – Eli Lilly, Bristol Myers Squibb), Sanofi, and Novartis – expressed their intent to establish a rebate mechanism. Each rebate program was structured differently with different reporting requirements. With the urging of 340B covered entities, including UnityPoint Health, HRSA did issue various formal letters to drug manufacturers to cease implementation of these models. HRSA did specify that rebate framework requiring disproportionate share hospitals to purchase drugs at prices that exceed "the maximum price[s] that covered entities may permissibly be required to pay" for those drugs would violate Section 340B(a)(1) of the PHS Act.[2] All five drug manufacturers withdrew their rebate programs at that time.

On August 1, 2025, HRSA announced the availability of the Rebate Pilot as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price on select drugs to all covered entities. The scope of this voluntary Rebate Pilot will be limited to the 10 drugs included on the CMS Medicare Drug Price Negotiation Selected Drug List.

General Comments:

Overall, UnityPoint Health is gravely concerned with the Rebate Pilot and urges that HRSA reconsider its implementation. First, HRSA lacks rationale for why it would "fundamentally shift how the program has operated." This transition is ill-advised and ill-timed as safety-net hospitals are in fragile financial positions[3], while pharmaceutical companies are generating significant revenue[4] and drug product prices continue to rise[5].

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[1] J&J beats in Q2 as pharma segment outperforms - https://www.msn.com/en-us/money/companies/j-j-beats-in-q2-as-pharma-segment-outperforms/ar-BB1q8UUt#:~:text=JNJ%E2%80%99s%20blockbuster%20drugs%20Stelara,%20Invega%20Sustenna,%20and%20Darzalex%20contributed%20to

[2] https://www.hrsa.gov/sites/default/files/hrsa/opa/sept-17-2024-hrsa-letter-johnson-johnson.pdf

[3] MedPAC, Chapter 3. Hospital inpatient and outpatient services: Assessing payment adequacy and updating payments, Report to the Congress: Medicare Payment Policy (March 2025) – In 2023, while the average hospitals' all-payer operating margin was 5.1%, one quarter of hospitals had an all-payer operating margin below –4%, with margins remaining lower for DSH and MedPAC-developed Medicare Safety-Net Index (MSNI) hospitals.

[4] 2025 Q2 earnings for Gilead and Eli Lilly, with links to Q2 earnings from Amgen, Pfizer, AbbeVie, Bristol Myers Squibb, AstraZeneca, GSK, Roche, and Johnson & Johnson https://www.csrxp.org/big-pharma-earnings-watch-gilead-and-eli-lilly/

[5] ASPE Issue Brief, Changes in the List Prices of Prescription Drugs, 2017-2023 (October 6, 2023) - *Over the period from January 2022 to January 2023, more than 4,200 drug products had price increases, of which 46 percent were larger than the rate of inflation. The average drug price increase over the course of the period was 15.2 percent, which translates to*

Second, the Rebate Pilot does not need to be launched to identify the harm to covered entities and beneficiaries that will result. The rebate model departs from the traditional upfront discount system, risking hospitals paying higher drug costs without reasonable certainty as to when or if rebates will be paid. Over the course of one year for the piloted drugs alone, UnityPoint Health will be forced by HRSA to front to drug manufacturers an estimated $21 million from our hospitals that Congress has designated as serving vulnerable populations. While cash flow implications may jeopardize whether some covered entities remain viable, it is certain that all covered entities will need to reprioritize how to "stretch scarce federal resources" by reaching **less and not** more eligible patients and providing **fewer and not** more comprehensive services. Third, for an Administration that champions deregulation, the Rebate Pilot is the poster child of administrative burden and adds layers of red tape. Under the Rebate Pilot, HRSA is inappropriately ceding its authority to regulate both covered entities and drug manufacturers to one of those interested parties. Additionally, because the Rebate Pilot is ill-defined and lacks operational guardrails, covered entities will need to divert significant compliance resources to the potential 9 new pilots so HRSA "can better understand the merits and shortcomings of the rebate model from all stakeholders' perspectives."

The Rebate Pilot was conceived without input from covered entities, which are essentially required to participate should the drug manufacturers they work with elect to participate. Given the lack of collaboration with 340B covered entities, UnityPoint Health's input is intended to strengthen the proposed Rebate Pilot.

Rebate Pilot Rationale

HRSA is launching the Rebate Pilot due to the "significant amount of feedback received" by the agency. Let's be clear that feedback should not be construed as significant stakeholder support for rebates. As noted in the background narrative, five drug manufacturers attempted to start unlawful rebate programs in violation of 340B regulations. Those manufacturers withdrew their programs only after HRSA sent letters threatening civil penalties and/or termination of their pharmaceutical pricing agreement. The "feedback" from covered entities consisted of opposition to these programs, and UnityPoint Health is unaware of any covered entity that supported 340B rebate programs proposed by manufacturers. The Rebate Pilot is proceeding solely at the request of the pharmaceutical industry.

Drug manufacturers raised concerns to the agency regarding 340B Medicaid duplicate discounts and diversion. HRSA is introducing the Rebate Pilot as a "methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved." Yet, HRSA presents no evidence that the current upfront discount program is not fair or transparent. We contest the notion that covered entities have systematic program integrity issues or that program integrity will be enhanced by a rebate model. First, covered entities invest significant resources (staffing, software, and vendor services) to comply with the 340B statute and HRSA's regulations and guidance. HRSA conducts audits of approximately 160 (or 6%) 340B hospitals annually.[6] In contrast, HRSA audits only five (0.6%) of participating drug manufacturers.[7] Yet in FY 2022, 75% of audited drug manufacturers required repayment to 340B hospitals while only 28% of audited 340B hospitals' required

$590 per drug product. Accessed at https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs

[6] https://www.aha.org/guidesreports/2025-06-16-more-drug-company-oversight-needed-maintaincompliance-340b-program-rules

[7] Id.

repayments to drug manufacturers.[8] Ironically, the Rebate Pilot allows drug manufacturers to create pilot plans and "even exceed or go beyond these [HRSA] criteria" when it is the drug manufacturers that are lax in complying with HRSA's current rules and guidelines. Second, the Rebate Pilot's criteria prohibits drug manufacturers from denying rebates "based on compliance concerns with diversion or Medicaid duplicate discounts." Instead, diversion or duplicate discounts are treated just like the current upfront discount program with complaints to HRSA or statutory mechanisms of audits and administrative dispute resolution (ADR). What is different is that HRSA is enabling drug manufacturers to create new avenues for denials and to further delay payments. HRSA's Rebate Pilot is inviting more program requirements and greater administrative burden.

According to HRSA, drug manufacturers brought forward different proposed rebate models for the 340B Drug Pricing Program, primarily to address 340B and Maximum Fair Price (MFP) deduplication. HRSA elected to limit the Rebate Pilot to the NDC-lls included on the CMS Medicare Drug Price Negotiation Selected Drug List, regardless of payer, and therefore also to the drug manufacturers with Medicare Drug Price Negotiation Program Agreements. We caution that HRSA should not capitulate to arguments that a rebate model is the only method by which drug manufacturers can comply with both the Inflation Reduction Act's MFP process and the 340B statute. This is a false narrative. CMS has already disposed of this issue and has indicated that the MFP can be provided as a prospective, upfront price.[9] If the Rebate Pilot is based "primarily" on the 340B nonduplication provision, it should be withdrawn outright.

As we read the 340B Program Notice, we were struck by the lack of any reference to patients and potential adverse, unintended patient impacts resulting from the Rebate Pilot. The only reference to patients is the plan criteria that the IT platform protect patient identifying information. While HRSA may assume that covered entities will also include patient and community impact within our responses, this omission demonstrates a fundamental misunderstanding of the significance of changing the 340B Drug Pricing Program from an upfront discount to a rebate. This is not merely a transactional change but a change that is intended to decrease overall funding impacting patient services to 340B hospitals that serve low-income, rural, and underserved patients. As funding diminishes from added compliance costs, denial rates, and rebate delays, patients lose services and access. If rebates represent a benefit to patients and their care, HRSA has not articulated that nor are drug manufacturers required to describe how their plan to shift to a rebate will better serve patients. Afterall, Congress created the 340B Drug Pricing Program as a prerequisite for drug manufacturers desiring to provide their products to Medicare patients.

Rebate Pilot Adverse, Unintended Impacts

UnityPoint Health is a nonprofit health care system. Our nonprofit hospitals serve as safety-net providers for medically complex and underserved populations with a thin 3% operating margin in 2024 – the 340B savings benefit represents this margin. With continuing reimbursement and staffing pressures, this positive margin has been a work in progress, and UnityPoint Health hospitals have implemented several budget modifications to conserve resources and work to ensure that patients can continue to receive the care they need. The Rebate Pilot will result in significant and extensive costs for our 340B hospitals, which will reduce resources available

[8] Id.

[9] https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-andmanufacturer-effectuation-mfp-2026-2027.pdf

for patient care and access. As a consequence, UnityPoint Health will need to reprioritize how to "stretch scarce federal resources" to maintain reaching eligible patients and providing needed services.

Patient services impact: The average public payer mix (Medicaid and Medicare) for UnityPoint Health hospitals is 68%. The rural communities we serve include a larger proportion of older adults with greater health complexities and less financial resources. Our community hospitals each target 340B funds to meet local community needs covering a wide range of services from assisting with affordable medications to shoring up underfunded services or providing needed services that are not currently reimbursed. We highlight some of our 2025 initiatives:

- Provide pharmacy/medication programs: UnityPoint Health hospitals used the 340B Drug Pricing Program to provide discounted drugs to low-income patients, offer meds-to-beds programs to reduce hospital readmissions, supply community partners with Narcan kits, offer medication delivery and bubble-packs to targeted populations, and expand medication therapy management clinics to combat chronic disease. These pharmacy initiatives have yielded positive outcomes for individual patients.
- Bolster team-based care: UnityPoint Health hospitals used the 340B Drug Pricing Program to provide heightened care coordination services in emergency departments to prevent avoidable visits, oncology navigation services, and targeted chronic disease management.
- Sustain under-funded service lines: As Iowa's largest provider of behavioral health services, UnityPoint Health used the 340B Drug Pricing Program to underwrite behavioral health services, including child and adolescent psychiatry, overall inpatient behavioral health services, and walk-in behavioral health services. As the largest provider of obstetrics and maternal health in the state of Iowa and our Illinois and Wisconsin markets, funding supports neonatal services, transportation involving neonate hospital transfers, OB/ED hospitalists, donor milk dispensary operations, and pre-natal education. Other vital services include inpatient hospice services, inpatient pediatrics services, child development center support, and assistance for forensic nurse examiners programs.
- Stand up supportive and prevention services: UnityPoint Health strive to keep individuals out of the hospital and 340B Drug Pricing Program funds are used for non-emergent transport, lifestyle changes such as cardiopulmonary exercise programs and healthy eating and nutrition classes, and no-cost or low-cost cancer and heart health screenings.

The extent to which 340B funds are available will influence how and if our various hospitals will be able to continue the above initiatives.

Patient access impact: We anticipate that patient access will be impacted by diversion of funding for capital improvements and hospital operations for underfunded service lines, like behavioral health, maternal health, pediatrics, and emergency care. Recently several of our hospitals have used 340B Drug Pricing Program funds to upgrade security infrastructure, including limiting access points (i.e. reducing the number of entrances), installing panic buttons, and installing advanced, video-monitored security systems in Neonatal Intensive Care Units. These were needed capital projects that lacked reimbursement or donor funds. As for service line closures, a recent analysis found that a significant number of rural hospitals lose money delivering patient services – in the UnityPoint Health footprint, rural hospitals with losses on inpatient services are 30% in Illinois, 20% in Iowa,

and 27% in Wisconsin.[10] 340B Drug Pricing Program funds do enable rural hospitals to keep doors and services open. When service lines or hospitals close, those residents must travel further for care impacting health outcomes when care is urgent or complex.[11]

Administrative burden impact: Unlike a proposed rule, this notice does not provide information collection requirements (ICRs) or a regulatory impact analysis – the latter detailing statement of need and a detailed economic analysis with alternatives considered. Additionally, HRSA skirts Executive Order 14192 – "Unleashing Prosperity Through Deregulation." The Rebate Pilot will create enormous administrative burdens that are being mandated without an analysis of impact to beneficiaries and covered entities and without notice to covered entities or sufficient time for HRSA to incorporate meaningful input.

From an operations perspective, the Rebate Pilot targets individual claims. As proposed, covered entities purchase pilot drugs at a price above the 340B discounted price. After purchase, the pilot drug goes into our inventory until it is eventually dispensed to a 340B patient, which could take weeks or months. At that point, covered entities must gather and submit data required by drug manufacturers. The timeframe from purchase to dispense to submitting data depends on the individual needs of our patients at any given time. There are additional complexities for physician-administered drugs covered under a medical benefit, which hospitals maintain separately from pharmacy claims due to different filing requirements. The high financial outlay (an estimated $21 million over one year for UnityPoint Health) creates a sense of urgency for covered entities to submit the data as soon as possible. Because covered entities are currently not required to collect and submit most of these data points to drug manufacturers, this will require extra resources, staffing, and compliance efforts. At UnityPoint Health, our 2026 calendar year budget had been set prior to this notice. Costs and cash flow disruption were not included in the budget. Due to the numerous outstanding implementation questions, it is difficult to forecast budget expenses for the Rebate Pilot or to estimate those expenses across 9 potential pilots. Existing staff will be taxed to divert time and effort to the Rebate Pilot along with current 340B Program duties, and we will likely be forced to outsource some if not all Rebate Pilot compliance at additional expense. We question whether HRSA intends covered entities to use scarce federal resources to contract with third-party vendors, instead of providing patient services.

Covered entities have prior experience submitting data under drug manufacturers' restrictive contract pharmacy policies, and all 9 potential drug manufacturer participants impose unilateral contract pharmacy restrictions. UnityPoint Health's experience has not been positive, and patient access has been restricted. Contract pharmacy programs operated by these same manufacturers enhance our concern about rebate delays, as access to 340B pricing has been inconsistent at best, even when all data requirements have been met. In addition, drug manufacturers have not been fully transparent about additional requirements and limitations under their individual policies, resulting in additional delays or lack of pricing altogether. We request that HRSA take these well-documented issues into account.

[10] Center for Healthcare Quality & Payment Reform, "Rural Hospitals At Risk of Closing" (August 2025) accessed at https://ruralhospitals.chqpr.org/downloads/Rural_Hospitals_at_Risk_of_Closing.pdf

[11] Clark NM, Hernandez AH, Bertalan MS, et al. Travel Time as an Indicator of Poor Access to Care in Surgical Emergencies. JAMA Netw Open. 2025;8(1):e2455258. doi:10.1001/jamanetworkopen.2024.55258

Rebate Pilot Guardrails

HRSA lists 14 Rebate Pilot criteria across four categories to be addressed in each applicant's plan. Drug manufacturers choosing to participate must submit plans not exceeding 1,000 words[12] (an average of 71 words per criteria) on or before September 15, 2025. The Rebate Pilot criteria are vague and incomplete, in that existing criteria may be exceeded and/or other criteria may be added. This does not facilitate Rebate Pilot transparency from which to solicit meaningful stakeholder input. In terms of process, changing criteria shortens any advanced notice of Rebate Pilot parameters for which covered entities must comply and be prepared to implement.

Should HRSA decide to move forward with the Rebate Pilot, we urge HRSA to methodically and thoughtfully embed the below guardrails in the Rebate Pilot:

Timing of rebate requests: HRSA, and not drug manufacturers, should direct whether rebates apply to drug units or full package sizes. We encourage HRSA to start the 45-day rebate request window after a full package has been dispensed. This will prevent different interpretations and increased administrative burdens.

Centralized IT platform: To reduce administrative complexity from multiple drug manufacturers' differing rebate systems, HRSA should require a single, centralized data submission platform managed by HRSA or a neutral, third-party entity. The potential of navigating 9 disparate pilots over 9 separate IT platforms is daunting, especially with the Rebate Pilot's accelerated implementation date.

Targeted data collection list: To minimize reporting burden, HRSA should not permit drug manufacturers to individually add items or alter collection fields. In particular, we oppose the inclusion of submitting invoice data to prove 340B drugs were purchased at WAC and prior to the date of dispense, which is extremely burdensome and already available through audits.

Reimbursement of administrative costs: HRSA should ensure that drug manufacturers reimburse all additional administrative costs incurred by covered entities due to the Rebate Pilot, including staffing expenses and third-party administrator fees. HRSA should issue guidance to address the process by which additional expenses will be reimbursed, and monitor cost reimbursement for compliance.

Clarification of rebate denial process: Because drug manufacturers have statutory authority to audit covered entities after providing the 340B price, the Rebate Pilot should not permit drug manufacturers to also deny claims prior to providing the 340B price. Since HRSA appears to be allowing this practice, HRSA should specify in an exhaustive list of when drug manufacturers can deny claims under the process. We remain concerned that drug manufacturers may deny claims for a host of reasons, which require data from other covered entities, be based on overly narrow codes, or implicate other drug manufacturer policies outside the Rebate Pilot. To further streamline this process, we reiterate AHA's recommendation that HRSA should create a standard denial form including at minimum 1) a narrative description of why a rebate claim is being denied; 2) supporting primary source materials justifying such a denial; and 3) a signature or attestation by a drug manufacturer employee, along with their telephone number or email address.

Oversight of rebate disputes: HRSA should develop rigorous mechanisms to monitor and address improper rebate denials and create a separate, timely dispute resolution process distinct from the existing Administrative

[12] This plan word count is exceeding short, as the notice word count itself is 1530 (starting after "Supplementary information:").

Dispute Resolution (ADR) system. The very nature of rebates as overcharges may statutorily limit the use of ADR and the duration of the ADR process further delays withheld payments.

Need for strict enforcement and penalties: Strict enforcement guidelines are needed to ensure that drug manufacturers are participating in "good faith" under the Rebate Pilot. HRSA should impose civil monetary penalties on drug manufacturers for non-compliance[13], including improper delayed or denied rebates and failure to cover administrative costs. While the 10-day rebate payment window is appreciated, HRSA should also require interest payments[14] on late rebates to incentivize timely payments.

Transparency and evaluation of pilot: HRSA should define clear success metrics, conduct a thorough assessment of the Rebate Pilot's impact on providers and communities, and share findings with Congress before any Rebate Pilot expansion.

We appreciate the opportunity to provide input on this notice and its impact on our hospitals, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,

Scott Leigh

Scott Leigh, Pharm.D.
Manager, 340B

Cathy Simmons

Cathy Simmons, JD, MPP
Executive Director, Government & External Affairs

[13] (d)(1)(B)(vi) of the 340B statute
[14] 42 U.S.C. 256(d)(1)(B)(ii)(II)