Executive Order – Access to Affordable Life-Saving Medications Rescission of Regulation

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Implementation of Executive Order on Access to Affordable Life-Saving Medications; Rescission of Regulation

On October 1, 2021, the U.S. Department of Health and Human Services (HHS) issued a final rule rescinding the previously issued final rule entitled "Implantation of the Executive Order on Access to Affordable Life-Saving Medications."(2020), The rationale behind rescinding the 2020 Rule was that the overall impact of the additional administrative cost and burden that the 2020 Rule would have placed on health centers would have harmed the centers and the patients they serve. **This rule is effective on November 1, 2021.**

Background

The 2020 Rule established a new requirement directing all H receiving grants under section 330(e) of the Public Health Service Act that participate in the 340B Program, to the extent that they plan to make insulin and/or injectable epinephrine available to their patients, to provide assurances that they have established practices to provide these drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program. This extension applied to health center patients with low incomes, who have high cost sharing requirements for either insulin or injectable epinephrine; have a high unmet deductible; or who have no health insurance.

On March 22, 2021, the effective date of the "Implementation of Executive Order on Access to Affordable Life-Saving Medications" rule was delayed to July 20, 2021 (86 FR 15423), to allow HHS an additional opportunity to review and consider further concerns raised by the rule, including whether revision or withdrawal of the rule may be warranted. The 2021 Notice of Proposed Rulemaking (2021 NPRM) provided for a 30-day comment period, and **HHS received 332 comments. Approximately 316 commenters expressed concern that the impact of implementing the 2020 Rule would be a reduction in access to care for underserved populations and the costs allocated in the 2020 Rule would reduce resources available to provide essential primary care for patients. 300 commenters expressed concerns that the 2020 Rule would divert health center resources away from the COVID-19 pandemic response and 301 commenters stated that implementing the Rule would only improve medication access for a small group of people, ultimately resulting in a loss of 340B savings.** Out of all the comments, only 12 commenters opposed the proposed rescission of the 2020 Rule, many of whom are pharmaceutical manufacturers.

This year, many contract pharmacies experienced the effects when several drug manufacturers stopped honoring 340B discounts. Such discounts are a critical resource across several health systems, including Tribal and Urban health programs. In response, HHS issued an advisory opinion that opposed the drug manufacturers decision and sent six letters to drug manufacturers addressing the issue. Advocacy efforts at NCUIH and the voice of Tribal leaders during the February 2021 Secretary's Tribal Advisory Committee (STAC) contributed to HHS's awareness and action to resolve the issue.

"…HRSA found that six drug manufacturers, including AZ, Ely Lily, and others, were in violation of the 340B program rule, by "knowingly and intentionally charg[ing] a covered entity more than the ceiling price for a covered outpatient drug may be subject to a Civil Monetary Penalty (CMP) not to exceed $5,000 for each instance of overcharging." Adding that, "the manufacturers must refund or credit the covered entities for any over-charges and begin charging no more than the ceiling price immediately to covered entities."

Current Action

HHS agreed with commenters' concerns regarding the reduced access to care resulting from the additional burden required of health centers to implement the 2020 Rule and shared their concerns that this rule would result in a loss of 340B revenue. Loss in revenue along with an increased administrative burden would reduce resources available to support critical services to health center patients.

HHS notes the concerns expressed by majority of commenters that the "low income" definition of 350 percent of the Federal Poverty Guidelines (FPG) applicable to patients receiving these two classes of drugs (insulin and/or injectable epinephrine) would have created significant administrative challenges for health centers. **HHS's consideration of the 2020 Rule's impact was informed, in part, by the demands on health centers resulting from the COVID-19 pandemic.**
As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

NCUIH will continue to closely monitor and track the 340B issue and 2020 Rule-related issues, concerns, and comments.

When talking about health centers that are getting 330 grants/participate in the 340B program, I like to capitalize it but you don't necessarily have to. HRSA's Health Center Program co-opted the term "health center" so in my mind if it's not capitalized, I wonder if whoever's using the term is referring to the HRSA designation or not. Here's some info on the Health Center Program and the statute about it: https://bphc.hrsa.gov/about/what-is-a-health-center/index.html and Health Center Program Statute: Section 330 of the Public Health Service Act (42 U.S.C. §254b)

Health Center Program Regulations: 42 CFR 51c and 42 CFR 56.201 – 56.604