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July 15, 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: Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation (OMB Number 0906-NEW)

Dear Administrator Engels:

On behalf of our more than 2,000 member hospitals and health systems that participate in the 340B Drug Pricing Program, the American Hospital Association (AHA) appreciates the opportunity to respond to this Information Collection Request (ICR) about the Health Resources and Services Administration's (HRSA) proposed 340B Rebate Model Program. The AHA previously submitted comments in response to HRSA's Feb. 26, 2026, ICR. We resubmit those comments here. *See* Attachment A.

The facts have not changed since our initial submission. The proposed Rebate Program will inflict *more than a billion dollars* in annual costs on 340B hospitals alone. A meaningful percentage of those costs — far more than 5 hours of labor per week — will be spent on consolidating and submitting the information that 340B hospitals will be required to provide to drug companies and their chosen third-party vendor.

What appears to have changed, however, is the scope of this ICR. The current ICR notice makes clear that, under the Paperwork Reduction Act (PRA) of 1995, the agency is evaluating only a portion of the Rebate Program's overall costs. HRSA notes that it previously considered burdens associated with "reconciling submissions and tracking rebate status" and "addressing errors, denials, or follow-up requests," but those two categories of costs are now considered outside the scope of the ICR. Instead, the current ICR draws a distinction between "overall operational impacts" and "the incremental time required to complete individual reporting responses under the PRA framework." Consequently, the ICR will exclude a broad range of costs, including "float costs," non-economic costs, the massive costs at the back-end of the rebate process to track and reconcile rebates, and costs associated with disputing errors, denials or

follow-up requests. While the agency may believe that approach best adheres to the purposes of the Paperwork Reduction Act of 1995, *see* 44 U.S.C. § 3501; *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36–37 (1990), it is of limited value in assessing the overall costs and benefits of the proposed Rebate Program itself, *e.g., Michigan v. EPA*, 576 U.S. 743, 752 (2015).

Even so, it is still important that the agency's Paperwork Reduction Act estimates be accurate. But rather than crediting the empirical calculations of the 340B covered entities that will actually bear the costs of collecting and submitting the required information, HRSA appears to have discounted them. In holding firm to its 5 hours-per-week estimate, the agency seems to have accepted the drug industry's erroneous and conclusory premise that the required "data elements are commonly available and already generated, maintained, and transmitted by covered entities or their vendors." In fact, HRSA's Supporting Statement concludes (at 9) that the "implementation costs" for 340B hospitals "are likely to remain low" because "the data that would be submitted to drug manufacturers reflects information that covered entities already routinely generate, maintain, and transmit to third parties for billing and reimbursement purposes."

The drug industry's premise is wrong. HRSA's uncritical acceptance of that premise leads to a burden estimate that does not reflect the realities covered entities will face. HRSA's ensuing conclusion about "low" implementation costs, therefore, misses the mark.

First, HRSA's analysis does not fully account for what 340B hospitals have told the agency about how their information systems work in the real world. Under the proposed Rebate Program, the agency would require hospitals to submit data fields from two general categories: "Pharmacy Claims Data Fields" and "Medical Claims Data Fields." Our members inform us that these two sets of fields are commonly housed on different electronic systems within their hospitals. HRSA seems to recognize this. The Supporting Statement (at 5) explains that "some payer information fields (ex. BIN/PCN) are fields not routinely requested for these [contract pharmacy] transactions. Additionally, medical claims data is generated from different sources than from retail pharmacy claims." Similarly, the information that hospitals submit to Medicare, Medicaid, and commercial insurers for *billing purposes* is kept on still other electronic systems, and hospitals do not submit all of the required information (*e.g.*, wholesaler invoice number and product sterilization number) to insurers.

Put simply, the data fields that the Rebate Program will require do not exist in one place, and the idea that all hospitals can seamlessly integrate data between disparate systems is unfounded and unreasonable. As one 340B hospital explained in an earlier comment letter that is part of the ICR record, a Rebate Program "would require us to extract and reconcile data from multiple internal and external systems and manually assemble submission files in ways that are not part of our current 340B processes." And

because they are not part of those existing processes, HRSA has vastly undercounted the cost and labor required to assemble it for submission to the drug companies.

So while it may be true that hospitals "generate, maintain, and transmit" certain aspects of this information for certain purposes, that premise overlooks the reality that combining this disparate information and submitting it to drug companies for the purpose of obtaining 340B discounts will require time, work and money. It is not enough for HRSA (at 5) to rely on the drug industry's position that a Rebate Program would not "require covered entities to collect or maintain any new or additional information beyond what is already captured in the ordinary course of billing and claims processing for Medicare, Medicaid and commercial payers." The initial "collect[ing] or maintain[ing]" of data is not the most burdensome part of the submission process; the added costs and labor hours stem from the combining of the data from different sources and then ensuring that it is accurate and capable of being submitted without rejection.

Perhaps the following analogy will make all of this more understandable. At the Department of Health and Human Services (HHS), information is stored across a number of different electronic systems, including different subagencies (*e.g.*, Office of the Secretary, Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, etc.) and sometimes different components within those subagencies. Nevertheless, that information is "commonly available"; HHS has "already generated [and] maintained" it. But when a Freedom of Information Act (FOIA) request comes in, HHS must expend time, labor, and money to 1) combine that information from across the different systems, 2) review that information to make sure it is accurate and capable of release, and then 3) transmit it to the FOIA requester. *See, e.g.*, Fourth Decl. of William H. Holzerland, *Citizens for Responsibility and Ethics in Washington v. United States Centers for Disease Control and Prevention*, Case No. 25-1020, Dkt. 43-3 ¶ 14 (D.D.C. Sep. 4, 2025) ("The time needed [to process FOIA requests] depends on factors such as … the need to search in multiple offices or systems…."). That process can be quite expensive and burdensome. So too for hospitals under a Rebate Program.

Ultimately, HRSA cannot dismiss or lose sight of the fact that 340B hospitals have built, tested and refined their information systems based on 30 years of operating under an upfront discount model. They never had to do Rebate Program submissions before. So the fact that this information exists *somewhere* on a hospital's many networks does not mean that it is costless to retrieve it from different places, combine it in the way that the drug companies require, and submit it for discounts they previously would have received at the time of sale. The cost- and hours-estimates that the AHA and its hospital members submitted in the first round of comments reflected this decades-old reliance. HRSA should not discard these estimates while uncritically accepting comments from those who do not operate hospital information systems day-to-day.

Second, HRSA's assumption that hospitals "already routinely generate, maintain, and transmit to third parties for billing and reimbursement purposes" ignores critical real-

world timing differences between billing and the proposed Rebate Program. According to the Supporting Statement, hospitals will be required to submit information within 45 days of dispense. But hospitals have much longer — often 90 or 120 days — to submit claims for billing purposes.

This time difference is significant. For starters, the accelerated Rebate Program timeline means that hospitals will need to devote additional labor and money to meet a 340B submission deadline they otherwise do not have to meet for "billing and reimbursement purposes." Needless to say, it is easier to collect and submit information when you have more time to do so. Thus, it is wrong to argue that "the data sharing requirements contemplated with rebates are materially similar to existing obligations imposed by Medicare, Medicaid, and commercial payers." In reality, the timing is materially *dissimilar*.

In addition, the 45-day timeline means that some information will not even be available for submission by the Rebate Program deadline. Consider the example of a baby who came to a 340B hospital's emergency department and was subsequently admitted for care in a Neonatal Intensive Care Unit. Sadly, babies often require NICU care for far longer than 45 days. In the real world of hospital operations, the data required under a Rebate Program would not even be available for submission until *after* the baby has been discharged. The same is true for countless other patients who require care for close to or longer than 45 days. Again, this is how hospital information systems have been structured and have operated for decades, *i.e.*, without the need to submit information before discharge simply to receive a 340B discount that is owed by statute. Under the Rebate Program, however, hospitals will lose out on 340B discounts or have to expend massive time and resources altering their internal systems to meet the data submission requirements of a one-year, so-called "pilot program." Nothing in the statute allows an arbitrarily chosen 45-day deadline to determine whether a covered entity will receive a discount owed by law.

Third, HRSA repeatedly emphasizes that the Rebate Program will involve a "limited set of drugs." But that is no answer. Although data will need to be submitted for "only" up to 25 drugs, a hospital's internal information systems cannot be easily altered just for those drugs. Our members tell us that they will need to make wholesale changes to their systems to accommodate a Rebate Program. Just as HHS cannot easily alter its internal information systems solely to capture only those documents that are or might be subject to a FOIA request, hospitals cannot easily alter their systems only for information about drugs required under a Rebate Program.

Fourth, HRSA notes that some commenters asserted that "particularly after initial implementation, ongoing reporting activities may be automated or integrated into existing workflows, thereby reducing incremental burdens on covered entities." This statement is merely speculative and has no actual evidence to support it. Moreover, automation is not costless even when it is feasible. Hospitals — particularly those in

rural and other underserved areas — do not have the resources to invest in this effort, nor should they have to make those investments just so that they can obtain discounts owed by statute. HRSA makes no suggestion that automation can occur within the timeframe that the pilot program envisions. If HRSA is serious that this is a one-year, so-called "pilot," then the alleged automation efficiencies cannot be implemented in that time frame. Our members inform us that any automation changes will take years. Thus, the full cost of implementing the Rebate Program's information submission requirements, much of which will require manual labor by additional full-time employees, will be borne during the purported one-year "pilot" period.

Fifth, HRSA's 5 hours-per-week estimate does not account for the problems associated with the drug companies' preferred third-party vendor. Both the AHA and its members have explained the many technical difficulties they have had with these vendors. In fact, hospitals are *already* experiencing those problems in connection with the Medicare Drug Price Negotiation Program; members have informed the AHA (and HRSA in their comment letters) that the third-party vendors create additional burdens through improper delays and denials based on incorrect assertions of submission errors. Even with what the Supporting Statement calls a "technical assistance/customer service component," resolving these difficulties takes time and money. These vendor-associated challenges require hours of additional labor — most often manual labor to follow up on mistakes and to ensure that data submitted will actually be accepted. A 5-hour-per-week estimate does not capture the added costs that the third-party vendor will create, and HRSA's analysis should fully account for this important aspect of the problem in its ICR Notice and Supporting Statement.

Sixth, the agency's cost analysis is based solely on hourly burden. It does not include one-time monetary costs to set up a new data collection system or ongoing non-labor fees to keep those systems running. In addition, as one ICR commenter explained, HRSA cannot rely on "solely the time required to submit data"; it must also consider costs related to "cybersecurity, data governance, [and] staff training." These omissions demonstrate either the narrowness of the Paperwork Reduction Act analysis or a significant error in how the agency is conducting the burden analysis here. Either way, the failure to consider non-hourly burdens leads to a significant undercounting of the costs that a Rebate Program will inflict on 340B covered entities. HRSA's approach also contradicts the ICR notice itself. The notice's Burden Statement defines burden to include "the time needed to" "develop, acquire, install, and utilize technology and systems" and "to train personnel." That is precisely what the excluded estimates measure. HRSA cannot define these costs into the ICR's burden statement and then define them out of its burden estimate.

Seventh, OMB and the public are being asked to evaluate a collection whose requirements do not yet exist. The ICR notice states that "[s]pecific requirements detailing the type and frequency of such submittals will be defined in a Federal Register notice" at some future date. Neither OMB nor commenters can meaningfully assess the burden

imposed by data elements, formats, and submission deadlines that HRSA has not yet defined. Indeed, HRSA's burden table already assumes that covered entities will submit claims data 52 times per year, even though the notice says the frequency of submissions "will be defined" later.

Finally, the AHA has serious concerns about how HRSA calculated the 5-hour-per-week estimate. The agency notes in the Supporting Statement that it chose its 5-hour-per-week estimate as a "reasonable median burden" since the "actual burden may be lower for some entities and higher for others." Having reviewed the comment submissions in the record, however, the AHA does not believe that this math is accurate. Going forward, HRSA must explain in greater detail: 1) exactly how it came to its 5-hour "median" figure based on the *actual numerical estimates* in the record, rather than broad conclusory assertions about what burdens "may be" lower and higher; 2) specifically, what below-5-hours-per-week estimates it received to offset the many above-5-hours-per-week it received from many other hospitals and other covered entities. It should not be difficult, for example, for HRSA to produce a chart showing all of the below-5-hours-per-week estimates that would allow the agency's 5-hour estimate to sit at the median.

More fundamentally, HRSA must explain why it used a median estimate rather than one that better captures what labor covered entities will have to devote to the Rebate Program. Reliance on a median can obscure substantial variation among regulated entities and can materially understate aggregate burden when compliance costs are unevenly distributed, or the population of covered entities that experience the burdens is not evenly distributed. Because the median reflects only the midpoint observation, it fails to capture the burden imposed on entities facing significantly above-median costs and therefore may not provide a reliable estimate of the rule's overall impact. Ultimately, if HRSA does not provide meaningful responses about (1) the numbers it actually used, (2) the math it performed to reach a 5-hour-per-week "median" estimate, and (3) why a median is the best measure in the first place, the agency will be ignoring both record evidence and important aspects of the problem.

All in all, HRSA's 5-hour estimate understates the work required to submit the information that will be required under the Rebate Program. As demonstrated above, the agency relies on a series of flawed premises to reach that incorrect estimate. Once those premises are corrected, HRSA cannot discount the higher estimates that hospitals and other covered entities submitted in the earlier round of comments. Those estimates — which were far more detailed than the conclusory statements submitted by drug companies and their trade associations — accurately reflect the real world of hospital operations. Hospitals, not drug companies, best understand what will be required to complete the limited tasks considered under this ICR. Their estimates of costs under the Paperwork Reduction Act should be privileged. And when the *overall* costs of the Rebate Program —*i.e*., not just the narrow category that is being

considered in this ICR — are taken into consideration, they vastly outweigh any purported benefits.

The AHA appreciates your careful consideration of these issues. We are eager to meet to address any questions that you might have about the Rebate Program's tremendous costs and burdens on 340B covered entities.

Sincerely,

/s/

Chad Golder
General Counsel and Secretary

Attachment: Appendix A