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April 20, 2026

The Honorable Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20852

Re: Request For Information: 340B Rebate Model Program

Dear Administrator Engels,

On behalf of the University of California Health (UC Health), we appreciate the opportunity to comment on the Health Resources and Services Administration's (HRSA) Request for Information (RFI) on the 340B Rebate Model Program (rebate model). UC Health's six academic health centers play a leading role in California's health care safety net and are the state's second largest provider of Medicaid inpatient services, despite having only 7% of the hospital beds in California. Currently, UC Health has 19 "covered entities" that participate in the 340B program including: 12 Disproportionate Share Hospitals (DSH), three Hemophilia Treatment Centers (HTC), two Federally Qualified Health Centers (FQHC), one Children's Hospital, and one Ryan White Clinic across our five campuses that operate 340B programs. We provide an outsized amount of complex tertiary and quaternary care to low-income patients across the state and serve patients from 99% of the zip codes in California. In addition, in the 2023-24 fiscal year, UC's academic health centers provided an estimated \$4.0 billion dollars in uncompensated care to patients insured by Medicaid and Medicare. The 340B Program is essential to the work we do to provide world class healthcare to Californians with limited means and access to care.

The adoption of a rebate model will fundamentally shift how the 340B Program has operated for over 30 years. Enacting a rebate model, even if initially limited in scope, conflicts with the 340B statute and decades of agency guidance and introduces avoidable administrative and financial burdens to safety-net providers, including UC Health. **UC Health urges HRSA not to implement a 340B Rebate Model Program.**

If HRSA attempts to implement a rebate model and radically departs from its past policies, it must offer a sufficiently detailed 340B Rebate Model Program Proposal. Prior to implementation, stakeholders should be engaged to offer meaningful analysis and feedback. The current RFI includes a list of questions that are untethered to a concrete proposal. Without a specific proposal to analyze, any information received from this RFI will be unreliable and cannot be used for reasonable or rational policymaking.

A rebate model would impose onerous administrative requirements and costs on covered entities, diverting critical resources from patient care—outcomes that conflict with the program's statutory intent. UC Health, nonetheless, appreciates the opportunity to provide input through this RFI to document the significant costs and harm a rebate model would create for our hospitals and the patients we serve. UC Health urges HRSA to reevaluate its current approach to a rebate model to allow all stakeholders time to work together on ways to strengthen, rather than weaken, this vital safety net program.

I. Current 340B Administrative Framework and Baseline Costs

During the most recent fiscal year, UC Health processed over 42 million 340B transactions across all covered entity sites. This figure represents the total volume of 340B-eligible drugs dispensed or administered to patients and encompasses all channels through which 340B drugs reach our patients; including in-house pharmacies, hospital/clinic administered medications, and contract pharmacy arrangements.

UC Health employs 30 full-time employees (FTEs) dedicated solely to managing the 340B Program. Beyond their salaries and benefits, the organization incurs over \$17 million annually in direct administrative costs to operate and maintain the program. Direct costs include administrative fees paid to contract pharmacy partners, maintenance fees for split-billing software used to manage mixed-use purchasing across our covered entities, compliance software platforms used to continuously audit and validate 340B claims, and fees for independent third-party auditors who conduct annual program audits.

The primary cost drivers for our 340B Program administrative costs are, in order of significance:

- **Staffing:** which represents our largest cost driver and is reflected in the 30 dedicated FTEs required to manage and oversee the program across our different covered entities.
- **Third-party administrator (TPA) fees:** include administrative fees paid to contract pharmacy partners and independent auditors to ensure program integrity.
- **Technology platforms:** including split-billing software and compliance systems used for ongoing auditing and monitoring of 340B claims across all universes.

II. Administrative and Operational Burden Under a 340B Rebate Model

Potential Administrative and Operational Costs

UC Health expects an inordinate amount of administrative burden to operate a potential rebate model. We estimate approximately 300-400 hours per month of additional work would be required across five academic health centers that operate 340B Programs. The additional work is dedicated solely to rebate data collection, validation, and reconciliation activities required under a rebate model. Beyond new hires, existing 340B Program staff, currently allocated across our 30 dedicated FTEs, would be required to absorb additional daily administrative functions. This reallocation would divert existing staff from critical program oversight, compliance monitoring, and patient-facing support functions they currently perform. This estimate does not include the additional cost of engaging third-party vendors to manage portions of the rebate process, which we anticipate would be required and create additional work. In addition, UC Health estimates approximately 80 hours of one-time startup effort per campus to prepare systems, build reports, train staff, and configure workflows necessary to participate in a rebate model. This estimate is based on the original 10 drugs selected by HRSA for the Rebate Model Pilot Program proposed in 2025.

Incremental, Start-up, and On-going Costs and Coverage

Implementing a rebate model creates both one-time and recurring administrative costs across IT, legal, compliance, regulatory affairs, revenue cycle, and 340B Program staff. Requiring covered entities to operate dual 340B frameworks — one for rebate and one for upfront discount — compounds operational complexity and compliance risk without any corresponding benefit. By requiring covered entities to run dual 340B Programs — one for a rebate model and one for the upfront discount model — organizations must implement two different administrative frameworks, thereby increasing operational complexity, costs, and compliance risk.

One-Time Startup Costs: We estimate approximately 80 hours per campus to build reports, configure systems, train staff, and establish submission workflows. This represents a cross-functional investment well beyond the 340B staff alone.

Recurring Costs: On an ongoing basis, we estimate an increase of 3–4 hours per day per campus, plus approximately one additional FTE per campus to manage rebate-related functions. Even with a third-party vendor, internal staff will still be required to oversee and validate that work. Vendor support costs are estimated at \$100,000–\$350,000 per campus annually — costs that are entirely new and incremental to our existing administrative baseline.

Technology Infrastructure

Implementing a rebate model equivalent to the 2025 pilot program would require a new or modified IT infrastructure across our covered entity portfolio. Our 340B transaction data currently resides across multiple disparate systems covering in-house pharmacies, clinic-

administered medications, mixed-use spaces, and locations that house pure 340B inventory, otherwise known as “clean sites.” None of our current IT infrastructures are designed or configured to support rebate submission workflows. In some cases, engaging software vendors to collect, submit, and reconcile rebate data is necessary, which is a functionality we do not currently utilize. This would represent a new net cost to UC Health. In other cases, we would need to build internal reports from scratch and establish entirely new processes for validating, submitting, and reconciling that data. These types of workflows are not currently required or performed under the upfront discount model. In either approach, substantial investment in new infrastructure, configuration, testing, and ongoing maintenance would be required. The complexity is further compounded by the manual intervention needed to reconcile data inconsistencies across systems, such as mismatched units of measure and missing data fields, which cannot be fully automated. Collectively, these IT demands represent a significant one-time and ongoing cost burden that does not exist under our current administrative infrastructure.

III. Methodology and Assumptions

Our estimates were created based on the assumption that a 340B Rebate Model Pilot Program will be consistent with the rebate model HRSA proposed and attempted to implement in 2025, and would include only the original 10 drugs, not any additional drugs that may be subject to the Medicare negotiated Maximum Fair Price (MFP) starting in 2027. These cost estimates are based on our experience from the proposed 340B Rebate Pilot Program in 2025 as well as a direct operational assessment of our current 340B Program infrastructure.

The lack of specificity regarding HRSA’s new proposal for a 340B Rebate Model Program makes it impossible to offer an informed estimate of the administrative and operational costs for a potential future rebate model. If HRSA were to include MFP drugs from 2027 and beyond in any rebate model, or make any other changes to the number or types of drugs originally proposed in the 2025 340B Rebate Pilot Program, our cost estimates would substantially increase.

The 80-hour one-time startup estimate was created by evaluating the hours necessary to create the reports, data pulls, training of dedicated staff, and submission workflow across our multiple transaction systems. Similarly, the daily hour estimates were created based on our direct experience in preparing for the 340B Rebate Model Pilot last year, as well as evaluating the additional data collection, data validation, and submission that a rebate model would require.

From our experience in preparing for the 340B Rebate Pilot Program from last year, the data necessary to submit the rebate is not available from a single database. The data that we have available, as it relates to our 340B transaction data, is available from multiple disparate systems. The various systems include in-house pharmacies, clinic-administered medications, mixed use areas, and clean sites. These various systems exist to serve key operational and regulatory compliance roles and were not designed to serve as a data source for a 340B Rebate Model

Program. Therefore, gathering, aggregating, and reconciling data across these platforms imposes a new administrative and operational burden, including a full separate build of the data. In addition, the estimates that we created acknowledge the reality that a large portion of the data preparation would still need to be done manually. The manual nature of this work is significant and cannot be eliminated through automation. Specific examples of manual tasks include:

- Correcting data fields where payer IDs and provider National Provider Identifications (NPIs) are blank and must be manually populated with the appropriate value before submission.
- Validating and overriding units of measure to comply with rebate submission requirements, particularly for injectable medications that may be dispensed in different units across our systems.
- Reconciling data pulled from multiple disparate systems that do not communicate with one another and require manual cross-referencing to ensure accuracy and completeness.

IV. Other Anticipated Costs and Impacts of a Potential 340B Rebate Model Pilot Program

Additional Costs

Beyond the administrative and operational costs previously outlined, the most significant additional cost UC Health would incur under a rebate model is the increased drug acquisition cost resulting from drugs purchased at Wholesale Acquisition Cost (WAC) rather than the upfront 340B discounted price. Under a rebate model equivalent to the 2025 pilot program, we would be required to purchase these drugs at WAC and subsequently seek reimbursement of the discount through a manufacturer rebate process. Across all our campuses, we estimate this would result in approximately \$120 million in *additional* annual drug acquisition costs for 2025 pilot drugs alone, approximately \$10 million per month. This represents a substantial and recurring financial burden that would directly strain our organization's operating capital and budget, diverting resources that currently fund critical care programs and services for our vulnerable patient populations.

Additional costs will arise due to inappropriately denied rebates. Transitioning from an up-front rebate to a manufacturer-provided rebate grants manufacturers an advantage over covered entities. The administrative cost of monitoring, documenting, and disputing inappropriate denials is difficult to estimate, but likely to be significant. The 2025 rebate model did not include a dispute resolution process, and did not go live, so there is no data available to determine the frequency of manufacturer denials.

Impacts to Patient Access

Implementation of a rebate model would have direct impacts on patient access to drugs across our covered entity portfolio. The \$120 million in additional annual drug acquisition costs would place significant strain on our operating budget, directly threatening the community benefit programs UC Health currently funds with 340B savings. Patients receive medications at no cost

to qualifying members or receive 340B discounts directly at the point of dispensing. Under a rebate model, we anticipate these programs would be significantly reduced or eliminated. Additionally, the increased cost of purchasing drugs at list price would necessitate reductions in on-hand drug inventory across our campuses, which could result in dispensing delays and directly impact the continuity and initiation of therapy for patients managing serious or chronic conditions. For example, Stelara (ustekinumab) 90mg prefilled syringe is used to treat serious chronic conditions such as Crohn's disease, ulcerative colitis, and psoriasis. This medication carries a WAC price of over \$28,000 per package (over 5 times more than the 340B cost). Under a rebate model, UC Health would be required to purchase this drug at WAC rather than at the 340B discounted price, which would make it financially untenable to maintain adequate inventory levels. Stelara is just one example among the pilot drugs where the financial burden of WAC purchasing would directly translate into reduced inventory and potential delays in patient access to critical therapies.

Cash Flow Impacts

The 340B statute requires that manufacturers offer covered entities the ability to purchase covered, outpatient drugs at or below the ceiling price. A rebate model that is voluntary for manufacturers, but mandatory for covered entities, would allow manufacturers to selectively impose additional costs on covered entities for their own administrative and cash flow convenience. By allowing manufacturers to transfer costs to covered entities, a rebate model effectively increases the price of covered outpatient drugs above the ceiling price. This is especially true, from a cash-flow perspective, because the impact of a rebate model is to directly transfer the cash-flow costs of manufacturers onto covered entities.

Under our current wholesaler contracts, payment for both 340B and non-340B drugs are due every 15 calendar days, with no differentiation in payment terms between the two and no early payment discounts. Payment timing under a rebate model would have a direct and significant impact on our organization's cash flow. As mentioned before, under a rebate model, UC Health would be required to purchase drugs at WAC, resulting in approximately \$120 million in additional annual drug acquisition costs. **To account for the increased upfront cost, our wholesaler would require the UC Health covered entities to increase their prepay deposit account by approximately \$30 million per quarter systemwide, or close to \$120 million per year.** This is an immediate and outlay of cash that's directly tied to the rebate model. Since our drug invoices are due within 15 calendar days, even a brief gap in invoice payment and rebate receipt would expose UC Health to substantial interest charges. Based on our current experience with the MFP effectuation for the 10 selected Inflation Reduction Act (IRA) drugs, we are already experiencing significant lag in claims processing from the Medicare Transaction Facilitator (MTF) to the manufacturer rebate portal, Beacon. There are additional delays from Beacon back to the MTF before remittances reach our accounts, a process that is currently taking 30 days or more. While we understand a rebate model may not be limited to Medicare Part D drugs, we anticipate similar or greater lag times in claims processing and remittance for non-Part

D claims, which would further compound the cash flow strain on UC Health.

V. Rebate Denials

Dedicated Process to Resolve Rebate Disputes.

Any potential 340B Rebate Model Program should clearly communicate how to resolve rebate delays, denials, or any other administrative or logistical issues emerging through implementation of the rebate model. Providing a general email address to lodge complaints will not suffice and is insufficient given the implications of the rebate model on covered entity finances. If the agency requires hospitals to raise concerns through the existing 340B Administrative Dispute Resolution (ADR) process, this process will not suffice. The ADR process can take years before a decision is rendered, which would mean that our hospitals would have to forgo a rebate and advance large sums of cash for an extended period — much longer than the 10 days allowed under the agency's notice. Therefore, we strongly recommend that HRSA create a separate process to collect, respond to, and adjudicate any disputes related to its rebate model pilot program.

This separate process should allow for expedited review and timely decisions of any rebate-related claim disputes. Most important, the agency should provide (1) a designated human point-of-contact to receive complaints (and follow-ups on those complaints) and (2) a specific mandatory timeline for when those complaints are addressed. HRSA should take these extra measures to ensure that all safety net hospitals, including UC Health, have an accessible and timely mechanism to raise concerns and resolve rebate-related disputes.

Denial Documentation Requirements

UC Health is concerned that manufacturers may issue a high volume of rebate denials or delays for improper reasons, particularly given that program integrity concerns are not a permissible basis for denial. We also recognize that drug companies have developed ways to evade the rules of the 340B Program. Any denial documentation must include: (1) a narrative description of why a rebate claim is being denied (2) supporting primary source materials (e.g., claims information, indication of which other covered entity received a rebate) justifying such a denial; (3) a signature or attestation by a drug company employee, along with their telephone number or email address, so that covered entities can reach them to address any incorrect denials; (4) a mandatory timeline by which the covered entity must receive a response from the drug manufacturer; and (5) an automatic reversal of the rebate denial if the drug manufacturer does not respond within that time period. HRSA should also consider creating a standard denial form to streamline the administrative process and provide covered entities with sufficient information to understand (and potentially challenge) a denial.

To ensure manufacturers do not have an incentive to deny claims temporarily to gain cash flow benefits; manufacturers should also be required to put aside any disputed rebate amount in a separate, non-interest-bearing account during the pendency of any dispute.

Denying Rebates Based on Unilateral Contract Pharmacy Restrictions

HRSA has not addressed whether drug companies can deny 340B rebates for contract pharmacy claims based on the drug companies' unlawful and unilateral contract pharmacy restrictions. As HRSA is aware, since 2020 dozens of drug companies have imposed restrictions on access to 340B discounted pricing through contract pharmacies. These restrictions have created enormous financial and administrative burdens for 340B covered entities nationwide.¹ If drug companies are allowed to deny rebates for contract pharmacy claims based on unilaterally imposed restrictions, it will compound the harm these restrictions have already caused 340B hospitals. Therefore, HRSA should clarify that drug companies are not allowed to use 340B rebate denials as a backdoor to enforce their unlawful contract pharmacy policies or any other unilateral contractual or policy restrictions.

VI. Data Collection by Covered Entities

UC Health collects, maintains, and retains 340B Program data across multiple systems spanning our in-house pharmacies, clinic-administered medications, mixed-use areas, and clean sites across all five campuses that operate 340B Programs. Given the complexity of our covered entity portfolio, data is not housed in a single unified system but rather across multiple disparate platforms that each require separate reporting and reconciliation processes. We utilize third-party vendors for key functions including split-billing, contract pharmacy qualifications, in-house pharmacy qualifications, compliance monitoring, and audit support, all of which involve the collection and retention of 340B transaction data.

Ensuring Accuracy

UC Health employs multiple layers of oversight to ensure the accuracy, completeness, and consistency of our 340B Program data. Our 30 dedicated 340B FTEs conduct regular audits across our multiple systems to ensure that 340B drugs are given to eligible patients and no duplicate discounts have occurred. Our third-party vendors, who assist us with split billing, contract pharmacy, and in-house management of our pharmacies and claims, also conduct their own checks and balances to guarantee that only 340B eligible claims are qualified. UC Health also employs the services of independent third-party auditors to conduct a comprehensive audit of our 340B Programs on an annual basis.

Shift in Data Collection

A rebate model would significantly change our current data collection activities, introducing both one-time and ongoing changes. On a one-time basis, our organization would need to build entirely new reports from scratch, configure new data submission workflows, and establish

¹ <https://www.aha.org/2022-11-14-survey-brief-drug-companies-reduce-patients-access-care-limiting-340b-community-pharmacies>

validation and reconciliation processes that do not currently exist. On an ongoing basis, daily collection, manual validation, and submission of rebate claims data would be required across systems not designed for this purpose.

Establishing a Centralized Platform for Data Submissions

The current framework allows each drug company to establish its own process for making the 340B price available under the rebate model. Despite the guardrails provided, each drug company has been given the latitude to use its own IT platform and require a different set of data elements to submit for a rebate. As a result, our hospitals would have to manage many different rebate model schemes. We cannot overstate the complexity and administrative burden this will introduce. This is an example of unnecessary and inefficient variation in the health care system that contributes to an estimated 30% of all health care spending going toward administration instead of patient care.²

Under the current framework, our hospitals would submit data to IT platforms that are either directly owned by drug companies or by third parties that work closely with drug companies. These IT platforms will not be neutral parties. We are concerned about the risk of conflicts of interest or improper use of the data for purposes outside the scope of this rebate model pilot program. For example, one of the IT platforms that will likely be used by some of the drug companies — Beacon by Second Sight Solutions — is a wholly owned subsidiary of the Berkeley Research Group (BRG), which is a consulting firm that has a long history of working for drug companies and their trade association, PhRMA.³ BRG has released a number of reports funded by PhRMA and critical of the 340B Program.⁴ In addition, Second Sight Solutions is also the parent company of 340B ESP, the IT platform of choice for several drug companies that have imposed unlawful 340B contract pharmacy restrictions.⁵ HRSA should impose strict guidelines on how information may be used — specifically, restricting the use of that information to exclusively those purposes necessary to implement the limited pilot program. In addition, HRSA should strictly penalize drug companies if information is used for any other purpose. Such penalties should be proportional to, and compensate covered entities for, the value of the information that is improperly exploited.

To most effectively remedy these concerns, HRSA should identify and engage a single neutral, third-party entity to serve as a clearinghouse for any data submissions required under the agency's rebate model. The agency already has a potential solution; in the calendar year (CY) 2026 Physician Fee Schedule rule, the Centers for Medicare & Medicaid Services (CMS) proposed to pilot a 340B claims data repository for use in identifying 340B units for the calculation of Medicare inflation rebates required under the IRA.⁵ HRSA could use this same

² <https://www.commonwealthfund.org/publications/issue-briefs/2023/oct/high-us-health-care-spending-where-is-it-all-going>

³ <https://beaconchannelmanagement.com/>

⁴ https://media.thinkbrg.com/wp-content/uploads/2024/05/13163125/340BProgram_Relative_Size_WP_2022Update.pdf

⁵ <https://www.340besp.com/>

repository for the rebate model pilot program. This would (1) minimize some of the administrative burden associated with the rebate model by allowing hospitals to submit claims data to a single entity; (2) limit the ability of drug companies to use any data for reasons outside the scope of this rebate model; and (3) allow the agency to more easily oversee the pilot program.

VII. Duplicate Discount Prevention: Current Practices and Rebate Model Implications

Duplicate Discount Prevention

UC Health has robust duplicate discount prevention processes in place that are largely automated and require minimal manual intervention. Claim-level identifiers are applied for all 340B eligible Medicaid transactions, automatically as mandated by California State Medicaid requirement. Any rebate model should be designed exclusively to avoid duplicate discounts prohibited by 340B statute; specifically rebates paid to a State Medicaid Program (per 42 U.S.C. § 256b(a)(5)(A)).

UC Health recommends that any data submission requirements under a potential 340B Rebate Model Program be strictly limited to the minimum data elements necessary to identify and prevent duplication under the IRA. For pharmacy claims, we recommend limiting required data elements to the following: claim ID, date of service, 11-digit NDC, and quantity dispensed for Medicare Part D claims only. Payer information should not be required, as under the IRA, claims information is already transmitted to manufacturers through the MTF. Submitting payer data is duplicative and unnecessary for duplicate discount identification purposes. The original 340B Rebate Pilot Program's data specifications included additional fields such as prescriber ID, service provider ID, BIN, and PCN numbers, none of which are necessary solely for the purpose deduplication. Extensive data requirements introduce unnecessary privacy risk and administrative burden.

UC Health strongly recommends that HRSA refrain from requiring medical claims data submission entirely. If the primary goal of the rebate model is to deduplicate claims under the IRA, there is no basis for collecting non-Part D claims data, as the 10 IRA drugs selected for the current pilot are all Medicare Part D drugs and Medicare Part B drugs are not subject to Maximum Fair Price (MFP) under the Medicare Drug Negotiated Program (MDPNP) until 2028 at the earliest. Requiring medical claims data, including health plan ID, payer name, or any other payer-related fields, would impose a significant and unnecessary administrative burden on covered entities without any corresponding program integrity benefit. HRSA should revisit medical claims data requirements only if and when Medicare Part B drugs are included in a future iteration of the rebate model.

Duplicate Discounts Become Harder to Prevent Under a Rebate Model

Under the current system, 340B identifiers are automatically attached to Medicaid claims at the

time of billing and no manual steps are required. This built-in safeguard effectively eliminates the risk of duplicate discounts. A rebate model would dismantle that safeguard. Claims would initially be billed at full price (WAC), and the 340B identifier would only be applied later — manually — after the manufacturer rebate is received and the claim is rebilled. This creates several problems:

- **Timing conflict:** Prior to last year's rebate pilot, California's Medicaid agency issued guidance that 340B claims must be held until the rebate is received. This causes two issues: first, the provider has to adjudicate the claim to determine the patient's liability before the drug is dispensed. Second, to receive a rebate, covered entities must submit claims information to the manufacturer. This puts covered entities in an impossible position as they cannot hold Medicaid claims, dispense the drug, and have claim-level information to submit for a 340B rebate simultaneously
- **Cash flow risk:** Holding claims delays reimbursement, creating direct financial strain on covered entities.
- **Human error risk:** Because rebilling is entirely manual, there is a real risk that a covered entity receives the manufacturer rebate but never completes the rebilling step. The result: the state reimburses at full price while the covered entity has already received the rebate — exactly the duplicate discount scenario the rebate model is supposed to prevent.

In short, the current automated process prevents duplicate discounts by design. A rebate model would replace that with a manual, error-prone process that increases the very risk it claims to address.

Challenges Encountered with the Maximum Fair Price under the Medicare Drug Negotiated Program

Since the program started on January 1, 2026, UC Health has implemented several operational and administrative changes to manage the intersection of 340B and Medicare Drug Negotiated Program (MDNP) and the Maximum Fair Price (MFP). We have implemented claim-level identifiers to flag 340B eligible Part D transactions to prevent duplication, but our staff is still required to regularly review claims through the manufacturer rebate portal to identify and correct instances where 340B-eligible claims have been incorrectly classified as non-340B.

Since January 1, 2026, UC Health has encountered numerous instances where manufacturers have not correctly applied the non-duplication provision, resulting in non-340B claims being incorrectly identified as 340B in the manufacturer rebate portal, effectively denying us access to the MFP on those claims. Upon identifying these discrepancies through our claim-level review process, we have been required to actively dispute these claims directly with manufacturers. This dispute has been particularly burdensome, as manufacturers are arbitrarily attaching 340B invoices to the non-340B claim and requesting claim-level data to support dispute resolution.

Furthermore, the only path to recovering the rebate on these disputed claims is submitting 340B claims, predominantly non-Part D, to a separate manufacturer portal so that the invoice number can be dissociated from the claim and the rebate processed accordingly. This process is entirely new, highly manual, not scalable at our transaction volume, and is consuming a significant and unanticipated amount of staff time with no clear or consistent resolution timeline across manufacturers.

VIII. Required Reporting

To ensure meaningful oversight and accountability under a potential 340B Rebate Model Program, UC Health recommends that HRSA establish robust and standardized manufacturer reporting requirements submitted monthly. At minimum, manufacturer reporting requirements should also include quarterly aggregate summaries. Specifically, manufacturers should be required to report the following data elements to HRSA:

- Total rebate requests received, including the number of claims and corresponding dollar amounts
- Total rebates paid, including payment amounts and timeliness relative to the required ten calendar day payment window (based on last year's pilot)
- Total rebates paid outside of the required payment window, including the number of claims, dollar amounts, and reasons for delayed payment
- Total rebates denied, including the number of claims, dollar amounts, and specific documented reasons for each denial
- The rate of denial by claim type, drug, and covered entity type
- Total good faith inquiries that are currently open, including the number of claims associated with each open inquiry and the length of time each inquiry has been pending
- Total good faith inquiries resolved, including resolution timelines and outcomes
- Any operational or systems issues experienced by the manufacturer or its contracted platform that resulted in claim processing delays or errors

UC Health recommends that HRSA require the following data publicly available on a quarterly basis to enable transparent program evaluation by covered entities, policymakers, and other stakeholders:

- Aggregate rebate payment and denial rates by manufacturer and by drug
- Aggregate denial reasons across all participating manufacturers
- Average rebate payment timelines by manufacturer
- The number and dollar value of outstanding good faith inquiries; and any patterns of non-compliance with payment timeliness requirements

Publicly disclosing these data is critical to hold manufacturers accountable and ensure that covered entities and HRSA have the information necessary to identify systemic issues.

IX. 340B Program Integrity

Commitment to Transparency

To promote transparency, the 340B Program is subject to HRSA oversight, enforcing strict compliance rules. UC Health adheres to 340B compliance rules and is transparent about its use of 340B savings. These enforcement efforts include an annual recertification for all covered entities and audits of both providers and manufacturers to ensure program integrity. HRSA has conducted over 2,200 audits on 340B covered entities since 2012. Each UC academic health center that participates in the 340B Program, has signed the [America's Hospital Association, 340B Good Stewardship Principles](#) which include commitments to communicate the value of the 340B Program, disclose 340B estimated savings that are calculated using a standardized method, and continue rigorous internal oversight of our participation in the program. This information is posted on public websites:

- UC Davis Health: <https://health.ucdavis.edu/news/public-reporting/340b-program>
- UC San Francisco Health: <https://www.ucsfhealth.org/about/our-340b-story>
- UC Los Angeles Health: <https://www.uclahealth.org/discover/about-ucla-health/government-relations/340b-community-health-program>
- UC Irvine Health: <https://www.ucihealth.org/patients-and-visitors/financial-resources/insurance/340b-program>
- UC San Diego Health: <https://health.ucsd.edu/about-us/340b-program/>

In addition, HRSA's own 340B audit data show that between fiscal years (FY) 2018 and 2022, audit findings across 340B hospitals for duplicate discount and diversion decreased by a combined 62%.⁶ Only 10.7% of 340B hospital audits had at least one finding of diversion; just 13.2% had a duplicate discount finding in FY 2022.⁷ UC Health has developed robust internal audit protocols to conduct periodic self-audits of our 340B Program; ensuring compliance by preventing diversion and duplicate discounts. In contrast, between FYs 2018 and 2022, 60% of drug companies had at least one adverse audit finding. And the trends are even more notable with respect to audit findings requiring repayment. In FY 2022, 75% of drug companies that were audited required repayment to 340B hospitals while only 28% of 340B hospitals' audit findings involved any repayments.⁸ The data show that HRSA conducts approximately 160 audits of 340B hospitals annually — or about 6% of the 340B hospital field. By contrast, it conducts roughly five audits of drug companies — or about 0.6% of participating drug companies.⁹ In combination with the data showing the rate of audit findings for drug companies in a much smaller sample size, this discrepancy underscores the need for more scrutiny on drug

⁶ <https://www.aha.org/guidesreports/2025-06-16-more-drug-company-oversight-needed-maintain-compliance-340b-program-rules>

⁷ Id.

⁸ Id.

⁹ Id.

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companies. Drug companies are advocating for a 340B rebate model as a solution to a problem that does not exist. HRSA should reconsider the implementation of a 340B rebate model pilot program.

While UC Health appreciates the opportunity to provide feedback, a rebate model would limit covered entities' ability to support current levels of community benefits and fund critical patient care programs and services. UC Health uses savings in many ways, including funding a range of community benefits. UC Health utilizes 340B savings to provide a variety of clinical care to Medicaid and underserved patients including access to specialty programs that perform lifesaving treatments. Examples of complex care include organ transplants, complex cancer care, immunological care (including stem cell transplants), neurological care, cardiovascular care, and heart surgery. Under a rebate model, UC Health will need to advance millions of dollars to drug companies, coupled with the potential for rebate delays and denials, and have fewer funds to devote to providing community benefits. Similarly, UC Health will have fewer savings to invest in maintaining, improving, and expanding access to an array of vital patient programs and services; it is critical for HRSA to develop strict safeguards for a 340B Rebate Model Program.

UC Health urges HRSA to offer a concrete and detailed rebate model pilot program proposal for comment prior to attempting such a drastic change in policy that would have adverse impacts on providers and patients.

We appreciate your careful consideration of these issues and are ready to collaborate on solutions that strengthen this vital safety-net program. If you have any questions, please contact Kent Springfield at (202) 993-8810 or kent.springfield@ucdc.edu.

Sincerely,

A handwritten signature in blue ink that reads "Tam Ma". The signature is written in a cursive, flowing style.

Tam Ma
Associate Vice President, Health Policy and Regulatory Affairs
UC Health