

HRSA Issues Proposed Rule Requiring Community Health Center Grant Recipients to Provide Certain Drugs to Low-Income Patients at 340B Prices

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On September 24, 2020, the Health Resources and Services Administration (HRSA) released a [proposed rule](#) that, if finalized, would require 340B-participating recipients of federal grants under Section 330(e) of the Public Health Service Act (known as community health centers (CHCs)) to provide insulin and injectable epinephrine to low-income patients at 340B acquisition prices. HRSA will accept public comments on the proposed rule until October 28, 2020.

IN DEPTH

The proposed rule follows President Trump's "[Executive Order on Access to Affordable Life-saving Medications](#)" and would add a requirement to future CHC funding awards under Section 330(e). The new condition of funding would require that the grantee "establish[] practices [to] provide insulin and injectable epinephrine at or below the discounted price paid by the health center grantee or sub-grantee under the 340B Drug Pricing Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or have no health insurance."

The proposed rule defines certain terms, including:

- Individuals with low incomes: individuals and families with annual incomes no greater than 350% of the Federal Poverty Guidelines
- High cost sharing requirement: a cost sharing requirement that exceeds 20% of the amount the health center charges its patients for the drug
- High unmet deductible: the amount a patient owes toward her high deductible at any time during a plan year in which the outstanding deductible portion exceeds 20% of the total

deductible.

Analysis and Takeaways

HRSA's proposed rule would amend 42 CFR 51c, a section of the federal regulations governing CHC grants, rather than regulations governing the 340B Program at 42 CFR 10. This approach should provide some comfort to 340B Program stakeholders that the requirements of the Executive Order will not be expanded to other 340B covered entity types. However, the limited scope will result in additional administrative burdens on 330(e) grantees and their sub-grantees, as well as reduced grant "program income" to support the programs under their grants. Notably, 330(e) grantees are already required to use any revenue generated from their 340B Program participation to support programs and patients served under their grants.

Based on the comment period and standard rulemaking timeframes, it is unlikely that the proposed rule will be finalized before the beginning of the next presidential term, which begins on January 20, 2021.

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