NOTE: THE SECTIONS OF THE MODEL COMMENT LETTER HIGHLIGHTED IN YELLOW ARE FOR HOSPITALS TO INSERT THEIR NAMES AND ANY ORGANIZATION-SPECIFIC INFORMATION.

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 Pilot Program, HHS Docket No. HRSA-2026-03042

Dear Administrator Engels:

On behalf of **[insert name of hospital and location]**, we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) "Request for Information: 340B Rebate Model Pilot Program." Among other things, this RFI asks "whether HRSA should implement a rebate model under the 340B program" instead of the upfront discount model that has worked successfully for decades. The answer is "no."

As explained below, *any* rebate mechanism will impose enormous costs and burdens on **[insert name of hospital and location]** that far outweigh any benefits that might come from it. HRSA's own calculations of costs are extraordinary. More fundamentally, HRSA's desire to test a rebate model is seemingly based on the incorrect premise that it must balance the interests of 340B hospitals and drug companies when choosing a discount mechanism. In reality, HRSA must give primacy to the needs of covered entities so that they can "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Preserving the upfront discount mechanism, which **[insert name of hospital and location]** has relied on for years, is the best way to fulfill that purpose of the 340B program.

The RFI poses 30 questions and encourages commenters to include supporting facts, research, and evidence in their responses. **[Insert name of hospital and location]** has done its best to provide detailed answers in the limited time available to us. For purposes of estimating costs, we have assumed that any future Rebate Program will include the 10 drugs that HRSA previously approved for its original Program and those that have been approved under the Medicare Drug Price Negotiation Program (MDPNP) for 2027, per HRSA's February 25, 2026 Information Collection Request. With the addition of the 2027 drugs, our cost estimates have increased over the estimates we had calculated for the 2026

drugs alone. After all, more drugs and more drug companies means *more* claims to submit, *more* rebates to track and reconcile, *more* money that we will need to float to drug companies while we await our statutory discount, *more* likely disputes over delays and denials, and therefore *less* money that **[insert name of hospital and location]** can spend on patient care and comprehensive health care services.

Administrative Costs Under A Potential 340B Rebate Program. Any rebate program would require **[insert name of hospital and location]** to spend significant sums on new administrative costs. When we chose to participate in the 340B program, **[insert name of hospital and location]** understood that we would incur some reasonable administrative costs. We designed our hiring, operations, and program administration around an upfront discount model. A shift to a new kind of discount mechanism demands new resources, imposing considerable additional costs and burdens on our institution that go far above and beyond what we had expected and planned for as a 340B hospital—and far above and beyond what we are experiencing now.

- Estimate the incremental administrative and operational costs your organization would incur under a 340B Model Rebate Pilot Program, distinguishing between one-time startup costs and ongoing costs.
    - These figures can be measured in terms of hours to complete the activities or in dollar amounts in the aggregate, or both.
    - **NOTE THAT HRSA IS NOW INDICATING UP TO 25 DRUGS COULD BE INCLUDED IN THE REBATE PROGRAM, SO PLEASE ACCOUNT FOR THAT IN YOUR ESTIMATES. THESE ARE THE DRUGS THAT MEDICARE HAS NEGOTIATED PRICES FOR APPLICABILITY IN 2026 and 2027.**
- Identify and quantify any key cost drivers (e.g., increased staffing, diverting current staff, IT systems, third-party vendors, compliance activities, labor hours, process for challenging denials). Be specific where possible (e.g., how much are your TPAs charging to set up the data feeds necessary to comply, did the TPAs quote additional costs for the rebate pilot, did other vendors quote costs)
- Specify the activities or functions these incremental costs would cover (e.g., claims processing, data submission, reconciliation/chasing down rebates, audit support, challenging denials) and what, if any, effect the change of some drugs to a rebate model would have on current administrative costs under the upfront 340B discount.
- Identify any additional costs to your organization associated with implementation of a potential 340B Rebate Program not otherwise captured above (e.g., legal

review, training, consulting services, reduction in services offered, and specify whether these costs are one-time or recurring.)

- If notable, compare those administrative costs to your marginal savings from 340B (either total or for those 25 potential drugs) to show how much this will eat into the benefits of the 340B Program.
- **BE AS SPECIFIC AND COMPREHENSIVE AS POSSIBLE—INCLUDE ALL POTENTIAL COSTS TO PROVIDE A FULL PICTURE OF WHY THE REBATE MECHANISM IS SO EXPENSIVE AND BURDENSOME**.

Staffing Impacts Under a Potential 340B Rebate Program. [Insert name of hospital and location] does not currently have the staff needed to comply with a Rebate Program.

- Indicate whether implementation of a potential 340B Rebate Model Pilot Program would require additional full-time employees or would cause current medical provider employees to reallocate work hours from medical care to perform administrative functions (quantifying wherever possible).
- If yes, identify the anticipated number of additional full-time employees; describe their roles, responsibilities, and functions. Estimate how much advance notice you would need to hire these employees.
- Explain why HRSA's current estimate of only 5 hours per week in additional work (for up to 25 total drugs, including both the 2026 and 2027 drugs approved under the IRA Drug Price Negotiation Program) is a gross underestimate.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Program. [Insert name of hospital and location] has designed its technological systems and operational infrastructure in reliance on an upfront discount model. Any shift to a rebate mechanism will force us to incur significant costs to change those systems.

- Describe any new or modified IT systems, software, or data infrastructure that would be required to implement a potential 340B Rebate Model Pilot Program.
- Provide estimated costs for system development, procurement, maintenance, or integration that would be required to implement a potential 340B Rebate Model Pilot Program and specify whether any such costs would be one-time or recurring.

- Highlight particularly why it's difficult to provide medical claims data and how that would likely involve manual work to provide that data to your TPA since they do not have a data feed directly into your EHR.

Data Collection By Covered Entities. During the prior iteration of the Rebate Program, both HRSA and the drug companies stated that a rebate mechanism would not impose new data-related burdens on 340B hospitals like ours. For example, both insisted that hospitals already provide the required information through 340B ESP. That is incorrect.

- Describe how your organization currently collects, maintains, retains, and validates or audits data related to 340B Program participation, including whether third-party vendors are used to carry out some or all of these activities.
- Describe whether a potential 340B Rebate Model Pilot Program would change current data collection activities and whether any such changes would be onetime or ongoing.
- Describe whether you will need to pull information from different internal hospital systems to comply with the data demands, whether you will need to manually do any work, etc.
- HRSA has said in its Information Collection Request: "OPA expects that data submitted by covered entities to manufacturers will be comparable to data already being collected and maintained by covered entities through existing third-party vendor relationships or data that is already being provided to manufacturers with respect to certain contract pharmacy policies, in-house pharmacy claims requests, and data elements provided for claims with drugs dispensed under the Medicare Drug Price Negotiation Program. **Therefore, the burden associated with a potential 340B Rebate Model Pilot Program data requests may not be significant**." Is this true? Will it be this easy? Why not?
- **IF YOU DO NOT BELIEVE THAT A REBATE PROGRAM WOULD CHANGE DATA COLLECTION FOR YOUR HOSPITAL, YOU CAN REMOVE THIS SECTION.**

Payment Timing And Potential Cash Flow Impacts. Unlike the existing upfront discount mechanism, any rebate mechanism will force **[insert name of hospital and location]** to effectively provide drug companies interest-free loans as we await the discounts that we are owed under the 340B statute. Even if drug companies paid within a 10-day period as required under the prior iteration of the Rebate Program, that delayed discount will have meaningful impact on our institution and the patients we serve.

- Describe with specificity whether payment timing (e.g., within ten calendar days of submission of a complete claim) under a potential 340B Rebate Model Pilot Program would affect your cash flow, including any financial risks to your organization.
    - Do you have sufficient cash on hand to withstand a rebate model?
    - Will a rebate model put your institution at risk of violating your bond covenants?
    - Do you have any loans or other financial covenants that contain certain liquidity requirements that could be impacted by having to float the drug companies?
- Describe with specificity whether a rebate-based payment model would alter payment timing compared to current drug wholesaler arrangements.
    - In the past, HRSA credited the position of drug companies that "the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC amount is due." Is this true? If not, explain why.
- A potential 340B Rebate Model Pilot Program could require that all rebates be paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission. Is 10 days short enough?
- **IF YOU DO NOT BELIEVE THAT A 10-DAY PAYMENT WINDOW WOULD CAUSE ADVERSE IMPACTS FOR YOUR HOSPITAL, YOU CAN REMOVE THIS SECTION.**

Adverse Impacts of These Additional Costs And Burdens. All of these many different costs and burdens add up. Unfortunately, that means that **[insert name of hospital and location]** will no longer be able to use our 340B savings as effectively and comprehensively as we did under an upfront discount model. As a result, our patients and community will suffer in concrete ways.

- Comment on the impact of these incremental costs.
    - What will your hospital no longer be able to do as a result of these additional administrative costs?
    - What patient services might be reduced or cut?
    - What critical projects will need to be paused or canceled?
    - Has uncertainty over whether HRSA will proceed with a rebate program affected your hospital's financial planning in any way? How? Have you already delayed any projects?

- **DESCRIBE AS BEST AS POSSIBLE THE IMPACT ON YOUR PATIENTS AND COMMUNITY TO SHOW WHY A REBATE MODEL IS SO HARMFUL.**

- **IF APPLICABLE:** Identify any characteristics about your hospital or the community you serve that will help HRSA understand the full impact of these costs. For example, do you serve a disproportionate number of Medicare and Medicaid patients? Is your hospital the only one in your area that provides certain services, and if so, how far will patients have to travel to obtain the cut or reduced services?
- **IF APPLICABLE**: Identify any specific impacts on access to drugs for patients that may occur as a result of a potential 340B Rebate Model Pilot Program. For example, will your hospital no longer be able to stock high-priced drugs because you cannot afford to float the difference between the full price and the 340B price?

Reliance Interests. The RFI expressly invites comment on "reliance interests in continuing to obtain the 340B ceiling prices through upfront discounts and whether such reliance interests are reasonable in light of the Secretary's express statutory authority to provide for discounts via 'rebate or discount.'" Respectfully, that framing rests on a flawed premise. The mere existence of statutory authority does not imply that the agency will—or reasonably may—exercise it in a particular manner. That is especially so here, where the 340B Program has, since its inception, consistently provided discounts through upfront pricing rather than post-sale rebates. **[Insert name of hospital and location]** reasonably relied on this history when designing its internal operations, staffing, third-party contractual relationships, and financial planning for the use of 340B savings—all based on an upfront-discount model. A fundamental switch now would disrupt these settled reliance interests engendered by the agency's prior policy. Absent any identified problems with the upfront discount model, and given the massive costs that this disruption will impose on 340B hospitals like ours, there is no reason to switch to a rebate mechanism, even in so-called "pilot" form.

- Add any specific examples of how 340B savings through upfront discounts are budgeted into your finances (e.g., cash-on-hand financial projections, annual 340B savings, impact to long term planning/projects for new services, repairs, etc.).

Problems With the Beacon IT Platform. Under HRSA's original Rebate Program, the approved drug companies were planning to use Second Sight Solutions' Beacon IT platform to operate the Program. In the few weeks we had to prepare for the start of that Program, we encountered serious problems with Beacon.

- Describe any programs you had with Beacon.
    - Describe problems with Beacon's Terms and Conditions.
    - Describe problems with Beacon's shifting data and other requirements.
    - Describe problems with Beacon's customer service when problems arose.
- Provide any recommendations for ensuring a potential 340B Rebate Program has the appropriate guardrails in place to mitigate any privacy and security concerns related to patient information and data submission, including any agreements that may be required by third parties.

Efforts To Avoid 340B/MDPNP Duplicate Discounts. HRSA has already made clear that drug companies have other available options to address the need to deduplicate 340B and MDPNP pricing. Given the tremendous costs that a rebate mechanism will impose on **[insert name of hospital and location],** HRSA should rely on those other options. Any other decision would impermissibly privilege the interests of drug companies over those of covered entities, their patients, and the communities they serve.

Likewise, we support the AHA's position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate mechanism. In particular, we urge HRSA to adopt a third-party clearinghouse, rather than a rebate mechanism, to advance 340B/MDPNP deduplication, program integrity, and any other potential benefits. At a minimum, HRSA must provide a reasoned explanation for why the third-party clearinghouse is neither viable nor less costly than a rebate mechanism.

- **IF APPLICABLE—ALTERNATIVE #1:** If no drug company has raised a 340B/MDPNP deduplication issue with you to date, state that explicitly. Or if there was a deduplication issue that was raised and addressed promptly, describe that as well. **THE AIM HERE WOULD BE TO SHOW THAT A REBATE MODEL IS NOT NEEDED TO ADDRESS DEDUPLICATION ISSUES.**
    - Describe how deduplication has been managed to date, and explain how there have been no issues.
    - Explain how your current 340B/MDPNP deduplication approach has been less burdensome than HRSA's previously proposed rebate program.

- [**IF APPLICABLE—ALTERNATIVE #1**: if you've had issues with 340B/MDPNP deduplication since January 1, 2026 describe your experience and explain why a change to a rebate model is still unnecessary and would not solve the

existing issues with the deduplication process and/or would only make those issues worse.]

IF YOU DO NOT HAVE SUFFICIENT HELPFUL INFORMATION FOR THIS SUBSECTION, YOU DO NOT HAVE TO ANSWER THESE QUESTIONS AND CAN ONLY INCLUDE THE INTRODUCTORY PARAGRAPHS.

For all of these reasons, [insert name of hospital and location] respectfully submits that the costs of *any* Rebate Program will outweigh any expected benefits. HRSA therefore should abandon the concept altogether and embrace a neutral, third-party clearinghouse.

If, however, HRSA chooses to move forward with this ill-conceived effort, it must allow **[insert name of hospital and location]** and other covered entities to comment on the specifics of its new program. While we have endeavored to provide the most detailed information possible, we are doing so without precise knowledge of which drugs will be included in a Rebate Program and many other critical details (*e.g.*, data required, possible grounds for denial of rebates, dispute resolution processes, other guardrails). A failure to permit additional comments on the specific features of the program will be, in effect, a wholesale failure to consider important aspects of the problem.

We appreciate your consideration of these comments and look forward to working with HRSA on this important issue, which has profound implications for the millions of patients who rely on the 340B Program. Please contact me if you have questions.

Sincerely,

Name
Title
Repeat Hospital Name and Location