kalderos

Submitted by email to paperwork@hrsa.gov

Due October 7, 2024

Carole Johnson
Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Information Collection Request Title: 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, OMB No. 0906-xxxx—New

Dear Administrator Johnson:

Kalderos appreciates the opportunity to provide comments on Information Collection Request Title: 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process (hereinafter "ICR") from the Health Resources and Services Administration, Department of Health and Human Services ("HRSA" or the "Agency").

Kalderos is building unifying technologies that bring transparency, trust, and efficiency to drug discount and rebate programs, including the 340B Drug Discount Program (the "340B Program"), in compliance with applicable requirements. We are on a mission to solve systemic problems within the healthcare system, redefining how the business of healthcare performs. Kalderos seeks to solve problems in drug discount and rebate programs by connecting stakeholders; enabling simple, streamlined communication; and applying machine learning to create smart data science tools. We are genuinely committed to being an honest broker, administering a fair, balanced process that assists providers (including 340B covered entities), payors, and manufacturers to ensure the right drug price is applied to the right transaction through a proactive compliance mindset, consistent with applicable laws and contract terms.

Through its current service offering—Discount Monitoring—Kalderos collects data from manufacturers and state Medicaid agencies to identify duplicate discounts, including duplicate discounts stemming from discounts provided under the 340B Program and discounts provided under the Medicaid Drug Rebate Program ("MDRP"). Kalderos also reaches out to covered entities to confirm 340B dispenses through its easy-to-use platform. When validated through Kalderos' propriety system, Kalderos and manufacturers can initiate disputes of rebate claims from state Medicaid agencies that are duplicate discounts.

Kalderos also has developed a direct discount platform, Truzo, which includes a technology-driven model for effectuating the 340B price directly to covered entities as a rebate. Under the Truzo Platform, a covered entity pharmacy initially acquires the drug at the non-340B price (e.g., WAC), dispenses the drug to a patient from the pharmacy's own inventory, and

collects both the patient's copayment and the payor's reimbursement. If the dispense is 340B eligible, the covered entity submits a request for a 340B rebate from the manufacturer for the drug dispensed to the patient. This request is submitted to the manufacturer via Kalderos' Truzo Platform. The manufacturer then pays the rebate to the covered entity within days.

I. HRSA Must Specify "Sufficient Documentation" for 340B Administrative Dispute Resolution ("ADR") Claim.

As required in the 340B ADR Final Rule[1] ("Final Rule") and finalized at 42 C.F.R. § 10.21(b), covered entities and manufacturers are required to submit claims with sufficient documentation, to show that: 1) the claim alleges a violation of an overcharge, duplicate discount, or diversion; 2) the claim has been filed within 3 years of the alleged violation; and 3) the petitioner has engaged in good faith efforts to resolve the claim. Under the proposed ICR process, the Office of Pharmacy Affairs ("OPA") will dismiss claims that fail to meet documentation requirements without assigning them to a 340B ADR Panel. However, neither the Final Rule nor ICR specify what data would qualify as "sufficient documentation" to show that a violation has occurred.

We encourage HRSA to provide a standard for what "sufficient documentation" is necessary to support a claim and that "sufficient documentation" must include claims data and the exchange of such data prior to filing a claim as part of the good faith effort requirement. The process to obtain data necessary to identify duplicate discounts, diversion, and overcharges is multi-faceted and requires the parties to exchange information to identify appropriate claims. Manufacturers already must collect claims-level data before initiating an audit of a covered entity, which is a required step before a manufacturer can file an ADR claim. In fact, HRSA recognized in its Final Rule that it anticipates that the number of manufacturer ADR claims will be low for this reason.[2]

While we understand that the process under 42 C.F.R. § 10.22 enables covered entities to request information necessary to support its claim from manufacturers, covered entities should be required to independently produce sufficient data when submitting a claim to survive dismissal by OPA. "Sufficient documentation" should include clear evidence of an overcharge based on claims data demonstrating a purchase price (inclusive of any adjustments) above the 340B ceiling price. HRSA should require the same standard of "sufficient documentation" for both manufacturers and covered entities. Such a requirement is necessary to ensure an equitable ADR process and to prevent information asymmetry. This will encourage covered entities to collect data upfront and lead to greater accountability and transparency across the ADR process.

II. HRSA's Time Estimate to Review Claims is Insufficient, Unless Data Sharing and Analysis Is Required.

HRSA estimates that the agency will spend 2.5 hours to review a claim. This estimate is insufficient for a review of the data necessary to identify duplicate discounts, diversion, and overcharges unless the parties share claims data and perform data analysis before an ADR claim

[1] 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 89 Fed. Reg. 28643 (Apr. 19, 2024, to be codified at 42 C.F.R. pt. 10).
[2] *Id.* at 28644–45.

is filed. Without the proper claims data, parties will be unable to provide sufficient documentation to support a claim under the ADR process—and certainly not a review within 2.5 hours.

As discussed above, Kalderos has the technology and experience necessary to assist manufacturers and covered entities with submitting and responding to 340B good faith inquiries and ADR claims, such that with the use of Kalderos' Truzo Platform, the estimate for HRSA to review could, in fact, be 2.5 hours and likely much less. Using Kalderos' Discount Monitoring tool, Kalderos has reviewed over 193 million claims and identified over $1 billion in duplicate discounts and other discount errors. We have found from operating the Discount Monitoring platform that identifying when the right discount applies to the right dispense, without triggering duplicate discount provisions, is a difficult task and costs significant time, money, and resources. There is a significant need for the transparent provision of robust claims data to inform the dispute resolution process. Obtaining and accessing such data has presented a significant challenge. The Discount Monitoring platform takes data from manufacturers and state Medicaid programs and sends them to covered entities for 340B payment confirmation. Unfortunately, we have faced issues with states and covered entities not responding to data requests.

With Kalderos's Truzo Platform, parties directly exchange claims-level data to effectuate a discount to the covered entity, preventing nearly 100% of noncompliant discounts. Under this platform, all parties are able to access a central ledger of claim and discount information, ensuring complete transparency. This benefits both covered entities and manufacturers. The Final Rule placed the burden on manufacturers to obtain relevant information (directly or through third parties) to support or defend ADR disputes. However, it did not provide a process for manufacturers to comply with this onerous requirement, as some of the existing stakeholders in the 340B discount process, including wholesalers and third-party administrators, are not agents of manufacturers and are not obligated to provide this information. The Truzo Platform addresses this issue and provides a means through which covered entities and third parties can access claims-level data, giving covered entities more control over the ADR process. The platform also makes the prevention of duplicates related to the Maximum Fair Price (MFP) process possible.

Kalderos's transparent approach fosters trust and creates positive working relationships with all stakeholders, reduces the overall burden on the ADR processes by avoiding data-driven stalemates and allows OPA to focus on material disputes. The Truzo Platform will produce sufficient documentation to support ADR claims, quickly collecting, processing, and verifying the information required for disclosure. This will significantly reduce the burdens of submitting and responding to claims from all parties, including reducing burdens on HRSA's review period per claim.

* * *

Thank you for the opportunity to submit these comments on the ICR. If you have any questions about these comments, please do not hesitate to contact me at angie.franks@kalderos.com.

Sincerely,

Signed by:
Angie Franks
C01E098E1C33473...

Angie Franks
Chief Executive Officer
Kalderos