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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 51c

**RIN 0906–AB30**

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

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

**ACTION:** Final rule; rescission of regulations.

**SUMMARY:** HHS is rescinding the final rule entitled ''Implementation of Executive Order on Access to Affordable Life-Saving Medications,'' published in the December 23, 2020, **Federal Register** (2020 Rule). HHS is rescinding the 2020 Rule due to the excessive administrative costs and burdens that implementation would have imposed on health centers. In particular, the 2020 Rule required health centers to create and maintain new practices necessary to determine patients' eligibility to receive certain drugs at or below the discounted price paid by the health center or subgrantees plus a minimal administration fee. HHS finds the 2020 Rule's implementation would have resulted in reduced resources available to support critical services to health center patients—including those who use insulin and injectable epinephrine. HHS's consideration of the 2020 Rule's impact was informed, in part, by the demands on health centers resulting from the COVID–19 pandemic. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

**DATES:** This rule is effective November 1, 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 June 16, 2021, HHS published a Notice of Proposed Rulemaking (2021 NPRM) in the **Federal Register** (86 FR 32008) to rescind the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule. The 2021 NPRM provided for a 30-day comment period, and HHS received 332 comments. HHS carefully considered all comments in developing this rule, as outlined in Section VI below, and presents a summary of all significant comments and HHS responses.

### II. Background

HHS published the subject NPRM in the **Federal Register** on September 28, 2020 (85 FR 60748), and the 2020 Rule on December 23, 2020 (85 FR 83822). The 2020 Rule established a new requirement directing all health centers receiving grants under section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) that participate in the 340B Program (42 U.S.C. 256b), to the extent that they plan to make insulin and/or injectable epinephrine available to their patients, to provide assurances that they have established practices to provide these drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program (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 who have no health insurance.

On June 16, 2021, after a careful reassessment of the comments submitted in response to the proposed rule published at 85 FR 60748 (September 28, 2020) and consideration of the comments received on the proposed rule to delay the effective date published at 86 FR 13872 (March 11, 2021), HHS published the 2021 NPRM to rescind the 2020 Rule. The 2021 NPRM cited significant concerns regarding health centers needing to divert vital resources to implement the 2020 Rule. The 2021 NPRM requested comment on the administrative burden and costs to comply with the 2020 Rule and thus maintain eligibility for future Health Center Program grants. The 2021 NPRM also requested comment on whether a rescission would assist health centers in continuing to provide primary care services to medically underserved and vulnerable populations. HHS noted the administrative burdens associated with the 2020 Rule, particularly in light of health centers' continuing role in ensuring equitable access to COVID–19 vaccination and maintaining the capacity to provide primary and preventive care that addresses the ongoing and evolving needs of hard-to-reach and disproportionately affected populations. HHS also noted that the 2020 Rule would carry increased administrative costs and administrative burden and would result in reduced resources being available to support services to health center patients. In addition, most comments submitted previously noted that, in many cases, health centers already voluntarily provided medications at reduced prices to their patients.

The 2021 NPRM comment period ended on July 16, 2021. After review and consideration of all submitted comments, HHS has concluded that the 2020 Rule created excessive administrative burden for health centers, which in turn would have resulted in reduced resources for health center patient services. HHS has determined that the overall impacts of the administrative burden outweigh benefits to patients from the reduction in prices of insulin and injectable epinephrine. Therefore, HHS is issuing this final rule rescinding the 2020 Rule, which was published at 85 FR 83822.

The 2020 Rule became effective on July 20, 2021, prior to publication of this rescission. Due to the timing of Health Center Program funding, grants awarded in Fiscal Year 2022 would be the first opportunity for HRSA to impose the requirements of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule, and so the requirements have not yet been implemented.

### III. Statutory Authority

The statement of authority for 42 CFR part 51c cites to sections 330 (42 U.S.C. 254b) and 215 of the Public Health Service Act, (42 U.S.C. 216), respectively.

### IV. Overview of This Rule

HHS is rescinding the 2020 Rule and therefore deleting the associated revision to the regulations codified at 42 CFR 51c.303(w). 42 CFR 51c.303(w) stated: ''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.''

This final rule also states that the program term established by the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule will not be included on any Notices of Award issued to health centers receiving grant funds under section 330(e) of the Public Health Service Act. Due to the timing of Health Center Program funding, placement of that program term on health center awards would have first been applied to funds awarded in Fiscal Year 2022. As HHS has issued this final rule prior to the issuance of such awards, this program term has not been placed on Health Center Program awards.

This final rule does not revoke Executive Order 13937, which may only be revoked by executive order. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

## V. Rationale for Rescission

HHS is rescinding the 2020 Rule because the overall impact of the additional administrative costs and burden that the 2020 Rule would have placed on health centers would have harmed health centers and the patients they serve.

In implementing the requirement of the 2020 Rule, health centers would have had to absorb significant additional costs in financial resources, time, and ongoing support staff to create and maintain new reporting, monitoring, technical and administrative re-engineering, staff training, and workflow re-designs to assess eligibility based on the numerous different categories set forth in the 2020 Rule for patients to receive insulin and injectable epinephrine.

The 2020 Rule would have significantly increased the administrative burden on health centers because it would have required health centers to track and monitor in real time: (1) Whether patients were receiving insulin or injectable epinephrine through a 340B pharmacy, (2) whether patients' incomes met the threshold in the 2020 Rule (which is different from the standard used for the Health Center Program sliding fee discount schedule and therefore would have had to be calculated separately), and (3) whether patients had a high unmet deductible each time they filled their prescriptions—which may have been further complicated due to medical billing and claims processing delays or whether they had a high deductible or high cost-sharing requirement as part of their insurance plan. These burdens would have also required that health centers work with their contract pharmacies to implement these new requirements, which would have created extra administrative costs. HHS has determined that, under the 2020 Rule, health centers and pharmacies would have found it challenging to ascertain in real time a patient's eligibility for discounted pricing under the 2020 Rule based on whether or not that patient continued to have a high unmet deductible, as defined in the 2020 Rule, particularly due to delays in medical billing and claims processing.

HHS also notes that the 2020 Rule codified a new definition, applicable only to these two classes of drugs, for ''individuals with low income,'' to include those individuals with incomes at or below 350 percent of the amount identified in the Federal Poverty Guidelines (FPG). This new definition contrasted with the Health Center Program's sliding fee discount schedule requirement for Health Center Program grantees applicable to individuals with incomes at or below 200 percent of the FPG, pursuant to 42 CFR 51c.303(f). Under this subsection, health centers must establish a sliding fee discount schedule for services provided to patients with incomes between 100 and 200 percent of the FPG, with a full discount to individuals and families with annual incomes at or below 100 percent of those set forth in the FPG. Health centers also may collect nominal fees for services from individuals and families at or below 100 percent of the FPG, and no sliding fee discount may be provided to individuals and families with annual incomes greater than 200 percent of the FPG. Health centers must also demonstrate to HHS that they maintain and apply such sliding fee discount schedules to the provision of health services, which requires them to establish and maintain processes for identifying patient income levels for billing purposes consistent with these requirements.

In its decision to rescind the 2020 Rule, HHS notes the concerns expressed by the vast majority of commenters that the ''low income'' definition of 350 percent of the FPG, applicable to patients receiving these two classes of drugs, would have created significant administrative challenges for health centers. HHS is issuing this rule in recognition that the 2020 Rule would have resulted in additional administrative burden and costs, resulting in a diversion of resources from needed patient care, especially during the COVID–19 pandemic, in order to cover such increased administrative costs.

As commenters have noted, the rule would have forced health centers to construct two different eligibility systems. As the 2020 Rule's definition of ''low income'' is inconsistent with standards applied in the Health Center Program and in other comparable federal programs with an income eligibility threshold, this would have imposed new administrative burdens on health centers to implement. Furthermore, the 2020 Rule would require health center staff, who are not clinicians, to ask patients at the time of screening if they use insulin or injectable epinephrine, which may raise concerns related to the sharing of protected health information if not conducted in a confidential setting.

Rescinding the 2020 Rule prevents unnecessary costs to health centers that are on the front lines of fighting COVID–19 and providing care to millions of Americans. The 2020 Rule would have resulted in increased administrative costs and administrative burden and reduced resources available to support critical services to health center patients, including those who use insulin or injectable epinephrine and who receive other services from health centers.

## VI. Public Comments and Responses

HRSA received a total of 332 comments from the public, including: Health centers, associations and organizations representing health centers, a health center controlled network, individual health center staff and clinical professionals, individuals and organizations concerned with the high cost of insulin or injectable epinephrine, an association representing pharmacies, an association representing hospitals participating in the 340B Program, a health insurance issuer, a health innovation and research non-profit organization, a pharmaceutical manufacturer, and an association representing pharmaceutical manufacturers.

The vast majority of comments (318) favored rescission of the 2020 Rule. There were 12 comments opposing rescission of the 2020 Rule and supporting its implementation. Two remaining comments did not explicitly support or oppose the rescission of the 2020 Rule.

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. This final rule only applies to health centers funded under Section 330(e) of the Public Health Service Act, and not to other FQHCs. For consistency, this final rule uses ''health center'' throughout.

*1. Support for Rescission*

Approximately 318 commenters supported rescission of the 2020 Rule. Commenters cited a number of reasons for their support, which are summarized below.

*Comment:* Approximately 316 commenters expressed concern that the net impact of implementing the 2020 Rule would be a reduction in access to care for underserved populations. These commenters described the anticipated administrative burden and cost for health centers to implement the rule and noted that these costs would reduce resources available to provide essential primary care services to patients.

A subset of these commenters (61) detailed the specific administrative burdens and costs that would result if the 2020 Rule were implemented, including:

- Determining in real time whether a patient has a high remaining deductible. The remaining deductible amount can be inaccurate as it may change as a result of pending and delayed medical bills;
- Adjusting the charge for qualifying patients for every form of insulin and injectable epinephrine every quarter, when the 340B price changes; and
- Keeping pharmacy partners/contractors informed and ensuring their compliance with new charges and eligibility rules.

Another subset of commenters (59) also noted that HRSA estimated it would require one full-time equivalent (FTE) staff member per health center to implement the 2020 Rule, resources the commenters stated would be better spent increasing access in other ways. For example, commenters stated that one FTE would have greater impact on patient pharmaceutical access by focusing efforts such as helping patients apply to pharmaceutical manufacturers' Patient Assistance Programs and for enabling services to connect patients to other services in the community.

*Response:* HHS agrees with these commenters' concerns regarding reduced access to care resulting from the additional burden required of health centers to implement the 2020 Rule. Specifically, the 2020 Rule would necessitate some health centers redirecting resources that might have otherwise gone to support patient care to support additional staff to ascertain whether a high unmet deductible has been met in real time.

*Comment:* Approximately 305 commenters noted that the 2020 Rule's definition of ''low income'' as persons below 350 percent of the FPG was inconsistent with other federal programs. These commenters further stated that having different definitions across programs increases administrative burden of implementing the 2020 Rule.

A subset of these commenters (58) outlined specific issues that these differing ''low income'' definitions would cause for health centers implementing the 2020 Rule:

- Health centers would need to establish new policies and procedures for eligibility determinations;
- Eligibility workers would need to ask all patients if they use insulin or injectable epinephrine to appropriately screen them, which would require patients to share protected health information with non-clinicians;
- The higher income threshold would reduce health center savings on these medications, reducing revenue that could be used to support patient services for all patients; and
- A higher income threshold would reduce the cost that health centers could charge insurers for insulin and injectable epinephrine, effectively transferring savings from the health centers to insurers. The commenters explained that this is because insurance contracts generally prohibit health centers from billing insurers more than their ''usual and customary'' rate for each specific drug, and if the 2020 Rule were not rescinded, it would be very difficult for health centers to argue that the 340B price is not their usual and customary, as very few cash patients would not qualify for the 340B price.

*Response:* HHS agrees with these commenters' concerns that the definition of ''low income'' in the 2020 Rule increases the administrative burden of implementing this rule. For example, the 2020 Rule's inconsistency with current health center requirements would require health centers to create new policies, procedures, and workflows to ensure that eligible patients would be charged the 340B price or less for insulin and injectable epinephrine. Additionally, HHS shares commenters' concerns regarding the sharing of protected health information with non-clinicians.

*Comment:* Approximately 300 commenters expressed concern that implementation of the 2020 Rule would divert health center resources away from the COVID–19 pandemic response.

A subset of these commenters (57) further noted that health centers are making meaningful contributions to COVID–19 testing, treatment, and vaccination, and that these contributions are very resource-intensive. These commenters stated that reducing burden by rescinding the 2020 Rule would allow this vital work to continue.

*Response:* HHS appreciates the role health centers continue to play in the response to the COVID–19 pandemic. HHS shares commenters' concerns about the potential for implementation of the 2020 Rule to divert resources away from health centers' ongoing critical role in the COVID–19 pandemic response, stabilization, and recovery.

*Comment:* Approximately 301 commenters stated that implementing the 2020 Rule would only improve medication access for a small population of patients, and health center services would be drastically reduced for all health center patients given the increase in administrative costs and loss of 340B savings.

A subset of these commenters (59) noted that the 2020 Rule would have no impact on the overall price of the covered medications outside of the 340B Program; those prices are set by manufacturers and would not be changed by this rule. Further, these commenters stated that 90 percent of diabetic patients in the United States are not health center patients, and therefore the 2020 Rule would not impact what the majority of diabetic patients pay for insulin. Commenters also stated that health center patients with diabetes are already likely to qualify for discounted pricing through health centers.

*Response:* HHS appreciates the detail provided by commenters in support of their conclusion that the 2020 Rule would not meaningfully impact medication access for health center patients or individuals who are not health center patients. HHS agrees that the 2020 Rule would be unlikely to impact the underlying price of these two medications. HHS also agrees that the 2020 Rule would likely improve medication access for only a small population of health center patients.

*Comment:* One commenter, an association of chain drug stores, stated that the 2020 Rule would place undue burdens on 340B-covered entities as well as their contract pharmacies. The commenter also stated that the 2020 Rule had not sufficiently resolved

several concerns, including concerns regarding the need for specific guidance to 340B-covered entities for determining the patient's deductible at the pharmacy point-of-sale and communicating patient eligibility to contract pharmacies and additional clarity with respect to administration fees. The commenter argued that because these concerns were not addressed in the 2020 Rule, the proper course of action would be for HRSA to rescind the 2020 Rule.

*Response:* HHS acknowledges that the 2020 Rule would result in significant administrative burden on health centers, which may be passed on to the pharmacies with which they contract to provide access to medications.

*Comment:* One commenter, a health insurance issuer, stated support for rescinding the 2020 Rule. The commenter also stated that as HHS considers alternative approaches to implementation of Executive Order 13937, it should prioritize options that can be implemented with minimal administrative burden to the parties involved in the 340B Program, including health centers, their private sector partners, and patients served. The commenter further stated that any alternative approaches should ensure that HRSA maintains a regularly updated directory of health centers, require health centers to adjudicate 340B claims of patients who have health insurance, and require pharmacy providers to adhere to 340B claim stamping using the National Council for Prescription Drugs Programs submission clarification code.

*Response:* HHS acknowledges the comment and support for minimizing administrative burden. Alternative methods for implementation of Executive Order 13937 are beyond the scope of this rulemaking.

*2. Opposition to Proposed Rescission*

Twelve commenters opposed the proposed rescission of the 2020 Rule. Commenters cited a number of reasons for their opposition, which are summarized below.

*Comment:* Six commenters opposed HHS's proposed rescission of the 2020 Rule noting the importance of insulin and the additional costs that could be imposed on the health system if patients were not taking the necessary amounts of insulin to avoid additional complications.

*Response:* HHS shares commenters' concerns about the additional health care costs that can result from a lack of access to timely and appropriate primary health care. The fundamental purpose of the Health Center Program is to ensure access to care for underserved and vulnerable populations; Section 330 of the Public Health Service Act requires health centers to provide comprehensive primary health care to patients without regard to the patient's ability to pay. HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to help provide comprehensive primary health care to as many health center patients as possible and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit.

*Comment:* Five commenters opposed HHS's proposed rescission of the 2020 Rule noting that the cost of monthly medications poses a financial burden to patients which can be life-threatening, especially for underserved populations who depend on lower medication costs. These commenters further stated that HHS should consider the cost to patients and not just the financial burden on healthcare systems. A subset of these commenters (3) stated that if medication costs increase, these patients will likely stop taking their medication or be forced to choose between food, rent, or medication. Another subset of these commenters (2) opposed HHS's proposed rescission of the 2020 Rule noting that human life is of greater value than costs to institutions, and that the increased burden on health centers does not justify taking away affordable medications from underserved populations.

*Response:* HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to the availability of fewer resources to help provide comprehensive primary health care to as many health center patients as possible and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit. HHS believes the 2020 Rule would improve medication access for only a small percentage of health center patients while not meaningfully impacting medication access for the majority of health center patients.

*Comment:* Four commenters opposed HHS's proposed rescission of the 2020 Rule noting that they disagree with HHS's reasoning for rescinding the 2020 Rule. The commenters stated that administrative burden and administrative costs do not justify limiting access to lifesaving medications to low income patients who do not have insurance or otherwise cannot afford their medications.

*Response:* HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to help provide comprehensive primary health care to as many health center patients as possible and that decreased resources would result in the cost of the 2020 Rule outweighing its benefit. Executive Order 13937 remains in effect and HHS is exploring alternative approaches to address the high costs of prescription drugs, such as insulin or injectable epinephrine.

*Comment:* Two commenters opposed HHS's proposed rescission of the 2020 Rule noting that health care institutions (including health centers) can address increasing costs of providing essential programs, including during the COVID–19 pandemic, without HHS rescinding this rule. Comments included suggested alternative health center cost cutting methods such as allocating resources, improving workflows, and using employee retention strategies.

*Response:* HHS is rescinding the 2020 Rule to maximize resources health centers have to provide access to high quality, comprehensive primary health care in the most efficient way and to as many health center patients as possible. HHS believes the 2020 Rule would improve medication access for only a small percentage of health center patients. Examining other cost cutting measures to decrease the burden on health centers is beyond the scope of this proposed rulemaking.

*Comment:* Two commenters opposed HHS's proposed rescission of the 2020 Rule noting that it would benefit numerous health center patients through greater access to affordable insulin and it should be kept for that reason. One of those commenters further noted that, unlike patients under 200 percent of the FPG who already receive significant discounts from health centers and would be less impacted by the 2020 Rule, patients between 200 and 350 percent of the FPG would greatly benefit from this rule going into effect.

*Response:* While the 2020 Rule would likely provide benefits to a small number of health center patients with diabetes and severe allergic reactions, HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

*Comment:* One commenter opposed HHS's proposed rescission of the 2020

Rule noting that HHS should not place a charge on American families to pay for administrative costs at health centers, nor administrative costs caused by the COVID–19 pandemic.

*Response:* HHS appreciates this comment and is committed to maximizing resources for health centers to provide comprehensive primary health care to health center patients without regard for patients' ability to pay.

*Comment:* One commenter opposed HHS's proposed rescission of the 2020 Rule noting that it would allow health centers to divert resources to other services at the expense of the community's health needs during the COVID–19 pandemic, specifically, access to the lifesaving medications of insulin and injectable epinephrine.

*Response:* HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible, including those who use insulin or injectable epinephrine, and that decrease in resources would result in the cost of the 2020 Rule outweighing its benefit. In addition, as noted in the 2020 Rule, in many cases, health centers already voluntarily provide medications, including insulin and injectable epinephrine, to their patients at reduced prices.

*Comment:* One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule noting that most of its insulin products are available to covered entities for pennies and rescinding the 2020 Rule would make covered entity patients pay more for the medications. The commenter also noted that covered entity patients in most cases could receive larger discounts from the company's own discount programs for medications.

*Response:* Nothing in this rule rescinding the 2020 Rule prohibits health center patients from accessing pharmaceutical company and charity discount programs to find the most affordable medications, including for insulin or injectable epinephrine.

*Comment:* One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that it provides insulin to several charitable organizations including its own foundation, which provide insulin for free for qualifying patients at or below 400 percent of FPG and covered entities should be held to the same standard. Additionally, this commenter noted that it participates in a number of programs that allow patients, regardless of their income, to purchase insulin at no more than $35 a month.

*Response:* HHS commends those who are working to ensure underserved patients are able to access discounted medications. As noted above, HHS is concerned that the increased costs due to the extra administrative burden placed on health centers to comply with the 2020 Rule would lead to fewer resources available to provide comprehensive primary health care to as many health center patients as possible, including those who use insulin or injectable epinephrine.

*Comment:* One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that grantees that are covered entities under the 340B Program should not be able to charge large markups on drugs purchased through the 340B Program to uninsured or underinsured individuals to fund their operations.

*Response:* With regard to the commenter's concern regarding the general requirements of the 340B Program, those requirements, including charges for drugs purchased through the 340B Program by covered entities, are beyond the scope of this rulemaking.

*Comment:* One commenter, a pharmaceutical manufacturer, opposed HHS's proposed rescission of the 2020 Rule, noting that the commenter is able to verify income and insurance information with minimal burden and that six covered entities have worked with the commenter to provide insulin to their patients for pennies, demonstrating that the 2020 Rule would not be overly burdensome.

*Response:* HHS has concerns that under the 2020 Rule's definition of ''high unmet deductible,'' health centers and pharmacies with which they contract may find it challenging to ascertain in real time a patient's eligibility for pricing based on whether or not the patient continues to have a ''high unmet deductible'' that meets the 2020 Rule's definition of the term. The 2020 Rule defined ''high unmet deductible'' as ''the amount 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.'' Determining whether a patient's plan year spending toward their deductible meets this definition has the potential to be particularly challenging due to medical billing and claims processing delays. For these and other reasons, HHS believes the administrative burden and costs the 2020 Rule places on health centers outweigh the benefits.

*3. General Comments*

*Comment:* One commenter, an association of pharmaceutical manufacturers, while not opposing rescission of the 2020 Rule, noted that the 340B Program has grown exponentially in recent years without a commensurate benefit to the underserved patients.

*Response:* The growth of the 340B Program is beyond the scope of this rulemaking.

*Comment:* One commenter stated that the 340B Program is essential to the well-being of all patients that receive care at health centers and asked that the 340B Program be kept in place.

*Response:* HHS acknowledges the importance of the 340B Program to patients served by health centers. This rulemaking does not change the 340B Program.

*4. Request To Revoke Executive Order 13937*

*Comment:* Approximately 300 commenters urged revocation of the ''Executive Order on Access to Affordable Lifesaving Medications,'' on which the 2020 Rule was based. These commenters expressed many concerns with the underlying Executive Order and requested that it be revoked.

*Response:* Revoking Executive Order 13937, ''Access to Affordable Lifesaving Medications'' is beyond the authority of HHS and outside the scope of this final rule.

*5. Miscellaneous*

Other commenters raised a variety of issues that HHS determined did not pertain to the rescission of the 2020 Rule. This rulemaking does not address those issues as they are outside of its scope.

## VII. Regulatory Impact Analysis (RIA)

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).

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). HRSA estimates that, on average, each health center would have needed to hire one additional full-time equivalent (FTE) eligibility assistance worker at approximately $50,000 to support necessary additional administrative processes, totaling approximately $68,750,000 across health centers.

As stated in the RIA for the 2020 Rule, HRSA determined that the 2020 Rule was not economically significant, given that the administrative burden of $68.7 million described above fell below the ''economically significant'' threshold of $100 million. HRSA relies on that same analysis now, finding that rescission of that rule will have an economic impact of the same amount, $68,750,000, in administrative savings to health centers, and that such amount is below the ''economically significant'' threshold of $100 million. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options for implementation.

HHS welcomed but did not receive comments on whether the proposed rescission of the 2020 Rule is a ''significant regulatory action'' under Section 3(f) of Executive Order 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. As we did in the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' 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 by 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 September 31, 2020, the Health Center Program provides grant funding under section 330(e) of the Public Health Service Act to 1,315 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 purposes of the RFA. HHS estimates the economic impact on small entities as a result of rescinding the 2020 Rule will be minimal. HHS welcomed but did not receive comments concerning the economic impact of the proposed rescission of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule on health centers for the purposes of the RFA.

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.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. As stated in the RIA for the 2020 Rule, HRSA determined that the administrative burden of $68.75 million described above fell below the Unfunded Mandates Reform Act's threshold of $158 million. HRSA relies on that same analysis now, finding that rescission of that rule will have an economic impact of the same amount, $68.75 million in administrative savings to health centers, and that such amount is below the threshold of $158 million.

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 will 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 will 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 rule is projected to have no impact on current reporting and recordkeeping burden for health centers. This rule will 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.

Dated: September 28, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

**List of Subjects in 42 CFR Part 51c**

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

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 citation for part 51c is revised to read as follows:

**Authority:** Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254b); sec. 215, Public Health Service Act, 58 Stat. 690, (42 U.S.C. 216).

**§ 51c.303 [Amended]**

■ 2. Amend § 51c.303 by removing paragraph (w).

[FR Doc. 2021–21457 Filed 9–30–21; 8:45 am]

**BILLING CODE 4165–15–P**

## NATIONAL SCIENCE FOUNDATION

### 45 CFR Part 670

**RIN 3145–AA63**

## Conservation of Antarctic Animals and Plants; Correction

**AGENCY:** National Science Foundation.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects the Regulation Identification Number that appeared in a final rule published in the **Federal Register** on May 25, 2021, regarding changes to changes to Annex II to the Protocol on Environmental Protection to the Antarctic Treaty (Protocol) agreed to by the Antarctic Treaty Consultative Parties.

**DATES:** This final rule correction is effective October 1, 2021.

**FOR FURTHER INFORMATION CONTACT:** Bijan Gilanshah, Assistant General Counsel, Office of the General Counsel, at 703–292–8060, National Science Foundation, 2415 Eisenhower Avenue, W 18200, Alexandria, VA 22314.

**SUPPLEMENTARY INFORMATION:**

*Correction*

In final rule FR Doc. 2021–10807, beginning on page 27985 in the issue of May 25, 2021, make the following correction: On page 27985, in the third column, the Regulation Identifier Number is corrected to read ''RIN 3145–AA63.''

Dated: September 28, 2021.

**Suzanne H. Plimpton,**

*Reports Clearance Officer, National Science Foundation.*

[FR Doc. 2021–21365 Filed 9–30–21; 8:45 am]

**BILLING CODE 7555–01–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 25, 63 and 73

**[IB Docket No. 21–265; FCC 21–87; FR ID 39973]**

## Mandatory Electronic Filing of Applications and Reports Administered by the International Bureau

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** In this document, the Commission requires that any remaining applications and reports administered by the International Bureau and filed on paper or through an alternative filing process be filed only electronically through the Commission's International Bureau Filing System. Specifically, the Commission modifies its rules to mandate the electronic filings of applications for permits to deliver programs to foreign stations, applications for International High Frequency Broadcast Stations, and quarterly reports filed by U.S.-authorized carriers that are affiliates of foreign carriers with market power on the foreign end of a U.S.-international route, and to remove a duplicate paper filing requirement for satellite cost-recovery declarations.

**DATES:** Effective October 1, 2021.

**FOR FURTHER INFORMATION CONTACT:** Jocelyn Jezierny, Telecommunications and Analysis Division, International Bureau, *Jocelyn.Jezierny@fcc.gov,* 202–418–0272.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order, FCC 21–87, adopted and released on July 13, 2021. The full text of this document is available at *https://docs.fcc.gov/public/attachments/FCC-21-87A1.pdf.* To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

### Final Regulatory Flexibility Analysis

Because these rule changes are being adopted without notice and comment, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* does not apply to this Order.

### Paperwork Reduction Act

This Order does not contain new or substantively modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, 44 U.S.C. 3501–3520. Specifically, the changes to existing information collections, including mandatory electronic filing for Section 325(c) Applications, IHF Applications, and Dominant Carrier Section 63.10(c) Quarterly Reports are non-substantive. Because these changes are non-substantive, there is also no new or modified information collection burden for small business concerns with fewer than 25 employees pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

After the adoption and release of this Order, the Commission submitted the changes to the Office of Management and Budget (OMB) and received the OMB approvals. The Commission also received emergency approval from OMB for certain requirements that were inadvertently omitted from existing information collections. The relevant OMB Control numbers are 3060–0678, 3060–0686, 3060–1035, 3060–1133, and 3060–1290.

### Congressional Review Act

The Commission will not send a copy of this Order to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties.

### Synopsis

### I. Introduction

1. Over the past decades, the Commission has made significant progress to upgrade and modernize its licensing systems and filing procedures.[1] Today, we continue these efforts and require that any remaining applications and reports administered by the International Bureau and filed on paper or through an alternative filing process be filed only electronically through the Commission's International

[1] *See, e.g., International Bureau Announces a Change in the Procedure for Filing Coordination Notifications for Earth Stations on Vessels Operating in the C-Band,* Public Notice, DA 11–132, 26 FCC Rcd 564 (IB 2011) (requiring coordination notification for Earth Stations on Vessels operating in the C-band to be filed electronically via the International Bureau Filing System (IBFS)); *Completing the Transition to Electronic Filing, Licenses and Authorizations, and Correspondence in the Wireless Radio Services,* Order, 35 FCC 10781 (2020) (*2020 Wireless Radio Order*) (requiring electronic filing of certain applications for licenses in the Wireless Radio Services); *Amendment of Certain of the Commission's Part 1 Rules of Practice and Procedure and Part 0 Rules of Commission Organization,* Order, 29 FCC Rcd 14955 (2014) (requiring electronic filing of certain applications under sections 214(a) and 251(c)(5) of the Communications Act of 1934, as amended (Act)).