October 31, 2020

The Honorable Lamar Alexander
Chairman
U.S. Senate
Committee on Health, Education, Labor & Pensions
428 Dirksen Senate Office Building
Washington, DC 20510
340B@help.senate.gov

The Honorable Greg Walden
Ranking Member
U.S. House of Representatives
Committee on Energy and Commerce
2322 Rayburn House Office Building
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Dear Chairman Alexander and Ranking Member Walden,

Thank you for the opportunity to submit suggestions on how to improve the 340B Drug Discount Program. The patient, the most important stakeholder, is increasingly vulnerable under today's 340B program as incompatible systems belonging to covered entities, contract pharmacies, manufacturers and state Medicaid programs are unable to reconcile complex drug claim information to prevent program noncompliance. In 2016, I co-founded Kalderos, a company that applies new technology to this problem through a transparent, multi-sided platform, clearing the pathway for covered entities to access appropriate 340B discounts and provide patients with the care they need.

"When the bulls fight, the grass loses."

The current controversy between covered entities, contract pharmacies and manufacturers is a culmination of a conflict that has been building for some time. When the 340B program fails to operate as Congress intended, covered entities and contract pharmacies experience confusion about compliance and anxiety about liability, and manufacturers experience excessive losses in revenue. But as these "bulls" fight, without question it is patients who lose, those who are most vulnerable.

Consider the case of Community Health & Wellness Partners of Logan County, a federally qualified health center (FQHC) with offices in West Liberty, Russells Point and Bellefontaine, Ohio. During a public health crisis, the state instituted a program to provide an essential drug to Medicaid patients via FQHCs, which can purchase drugs under the 340B program.

As an FQHC, Community Health & Wellness Partners purchased drugs solely under the 340B program to administer to Medicaid patients, enabling the clinic to treat high-risk patients at lower cost. Unfortunately, when the claim reached the state level, the staff who administered the Medicaid Drug Rebate Program was not aware of the state guidance sending Medicaid patients to FQHCs. The state requested, and received, millions of dollars in Medicaid rebates that duplicated 340B discounts.

When Kalderos facilitated a good faith inquiry between the FQHC and the manufacturer, the covered entity (i.e., the FQHC) was shocked to learn that the state had requested Medicaid rebates. The covered entity assumed the state knew the drugs it dispensed to Medicaid patients were already discounted under the 340B program and were therefore not eligible for Medicaid rebates.

Concerned about their own liability, the FQHC considered halting its purchases of this critical drug under the 340B program even though this would harm its ability to deliver needed care to a vulnerable population. Fortunately, Kalderos eased the clinic staff's fears, as the manufacturer would dispute the 340B duplicate discount transactions with the state. In this case, incompatible systems between the covered entity, the state Medicaid program and the manufacturer put patient care at risk.

Replenishment model vs. rebate model

The replenishment model is the inventory management method used by most covered entities and all contract pharmacies to acquire drugs at 340B pricing. Under this model, covered entities or contact pharmacies make an initial drug purchase from a wholesaler at a non-340B price, usually wholesale acquisition cost (WAC). After they have dispensed a preset number of units to 340B patients, they are allowed to replenish this drug at 340B pricing. The wholesaler sells the covered entity additional drugs at these discounted prices and then sends a chargeback to the manufacturer to make up the difference between the amount the wholesaler paid (likely WAC) and the lower amount they received (340B pricing).

The problem is when the manufacturer receives the chargeback from the wholesaler, it lacks any identifiers allowing the manufacturer to connect individual dispenses to the separate set of claims data provided by state Medicaid programs to validate Medicaid Drug Rebate Program rebates. Dealing with two incompatible systems, the manufacturer has no reliable way to identify duplicate discounts.

However, there is a better way. The rebate model, such as that used by AIDS Drug Assistance Programs, allows all parties to exchange claims data before payment is made, enabling them to correct any issues, reducing the risk of duplicate discounts to near zero, easing the transaction and providing transparency to each stakeholder.

The good news is that Kalderos has built a platform to support this model, and it is available today.

Protect the patient

Founded in 2016, Kalderos delivers unifying technology to resolve the incompatibility between stakeholders by increasing transparency, restoring trust and, most importantly, protecting the patient. Before Kalderos had a single customer, we met with senior officials from the Health Resources and Service Administration (HRSA) to introduce ourselves and share our vision.

Our first product delivered easy-to-use technology simplifying the process of “good faith inquiries” between covered entities and manufacturers. These “good faith inquiries” were defined by HRSA’s audit guidance as an appropriate first step in a suspected duplicate discount transaction. Previously, these informal inquiries required complex data analysis and time-consuming back-and-forth between multiple parties.

Fortunately, Kalderos’ platform uses machine-learning methods to standardize data analysis and is free for covered entities to use, making it easier for them to respond to “good faith inquiries.” With Kalderos’ platform, these disputes can be resolved directly between covered entities and manufacturers, allowing covered entities and state Medicaid programs to focus on caring for vulnerable patients.

To date, Kalderos’ platform has reached nearly 4,000 covered entities, which have used our tool to review more than 500,000 Medicaid claims in “good faith inquiries,” leading to the identification of over $100 million in noncompliant discounts.

Kalderos’ multi-sided platform

With the launch of *340B Pay* in September 2020, and its tools, *Request* and *Verify*, Kalderos now offers a solution to prevent costly duplicate discounts before they occur. This first of its kind application allows covered entities, large and small, to request 340B rebates and manufacturers to verify and pay them through a third-party payment partner, eliminating the need to chase down noncompliant discounts after the fact.

The 340B program does not need to be redesigned, but it does need a technologically up-to-date platform to better serve the stakeholders. What is needed is a multi-sided platform: an intermediary providing the robust infrastructure to connect all stakeholders in a clear, transparent, equitable way. A multi-sided platform sits at the center, enabling direct interactions that would otherwise be impossible.

Given the complexities of the U.S. healthcare system, multi-sided platforms have already proven effective. One example is CoverMyMeds, which simplifies the prior authorization process connecting doctors, pharmacies and payers, thereby helping patients get access to their prescribed medicines sooner. Another example is Surescripts, which enables everyday e-prescribing by connecting pharmacies, prescribers and pharmacy benefit managers, increasing both efficiency and adherence.

Kalderos is another multi-sided platform. Our platform connects 340B covered entities, manufacturers and state Medicaid agencies to improve identification of duplicate discounts, and to exchange the claims data necessary to avoid duplicate discounts in the first place.

To address the challenges in the 340B program, potential solutions must respond to the needs of all stakeholders, retain insight into the full lifecycle of drug distribution and oversee multiple overlapping drug discount programs.

We built the Kalderos platform to meet that need by:

- Respectfully engaging with all stakeholders including covered entities, manufacturers and state Medicaid systems, along with federal agencies such as Health and Human Services, the Heath Resources and Services Administration and the Centers for Medicare and Medicaid Services.
- Conducting extensive focus group testing with covered entities and manufacturers to ensure the platform is convenient, simple to use and transparent.

Kalderos provides a user interface for all stakeholders and the ability to connect to Kalderos as a service via our application programming interface. This means our platform is available to organizations of all kinds regardless of size or resources.

Our platform provides the same rebate process regardless of whether the drug is dispensed at a contract pharmacy or a covered entity. This enables covered entities to continue benefiting from relationships with contract pharmacies while taking more control over that relationship and restoring transparency to the process. Importantly, the service involves no expense to covered entities.

Recently, in my role as Kalderos' CEO, I participated in a live webinar hosted by industry publication *Drug Channels*. In this webinar, I explained the 340B rebate model in more detail, describing how it can provide a solution that works for the good of all stakeholders. A recording of the webinar and accompanying slides are now freely available at our website: https://blog.kalderos.com/library/webinars/improve-compliance-and-create-transparency-with-340b-rebates.

How can Congress help?

As Congress turns its attention to the problems in the 340B program, we respectfully urge lawmakers to actively support those alternative models that are designed to enable all stakeholders to participate in the program transparently and with clarity. This is the only way to address a broken system and ensure both compliance and fairness. The rebate model accomplishes these goals and is entirely consistent with the 340B statute and the related 340B Pharmaceutical Pricing Agreement, neither of which limits the mechanism for offering 340B prices.

Despite the ability of the rebate model to address the failings in the existing program, some stakeholders are reluctant to embrace transparency, no matter how fair the system will be to all participants. Accordingly, we urge Congress to support compliance, fairness and transparency by encouraging both covered entities and manufacturers to work together collaboratively and in good faith in implementing the rebate model. The exchange of the information necessary to bring transparency to the 340B program will enable all parties to ensure that 340B prices are offered and honored, duplicate discounts are avoided and diversion prohibited.

The rebate model eases the burden of compliance on covered entities and gives them control of the funds they save through the program. We believe that the transparent Kalderos platform provides the 340B program with lifesaving infrastructure.

We would welcome the opportunity to continue the conversation with you. Thank you for this opportunity.

Respectfully submitted,

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