AMERICAN ACADEMY OF FAMILY PHYSICIANS

March 11, 2021

Norris Cochran
Acting Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: RIN 0906-AB25; Implementation of Executive Order on Access to Affordable Life-Saving Medications; Delay of Effective Date

Dear Acting Secretary Cochran:

On behalf of the American Academy of Family Physicians (AAFP), which represents 136,700 family physicians and medical students across the country, I write in response to the proposed delay of effective date on Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life-saving Medications" as published by the Department of Health and Human Services (HHS) in the March 11, 2021 *Federal Register*.

The AAFP commends HHS for its efforts to improve the affordability of and access to insulin and epinephrine for patients of community health centers (CHCs). Family physicians account for about half of primary care physicians employed by CHCs, with about 14 percent of AAFP's members currently working in CHCs.[1,2] Our members are concerned with the rising cost of insulin and epinephrine and the negative impact that these rising costs have on patient access and health outcomes. While we are supportive of policies to make these medications more affordable for patients, the AAFP is concerned that the final rule will have limited benefit for low-income patients and reduce the profit margin of community health centers, which is ultimately used to improve access to care for other patients and services.

The final rule will require that CHCs establish practices to make insulin and injectable epinephrine available to low-income patients at or below the price the health center paid through the 340B Drug Pricing Program (340B), plus a minimal administration fee. Low-income patients are defined as those with annual incomes at or below 350 percent of the federal poverty level (FPL) who:

- Have insurance with a high cost-sharing requirement for either insulin or injectable epinephrine, as applicable,
- A high unmet deductible, or
- Have no health insurance.

We note that section 330(e) of the Public Health Service Act already prohibits the denial of services for CHC patients due to their inability to pay and requires CHCs to charge only a minimal fee for medications for patients under 100 percent FPL. Patients up to 200 percent FPL must be charged based on a sliding scale. According to HRSA, 90 percent of community health center patients have incomes at or below 200 percent FPL. Thus, this rule is likely to only benefit those patients that have

1133 CONNECTICUT AVE., N.W., STE. 1100 | WASHINGTON, DC 20036-4305 | (800) 794-7481 | (202) 232-9033

annual incomes between 200 and 350 percent FPL. Although these patients are also eligible for subsidized health plans from the individual market, we agree that they could incur significant savings if the final rule is implemented.

The AAFP is concerned that, if implemented, this rule could result in additional financial strain for CHCs, which already operate on very thin margins. This is particularly concerning given the continued impact of the COVID-19 pandemic on CHCs. Patients at community health centers are disproportionately low-income and people of color, who have been especially hard hit by the pandemic and rely on CHCs as a safety net. The 340B program gives small, community-based non-profits like health centers access to discounts that they could not negotiate on their own. By law, regulation, and mission, the money health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care. We are therefore concerned that this proposal could unintentionally increase barriers to accessing other services for CHC patients at a time when CHCs are already struggling to keep their doors open and patients are increasingly dependent on their services, including to receive COVID-19 vaccines.

The AAFP urges HHS to continue efforts to reduce pharmaceutical prices for low-income and other patients. Although reducing the cost of these two medications for low-income patients is laudable, this rule fails to meaningfully stem the ever-increasing prices of insulin, epinephrine, and other lifesaving medications. Evidence indicates that the year-over-year price increases of existing drugs are directly related to the growing costs incurred by patients.[3] Instead of addressing this issue, which is increasing health care costs and causing patients to forgo treatment, this rule requires CHCs, and in turn low-income patients, to absorb any associated costs.[4] We look forward to working with the agency on a more comprehensive policy to make medications more affordable for all patients.

Thank you for the opportunity to provide comments on the proposed delay of effective date. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at (202) 235-5126 or myinger@aafp.org.

Sincerely,

Gary L. LeRoy, MD, FAAFP

Gary LeRoy, MD, FAAFP
Board Chair

---

[1] 2020 AAFP Practice Profile Survey. American Academy of Family Physicians. 2020.
[2] Rosenblatt RA, Andrilla CHA, Curtin T, Hart LG. Shortages of medical personnel at community health centers: implications for planned expanstion. *JAMA* 2006;295:1042–9.
[3] Hernandez I, et al. The contribution of new product entry versus existing product inflation in the rising costs of drugs. *Health Aff* 2019. Available at: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05147
[4] Cohen RA and Villarroel MA. Strategies used by adults to reduce their prescription drug costs: United States, 2013. NCHS Data Brief. 2015.