



The Hospital + Healthsystem
Association of Pennsylvania

April 20, 2026

Thomas J. Engels
Administrator
Health Resources & Services Administration
5600 Fishers Lane
Rockville, MD 20857

RE: HRSA-2026-03042: Request for Information: 340B Rebate Model Pilot Program

Dear Administrator Engels:

On behalf of 235 member hospitals, health systems, and other health care organizations, The Hospital and Healthsystem Association of Pennsylvania (HAP) is grateful for the opportunity to comment on the Health Resources & Services Administration's (HRSA) second request for information on a 340B Rebate Model Pilot Program. In Pennsylvania, 72 hospitals (in 30 counties) participate in the 340B program and serve our most vulnerable populations. About half are in rural areas—15 of which also offer critical labor and delivery services. Eighty (80) percent of the state's Critical Access Hospitals (CAH) are part of this program.

Many 340B hospitals are the lifelines of their community, and the discounts they receive through the 340B program enable these organizations to maintain a broad array of services for their patients. However, these facilities are financially vulnerable. In Pennsylvania, 53 percent of the 340B hospitals operate with a negative margin. For hospitals, access to the savings the 340B program offers is the difference between a positive and a negative operating margin and a deciding factor when they consider what service lines to maintain. According to a report by the Commonwealth Fund, drugs purchased through the 340B program accounted for only 7 percent of the total U.S. drug market.

Further, chipping away at the financial viability of hospitals will have negative downstream effects on vulnerable patients. 340B hospitals use the savings they receive on the discounted drugs to reinvest in programs that enhance patient services and access to care, as well as provide free or reduced-price prescription drugs. Some examples of things that Pennsylvania 340B hospitals are doing with the savings include:

- Providing financial assistance to patients unable to afford their prescriptions.
- Providing clinical pharmacy services, such as disease management programs or medication therapy management.
- Funding other medical services, such as obstetrics, diabetes education, oncology services, and other ambulatory services.



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- Funding behavioral health services and substance abuse treatment programs.
- Establishing additional outpatient clinics to improve access.
- Creating new community outreach programs that address housing instability and food insecurity.
- Offering free vaccinations for vulnerable populations.

Pennsylvania’s 340B hospitals are already operating under significant financial and operational strain. The abrupt transition from the current 340B upfront drug discount model to a claims-based rebate model for 10 to 25 drugs, that represent a significant portion of most programs, creates new administrative, staffing, and technical challenges—while providing manufacturers with unchecked opportunities to delay or deny payments—that will put distressed hospitals on the path to closure.

HAP echoes the American Hospital Association’s position that there are viable, lawful, and less burdensome alternatives that could achieve the same potential benefits as a rebate model. In particular, we urge HRSA to adopt a third-party clearinghouse, to advance deduplication efforts and to maintain the integrity and mission of the program.

COSTS TO COVERED ENTITIES

Current Administrative Costs Under the Upfront 340B Discount

There are a number of administrative costs that covered entities (CE) incur under the current upfront discount model. Hospitals invest significant resources in 340B program oversight and compliance, ensuring policies are maintained, and diversion prevention controls are consistently monitored. Additional efforts to ensure duplicate discount prevention, including separate Medicaid workflows, are also in place and require consistent monitoring. Hospitals invest resources in maintaining audit readiness and data integrity and consistently conduct self-audits and internal sampling to ensure continued compliance. Significant investments in revenue cycle coordination are required, including eligibility workflows that support compliance with the definition of “patient,” as well as systems for split-billing and general oversight and reconciliation of the program’s financial aspects. Many CEs use third-party administrator services (TPA) to help with oversight of contract pharmacy services requiring additional financial and administrative resources.

Every 340B program is different and hospitals in Pennsylvania use different strategies to maintain the integrity of their programs. Generally, some rely on in-house staff dedicated to 340B operations for: contract pharmacy oversight; eligibility review and reconciliation; and compliance and audit support driving staffing costs. Other hospitals rely more heavily on TPAs, consultants, and external audit supports driving contracting costs. All programs require significant information technology (IT) support, a scarce



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resource regardless of the size of the hospital or health system, to build and monitor several IT systems and interfaces to support billing systems, pharmacy dispensing, wholesaler purchasing, and contract pharmacy arrangement—the cost of which may also vary based on the nature of the programs used and contract negotiation.

Administrative Costs Under a Potential 340B Rebate Model Pilot Program

Hospitals participating in the 340B program designed their programs and operations around an upfront discount model. A shift to a rebate model demands new resources, imposing considerable additional costs and burdens on our institutions that go far above and beyond what we had expected and what we are experiencing now.

Hospitals would see material start-up costs tied to building rebate submission workflows as the program requires coordination from multiple departments within the hospital including IT, pharmacy, finance, legal, and administration. Our members report that in the months leading up to the initial implementation date of January 1, hundreds of hours were spent mapping out the departmental changes that would need to be put into place to accommodate the pilot program. Many of the covered entities in our state still had not identified pathways for full compliance with the new data requirements nor had they identified pathways for successful claim submission when the pilot was suspended.

Additional start-up investments would need to be made to build IT systems to support the claims data element requirements, establish secure transmission, and ensure integration with manufacturer platforms. New accounting and finance workflows would need to be mapped out to handle receivables, and reconciliation. There would be start-up costs tied to staff training, legal review of data sharing terms, privacy protections, and contract amendments with TPAs, contract pharmacies, and wholesalers. Covered entities in Pennsylvania worked with TPAs for months to prepare for the rebate model proposed last year and by December, were still not ready to comply with the proposed program requirements. These TPAs would have had to submit claims manually, far from the “automated” process advertised by the agency.

In addition to the start-up costs, covered entities expect ongoing costs that will reduce savings in perpetuity. The transition to a claims-based rebate model requires continuous claim creation and submission for eligible drugs. Payment timelines will need to be monitored against the 10-day requirement and outstanding receivables will need to be tracked. New processes for denial intake, documentation review, and appeals or dispute resolution will be established, the cost of which will be ongoing. Our hospitals are also expecting additional workflows for the Medicare Drug Price Negotiation



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Program/Maximum Fair Price related rebate submissions and interactions with Medicare reporting requirements.

Agreements with wholesalers are built around the existing 340B model and will take time to renegotiate. Current agreements are structured based on purchasing patterns with very limited or no discounts on Wholesale Acquisition Cost (WAC) drug purchases. With the migration of the 340B program to a rebate model, covered entities are not given enough time to restructure these agreements, leaving them not only with cash float issues, but underlying cost increases due to increased 340B drug purchasing expenses by not realizing any wholesale distributor cost discounts on WAC accounts. A runway of at least three years should be provided to restructure these agreements in a way to hold health systems harmless from the abrupt shift.

Special consideration must be given for certain types of claims that will further add to the administrative burden imposed on covered entities. For example, claims for patients paying cash and claims that will be covered by the hospital's charity care program are not transmitted in the National Council for Prescription Drug Programs' claim format (the industry standard for pharmacy claim transactions), or to a switch provider (an intermediary that connects pharmacies to Pharmacy Benefit Managers and insurers for insurance adjudication). Instead, unique claims submission processes or custom business rules will need to be created and put into place. These custom business rules would have to be set up for each individual pharmacy and pharmacy billing system. There is a significant risk that these claims will be denied because of the complexity tied to setting up custom business rules to supply the required data elements to meet the claims submission requirement. The irony is, the claims for patients most impacted, are the same patients the program was created to assist.

The agency must also consider the cost of essentially running two 340B programs at the same time. Covered entities will have to manage a rebate model for the piloted drugs but sustain the traditional 340B program upfront pricing model for the rest. Our member hospitals will continue to conduct all the operational activities described above to maintain compliance with the current 340B program and then must implement separate processes for drugs purchased under the rebate model, thereby doubling the resources required to maintain billing and compliance functions, and further eroding the savings derived from the program.

While the agency indicates that the pilot program would be limited to 10 or even 25 medications, those parameters are misleading and don't capture the fact that just 10 drugs represent hundreds of national drug codes that vary based on strength, dosage, and form. HRSA must give covered entities, who have relied for years on upfront discount mechanisms, priority so they can stretch their/those resources.



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There are potential unintended consequences of implementing a rebate model that the agency has not yet contemplated, including potential implications to the cost to the Medicaid program, including programs like the AIDS Drug Assistance Program. In certain pharmacy provider participation agreements, pharmacies are required to report “Actual Acquisition Cost” (AAC) on claims and are subsequently reimbursed according to the AAC. Under a rebate model, the AAC would change from the 340B price to the WAC price; thereby significantly increasing the expense to the plan with unknown impacts to the level of benefits that those programs will be able to continue to offer. Further complicating the issue is the uncertainty providers face in what to populate in AAC in a shift to a rebate model. If providers and pharmacies are to report 340B costs in that field, they are only able to do so if a rebate is received, which means there will be significant resources required to submit those transactions.

Staffing Impacts Under a Potential 340B Rebate Model Pilot Program

The transition to a rebate model will, without a doubt, require additional full-time employees and staff hours to manage. The nature of the additional full-time equivalents (FTE) required will vary based on the size of the 340B program and the volume of rebate requests that would have to be submitted. Our rural hospitals and small community hospitals report that they would need at least one additional FTE to manage data sets and ensure that newly required data elements have accurately been incorporated into claims. The same small to medium-sized hospitals report that an additional FTE would be required for rebate reconciliation, ensuring that rebates are not inappropriately denied and that payments matched eligible purchases made at wholesale acquisition cost price points. Some covered entities choose to hire outside vendors to manage data, handle inquiries from manufacturers, and oversee reconciliation; but the service comes at a significant cost and ultimately diminishes the savings achieved through the program and intended to be reinvested into patient care. Depending on the rates of rebate request denials, additional FTEs may be needed to perform dispute management.

HRSA estimated that it would only take two hours per week to comply with the rebate model’s program requirements, but our covered entities have not found this to be true and question the basis for this projection. The complexity of the data elements needed to comply with IT platforms’ (like Beacon’s) user requirements and the rebate model’s data standards are immense. It will take a considerable amount of additional time for covered entities to prepare data, validate it, ensure that it is transmitted in a timely manner, confirm receipt, and reconcile payment. Some of the data elements will require manual chart review and manipulation to complete order sets. Small rural organizations estimate that a minimum of 40 hours a week would be required to manage the data alone, not to mention reconciliation of rebates and purchases.



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The agency also needs to account for time spent by covered entities on questions and requests for information from individual manufacturers (either the 10 manufacturers initially identified or more if the pilot program were to expand to additional drugs) and those from an IT platform (like Beacon) to validate documentation.

Systems and Infrastructure for Implementation of a Potential 340B Rebate Model Pilot Program

The programmatic and infrastructure changes required to transition to a claims-based rebate model and electronic data submission is incredibly complex. Covered entities will need to construct new internal programs that can compile the required data elements. Modifications need to be made to billing systems to support extraction of rebate-eligible claims. Current electronic health record systems need to be integrated in new ways with pharmacy systems and claims adjudication feeds to support the new programs. IT infrastructure changes will be needed to move the required information to manufacturers' platforms, including secure transmission tools tailored to file the transfer requirements. After all these changes are put into place, testing will be needed to ensure the integrity of the IT platform and its ability to communicate with the technology and programs constructed by covered entities. The cost associated with these changes will scale, based on the volume of eligible claims, but the impact will be significant regardless of the size of the program.

Several vendors have already emerged into this space offering to help covered entities navigate the additional burdens that they would face under a rebate model. Vendors offer to help manage data elements, ensure proper formatting, validate the completeness of data sets, and reconcile data submission and response from the IT platform to maximize lost rebates. A service of this nature would have cost \$20,000–\$30,000 for a small rural health system—money that is not currently spent on an up-front pricing model.

PAYMENT TIMING AND POTENTIAL CASH FLOW IMPACTS FOR COVERED ENTITIES

The very factors that impact a hospital's eligibility to participate in the 340B program (caring for high volumes of Medicaid patients) also increase sensitivity to cash flow disruptions and administrative costs. Since more than 50 percent of Pennsylvania's 340B hospitals operate at a negative margin, many programs will be unable to float the WAC price while they wait for rebates and will ultimately have to scale back the program. Patients' access to medication will be directly impacted.



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Covered entities also remain concerned by the agency's indication that the rebate model will expand to additional drugs in short order. The more drugs that fall under the rebate model, the greater the risk to 340B programs and to patient access. A report by 340B Health indicates that if the 340B program were to fully convert to a rebate model, an average size disproportionate share hospital (DSH) would, on average, float drug manufacturers \$72.2 million dollars per year. For DSH hospitals with more than 487 beds, that average annual float cost would likely be closer to \$208 million. Costs of this magnitude will not only require hospitals to scale back charitable programs for patients, but will jeopardize their ability to offer specialty service lines and, in some cases, their ability to remain open.

HRSA indicates in its proposal that approved rebate requests will be paid in 10 days. However, covered entities remain doubtful that manufacturers and any organization acting on their behalf will be able to meet that timeline. We have seen this process play out already under the Maximum Fair Price program. Our member hospitals report that refunds that are invoiced very quickly by the wholesaler for the applicable products are taking weeks (six or more) to be issued. There is no reason to believe that rebate requests would move more quickly. The impact of these delays would be exacerbated even further under the rebate model as covered entities would be required to buy the drugs at much higher prices than a group purchasing organization or retail prices, floating a loan to the drug manufacturers and hoping for rebates.

Several 340B hospitals in Pennsylvania, particularly rural hospitals, have negotiated prompt pay discounts with manufacturers or wholesalers. Under these arrangements, hospitals payments are made to manufacturers or wholesalers on a weekly basis. Thus, invoices would be payable prior to receiving a rebate, even if they were promptly paid within 10 days. It will not be feasible for hospitals to float the funds needed for drug orders, even if temporary.

Similarly, the previous guidance indicated that covered entities have 45 days to submit rebate requests. For many of Pennsylvania's smaller 340B hospitals, reaching a full package size within 45 days is unattainable and will delay their access to rebate dollars. Additionally, covered entities report that 45 days is not enough time to reconcile patient visit data and identify any missed opportunities for rebates. Sometimes it takes weeks to find an issue and resolve it, particularly with new programs and processes. Covered entities are concerned they may not be able to solve all administrative errors causing unnecessary and significant financial damage—not to mention that most delays are often in the spirit of maintaining compliance with other program requirements.



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REBATE DENIALS

HAP appreciates the safeguards HRSA attempted to put into place under the previous proposal by prohibiting manufacturers from denying rebates based on 340B program non-compliance. However, we remain deeply concerned by the limited protections proposed for covered entities should manufacturers begin to deny rebate requests broadly over “de-duplication concerns” (that a rebate was already provided for that claim). Once a rebate request is denied, covered entities would have had to move through the administrative dispute resolution (ADR) process and fight for their rebate—a process that has not been effective in the surprise billing space.

Pennsylvania 340B hospitals are deeply concerned that the ADR process will be costly and burdensome and will further diminish 340B dollars—particularly since they will have to float the WAC price while the matter is being resolved; and there is no guidance on how to determine which party is entitled to a claim. Based on HRSA’s previous guidance, covered entities stand to lose rebates while there are no penalties for manufacturers and little to no incentive for them to participate in the ADR process.

The power imbalance embedded in the rebate model proposed by HRSA last year creates opportunities for manufacturers to drive change in other areas they deem to be unfair and put parameters around eligibility requirements that have been debated by Congress for years. Earlier this month, AbbVie filed a new lawsuit challenging the federal government’s definition of patients and calling for significant new restrictions on covered entities. Similarly, drug manufacturers issue policy statements with no warning adding new requirements in order for covered entities to access discounted pricing; the most recent of which was a policy announced by Eli Lilly earlier this year. At least four drug companies have followed suit, requiring claims data submission as a condition of accessing 340B pricing.

HRSA must create penalties and implement safeguards that address manufacturer non-compliance, regardless of the path forward. Some ways the agency could do this include creating a uniform definition of a “complete claim” to reduce the number of denials based on incomplete data, centralized submission through a neutral party clearinghouse with automated completeness validation, interest charged on late payments, and requirements for key performance indicators for manufacturers that are publicly available.

DATA COLLECTION BY COVERED ENTITIES

The rebate model program, as previously proposed, required far more detailed claims level data than what is currently required or maintained under the up-front discount



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model. Complying with the data requirements would have necessitated additional ongoing data collection and processing as hospitals would have had to create rebate submission-ready claim files, track timelines, maintain payment status per claim, and retain any data needed for the dispute resolution process. Data requirements should be minimal and limited to only those elements needed to prevent duplicate discounts.

Even if an IT platform like Beacon is working with TPAs directly, maintenance of the data is still a huge burden for covered entities to sustain. TPAs are only as good as the data they collect, how they collect it, and the maintenance of those data feeds, all of which falls on covered entities. This maintenance requires constant work to validate data extracts, and ensure the feeds remain intact and are processing correctly. There is also a huge manual component for some of the data elements required, especially in the medical claims space.

340B PROGRAM INTEGRITY

Covered entities have expressed serious concerns regarding their ability to share the required data with drug manufacturers while maintaining compliance with HIPAA laws. Some of the required data elements included in the previous proposal are considered personal health information (PHI) and although the guidance indicates that plans should ensure that the IT platform has mechanisms in place to protect patient identifying information in a manner consistent with HIPAA, covered entities will not be protected in the event of a data breach. Covered entities also have no alternative to using the IT platform if they want to get their rebate. HRSA should consider safe harbor provisions for the duration of any pilot program.

The previous guidance also lacked any protection for covered entities from unnecessary and harmful terms and conditions associated with using required IT platforms for rebate request submission. The power imbalance unfairly penalizes covered entities that would have had to either agree to any terms or conditions of using the IT platform or forgo 340B dollars. Similarly, manufacturers would have easily been able to use the data for purposes outside the scope of the program with no recourse. Policy issues that have long been debated in Congress regarding caps on contract pharmacies and the definition of patient could be adjudicated by drug manufacturers in a vacuum.

The lack of indemnification and cyber security protection guarantees is concerning and must be evaluated. Last fall, when our member hospitals engaged Beacon in preliminary discussions, they could not get the organization to send the information needed to complete the required security assessments for third-party 340B vendors. Beacon reportedly refused to complete security questionnaires or vendor assessments. They instead were offering covered entities a document listing their security documentation



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for review. It is our understanding that the Beacon document lacked some of the information required to complete a proper assessment. Covered entities need to have access to the information needed to complete security assessments and properly protect the data of their patients.

Covered entities in Pennsylvania remain concerned that HRSA has not contested the claims data submission requirements led by Eli Lilly and followed by others earlier this year. Claims data submission requirements aimed at gaining access to pricing achieve the same end goal as a rebate model without the shift to a postpaid rebate and new administrative infrastructure costs. However, if HRSA continues to allow each manufacturer to introduce its own policies and requirements, it creates chaos for covered entities trying to comply with each. HRSA should instead work with manufacturers and covered entities on a neutral third-party clearinghouse to meet the transparency concerns of manufacturers while at the same time minimizing expenses to covered entities.

Sincerely,

Kate McCale
Vice President, Compliance and Regulatory Affairs