

kalderos

July 9, 2021

Via www.regulations.gov

Diane Espinosa
Acting Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Comments to Proposed Rescission of Executive Order 13937, “Executive Order on Access to Affordable Life-Saving Medications” - HHS Docket No. HRSA-2021-0003

Dear Acting Administrator Diane Espinosa:

Kalderos appreciates the opportunity to submit comments to the Health Resources and Services Administration (“HRSA”) proposed rule titled “Proposed Rescission of Executive Order 13937, ‘Executive Order on Access to Affordable Life-Saving Medications’” (the “Proposed Rule”).¹ We support HRSA’s proposal to rescind the final rule entitled “Implementation of Executive Order on Access to Affordable Life-Saving Medications,” published on December 23, 2020 (the “Final Rule”).

One in four Americans struggle to afford their prescription drugs.² Out-of-pocket costs for patients are an urgent and pressing challenge that all stakeholders in the U.S. healthcare system must work together to solve. The out-of-pocket cost of insulin is a particularly acute and immediate concern, and we appreciate any and all efforts to address it. However, as discussed below, we believe the Final Rule would be ineffective at reducing patient costs and would pose operational challenges to Federally Qualified Health Centers (“FQHCs”).

Kalderos’ mission is to develop the world’s first Drug Discount Management platform, a unifying technology that would bring transparency, trust, and efficiency to drug discount and rebate programs, including the 340B Drug Discount Program, in compliance with applicable laws and regulations. Kalderos seeks to solve the problems in drug discount and rebate programs by connecting the stakeholders; enabling simple, streamlined communication; and applying machine learning to create smart data science tools. With this background, we submit the following comments.

¹ 86 Fed. Reg. 32008 (June 16, 2021).

² Ashley Kirzinger, Lunna Lopes, Bryan Wu, Mollyann Brodie. “KFF Health Tracking Poll – February 2019: Prescription Drugs.” KFF. March 1, 2019.

Kalderos Supports HRSA’s Proposal to Rescind the Final Rule

We believe that the potential benefits of the Final Rule are limited given that most low-income, under-insured patients served by FQHCs can already access insulin and injectable epinephrine at discounted prices. Conversely, the Final Rule creates unnecessary burdens on FQHCs, poses operational challenges, and diverts necessary resources that could be used to care for patients. As a result, the Final Rule could harm FQHC patients by reducing access to needed services and potentially making it more difficult for these patients to access care in their communities. Though the Final Rule may have had good intentions in making life-saving medications more affordable for patients, the overall impact could have negative effects, both for these essential community health centers and for the patients they serve. Accordingly, we support the Proposed Rule’s rescission of the Final Rule.

a. Operational Challenges and Lack of Effectiveness

The rule requires that FQHCs develop and document “written practices” that would make insulin and injectable epinephrine available at the 340B discounted price to patients with incomes at or below 350% of the Federal Poverty Guidelines (“FPG”) and who lack health insurance, or have high cost sharing requirements, high deductibles, or high unmet deductibles. If the FQHCs impacted by this rule failed to develop and document these processes, they would no longer be eligible for federal grants under Section 330(e).

We agree with the Proposed Rule’s language that the implementation of the Final Rule would result in “undue administrative costs and burdens that implementation would impose on health centers.”³ During the rulemaking process, FQHCs and their supporters flagged many complications should health centers be required to implement the Final Rule.⁴

For example, one major concern was the unusual classification of “low income” as 350% of FPG. This income threshold is not used anywhere else, and adhering to it in one specific case would be administratively burdensome. FQHCs also noted concerns regarding the challenges of assessing ambiguous and moving targets around high deductibles, especially high unmet deductibles. As a result, a patient who qualifies for the discount one month might no longer qualify the next month. We agree that these requirements pose unnecessary burdens and challenges to FQHCs.

Finally, as noted above, FQHCs commented that they are already required to offer discounted, sliding schedule fees to patients with incomes at or below 200% of the FPG, representing the vast majority of patients they care for. Most health centers already make insulin and many other medications available to low-income patients at deeply discounted prices. As a result, we do not believe the Final Rule would result in meaningful patient savings.

³ 86 Fed. Reg. at 32008.

⁴ *Id.* at 32009 – 10.

b. Kalderos Supports FQHCs

The valuable work done by community health centers has never been more apparent, as we survey their efforts during the COVID-19 pandemic. Not only were these FQHCs on the front lines of COVID-19, providing care to the most vulnerable patients and communities, they have also been essential in helping bring the pandemic to an end by ensuring these underserved populations are able to receive the vaccine. The financial support they receive through their 340B savings is essential to this work.

As a corporate member of the National Association of Community Health Centers, Kalderos is proud to support community health centers both through our corporate sponsorships and through our innovative solutions for drug discount management.

Our goal has always been to enhance the integrity and sustainability of the 340B program so that it can continue to benefit safety net healthcare providers and the patients they serve. We believe that a sustainable 340B program should mean less administrative burden for providers such as FQHCs—not more. Accordingly, Kalderos supports the rescission of the Final Rule.

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Kalderos appreciates this opportunity to provide input about the Proposed Rule. If you have any questions about these comments, please do not hesitate to contact me at 773-934-3672, jdocken@kalderos.com.

Best regards,



Jeremy Docken