

This rule also does not have Tribal implications because it will not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Waste treatment and disposal.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 15, 2020.

Kenley McQueen,

Regional Administrator, Region 6.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906-AB25

Implementation of Executive Order 13937, "Executive Order on Access to Affordable Life-Saving Medications"

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Health and Human Services (HHS) proposes to implement the Executive Order 13937 (Executive Order) of July 24, 2020. The Executive Order requires that entities funded under section 330(e) of the Public Health Service Act (PHS Act or the Act), whether by receiving a federal award or a subaward, and who also participate in the 340B Drug Pricing Program, must establish practices to provide access to insulin and injectable epinephrine to low-income patients at the price the health center purchased these two drugs through the 340B Drug Pricing Program. The Executive Order supports the improved access to these life-saving medications by low-income individuals who do not have access to affordable insulin and injectable epinephrine due to either lack of insurance or high cost sharing requirements. HHS is seeking public comment on this notice of proposed rulemaking (NPRM).

DATES: Written comments and related material to this proposed rule must be

received to the online docket via <https://www.regulations.gov> on or before October 28, 2020.

ADDRESSES: Comments must be identified by HHS Docket No. HRSA-2020-0004 and submitted electronically to the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments and attachments will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information. Additionally, if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted as well.

FOR FURTHER INFORMATION CONTACT:

Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; email: jjoseph@hrsa.gov; telephone: 301-594-4300; fax: 301-594-4997.

SUPPLEMENTARY INFORMATION:

I. Background

On March 13, 2020, President Trump declared the ongoing Coronavirus Disease COVID-19 pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, territories, and the District of Columbia. With the COVID-19 emergency, many low-income individuals are experiencing significant economic hardship. These low-income individuals who are dependent upon the life-saving medications of insulin and/or injectable epinephrine are now less able to access these drugs at an affordable price. On July 24, 2020, President Trump issued Executive Order 13937 (Executive Order), "Executive Order on Access to Affordable Life-saving Medications," was issued to direct health centers that receive grants under section 330(e) of the PHS Act to support the improved access to certain life-saving medications by low income individuals. As provided in the Executive Order, it is the policy of the United States to enable Americans without access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs, such as Medicare and Medicaid, to purchase these

pharmaceuticals from a health center at the same price at which the health center acquired the medication through the 340B Drug Pricing Program.

Through the Executive Order, the President directed the Secretary of Health and Human Services (the Secretary) to take action, to the extent permitted by law, to ensure all future grants available under section 330(e) of the PHS Act, as amended, 42 U.S.C. 254b(e), are conditioned upon health centers having established practices to make insulin and injectable epinephrine available at the discounted price paid by the health center grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who:

- (a) Have a high cost sharing requirement for either insulin or injectable epinephrine;
- (b) have a high unmet deductible; or
- (c) have no health care insurance.

Under section 330(k)(3) of the Act, the Secretary may not approve an application for a grant under subparagraph (A) or (B) of subsection (e)(1) unless the Secretary determines that the entity for which the application is submitted meets the requirements enumerated in section 330(k)(3)(A)-(N). Section 330(k)(3)(N) requires that "the center has written policies and procedures in place to ensure the appropriate use of Federal funds in compliance with applicable Federal statutes, regulations, and the terms and conditions of the Federal award." Consistent with the Act, the HRSA would include in the Terms section of applicable Notices of Award (NOAs) issued under section 330(e) grant awards, the requirement that health center awardees comply with the discounted price provisions described herein.

This proposed regulation would apply to new grants and new project periods for service area, new access point, supplemental, and expanded services awards issued under section 330(e) of the PHS Act.

II. Statutory Authority

The statement of authority for 42 CFR part 51c continues to read section 330 of the PHS Act (42 U.S.C. 254b) and section 215 of the PHS Act, (42 U.S.C. 216).

III. Discussion of Proposed Rule

Overview

The Executive Order was issued to support the improved access to certain life-saving medications for low-income individuals. HRSA is proposing to

establish a requirement for awarding new grants under section 330(e) of the PHS Act (42 U.S.C. 254b) that the awardee have established written practices to make insulin and injectable epinephrine available 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 who: (a) Have a high cost sharing requirement for either insulin or injectable epinephrine, (b) have a high unmet deductible, or (c) have no health insurance. This NPRM also provides definitions relevant to this requirement.

1. What is the proposed requirement?

The proposed requirement for all awards under section 330(e) is as follows:

Under Executive Order 13937, issued July 24, 2020, if your health center, or a subrecipient, receives section 330(e) funding, is enrolled in the 340B Drug Pricing Program and purchases, is reimbursed, or provides reimbursement to other entities for insulin and injectable epinephrine, whether obtained using federal or non-federal funds, your health center must have established practices to make insulin and injectable epinephrine available to low-income health center patients (defined herein as those individuals or families with annual incomes at or below 350% of the Federal Poverty Guidelines)—who either have insurance with a high cost sharing requirement for either insulin or injectable epinephrine, as applicable, a high unmet deductible, or who have no health insurance—at or below the price the health center paid through the 340B Drug Pricing Program, plus a minimal administration fee. You are not required to charge third party payors this discounted price.

Consistent with the Executive Order, this Term would only apply to health centers receiving section 330(e) grant funds that participate in the 340B Drug Pricing Program (42 U.S.C. 254b). This requirement is limited to increasing affordable access to insulin and injectable epinephrine. The requirement to make these two drug categories available at or below the same price paid through the 340B Drug Pricing Program does not apply to other 340B drugs. Health centers subject to this requirement would be expected to provide drugs in these two categories at or below the price paid through the 340B Drug Pricing Program to health center patients only, and further only to those health center patients identified as low income, as described below. An individual would not be considered a

“patient” of the health center for this purpose if the only health care service received by the individual from the health center is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 FR 55,156 (Oct. 24, 1996). Nothing in this Program Term or the actions described in this NPRM prohibits or otherwise restricts a health center from setting the price for insulin or injectable epinephrine lower than the price the health center paid through the 340B Drug Pricing Program.

This Program Term would be included on all Notices of Award issued to health centers receiving grants under section 330(e) of the Act.

2. How would HRSA ensure that a health center has established practices in order to receive an award under section 330(e) under this proposed rule?

The Executive Order states that future grants under section 330(e) should be conditioned upon health centers or subrecipients participating in the 340B Drug Pricing Program, including through contract pharmacy arrangements, having established practices to make insulin and injectable epinephrine accessible at an affordable price to low income health center patients. To implement this requirement, all future awards made available under section 330(e) would include the requirement that health centers participating in the 340B Drug Pricing Program comply with the proposed regulation as described in the Program Term in order to receive a grant award. Specifically, these competitions would require health centers that receive section 330(e) funding and that participate in the 340B Drug Pricing Program to have established practices that implement the Executive Order by offering insulin and injectable epinephrine to patients at no more than the same price the health center paid through the 340B Program plus a minimal administration fee. Health centers that have one or more subgrantees that participate in the 340B Program must demonstrate such subgrantees have established practices to offer patients these 340B discounted drugs as described in this proposed rule. In particular, these practices would provide information to patients in an easily understandable format regarding their administration fees, and the low-income, high cost sharing, and high unmet deductibles standard as described in this proposed regulation.

How will the HRSA define the terms and phrases, such as “minimal administration fee,” in the Executive Order?

HRSA proposes to define the following terms and to assist health centers in complying with, and implementing the Executive Order.

1. “*Established practices*”: The health center demonstrates through its written policies, procedures, and/or other relevant documents that it has established practices to offer insulin and injectable epinephrine at no more than the discounted price paid by the health center under the 340B Drug Pricing Program plus a minimal administration fee.

2. “*Health center grantee or sub-grantee*”: The Executive Order cites section 1905(l)(2)(B)(i) and (ii) of the Social Security Act, as amended (42 U.S.C. 1396d(l)(2)(B)(i) and (ii)). These two subparagraphs refer to organizations receiving an award under section 330 of the PHS Act (health centers) directly or as a subrecipient of grant funding. For purposes of this NPRM, this definition of health center grantee or subgrantee would be defined as organizations receiving funding under section 330(e) of the PHS Act.

3. “*Minimal administration fee*”: This NPRM proposes that health centers would be expected to offer insulin and injectable epinephrine at or below the price the health center paid through the 340B Program, plus a minimal administration fee. As the Executive Order does not allow any other charge for these two categories of drugs, the minimal administration fee would be expected to include any dispensing fee, counseling costs, and any other charges associated with the patient receiving the medication. As the fee must be “minimal,” consistent with the stated policy of the Executive Order, the administration fee should not create a barrier to low income patients accessing these drugs, and health centers should make every reasonable effort to keep the fee as low as possible. Health centers may consider referring to the Medicaid dispensing fee in their state¹ as a comparison for what may be considered a minimal administration fee. Please note that when there is a separate fee associated with provision of the pharmaceutical service, such as a dispensing fee, health centers must apply a sliding fee discount to that fee. The Health Center Program Compliance Manual’s Sliding Fee Discount Program

¹ Please see <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/medicaid-covered-outpatient-prescription-drug-reimbursement-information-state/index.html> for further information.

Chapter specifies the requirements of a health center's sliding fee discount program for in-scope services including pharmaceutical services.²

4. *"Individuals with low incomes"*:

The NPRM proposes that low income would be defined as individuals and families with annual incomes of no greater than 350 percent of the Federal Poverty Guidelines.

5. *"High cost sharing requirement"*:

For purposes of this NPRM, cost sharing refers to a patient's out-of-pocket costs, including, but not limited to, deductibles, coinsurance, and copayments, or similar charges. More specifically, a cost sharing requirement that exceeds twenty percent of the amount the health center is charging patients for the drug would be considered a high cost sharing requirement.

6. *"High deductible"*: High deductible refers to a deductible amount that is not less than the amount required for a high deductible health plan as defined in section 223(c)(2)(A) of the Internal Revenue Code, which, for 2020, is any plan with a deductible of at least \$1,400 for an individual or \$2,800 for a family, with out-of-pocket costs not to exceed \$6,900 for an individual and \$13,800 for a family for in-network services. For 2021, the deductible limits would remain the same, while the limits for out-of-pocket costs would increase to \$7,000 for self-only coverage and \$14,000 for family coverage. When the Internal Revenue Service (IRS) updates these figures, HRSA will post the updated high deductible amounts on the Health Center Program website.

7. *"High unmet deductible"*: High unmet deductible refers to the amount a patient owes toward his/her high deductible at any time during a plan year in which the portion of the patient's high deductible for the plan year that has not yet been met exceeds 20% of the deductible, regardless of the total annual deductible of the health insurance plan.

8. *"Health insurance"*: Health insurance refers to private insurance, State and exchange plans, employer-funded plans, and coverage under titles XVIII, XIX, and XXI of the Social Security Act.

IV. Regulatory Impact Analysis

HHS has examined the effects of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review

(January 8, 2011), the Regulatory Flexibility Act (Pub. L. 96–354, September 19, 1980), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999). HHS has also considered E.O. 13771 and has determined that the associated designation will be informed by public comments received.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB).

HHS does not believe that this rule, if finalized, will have an economic impact of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. Because this proposed rule is limited in

scope to two classes of drugs that are of particular need and it aligns with the mission and related Health Center Program requirements of health centers to provide access to care for vulnerable individuals and families, HHS believes it will have minimal economic impacts on health centers. The economic impact is also expected to be minimal given the proposed rule is limited to only two drug products which are available under the 340B Program at significantly reduced prices. Therefore, OMB has not designated this proposed rule as "economically significant" under section 3(f)(1) of the Executive Order 12866. HHS welcomes comments concerning the economic impact of this proposed rule.

The Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a 3 percent impact on at least 5 percent of small entities.

For purposes of the RFA, HHS considers all health care providers to be small entities either by meeting the Small Business Administration (SBA) size standard for a small business, or for being a nonprofit organization that is not dominant in its market. The current SBA size standard for health care providers ranges from annual receipts of \$8 million to \$41.5 million. As of August 8, 2020, the Health Center Program provides grant funding under section 330(e) of the PHS Act to 1,310 organizations to provide health care to medically underserved communities. HHS has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small health centers; therefore, we are not preparing an analysis of impact for this RFA. HHS estimates that the economic impact on small entities would be minimal; therefore, we are not preparing an analysis of impact for the purposes of the RFA. HHS welcomes comments concerning the impact of this proposed rule on health centers.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires

² Please see <https://bphc.hrsa.gov/programrequirements/compliancemanual/chapter-9.html#titletop> for further information.

that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.” In 2019, that threshold level was approximately \$164 million. HHS does not expect this rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” This proposed rule would not “have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This proposed rule would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a federal agency from the public before they can be implemented. This proposed rule is projected to have no impact on current reporting and recordkeeping burden for health centers. This proposed rule would result in no new reporting burdens. Comments are welcome on the accuracy of this statement.

List of Subjects in 42 CFR Part 51c

Grant programs—Health, Health care, Health facilities, Reporting and recordkeeping requirements.

Dated: September 21, 2020.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Dated: September 22, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Accordingly, 42 CFR part 51c is proposed to be amended as follows:

PART 51c—GRANTS FOR COMMUNITY HEALTH CENTERS

- 1. The authority statement for part 51c is revised to read as follows:

Authority: Sec. 330, Public Health Service Act, (42 U.S.C. 254b); sec. 215, Public Health Service Act, (42 U.S.C. 216).

- 2. Section 51c.303 is amended by adding paragraph (w) to read as follows:

§ 51c.303 Project elements.

* * * * *

(w)(1) *Provision.* To the extent that an applicant has indicated that it plans to distribute, either directly, or through a written agreement, drugs purchased through the 340B Drug Discount Program (42 U.S.C. 256b), and to the extent that such applicant plans to make insulin and/or injectable epinephrine available to its patients, the applicant shall provide an assurance that it has established practices 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.

(2) *Definitions.* For purposes of this paragraph (w) exclusively:

(i) *Established practices.* The health center has written policies, procedures, and/or other relevant documents that it has established practices to offer insulin and injectable epinephrine at no more than the discounted price paid by the health center under the 340B Drug Pricing Program plus a minimal administration fee.

(ii) *Health center grantee or sub-grantee.* Organizations receiving an award under section 330(e) of the PHS Act (*i.e.*, health centers) directly or as subgrantees of section 330(e) grant funding.

(iii) *Minimal administration fee.* The minimal administration fee includes any dispensing fee, counseling costs, and any other charges associated with the patient receiving the medication. The administration fee may not create a barrier to low-income patients accessing these drugs, and health centers should make every reasonable effort to keep the fee as low as possible. Health centers may refer to the Medicaid dispensing fee in their state as a reference for minimal administration fees. When there is a separate fee associated with provision of the pharmaceutical service, such as a dispensing fee, health centers must apply a sliding fee discount to that fee.

(iv) *Individuals with low incomes.* Individuals and families with annual incomes no greater than 350 percent of the Federal Poverty Guidelines.

(v) *High cost sharing requirement.* A cost sharing requirement that exceeds twenty percent of the amount the health center charges its patients for the drug is a high cost sharing requirement. Cost sharing refers to a patient's out-of-pocket costs, including, but not limited to, deductibles, coinsurance, and copayments, or similar charges.

(vi) *High deductible.* High deductible refers to a deductible amount that is not less than the amount required for a high deductible health plan as defined in section 223(c)(2)(A) of the Internal Revenue Code, as implemented by the Internal Revenue Service.

(vii) *High unmet deductible.* High unmet deductible refers to the amount a patient owes toward his/her high deductible at any time during a plan year in which the outstanding deductible portion exceeds 20% of the total deductible, regardless of the total annual deductible of the health insurance plan.

(viii) *Health insurance.* Health insurance refers private insurance, State and exchange plans, employer-funded plans, and coverage under titles XVIII, XIX, and XXI of the Social Security Act.

(ix) *“Patient.”* For purposes of this subsection, an individual would not be considered a “patient” of the health center for this purpose if the only health care service received by the individual from the health center is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

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