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April 20, 2026

Administrator Thomas J. Engels
Health and Human Services Administration (HRSA)
Department of Health and Human Services
Attention: HHS Docket No. HRSA-2026-03042
5600 Fishers Lane
Rockville, MD 20857

RE: HHS Docket No. HRSA-2026-03042 – Request for Information: 340B Rebate Model Pilot Program; published at Vol. 91, No. 31 Federal Register 7287-7291 on February 17, 2026.

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

Dear Administrator Engels,

UnityPoint Health appreciates this opportunity to provide comments on this 340B Rebate Model Pilot Program Request for Information. 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 (9 TINs) 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 seeking stakeholders 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.

## GENERAL COMMENTS

*HRSA is assessing whether to implement a potential 340B Rebate Pilot and is seeking stakeholder input.*

**Comment**: Foremost, this RFI asks "whether HRSA should implement a rebate model under the 340B program" instead of the upfront discount model chassis that has operated successfully for decades. The short answer is "no."

- 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[1], while pharmaceutical companies are generating significant revenue[2] and drug product prices continue to rise[3].
- The Rebate Pilot does not need to be launched to identify the harm to covered entities and beneficiaries that will result. The Rebate Pilot 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 in excess of $33 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.
- 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.

As discussed in this letter, any rebate mechanism would impose substantial administrative and financial burdens on UnityPoint Health that far exceed any potential benefits. HRSA's own cost estimates underscore the magnitude of these burdens. More fundamentally, HRSA's stated interest in testing a

[1] 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.
[2] 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/
[3] 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 $590 per drug product.* Accessed at https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs

Rebate Pilot appears to rest on the flawed premise that the agency must balance the interests of 340B covered entities and drug manufacturers when determining a discount mechanism. The statute is clear, however, that priority must be given to enabling covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the existing upfront discount mechanism—on which UnityPoint Health depends—is the most effective way to advance this statutory purpose.

The RFI poses 30 questions and encourages commenters to provide supporting facts, research, and evidence. UnityPoint Health has endeavored to respond as thoroughly as possible within the limited timeframe. For purposes of estimating costs, we have assumed that any future rebate program would include the ten drugs previously approved by HRSA for its original program, as well as those selected for 2027 under the Medicare Drug Price Negotiation Program, consistent with HRSA's February 25, 2026, Information Collection Request. The inclusion of the 2027 drugs materially increases projected costs beyond our prior estimates for 2026 alone. Additional drugs and manufacturers necessarily mean more claims submissions, increased tracking and reconciliation requirements, greater cash flow demands while awaiting statutory discounts, and a higher likelihood of disputes related to delays or denials. These burdens would directly reduce the resources available for patient care and comprehensive health services. UnityPoint Health's concern is, and remains, the impact on the patients and communities we serve—not the interests of shareholders.

## COSTS TO COVERED ENTITIES

*HRSA seeks information on costs under the current upfront 340B discount framework as well as potential costs under a proposed 340B Rebate Pilot.*

**Comment**: UnityPoint Health supports efforts to reduce administrative burden for covered entities participating in the 340B Drug Pricing Program so that limited federal resources can be redirected from back-office compliance to patient access.

**Current Covered Entity Costs.** We appreciate HRSA's interest in better understanding covered entity costs and burden. However, we respectfully suggest that the transaction-level data requested in this RFI would be better leveraged to reduce existing burden—particularly burden stemming from manufacturers' 340B contract pharmacy restrictions. In CY 2025, UnityPoint Health processed more than 6.1 million 340B transactions across nine covered entities, including disproportionate share, sole community, and critical access hospitals. Per covered entity, transaction volume ranged from roughly 40,000 to more than 2 million across mixed-use, in-house, and contract pharmacy settings. Total 340B administrative costs in 2025 were approximately $17 million, driven primarily by third-party administrator fees, in-house staffing (340B analysts, IT, billing, and data support), external auditing, and contract pharmacy implementation.

**Estimated Rebate Pilot Administrative and Staffing Costs.** For more than 30 years, the 340B Program has operated as an upfront discount model, and UnityPoint Health has structured its staffing, systems, and operations accordingly. A shift to a Rebate Pilot would impose significant new and unanticipated administrative costs beyond those already borne by covered entities. We estimate first-year costs of $800,000 to $1 million, with approximately 30 percent attributable to one-time expenses such as Third-Party Administrator (TPA) implementation, project management, legal, and IT costs. Ongoing costs would

be driven largely by personnel. This cost estimate is conservative, assuming current rebate drug volume and manufacturers remain static—an assumption that is unlikely, particularly as utilization of high-cost drugs such as GLP-1s increases and more drugs are added to the Rebate Pilot.

Implementation of a Rebate Pilot would require at least five additional technical or analyst-level FTEs to manage dual processes for rebate and upfront-discount drugs. In the current healthcare labor market, recruiting and retaining this specialized staff is extremely challenging and now takes months to replace one analyst. It would be difficult to hire five FTEs prior to operationalizing the proposed Rebate Pilot, which would further strain hospital resources already under pressure from declining reimbursement.

HRSA's estimate of five hours per week to manage rebate-related activities significantly understates the operational complexity involved. Experience with Inflation Reduction Act-related rebate monitoring has already required hospitals to add staff or engage outside vendors, with frequent reconciliation errors and substantial time spent resolving good-faith inquiries. Many hospitals cannot afford external consultants and instead absorb this work internally, diverting staff from core auditing and compliance functions and potentially compromising program integrity.

**Estimated Rebate Pilot Infrastructure and Systems Impacts.** UnityPoint Health's technological infrastructure was built around an upfront discount model. Transitioning to a rebate mechanism would require costly system redesigns, new data builds, and extensive coordination across IT, TPAs, and vendors. Even preparing for a much smaller proposed rebate pilot[4] required significant investments by UnityPoint Health in external project management, IT development, and TPA reporting—illustrating the scale of effort such a shift demands.

**Other Rebate Pilot Implications.** While not fully captured in direct cost estimates, the diversion of staff and resources required to manage a Rebate Pilot presents a serious risk to program oversight and integrity. Covered entities ultimately remain responsible for compliance, yet increasingly lack control over the systems and policies governing program administration. We do not see a viable path by which a Rebate Pilot could be implemented without increasing administrative burden and costs, nor one that would offset the significant new demands placed on covered entities.

As a community-based, nonprofit healthcare system, participation in the 340B Program is ultimately about serving our patients and communities, and not about enriching stakeholders and investors. The Rebate Pilot will erode the total 340B benefit and impact patient services and access.

**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

[4] 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

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.[5] 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

[5] 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

when care is urgent or complex.[6]

## PAYMENT TIMING AND POTENTIAL CASH FLOW IMPACTS FOR COVERED ENTITIES

*HRSA seeks information related to the impact of the 340B Rebate Pilot on payment timing and cash flow and requests input on how to structure the pilot to address these issues.*

**Comment**: Unlike the existing upfront discount model, a rebate mechanism would require UnityPoint Health to advance full payment to manufacturers and wait for statutorily owed 340B savings—effectively providing interest-free loans to drug companies. Even if manufacturers were to remit rebates within 10 days, as contemplated under rebate proposals, the delayed realization of savings would have meaningful cash-flow implications for our health system and the patients we serve.

In today's healthcare environment, services designed to support our most vulnerable patients—often operating at a financial loss—are among the first to face cuts when resources are constrained. While UnityPoint Health does not anticipate that delayed or intermittently denied rebates alone would threaten overall system viability, the combined impact of delayed payment, increased administrative costs, and inevitable rebate disputes would directly challenge our ability to sustain high-value, non-revenue-generating patient programs.

For example, UnityPoint Health operates medication-focused services such as Meds-to-Beds, free adherence packaging, and patient medication assistance programs funded through 340B savings. These programs have demonstrably improved outcomes, including reduced hospital readmissions, yet generate no direct reimbursement. Similarly, in certain markets, our emergency departments are able to waive charges and furnish patients with no-cost medications—such as antibiotics—to prevent avoidable ED returns or admissions. These programs rely on stable 340B savings to support automation, staffing, and medication costs. Under a Rebate Pilot, the financial uncertainty and delayed access to savings place these programs at significant risk of reduction or elimination.

From an operational standpoint, UnityPoint Health currently operates under standard payment terms of 12 days, with a seven-day grace period before penalties—terms that apply consistently across 340B and non-340B purchases. Based on experience with routine invoice reconciliation, we believe it is likely, if not inevitable, that a Rebate Pilot would substantially increase late fees. Even absent a Rebate Pilot, UnityPoint Health already incurs six-figure annual late-fee exposure due to invoice corrections and disputes. A rebate structure would compound this risk and may ultimately force renegotiation of payment terms, adversely affecting existing volume-based and cost-minus discounts.

Finally, while the RFI invites comment on "reliance interests" in the upfront discount model, framing the issue solely around statutory authority overlooks decades of consistent agency practice. Since its inception, the 340B Program has operated as an upfront discount program, and UnityPoint Health reasonably relied on that structure in designing its staffing, internal controls, vendor contracts, financial planning, and patient-facing program investments. A fundamental shift to a rebate mechanism—even on a pilot basis—would significantly disrupt these settled reliance interests, impose substantial new costs on

[6] 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

covered entities, and undermine the very patient benefits the 340B Program is intended to support. In the absence of demonstrated shortcomings in the upfront discount model, there is no compelling justification for introducing a rebate mechanism that would destabilize program operations and patient access.

## REBATE DENIALS

*HRSA requests information on denial guardrails and process.*

**Comment**: Under HRSA's initial Rebate Program framework, manufacturers proposed to operate the program through Second Sight Solutions' Beacon platform. During the limited preparation period, UnityPoint Health identified significant concerns with Beacon's functionality, governance, and participation terms.

Our legal review found the Beacon terms and conditions to be materially unbalanced, offering extensive protections to the platform operator while providing minimal safeguards for covered entities, particularly with respect to patient data security, integrity, and liability. We also remain concerned that Beacon retains unilateral authority to modify participation terms without input from covered entities. Requests from internal and external legal counsel for clarification or revision were declined, raising broader concerns about whether program oversight and rulemaking authority are being effectively delegated to third-party vendors and, indirectly, to manufacturers.

These experiences inform our significant concern regarding manufacturer rebate denials under any rebate model. Hospitals are already encountering challenges with manufacturer review and denial of submitted data under the Inflation Reduction Act rebate requirements, and we would expect such disputes to increase substantially under a 340B rebate framework. Under the current upfront discount model, covered entities can readily determine whether 340B pricing has been applied at the point of purchase and work directly with wholesalers and manufacturers to resolve pricing issues—a process that has functioned effectively for decades.

Introducing a rebate framework that relies on post-sale adjudication by manufacturers and their vendors adds unnecessary complexity, creates new points of dispute, increases administrative burden, and diverts limited hospital resources away from patient care.

If HRSA proceeds with a Rebate Pilot, UnityPoint Health strongly urges the agency to prohibit manufacturers from denying rebates to 340B covered entities. At a minimum, HRSA should expressly bar denials based on alleged Medicaid duplicate discounts or diversion. While manufacturers would retain their statutory audit rights, prohibiting denials would significantly reduce administrative burden and cost for safety-net providers while still allowing manufacturers access to claims data for program-integrity purposes.

If HRSA nevertheless permits rebate denials, manufacturers should be required to provide detailed, claim-specific explanations sufficient for covered entities to meaningfully evaluate and resolve the denial. Absent such guardrails, a Rebate Pilot risks replicating—and magnifying—the administrative barriers that Congress sought to avoid in establishing the 340B Program.

## DATA COLLECTION BY COVERED ENTITIES

*HRSA seeks information on current practices, how this would change under a potential 340B Rebate Pilot, and recommendations related to data elements and any privacy/security guardrails.*

**Comment**: During the prior iteration of the Rebate Pilot, HRSA and manufacturers asserted that a Rebate Pilot would not impose new data-collection burdens on covered entities, suggesting that required information was already available through mechanisms such as 340B ESP. That assertion does not reflect operational reality.

UnityPoint Health relies on multiple systems, data pathways, and specialized staff to collect, reconcile, and monitor 340B-related data. Medical claims and most contract pharmacy claims are shared with our TPA for processing and reporting, while other contract pharmacy claims flow through proprietary accumulator systems operated by contracted pharmacies. Claims from covered-entity-owned pharmacies are processed through an accumulator housed within our electronic health record (EHR). All of these pathways require customized data extracts prepared and validated by our staff.

A significant portion of analyst time is devoted to auditing claims for 340B eligibility—both targeted and random—to ensure compliance with diversion and duplicate discount prohibitions. We maintain extensive processes for data validation, monitoring health plan changes, and maintaining appropriate TPA configurations. Dedicated IT resources trained in 340B compliance are essential to maintaining system integrity. Introducing a Rebate Pilot would fundamentally alter these workflows, shifting staff focus away from compliance and auditing toward retrospective validation of manufacturer and vendor interpretations of claims data.

A Rebate Pilot would also create substantial one-time and ongoing costs. Significant system builds would be required to collect and transmit new data elements—some of which are not currently captured or reported—through our EHR and TPA platforms. TPAs would similarly need to develop new data submission frameworks and reporting capabilities, costs that would almost certainly be passed on to covered entities. Rather than improving program integrity, a Rebate Pilot risks creating duplicative data exchanges and administrative "busywork" that offers little value to patients or program oversight.

**Sharing Claims Data with Manufacturers.** The RFI asks which medical and pharmacy claims data elements should be shared with manufacturers under a Rebate Pilot . UnityPoint Health does not believe covered-entity claims data should be shared with manufacturers. We are particularly concerned that manufacturers may seek access to covered-entity data to manage or offset commercial rebate obligations to pharmacy benefit managers—an objective unrelated to 340B program integrity. Covered entities should not be required to finance or facilitate oversight of manufacturers' commercial contracting arrangements, especially by purchasing drugs at non-340B prices. At a minimum, manufacturers should be expressly prohibited from using covered-entity rebate data for commercial purposes.

**Concerns with Proposed Data Governance Guardrails.** UnityPoint Health remains deeply concerned that the data-governance framework contemplated under a Rebate Pilot—particularly as reflected in the Beacon platform terms and conditions—fails to provide adequate protections for covered entities and introduces substantial compliance, operational, and financial risk.

- **Combination of Covered-Entity and Manufacturer Data.** The Beacon terms permit covered-entity

rebate data to be combined with manufacturer pricing data, 340B ceiling price information, and rebate program terms to evaluate rebate eligibility and compliance.[7] Combining these datasets may expose sensitive information, create compliance risks, and diminish covered entities' control over how their data are used. Broad reporting rights to external parties further heighten the risk of inappropriate disclosure or secondary use beyond program-integrity purposes.

- **Disclosure and Sublicensing of Rebate Data.** The agreement expressly allows Beacon to disclose and sublicense covered-entity rebate data and derived datasets to manufacturers, commercial payers, rebate claims processors, HHS, and state Medicaid agencies.[8] This expansive authority raises significant concerns about downstream uses of covered-entity data, including uses unrelated to 340B oversight. These provisions appear more aligned with facilitating data commercialization than safeguarding the interests of safety-net providers or the integrity of the 340B Program.
- **Aggregation with External Datasets.** Beacon is permitted to combine covered-entity rebate data with rebate records, claims data, pricing information, and datasets supplied by manufacturers, payers, other covered entities, and third parties.[9] Such aggregation materially increases the risk of data matching or re-identification and exposes covered entities to liability for errors or misuse occurring outside their control. It also creates complex and opaque compliance obligations that covered entities are ill-positioned to supervise or remedy.
- **Lack of Data Return or Retention Transparency.** The terms state that Beacon has no obligation to return data stored on its systems.[10] This raises serious concerns regarding long-term data retention, aggregation, and redistribution, particularly if covered-entity data are combined with other datasets and later shared while the originating covered entity loses visibility and control.
- **Disproportionate Limitation of Vendor Liability.** The Beacon agreement broadly disclaims any warranty that the rebate platform will operate without interruption, error, or delay, or that its outputs will be reliable or accurate.[11] At the same time, it disclaims liability for indirect, consequential, incidental, special, or punitive damages and caps Second Sight's aggregate liability

[7] Covered entities agree that Second Sight may enable rebate data to be "combined with Manufacturer pricing data, 340B ceiling price information and rebate program terms in order to confirm 340B rebate eligibility and compliance with 340B requirements and manufacturer rebate agreement terms."
[8] Covered entities allow Second Sight the ability to "disclose and sub-license the Rebate Data and any other data derived from the interpretation, analysis, and combination of the foregoing data with other data… to the manufacturers, commercial payers, rebate claims processors, HHS, or state Medicaid agencies…"
[9] Covered entities allow Second Sight to ""combine Rebate Data with rebate records, claims data, pricing information, and other datasets provided by manufacturers, payers (including Medicaid, Medicare, TRICARE and commercial payers), other covered entities, and third parties, as necessary to prevent duplicate rebates and validate rebate eligibility under the 340B program."
[10] Second Sight "shall have no obligation to return to you any data stored on Second Sight's systems."
[11] "SECOND SIGHT DOES NOT WARRANT THAT THE REBATE PLATFORM WILL BE UNINTERRUPTED, ERROR FREE OR WITHOUT DELAY, NOR DOES SECOND SIGHT MAKE ANY WARRANTY AS TO ANY RESULTS THAT MAY BE OBTAINED BY USE OF THE REBATE PLATFORM."

for direct damages at **$1,000**, except in cases of gross negligence or willful misconduct.[12] This limitation grossly understates the financial, operational, and compliance harm that could result from system outages, data errors, or processing delays. These terms effectively shift all meaningful risk to covered entities while insulating the platform operator from accountability—an arrangement incompatible with administration of a federal program involving sensitive patient data and substantial statutory drug discounts.

Absent strong, enforceable guardrails governing data ownership, use, disclosure, retention, and vendor accountability, a Rebate Pilot would significantly expand administrative burden and compliance risk for covered entities without corresponding benefit to program integrity or patient access.

## MANUFACTURER EFFORTS TO AVOID DUPLICATE DISCOUNTS

*HRSA seeks information on current practices and challenges preventing Medicaid and MFP duplicate discounts and suggestions for a minimum data set to be used by Pilot Program manufacturers.*

**Comment**:

**Avoidance of Duplicate Discounts.** UnityPoint Health's covered entities maintain robust controls to prevent duplicate discounts, including extensive auditing of 340B claims—often reviewing up to 100 percent of transactions to confirm eligibility. Our covered entities have undergone multiple HRSA audits in recent years, none of which identified duplicate discount findings. We are not aware of any manufacturer raising duplicate discount concerns in our markets. Assertions from manufacturers suggesting widespread duplication lack factual support and do not reflect the compliance realities of covered entities like ours. In practice, UnityPoint Health routinely loses access to 340B pricing without notice due to unilateral manufacturer actions, with no corresponding accountability for manufacturers. Considerable staff time and resources are required to identify and correct lost pricing.

Since January 1, 2026, UnityPoint Health has also been manually submitting data to support enforcement of the Medicare Drug Price Negotiation Program (MDPNP) under the Inflation Reduction Act. As part of this process, several contract pharmacies have elected to exclude Medicaid Part D claims from 340B eligibility, further eroding 340B savings for our patients and communities. The operational complexity associated with this process has already required engagement of an external vendor to manage monitoring and reconciliation, adding six-figure costs that are still being finalized.

**Alternative Approaches to Deduplication.** HRSA has already acknowledged that manufacturers have alternative tools available to address duplicate discount concerns without imposing a rebate mechanism. Given the substantial administrative and financial burdens a Rebate Pilot would impose on covered entities, HRSA should rely on these existing options. Choosing otherwise would improperly prioritize manufacturer convenience over the interests of safety-net providers and the patients and communities

[12] Second Sight "SHALL NOT BE LIABLE FOR ANY DAMAGES, ECONOMIC OR OTHER LOSS OR DAMAGE, WHETHER INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE, AND EVEN IF SECOND SIGHT HAS BEEN ADVISED OF THE POSSIBILTY OF SUCH DAMAGES. THE LIMITATIONS OF LIABILITY SHALL NOT APPLY TO SECOND SIGHT'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT. SECOND SIGHTS AGGREGATE LIABILITY FOR DIRECT DAMAGES UNDER THIS AGREEMENT WILL NOT EXCEED ONE THOUSAND DOLLARS ($1,000). THIS LIMITATON SHALL NOT APPLY TO DAMAGES ARISING FROM SECOND SIGHT'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT."

they serve.

We also support and reiterate the American Hospital Association's position that there are viable, lawful, and significantly less burdensome alternatives to a Rebate Pilot to address 340B and MDPNP deduplication. In particular, HRSA should pursue a third-party clearinghouse approach rather than a rebate mechanism. At a minimum, HRSA should provide a clear and reasoned explanation for why such a clearinghouse is not feasible or less costly.

We disagree that rebates are necessary or would improve 340B program integrity. HRSA's existing covered-entity audit program has consistently demonstrated strong compliance and minimal duplication issues. If additional safeguards are warranted, HHS could adopt alternative models—such as requiring Medicaid agencies to follow Oregon Medicaid's retrospective claims-exclusion approach—or explore a comparable federal-level process for MDPNP deduplication. These approaches would preserve program integrity without destabilizing the longstanding and effective upfront discount model.

## REQUIRED MANUFACTURER REPORTING

*HRSA seeks information on parameters for Pilot Program manufacturers to submit data to HRSA for compliance and program assessment as well as what reported information should be available to the public.*

**Comment**: UnityPoint Health agrees that HRSA should retain a direct role in overseeing any pilot program. Under the upfront cost model, oversight has been loped-sided – HRSA conducts audits of approximately 160 (or 6%) 340B hospitals annually. In contrast, HRSA audits only five (0.6%) of participating drug manufacturers. Yet in FY 2022, 75% of audited drug manufacturers required repayment to 340B hospitals while only 28% of audited 340B hospitals' required repayments to drug manufacturers.

## 340B PROGRAM INTEGRITY AND OTHER POTENTIAL BENEFITS OF A REBATE PILOT

*HRSA seeks information on potential 340B program integrity concerns as well as 340B program benefits from implementing the potential 340B Rebate Pilot.*

**Comment**: UnityPoint Health strongly disagrees that a Rebate Pilot would enhance the integrity of the 340B Program. Existing evidence—including routine HRSA audits—demonstrates that covered entities operate the program with a high degree of compliance, and manufacturers have not substantiated claims of widespread diversion or duplicate discounts. Assertions to the contrary appear driven by financial interests rather than by demonstrable patient- or program-integrity concerns.

From our perspective, a Rebate Pilot offers no incremental integrity benefit over the longstanding upfront discount framework. Instead, it introduces significant additional workflow, staffing demands, compliance risk, and administrative expense—diverting limited resources away from patient care. These added burdens directly undermine the statutory purpose of the 340B Program by reducing our ability to stretch scarce federal resources to reach more eligible patients and sustain high-value services.

For these reasons, UnityPoint Health concludes that the costs of any rebate mechanism would far outweigh any speculative benefits. HRSA should therefore abandon the Rebate Pilot and instead pursue less burdensome alternatives—such as a neutral third-party clearinghouse—that preserve program integrity while minimizing disruption to covered entities and patient access.

If HRSA nonetheless elects to proceed with a Rebate Pilot, it must provide covered entities a meaningful opportunity to comment on the specific design and operational details of the program. At present, covered entities are being asked to respond without clarity regarding key elements, including the drugs subject to rebates, required data elements, permissible grounds for rebate denials, dispute-resolution processes, and applicable guardrails. Failure to solicit and consider public input on these core aspects would constitute a failure to consider important dimensions of the problem and would further erode confidence in the proposed approach.

We are pleased to provide input on this RFI. 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.
340B Manager
UnityPoint Health

Cathy Simmons

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