kalderos

Submitted via email to paperwork@hrsa.gov

April 27, 2026

Thomas J. Engels
Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Information Collection Request: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB No. 0906-NEW

Dear Administrator Engels:

Kalderos appreciates the opportunity to provide comments on the Health Resources and Services Administration's ("HRSA") Information Collection Request ("ICR") on the 340B Rebate Model Pilot Program ("Pilot Program") published in the Federal Register on February 26, 2026.

Kalderos builds unifying technologies that bring transparency, trust, and efficiency to drug discount and rebate programs, including the Medicaid Drug Rebate Program ("MDRP"), the 340B Drug Discount Program ("340B Program"), and the Inflation Reduction Act of 2022 ("IRA"). Kalderos does so in compliance with applicable laws and regulations as it seeks to solve problems in drug discount and rebate programs by fostering transparency; connecting stakeholders; enabling simple, streamlined communication; and applying machine learning to create smart data science tools. Kalderos is genuinely committed to administering a fair, balanced process assisting providers (including 340B covered entities), payors, and manufacturers to ensure the right drug price is applied to the right transaction. To that end, Kalderos has developed solutions to facilitate coordination between dispensers and manufacturers, while simultaneously ensuring that there are systems in place to identify, dispute, and resolve noncompliance with drug discount and rebate programs.

Since 2019, Kalderos has engaged with HRSA to advocate for the implementation of a 340B rebate model and, at the same time, worked with interested covered entities and manufacturers to develop and implement a rebate model.

Kalderos' newest technology platform, Truzo®, is a technology-driven model capable of effectuating discounted pricing directly to covered entities and other dispensers as a rebate and is well-equipped to effectively and securely implement a unit-based 340B rebate model. Multiple manufacturers are already using Truzo® to collect claims data, and thousands of covered entities have signed up to the platform. Kalderos would welcome another opportunity to meet with HRSA and conduct an updated functional demonstration of Truzo®.

It is with this experience that we provide the following comments.

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I. The Burden on Covered Entities to Provide the Required Claims Data Information Is Not Significant

We agree with HRSA's statements in the ICR 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." We further agree that any burden will "not be significant."

HRSA estimates that, on average, covered entities will be required to spend five (5) hours providing the required claims data elements to each manufacturer under the Pilot Program, which it estimates will require 3,796,416 hours in total per covered entity on an annual basis. For the following reasons, Kalderos believes this is an overestimate of the time it will take covered entities to provide the required claims data information to manufacturers.

First, as HRSA recognizes, the data required to be provided by covered entities under the Pilot Program is readily available and matches what covered entities and their third-party administrators typically include when they attempt to "match" a drug dispensed to a 340B patient. It is also the very same information customarily provided by a pharmacy or a 340B covered entity to secure reimbursement for the drugs from a third-party payor, like Medicare or Medicaid.[1] In addition, several of the required data elements are also required by HRSA as part of its routine audit processes for covered entities and are included in the Agency's audit data request list.[2]

Moreover, this information is customarily provided when managed care entities, hospitals, physicians, retail pharmacies, group purchasing organizations, and states participating in the Medicaid program seek non-340B price concessions pursuant to discount and rebate agreements with manufacturers or other pricing programs. In other words, when providing price concessions, manufacturers routinely seek the information necessary to confirm that program requirements for those price concessions are met.

We also believe that the estimate overestimates the burden because covered entities will be able to send data relating to multiple manufacturers' drugs in a single submission. Existing systems will be able to group applicable claims and submit in a simple process. We do not believe each manufacturer will have a separate process for submitting data, and some may use the same vendor, meaning that submissions will be grouped and time will be reduced.

Finally, as discussed in greater detail in Section III below, the burden imposed on covered entities will be further reduced where covered entities use Kalderos' platform, Truzo®, to transmit the required information. Once a covered entity completes the Truzo® onboarding process for one

[1] For example, see claim-level information pharmacies are required to provide Illinois Medicaid at https://hfs.illinois.gov/content/dam/soi/en/web/hfs/sitecollectiondocuments/d0payersheetilpop20171127.pdf.

[2] *See* Apexus, Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities, available at https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf.

manufacturer, no additional action is required to submit data to other manufacturers using Truzo®. After the initial data submission, the process becomes largely automated, and we anticipate that most covered entities will spend approximately 1–2 hours per submission.

II. HRSA Should Require Covered Entities to Submit Additional Claims Data Beyond what was Included in the Original Pilot Program Notice

In the original notice announcing HRSA's initial proposed 340B Rebate Model Pilot Program ("Notice")[3], HRSA stated that covered entities would be required to submit the following pharmacy claims data information to manufacturers:

a. Date of Service

b. Date Prescribed

c. RX number

d. Fill Number

e. 11 Digit National Drug Code (NDC)

f. Quantity Dispensed

g. Prescriber ID

h. Service Provider ID

i. 340B ID

j. Rx Bank Identification Number (BIN)

k. Rx Processor Control Number (PCN)

The Notice further stated that manufacturers would be permitted to submit plans that include additional criteria beyond what HRSA included in the Notice.[4]

In a future notice announcing a potential future Pilot Program, HRSA should proactively anticipate and address these potential additional criteria. Specifically, in addition to the retail pharmacy claim fields listed above, HRSA should include claim-level data elements that would be found on medical (non-retail) claims from covered entities in order to effectively implement a rebate model.

These additional data elements are important because the vast majority of 340B utilization occurs outside of the retail class of trade at clinics, hospital outpatient departments, infusion centers, and similar facilities. Further, obtaining claim-level data from covered entities' medical claims for physician-administered drugs will become especially important as Medicare Drug Price Negotiation expands to drugs covered under Medicare Part B. Manufacturers will need this information in order to properly effectuate the Maximum Fair Price ("MFP") for those drugs when the time comes.

[3] 90 Fed. Reg. 38,165 (Aug. 7, 2025).
[4] *Id*. at 38,166.

Specifically, the following medical claim-level data elements will be needed for acute, outpatient encounters where 340B products are administered:

a. Health Plan ID (Insured's Policy, Group, or FECA Number)
b. Health Plan (Insured's Plan Name or Program Name)
c. Unit of Measure
d. Claim/EMR Transaction ID Number (Note: If the ID Number does not carry through to the rebate invoices from payers, patient identifiers may also be required)
e. HCPCS Code
f. Billed HCPCS Quantity (both administered and any wasted amounts; separate lines for each)
g. Place of Service Code (dispense/administration location; 340B ID for locations outside parent covered entity site)
h. Paid Date (date claim was submitted to payer, or finalized for cash paying patients)

HRSA should specifically require that these medical benefit claims data elements be part of a Pilot Program offering for physician-administered drugs.

In addition, for claims submitted through a patient's retail pharmacy benefit, the Pilot Program will need to account for scenarios involving multiple payors, such as dual-eligible patients covered by both Medicare and Medicaid. Accordingly, covered entities should be permitted to submit multiple BINs, PCNs, and group numbers to ensure proper processing of claims involving more than one payor. CMS should clarify that such data submissions are appropriate and can be managed by a rebate model vendor.

III. Additional Guidance Needed Regarding Manufacturer Data Submission

In the ICR, HRSA first identifies that manufacturers will be required to submit data to the Prime Vendor. The ICR contains little information regarding the selection of the Prime Vendor for this purpose, what data they will collect, how they will maintain the data, and what, if anything, will be done with such data,

While we are not opposed to data submissions and greater transparency, HRSA should provide more guidance regarding the manufacturer data submission. For example, any future guidance on the implementation of the Pilot Program should provide greater specificity regarding the data manufacturers will be required to submit to the 340B Prime Vendor. HRSA should also clarify that, to the extent claim-level data elements are required, the Prime Vendor has been appropriately vetted to ingest, process, and evaluate such data while safeguarding patient confidentiality and not raising conflicts of interest.

The ICR also states that manufacturers will be required to submit data to the 340B Prime Vendor "to evaluate program integrity." However, this function does not align with the Prime Vendor's role, which is to negotiate discounts on behalf of covered entities. The Prime Vendor

provides services and, receives payments from, other stakeholders and the data could be used for purposes unrelated to the rebate model pilot. HRSA must expressly limit how the data can be used by the Prime Vendor and ensure such guardrails are followed.

IV. Kalderos' Truzo® Platform Streamlines the Data Submission Process and Further Reduces the Burden Imposed on Covered Entities

The burden imposed on covered entities will be further reduced where covered entities use Kalderos' platform, Truzo®, to transmit the required claims data information.

Kalderos' Truzo® platform reduces the administrative steps required to effectively implement a 340B rebate model. The platform is designed to be fully self-service and many covered entities have reported fully onboarding in less than 10 minutes. Once fully onboarded, covered entities can submit data in near real-time. Further, Kalderos' platform has the capacity to interface and work with multiple vendors across the spectrum.

Kalderos' Truzo® platform was developed with robust security infrastructure to ensure technical scalability. Kalderos has invested significant resources so that Truzo® incorporates strong cybersecurity threat detection technology and processes, including SOC 1 (Financial) and SOC 2 Type II Security controls with consistent and ongoing security audits that conform to standard HIPAA compliance principles. The platform also includes multi-factor and SSO authentication, which provides enterprise grade security and ease of use. Further, cloud deployed services ensure that the platform operates at the highest levels of physical and network security, and payments are transported using signature verification and encryption tools.

Finally, Kalderos has a dedicated support team with deep industry knowledge, experience, and technical strength. We have received positive feedback from covered entities regarding their experience with Truzo.

Accordingly, Truzo® has the capabilities and security infrastructure necessary to securely and effectively administer a 340B rebate program. As noted above, we would welcome the opportunity to conduct another demonstration of the platform for HRSA.

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Thank you for the opportunity to submit these comments in response to the ICR. If you have any questions about these comments, please do not hesitate to contact me at rusty.hensley@kalderos.com.

Sincerely,

DocuSigned by:
Rusty Hensley
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Rusty Hensley
Chief Legal and Administrative Officer
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