DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906–AB25

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

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

ACTION: Final rule.

SUMMARY: This final rule implements an Executive Order requiring 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 that also participate in the 340B Drug Pricing Program (340B Program) must establish practices to provide access to insulin and injectable epinephrine to low-income health center patients at the price the health center purchased these two drugs through the 340B 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.

DATES: This final rule is effective on January 22, 2021.

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. Public Participation

On September 28, 2020, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (85 FR 60748) to implement Executive Order 13937 (Executive Order) of July 24, 2020, by amending the regulations implementing Section 330 of the Public Health Service Act (PHS Act or the Act), to require entities funded under Section 330(e) of the Act to establish practices to provide insulin and injectable epinephrine to low-income patients at the price the health center purchased these two drugs through the 340B Program. The NPRM provided for a 30-day comment period, and HHS received 226 comments. HHS carefully considered all comments in developing this rule, as outlined in Section V below, and presents a summary of all significant comments and HHS responses.

II. Background

As discussed in the NPRM, on March 13, 2020, President Trump declared the 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 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 Program. This final rule aligns with the goals of the President's mandate.

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 subgrantee under the 340B 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.'' Through this final rule, and consistent with the Act, HRSA will 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 regulation applies 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.

III. 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).

IV. Summary of This Rule

Overview

This rule codifies the proposed requirement described in the September 2020 NPRM implementing the Executive Order issued to support the improved access to certain life-saving medications for low-income individuals. This rule establishes 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 subgrantee under the 340B Program (plus a minimal administration fee) to health center patients 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 final rule also provides definitions relevant to this requirement.

Through this final rule, the requirement for all grant awards under section 330(e) of the PHS Act 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 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 percent of the Federal Poverty Guidelines (FPG))—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 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 only applies to health centers receiving section 330(e) grant funds that participate in the 340B Program (42 U.S.C. 254b and 256b). This requirement is limited to increasing affordable access to insulin and injectable epinephrine. The requirement to make insulin and injectable epinephrine available at or below the same price paid through the 340B Program does not apply to other 340B drugs. Health centers subject to this requirement are expected to provide drugs in these two categories at or below the price paid through the 340B Program to health center patients only, and only to those health center patients identified as low-income, as described below. An individual will 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. See 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 final rule 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 Program.

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

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

Through this final rule, HRSA defines the following terms 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 Program plus a minimal administration fee.

2. ''*Health center grantee or subgrantee*'': 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 final rule, this definition of health center grantee or subgrantee is defined as organizations receiving funding under section 330(e) of the PHS Act.

3. ''*Minimal administration fee*'': This final rule establishes that health centers receiving funding under section 330(e) of the PHS Act are 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 is 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 health center 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 state [1] 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 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*'': This final rule defines individuals with low incomes 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 final rule, 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 its 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

[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.

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

a patient owes toward their 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 percent of the deductible.

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.

V. Public Comments and Responses

HRSA received a total of 226 comments from the public, including individuals requiring insulin or injectable epinephrine and their family members, associations and organizations representing health centers and other stakeholders, health center staff and clinical professionals, health insurance issuers, and pharmaceutical manufacturers. The vast majority of commenters identifying themselves as individuals or the family members of those who rely on insulin or injectable epinephrine (22) were in favor of the proposed rule, although several suggested the proposed rule did not go far enough in reducing prices of these two medications. Many commenters (175), including many health centers, strongly urged that the proposed rule either not be finalized or be delayed in implementation, although most of these comments shared in the Administration's goal of ensuring access to these two life-saving medications. Most of the comments opposing implementation of the rule or suggesting delaying implementation also recommended changes to the language of the NPRM if it were to be implemented.

All comments were considered in developing this final rule. This section presents a summary of all major issues raised by commenters, grouped by subject, as well as responses to the comments. Commenters used the terms ''Federally Qualified Health Centers (FQHCs)'' and ''health centers'' interchangeably. For consistency, and as this rule applies to health centers funded under Section 330(e) of the PHS Act, and not to other FQHCs, this final rule uses ''health center'' throughout.

1. Support for the Proposed Rule

Approximately 23 commenters expressed support for the proposed rule. Commenters cited a number of reasons for their support, including the high cost of insulin and injectable epinephrine and concern over increasing costs of medications. Commenters also stated that lower cost medications lead to higher medication patient adherence and, as such, lower the costs to the overall health system. One commenter noted that the proposed rule would mostly benefit those between 200 percent and 350 percent of the FPG.[3] Many of these commenters felt the proposed rule should be expanded to include more medications and patients beyond those served by health centers.

Additionally, one commenter requested that HRSA include the proposed rule's requirements in all grants establishing 340B eligibility, and that the proposed rule's requirements should also apply to health centers' contract pharmacy arrangements.

Response: HRSA appreciates the commenters' support for the rule. Consistent with the direction provided to HHS in the Executive Order, HRSA is not expanding this final rule beyond health centers receiving grants under Section 330(e) of the PHS Act, to drugs beyond insulin and injectable epinephrine, or otherwise beyond the parameters identified in the proposed rule. As a clarification, health centers utilizing contract pharmacy arrangements must also adhere to this final rule.

2. Concerns Regarding the Proposed Rule's Enforceability

Two commenters expressed concerns with the proposed rule's enforceability. Commenters suggested that a rule implementing the Executive Order could be easily circumvented and could be challenging to enforce. More specifically, commenters stated that without explicit codes for documenting which health centers participate in the 340B Program, it would be difficult to monitor and enforce compliance. Another commenter suggested HRSA clearly identify which health centers are participating in the 340B Program to help private sector partners support the implementation of the proposed rule. In addition, the commenter stated that HRSA should specify methods that would be used to verify income and insurance status in order to successfully operate the program.

One commenter also included suggestions for ensuring compliance and eliminating loopholes, including: (1) Providing receipt information for the monetary exchange between patients and providers, (2) comparing the manufacturer's drug price against the price charged to patients, and (3) using incentives to ensure compliance beyond the loss of section 330(e) funding awards (*e.g.,* loss of medical license for non-compliance).

Response: HRSA appreciates these comments. HRSA provides oversight of all covered entities in the 340B Program, including health centers, and HRSA declines to add these suggested compliance requirements. In particular, the suggestion that non-compliance should result in the loss of a medical license is outside of HRSA's purview.

With regard to the other suggestions for monitoring compliance with the final rule, HRSA will monitor the ongoing implementation of this final rule and will make changes as appropriate to ensure its effective implementation.

3. Final Rule Is Not Needed as the 340B Program Is Operating as Intended

Approximately 52 commenters stated that the 340B Program is operating as intended when originally created and changes are not needed. Many of these commenters stated that health centers already provide discounted drugs to patients, regardless of their ability to pay. Commenters also noted that health centers are required by law to use 340B savings to expand access to health care for the underserved, and these savings are crucial to enabling health centers to offer other services to their patients in addition to providing discounts for drugs.

One commenter called on HRSA to take a more holistic approach to realign the 340B Program with its original intent and scope and support health centers' access to the 340 Program.

Response: HRSA acknowledges that health centers use 340B Program savings to benefit their patient population, as required by the Health Center Program, and many health centers provide discounted medications to their patients. Consistent with the Executive Order, this final rule applies only to insulin and injectable epinephrine and does not address other drugs health centers purchase through the 340B Program.

4. The Executive Order Reflects a Misunderstanding of Health Centers' Mission and Operations

Approximately 175 commenters suggested that the Executive Order, on which the NPRM is based, reflects fundamental misunderstandings about health centers' mission and operations, and does not recognize the essential role that health centers play in ensuring access to affordable pharmaceuticals for medically vulnerable populations. The commenters expressed concern with the

[3] The FPG are a federal poverty measure issued each year in the **Federal Register** by HHS. The guidelines are used for administrative purposes, such as for determining financial eligibility for certain federal programs. They are available at *https://aspe.hhs.gov/poverty-guidelines.*

Executive Order provision that suggested that health centers are benefiting inappropriately from the 340B Program at the expense of their vulnerable patients. The commenters argued that health centers do much more than pass on the 340B discount to their low-income patients, and often discount drug prices below the 340B price to ensure they are affordable. Additionally, commenters stated that all health centers are required to invest all 340B savings into activities that expand access to care for low-income populations, and that health centers are already part of the solution to unaffordable drug prices, and not part of the problem. Commenters also stated that health centers are widely praised for their strong track record of compliance with both the letter and the spirit of the 340B statute.

Response: The final rule implements the goals and intent of the Executive Order to make insulin and injectable epinephrine more affordable. HRSA acknowledges that health centers play a crucial role in providing access to comprehensive, high quality primary health care to all patients regardless of ability to pay. Further, HRSA is cognizant of health centers' compliance with the 340B statute and strong track record of using the savings generated to benefit patients. HRSA values its partnerships with all health centers and commends their efforts to ensure access to affordable drugs for all of their patients.

5. The Executive Order Reflects a Misunderstanding of the 340B Program

Approximately 161 commenters suggested that the Executive Order on which the NPRM is based reflects a fundamental misunderstanding of the 340B Program, and if implemented as written would decrease some patients' access to affordable drugs. The commenters argued that this misunderstanding of 340B pricing would result in some patients paying more for insulin, dramatic fluctuations in insulin costs from one quarter to another and requiring quarterly changes to a patient's prescription to keep them on the most affordable insulin brand available.

The commenters also disagreed with the Executive Order's statement that health centers pay only one penny for a month's supply of insulin or injectable epinephrine. The commenters suggested that this statement was not universally true given drug pricing fluctuations, with prices for drugs often varying from one penny in one quarter to over $100 in another quarter. These commenters stated that health centers cannot guarantee that the price of the insulin or injectable epinephrine that a patient will pay on a certain day is the exact 340B price. This 340B price fluctuation from quarter to quarter can create an undue administrative compliance burden on health center staff.

One commenter suggested that the drug price charged to the health center patient should be the average 340B drug price to account for the quarterly variations in pricing.

Response: The rule implements the goals and intent of the Executive Order to make insulin and injectable epinephrine more affordable. HRSA recognizes that health centers have a strong history of compliance with the 340B statute and that many already significantly discount drugs for their patients, either through in-house pharmacies or via 340B contract pharmacies.

Drug prices are set quarterly based on prices manufacturers submit to the Centers for Medicare & Medicaid Services. Although insulin and injectable epinephrine prices may vary from quarter to quarter, the final rule allows health centers to offer these drugs at lower than the 340B price despite these fluctuations. Given this flexibility, and consistent with the intent of the Executive Order, HRSA will not change the final rule to allow for the averaging of 340B prices.

6. Differences Between the Executive Order and NPRM

Approximately 143 commenters noted that the language in the proposed rule departs from language in the Executive Order. Specifically, the proposed rule would allow health centers to make insulin and injectable epinephrine available ''at *or below*'' the price the health center paid through the 340B Program, whereas the Executive Order requires that health centers make such medications available ''at the discounted price.'' Commenters suggested that the Executive Order prohibits health centers from providing these drugs at prices below the 340B Ceiling Price. The commenters agreed with the need to allow flexibility in providing further discounts to patients but expressed concern that the discrepancy in language between the Executive Order and proposed rule demonstrates the inappropriateness of both.

Response: HRSA intends to proceed with language in the proposed rule requiring health centers to make insulin and injectable epinephrine available ''at *or below*'' the price paid by the health center through the 340B Program. This final rule will allow a health center to provide either of these two medications to patients at a price below the 340B Price. The language in this rule is consistent with the intent of the Executive Order.

7. Change Proposed Definition of ''*Low-Income*''

Approximately 164 commenters requested that HRSA change its proposed definition of ''low-income'' from 350 percent of the FPG to 200 percent of the FPG to better align with definitions used by other federal programs and private entities. Commenters noted that income assessments are not typically conducted by clinical staff, and those who conduct the assessments do not and should not have access to the personal health information that would be required for them to conduct a separate income analysis for patients who require insulin or injectable epinephrine. Additionally, commenters stated that such staff may not be competent to determine which patients may need such drugs now or in the future. Commenters specifically argued that using a low-income definition different from the 200 percent of the FPG required by the Health Center Program would create significant burden on health center staff to determine eligibility for health center discounts differently from eligibility for the pricing created by the proposed rule. This discrepancy would also create potential burden when using a contract pharmacy, where staff may be unfamiliar with evaluating patient income and may be unwilling to do so. Commenters further noted HHS, the United States Census Bureau, and private groups use 200 percent of the FPG to define low-income for research purposes. Commenters stated that for every federal program with income eligibility thresholds, low-income is defined as 250 percent of the FPG or less. While the Patient Protection and Affordable Care Act uses a ceiling above 350 percent to identify those eligible for premium tax credits on the Exchanges, this is not a definition of low income, as premium tax credits are designed for both lower and middle class individuals. Finally, commenters argued that a 350 percent FPG threshold could eliminate health centers' ability to retain 340B savings from privately insured patients due to health insurance issuers frequently requiring health centers to bill no more than their usual and customary (U&C) rate. While health centers have been successful resisting issuers' attempts to define U&C rates as discounted rates provided to patients at or below 200 percent FPG, the commenters expressed concern that

defining low-income as 350 percent FPG will cover most health center patients, making it very difficult to argue that the 340B price for insulin and injectable epinephrine is not the health center's U&C rate. This change would effectively transfer the 340B benefit from health centers to private health insurance issuers.

Response: HRSA intends to proceed with the language in the proposed rule requiring health centers to make insulin and injectable epinephrine available at or below the price paid by the health center through the 340B Program to health center patients that have incomes at or below 350 percent FPG and that otherwise meet the criteria described in this rule. While HRSA appreciates the feedback on the definition of ''low income'', we do not agree that it is too burdensome to implement as written. The language in this rule is consistent with the intent of the Executive Order.

8. Clarify Eligible Patients Under the Rule

Approximately 162 commenters requested clarification of the regulatory language that only those patients who meet the 340B patient definition are eligible for the 340B (or lower) price. Commenters argued that the regulatory language must clearly state that the health center is required to charge the 340B price (or less) only to those low-income individuals who meet the definition of ''FQHC patient'' under the 340B Program. Without such language, health centers could be forced to provide 340B pricing (or less) to individuals who are not eligible to receive 340B-priced drugs from the health center. Commenters used the example that low-income individuals could demand the health center provide them with discounted insulin, without permitting the health center to assume responsibility for their care (a necessary step for 340B eligibility). In such situations, 340B compliance would require the health center to purchase the insulin at the regular price, while this regulation would require that the individual be charged the 340B price or lower—an outcome that would be both expensive and administratively burdensome for the health center. Commenters recommended an addition to the regulatory text to clarify that only eligible health center patients should be able to access these drugs at the 340B price.

Response: The intent of the rule is to provide insulin and injectable epinephrine at no more than the 340B price to health center patients and not to individuals who are not health center patients. HRSA understands commenters' concerns, and the language in 42 CFR 51c.303(w)(1) has been revised to clarify that the final rule applies only to ''health center patients.'' HRSA also notes that the NPRM states that a ''patient'' for purposes of this subsection means only health center patients who receive in-scope health center services beyond dispensing of drugs that are self-administered or administered at home. This definition is also being finalized in this rule.

9. Address Potential Conflict With Third-Party Payor Contract Terms

Approximately 161 commenters requested that HRSA add regulatory language ensuring that health centers are not forced to provide discounts to underinsured patients if doing so would violate the terms of their insurance contracts. These commenters noted that many health insurance issuers prohibit providers from charging patients less for a service or supply than the amount due under their deductible or cost sharing requirements.

Response: HRSA acknowledges that health centers need to comply with the terms of their contracts with third-party payors. HRSA clarifies in the final rule that provision of insulin and injectable epinephrine at or below the 340B discounted price is subject to potential restrictions in contracts with third-party payors. The language of the final rule reflects this clarification.

10. Change Definitions of ''High Cost Sharing Requirement,'' ''High Deductible'' and ''High Unmet Deductible''

Approximately 161 commenters requested HRSA clarify its definitions of ''high cost sharing requirement.'' Commenters specifically noted confusion surrounding the definition of ''high cost sharing requirement'' and asked whether it means that a low-income patient should be charged the lesser of their cost sharing amount, or the amount they would be charged under the proposed rule if they were uninsured. In addition, two commenters argued that health centers already provide their patients with medications at significant discounts and are thus concerned about defining ''high cost sharing requirement'' as 20 percent of an already discounted price. The two commenters noted that it is unlikely that a private health insurance issuer would define a charge that is 20 percent of an already discounted price as a ''high cost sharing requirement.'' Commenters requested the definition be rewritten to reflect that 20 percent of an already discounted price is not a high cost sharing requirement. One commenter requested clarification as to how ''high cost sharing'' would be calculated for a patient with an insurance plan that ties the patient's cost sharing to a deductible or co-insurance that may change over the course of a plan year and suggested that this kind of fluctuation in cost sharing would require communication with payors and should be worked out before a final rule is promulgated.

Two commenters requested that ''high deductible'' and ''high unmet deductible'' be changed to a specifically defined amount so that health center and contract pharmacy staff could determine eligibility from a patient's insurance card. They specifically noted the proposed definition of ''high deductible'' points to a section in the Internal Revenue Code and that it would be burdensome for intake staff to determine if a patient has a ''high deductible'' or a ''high unmet deductible'' using this definition. One commenter requested further clarification of ''high unmet deductible,'' asking if once a patient meets 80 percent of their deductible they are no longer eligible for the proposed rules' pricing. The commenter noted that, if so, the patient's deductible payments would need to be tracked throughout the plan year and made available at the point of sale through the claims adjudication process. Additionally, medical claims may need to be factored into the unmet deductible amount, which could be challenging due to the delays in processing medical claims for patients with a dual pharmacy/medical deductible.

Response: HRSA appreciates the feedback surrounding the definition of ''high cost sharing requirement.'' The rule does not state that a low-income patient should be charged the lesser of their cost sharing amount or the amount they would be charged under the proposed rule if they were uninsured. Rather, the rule states that such patients should be provided access to insulin and injectable epinephrine at no more than the price at which the health center purchased the drug through the 340B program. While HRSA appreciates the feedback on the definition of ''high cost sharing requirement,'' we do not agree that it is too burdensome to implement as written. HRSA also notes that health centers may choose to charge their patients less than the discounted price at which the health center purchased the drug through the 340B Program, regardless of the patient's insurance out-of-pocket costs or insurance status.

HRSA appreciates the feedback that the proposed rule may be difficult to implement for patients whose cost

sharing changes throughout the plan year. HRSA will monitor implementation of the final rule and will modify it if we determine that a modification is warranted.

HRSA appreciates the feedback that it will be difficult for health center intake staff to determine eligibility for the final rule's pricing on insulin and injectable epinephrine because the rule's definition of ''high deductible'' references the Internal Revenue Code definition. As reflected in the preamble of the NPRM, HRSA will publish the Internal Revenue Code definition of high deductible on the Health Center Program website. Such eligibility determinations may be integrated into existing processes utilized by health centers. Furthermore, it is HRSA's understanding that many insurance cards do print the deductible on their cards, and we agree that the ability to evaluate whether a plan has a ''high deductible'' based on such information may make evaluation less burdensome on health center staff. However, HRSA does not have the authority to require health insurance issuers to place deductible amounts on the proof of insurance cards they provide to patients.

HRSA appreciates the feedback on the definition of ''high unmet deductible'' and the potential difficulty with implementing this provision of the rule. To clarify, HRSA does intend that once a patient meets 80 percent of a high unmet deductible, the health center would no longer be required to provide that patient with insulin or injectable epinephrine at the 340B price as described by this rule, unless such patient separately meets the definition of either having a ''high cost sharing requirement'' or having no insurance. We realize this may have the potential to create additional burden on health centers and their contract pharmacies to ascertain a patient's eligibility for pricing under this rule. HRSA will monitor implementation of this final rule and will modify it if it is deemed that a modification is warranted.

11. Clarify Definition of ''Minimal Administration Fee''

Approximately 161 commenters requested clarification that, as a result of this rule, the ''minimal administration fee'' for insulin and injectable epinephrine will differ from the fees (if any) associated with dispensing other pharmaceuticals. Commenters noted that this rule will create significant additional administrative burdens for health centers, beyond the costs regularly associated with dispensing, counseling, and 340B compliance. One commenter requested that if the eligibility threshold under this rule is not aligned with the 200 percent of the FPG established for discounts to health center services under the Health Center Program, that HRSA define ''minimal administration fee'' to include costs associated with dispensing, 340B compliance, and the additional administrative work required to identify patients. Furthermore, they requested that HRSA clarify that this fee is unique to the dispensing of insulin and injectable epinephrine.

One commenter requested clarification that administration fees may include limited per prescription fees associated with operationalizing an overall 340B Program or contract pharmacy network. Because health centers often have arrangements with third-party vendors and/or contract pharmacies that include a per prescription fee, and such fees are often minimal, changes to how these fees are calculated and administered could cause patients to lose access to some pharmacies.

Response: The final rule defines ''minimal administration fee'' as a fee that may not create a barrier to low-income patients' access to insulin and injectable epinephrine. It would be inconsistent with the intent of the Executive Order and the rule to define ''minimal administration fee'' in a way that could create a barrier to accessing these drugs. A definition that included potential costs related to compliance could be seen as accepting that health centers will charge patients a higher fee to purchase insulin and injectable epinephrine than for other pharmaceuticals.

As all health centers are required to collect information regarding patient income, HRSA does not anticipate the need for a separate eligibility review. Entities participating in the 340B Program already manage different prices for 340B drugs on a quarterly basis. This final rule has clarified that only health center patients are eligible for insulin and injectable epinephrine at the prices set under this rule, and HRSA does not anticipate health centers incurring additional costs related to non-health center patients receiving these drugs. Monitoring and reporting compliance with this rule is not anticipated to be significant.

HRSA recognizes that the minimal administration fee described in the rule does not occur with other pharmaceuticals, including other 340B drugs, where multiple fees are listed separately. The rule defines the term, and states that health centers may, but are not required to, charge such a minimal administration fee for insulin and injectable epinephrine. HRSA acknowledges that this minimal administration fee is unique to this rule and insulin and injectable epinephrine as covered here, and that this rule does not create a new term that applies to the 340B Program beyond this rule. As noted in the rule, all definitions are provided ''for purposes of this paragraph exclusively.'' Therefore, HRSA declines to make revisions to this section.

12. Clarify ''Established Practices''

One commenter requested that HRSA clarify and provide additional guidance on the proposed rule's requirement for ''established practices.'' Because not all covered entities have mechanisms in place to adjudicate 340B claims for uninsured or underinsured patients, the commenter noted that many will have to take affirmative steps to develop systems and processes to support the provisions of the proposed rule, which have cost and time implications. These additional administrative costs could lead to reduced patient access to health center services or discounted drugs.

The commenter requested HRSA clarify that to the extent that 340B covered entities have existing contracts with third-party administrators or vendors regarding established practices, deference be given to the practices in those existing contracts. However, for those covered entities that do not have established practices in place, the commenter requested that HRSA provide clear guidance on how covered entities should notify contract pharmacies so that they are aware which patients are eligible for the discounted prices.

Response: HRSA proposed a definition of ''established practices'' in the NPRM and finalizes that definition in this rule. We understand that some health centers will have to establish new practices to ensure compliance with the requirements of this rule; however, HRSA does not anticipate that the administrative costs of establishing such practices will be substantial.

13. Suggested Technical Edits to (w)(1)

One commenter suggested several edits to the NPRM language proposed at 42 CFR 51c.303(w)(1). Specifically, they suggested that the regulatory language in subsection 51c.303(w)(1), as proposed in the NPRM, be edited to replace ''through a written agreement'' with ''indirectly.'' They argued that some 340B covered entities either do not have written agreements with contract pharmacies, or do not abide by such agreements. They further suggested

that ''discounted price paid by the health center'' be replaced with ''340B Ceiling Price,'' arguing that ''ceiling price'' be more clearly defined. They also suggested several typographical edits.

Response: As the commenter noted, health centers should have written agreements with contract pharmacies used for dispensing 340B drugs. HRSA believes that the use of ''written agreements'' as proposed in the NPRM will provide greater clarity for health centers in complying with this rule. It is HRSA's intent that a health center choosing to participate in the 340B Program must provide the two life-saving medications identified in this rule either directly or through a written agreement. Other forms of ''indirect'' distribution of the drug would not be compliant with the rule. HRSA will monitor implementation of this final rule and will modify it if it is deemed that a modification is warranted.

HRSA will not at this time use ''340B Ceiling Price'' as suggested by the commenter. The Executive Order intended for low-income patients to access insulin and injectable epinephrine at no more than the price paid by the health center through the 340B Program. As it is possible that the health center may have paid less than the 340B Ceiling Price, the language proposed in the NPRM is finalized in this rule.

HRSA appreciates the commenter's identification of several typographical edits and accepts those suggestions, which are reflected in the final rule.

14. Concern Regarding Market Distortions

Two commenters expressed concern regarding market distortions. One commenter argued that the proposed rule could exacerbate market distortions, as well as create new ones. Another commenter noted that applying this policy to the insured could deflect costs from insurance plans to patients and that the policy could perpetuate a situation whereby patients with insurance may be unable to utilize the benefit in a meaningful way. The commenter argued that allowing patients with insurance to access 340B Program pricing creates a perverse incentive for insurance plans to continue shifting out-of-pocket costs for 340B drugs to patients. They argued that this undermines the purpose of insurance, and that to the extent more patients remain in the deductible phase of the benefit for all if not most of the year, the health insurance issuer does not provide any coverage for the patient's prescription.

Response: HRSA appreciates the concern expressed in these comments. However, the purpose of the Executive Order and the rule is to reduce the cost of insulin and injectable epinephrine to patients. Therefore, HRSA will finalize the rule as described.

15. Concern Regarding Additional Burden on Contract Pharmacies

One commenter noted the NPRM expressly states there will be no additional paperwork or reporting burden for health centers associated with implementation. The commenter was concerned that implementation of the proposed rule could lead to additional paperwork, reporting, and regulatory burdens for independent pharmacies operating as contract pharmacies for health centers. The commenter requested clarification in the final rule that no additional burdens will be placed on contract pharmacies.

Response: Health centers and contract pharmacies operate as private entities and make independent decisions as to their contracting arrangements. HRSA will continue to monitor the impact of this final rule on health centers and their contract pharmacy arrangements and will modify it if it is determined that a modification is warranted.

16. Rule Is Economically Significant

One commenter disagreed with the proposed rule and believed it was economically significant and that it would have an impact on small entities. The commenter requested that HRSA be required to further evaluate the costs and benefits of finalizing the proposed rule and to look at alternatives to implementing the rule.

Response: This comment is addressed in the Regulatory Impact Analysis section of this final rule.

17. Legal Sufficiency of the NPRM

One commenter argued that the NPRM does not provide legal justification and is therefore arbitrary and capricious and contrary to the Administrative Procedure Act. The commenter requested that HRSA withdraw the NPRM.

Response: HRSA has indicated the statutory authority for the NPRM and final rule as Section 330 of the PHS Act (42 U.S.C. 254b) and Section 215 of the PHS Act (42 U.S.C. 216), and is issuing the final rule pursuant to Executive Order 13937. HRSA disagrees with the commenter that the rule is arbitrary and capricious. HRSA stated in the NPRM that the ongoing Coronavirus Disease COVID–19 pandemic has caused significant hardship among many low-income individuals and, because of this and consistent with the Executive Order, HRSA is attempting to ensure two life-saving medications, insulin and injectable epinephrine, are available at affordable rates. HRSA disagrees that the NPRM and final rule are inconsistent with the Administrative Procedure Act.

18. Miscellaneous

Other commenters raised a variety of issues that do not pertain directly to the implementation of Executive Order 13937 requiring entities funded under Section 330(e) of the PHS Act to establish practices to provide access to insulin and injectable epinephrine to low-income health center patients at the price the health center purchased these two drugs through the 340B Program, which was the focus of the proposed rule. This final rule does not address those issues as they are outside the scope of the proposed rule.

VI. Regulatory Impact Analysis

HHS has examined the effects of this 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 Executive Order 13771 (''Reducing Regulation and Controlling Regulatory Costs''), and received public comments describing new administrative costs for health centers. As a result, OMB has determined this rule is regulatory for purposes of Executive Order 13771.

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 will have an economic impact of $100 million or more in any 1 year, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. Because this rule is limited in scope to two classes of drugs that are of particular need and it aligns with the mission for health centers to provide access to care for vulnerable individuals and families, HHS believes it will have minimal economic impact. The economic impact is also expected to be minimal given the rule is limited to only two drug categories which are available under the 340B Program at significantly reduced prices. Indeed, approximately 91 percent of patients at affected health centers have incomes at or below 200 percent of FPG, and thus receive discounts on health services. (In addition, health centers are required to reinvest any income from the 340B Program into patient services.) Many commenters noted that health centers already provide medications at reduced prices to their patients. For example, some health centers reported charging $7 for a 1-month supply of insulin for individuals below 200 percent of poverty. As discussed earlier, in the summary of public comments, the final rule leads to new administrative costs for health centers in association with new processes and procedures. There are approximately 1,385 health center awardees that could experience these new costs.[4] HRSA estimates that, on average, each health center would need one additional full-time equivalent (FTE) eligibility assistance worker at approximately $50,000 to support necessary additional administrative processes, totaling approximately roughly $68,750,000. Therefore, OMB has not designated this rule as ''economically significant'' under section 3(f)(1) of the Executive Order 12866. HHS welcomed but received no public comments that demonstrated this rule will have an economic impact exceeding the threshold set by E.O. 12866.

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 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 the RFA.

HHS welcomed comments concerning the impact of this proposed rule on health centers and received one comment on this topic. The commenter argued that the rule will have a significant economic impact on a substantial number of small entities. The commenter argued that the stress this rule will cause to health centers may result in reductions in services, employment, and access to life-saving treatment. Specifically, the commenter stated that the rule will have the impact of (1) dramatically reducing 340B savings for health centers, (2) likely increasing the cost of life-saving medications nationwide, and (3) creating enormous administrative burdens for health centers, specifically because the NPRM proposed defining ''low-income'' as at or below 350 percent of the FPG, a different income threshold than the 200 percent used by the Health Center Program.

HHS acknowledges the commenter's concerns. However, HHS has not changed its determination that the RFA does not apply to this rule. The comment did not demonstrate that a reduction in 340B savings would meet the threshold of a 3 percent impact on 5 percent of small entities. A reduction in 340B savings is limited to those related to these two medication categories, and only when provided to low-income patients that are uninsured, or who have a high cost sharing requirement or high unmet deductible. The comment did not demonstrate or explain how this rule will increase the cost of medications nationwide. To the contrary, the rule will increase the access of certain low-income patients to affordable insulin and injectable epinephrine.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires 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 rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This 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 rule would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision

[4] See *https://data.hrsa.gov/tools/data-reporting/program-data/national.*

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 rule is projected to have no impact on current reporting and recordkeeping burden for health centers. This rule would result in no new reporting burdens. HHS welcomed but did not receive comments that this rule would result in new reporting burdens for health centers.

List of Subjects in 42 CFR Part 51c

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

Dated: December 16, 2020.

Thomas J. Engels,

Administrator, Health Resources and Services Administration.

Dated: December 17, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Accordingly, by the authority vested in me as the Secretary of Health and Human Services, and for the reasons set forth in the preamble, 42 Code of Federal Regulations Part 51c is amended as follows:

PART 51c—GRANTS FOR COMMUNITY HEALTH CENTERS

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

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

■ 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 for funding under Section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) has indicated that it plans to distribute, either directly, or through a written agreement, drugs purchased through the 340B Drug Pricing 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 to provide insulin and injectable epinephrine at or below the discounted price paid by the health center grantee or subgrantee under the 340B Drug Pricing Program (plus a minimal administration fee) to health center patients 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. Such established practices may reflect that provision of insulin and injectable epinephrine at or below the 340B discounted price is subject to potential restrictions through contracts with third-party payors.

(ii) *Health center grantee or subgrantee.* 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 health center 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 their high deductible at any time during a plan year in which the outstanding deductible portion exceeds 20 percent of the total deductible for the plan year.

(viii) *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.

(ix) ''*Patient.*'' an individual is not be considered a ''patient'' of the health center 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.

[FR Doc. 2020–28483 Filed 12–22–20; 8:45 am]

BILLING CODE 4165–15–P

SURFACE TRANSPORTATION BOARD

49 CFR Part 1002

[Docket No. EP 758]

Filing Fee Waiver Requests

AGENCY: Surface Transportation Board.

ACTION: Final rule.

SUMMARY: The Surface Transportation Board (Board or STB) clarifies and updates its rules regarding requests to waive or reduce certain filing fees.

DATES: This rule is effective on January 22, 2021.

FOR FURTHER INFORMATION CONTACT: Jonathon Binet at (202) 245–0368. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The Independent Offices Appropriations Act (IOAA), codified at 31 U.S.C. 9701, provides that each service of value provided by an agency to a person (except those on official business of the U.S. Government) shall be self-sustaining to the extent possible and, accordingly, permits agencies to establish fees for services provided by the agency. The Office of Management and Budget (OMB) subsequently established a policy of full cost recovery for government services under which agencies must assess and collect user fees. OMB Circular A–25, User Charges (July 8, 1993). Under these authorities, the Board's predecessor—the Interstate Commerce Commission (ICC)—adopted