- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rulemaking, which proposes to approve Maryland's certification that Maryland's SIP-approved emissions statement regulation meets the emissions statement requirement of section 182(a)(3)(B) of the CAA, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: May 28, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–11924 Filed 6–15–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906–AB25

Proposed Rescission of Executive Order 13937, ''Executive Order on Access to Affordable Life-Saving Medications''

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

ACTION: Proposed rule.

SUMMARY: The Department of Health and Human Services (HHS) proposes to rescind the final rule entitled ''Implementation of Executive Order on Access to Affordable Life-Saving Medications,'' published in the December 23, 2020, **Federal Register**. HHS is proposing the rescission due to undue administrative costs and burdens that implementation would impose on health centers. In particular, the final rule would require health centers to create and sustain new practices necessary to determine patients' eligibility to receive certain drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program, resulting in reduced resources available to support critical services to their patients—including those who use insulin and injectable epinephrine. These challenges would be significantly exacerbated by the multitude of demands on health centers related to the COVID–19 pandemic. HHS is seeking public comment on this notice of proposed rulemaking (NPRM). As Executive Order 13937 remains in effect, should the final rule be rescinded, other implementation approaches will be considered to effectuate the Executive Order.

DATES: Written comments and related material to this proposed rule must be received to the online docket via *https://www.regulations.gov* on or before July 16, 2021.

ADDRESSES: Comments must be identified by HHS Docket No. HRSA–2021–0003 and submitted electronically to the Federal eRulemaking Portal at *https://www.regulations.gov*. Follow the instructions for submitting comments. Comments and attachments will be posted to the docket unchanged. Because your comments will be made public, you are solely responsible for ensuring that your comments do not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information. Additionally, if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted.

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

SUPPLEMENTARY INFORMATION:

I. Background

HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** on September 28, 2020 (85 FR 60748), and a final rule on December 23, 2020 (85 FR 83822) entitled, ''Implementation of Executive Order on Access to Affordable Life-Saving Medications.'' This rule established a new requirement directing all health centers receiving grants under section 330(e) of the Public Health Service (PHS) 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.

Pursuant to the January 20, 2021, memorandum from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' and OMB Memorandum M–21–14, the effective date of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule, published in the December 23, 2020, **Federal Register** (85 FR 83822), was delayed from January 22, 2021, to March 22, 2021 (86 FR 7069), to give HHS officials the opportunity for further review and consideration of the rule.

On March 11, 2021 (86 FR 13872), HHS published a proposed rule to further delay the effective date of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule. On March 22, 2021, the effective date of the

''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule was delayed to July 20, 2021 (86 FR 15423), to allow HHS an additional opportunity to review and consider further questions of fact, law, and policy that may be raised by the rule, including whether revision or withdrawal of the rule may be warranted.

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 published at 86 FR 13872 (March 11, 2021), HHS is proposing in this NRPM to rescind the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule. As set forth more specifically below, HHS has significant concerns regarding health centers needing to divert vital resources to implement this rule, as the administrative burden and cost necessary to comply with the rule and thus maintain eligibility for future grants has the potential to constrain health centers' ability to provide ongoing primary care services to medically underserved and vulnerable populations. HHS has reconsidered previously submitted comments regarding the administrative burdens associated with the rule in light of the significantly increased, long-term reliance on health centers in responding to the COVID–19 pandemic, particularly related to health centers' role in addressing health equity and vaccine delivery for hard-to-reach and disproportionately affected populations that were not readily apparent at the time the rule was finalized in December 2020. Moreover, this rule will result in a loss of revenue from 340B savings for health centers participating in the 340B Program and this loss, along with increased administrative costs and administrative burden, will result in reduced resources being available to support services to health center patients. In addition, most commenters noted that, in many cases, these health centers already provide medications at reduced prices to their patients.

HHS has considered comments submitted by commenters prior to the final rule's promulgation and in response to the proposed rule published at 86 FR 13872 (March 11, 2021) in the development of this NPRM and will consider new comments submitted in response to this NPRM.

II. Statutory Authority

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

III. Discussion of Proposed Rule

HHS is proposing to rescind the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule. As the final rule has not become effective, this NPRM proposes that the existing regulation remain unchanged. In particular, this NPRM proposes to rescind the final rule and retract the related requirement for awarding new grants under section 330(e) of the PHS Act (42 U.S.C. 254b) that the awardee offering insulin and injectable epinephrine to its patients 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 NPRM proposes to rescind the rule that amended 42 CFR 51c.303, by deleting paragraph (w). This NPRM also proposes that the Program Term established by the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule not be included on any Notices of Award issued to health centers receiving grant funds under section 330(e) of the Act.

HHS is proposing to rescind this rule because, although certain health center patients might benefit from it, the additional costs and burden the rule would place on health centers could harm the program and the patients it serves as a whole. Allowing this final rule to become effective would increase the burden on health centers and divert necessary resources from patient care to the administration of new processes. In order to implement this new requirement, health centers would need to absorb significant additional cost, 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 for patients to receive insulin and injectable epinephrine consistent with the final rule.

Other more specific administrative burdens and costs imposed by the final rule that were shared by commenters included the need for health center staff to track patients' eligibility for the pricing described in the rule as it relates to: (1) Whether patients are receiving insulin or injectable epinephrine through a 340B pharmacy, (2) whether patients' incomes meet the threshold in the rule (which is different from that used for the Health Center Program sliding fee discount schedule and therefore has to be calculated separately), and (3) whether patients have a high unmet deductible each time they fill their prescriptions—which may be further complicated due to the delay in medical billing and claims processing—or whether they have a high deductible or high cost-sharing requirement as part of their insurance plan. These burdens would also extend to ensuring that all relevant information is transmitted to contract pharmacies. HHS has concerns that under the final rule, health centers and pharmacies with whom they contract may find it challenging to ascertain a patient's eligibility for pricing under this rule based on whether or not that patient continues to have a high unmet deductible in real time, particularly due to delays in medical billing and claims processing.

HHS is also concerned that the final rule creates a new required definition, applicable only to these two classes of drugs, of ''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 required definition is in contrast with the Health Center Program's required use of a sliding fee discount schedule standard 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). Health centers must currently 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. Therefore, given the differences between these standards,

HHS agrees with the concerns expressed by a substantial majority of commenters that describing ''low income'' as 350 percent of FPG for the purpose of the rule would require the establishment of a new, distinct, and higher ''low income'' threshold applicable to these two classes of drugs, and that applying this distinct standard for purposes of billing for these drugs would create significant administrative challenges for health centers. HHS shares commenters' concerns regarding the undue administrative burden and costs of the rule and the resulting diversion of resources from needed patient care, especially during the COVID–19 pandemic, in order to cover such increased administrative costs.

HHS also shares commenters' concerns that defining ''individuals with low incomes'' at 350 percent of FPG imposes the additional burden and cost of creating and operating two different eligibility systems. This definition of ''low income'' is inconsistent with standards applied in other comparable federal programs. Commenters noted that every federal program with an income eligibility threshold defines ''low income'' as 250 percent of the FPG or less. Commenters further noted that, while the Patient Protection and Affordable Care Act uses a ceiling of 400 percent of the FPG 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 income individuals. 26 U.S.C. 36B(b)(3)(A)(i).

Finally, commenters expressed concerns that the rule was based on a fundamental misunderstanding of the 340B Program since health centers are already required by the Health Center Program to use any savings to benefit their patient population (42 U.S.C. 254b(e)(5)(D)). HHS shares their concerns that this rule will result in a loss of 340B revenue for health centers participating in the 340B Program, and that this loss, along with increased administrative costs and administrative burden, will result in 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. HHS is undertaking this unusual step of issuing this NPRM to understand more about these concerns and to propose a potential rescission of this rule.

HHS invites comment on this NPRM proposing to rescind the final rule ''Implementation of Executive Order on Access to Affordable Life-Saving Medications.''

IV. Regulatory Impact Analysis (RIA)

HHS has examined the effects of this NPRM 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 need 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 final rule published December 23, 2020, HRSA determined that the rule is not economically significant, given that the administrative burden of $68.7 million described above falls 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. Also, as stated in the December 23, 2020 final rule, a number of patients served at health centers and covered by that final rule may already receive these two medications at reduced prices, further reducing the economic significance of this proposed rescission. In order to determine whether the proposed rescission of the rule is a ''significant regulatory action'' under Section 3(f) of Executive Order 12866, HHS welcomes comments concerning the economic impact of this proposed rescission of the ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule or implementation of the proposed rescission on the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

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'' final 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 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 NPRM would 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 ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' final rule would be minimal. HHS welcomes comments concerning the economic impact of this NPRM on health centers.

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 NPRM to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this NPRM in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' This NPRM 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 NPRM would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act of 1995

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

List of Subjects in 42 CFR Part 51c

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

Dated: June 10, 2021.

Xavier Becerra,

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 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. 2021–12545 Filed 6–15–21; 8:45 am]

BILLING CODE 4165–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 21–221; RM–11908; DA 21–600; FR ID 29165]

Television Broadcasting Services Las Vegas, Nevada

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Scripps Broadcasting Holdings, LLC (Petitioner), the licensee of KTNV–TV (ABC), channel 13, Las Vegas, Nevada. The Petitioner requests the substitution of channel 26 for channel 13 at Las Vegas in the DTV Table of Allotments.

DATES: Comments must be filed on or before July 16, 2021 and reply comments on or before August 2, 2021.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 45 L Street NE, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for the Petitioner as follows: Daniel Kirkpatrick, Esq., Baker & Hostetler, LLP, 1050 Connecticut Avenue NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at (202) 418–1647; or Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov*.

SUPPLEMENTARY INFORMATION: In support of its channel substitution request, the Petitioner states that the Commission has recognized that VHF channels have certain characteristics that pose challenges for their use in providing digital television service, including propagation characteristics that allow undesired signals and noise to be receivable at relatively far distances and nearby electrical devices to cause interference. According to the Petitioner, it has received many complaints from viewers unable to receive a reliable signal on channel 13. In addition, the Petitioner demonstrated that its proposal would result in a loss area of 460.9 square kilometers, containing only five people who will continue to receive service from two other full power television stations.

This is a synopsis of the Commission's *Notice of Proposed Rulemaking,* MB Docket No. 21–221; RM–11908; DA 21–600, adopted May 21, 2021, and released May 21, 2021. The full text of this document is available for download at *https://www.fcc.gov/edocs*. To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed 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). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

Members of the public should note that all *ex parte* contacts are prohibited from the time a Notice of Proposed Rulemaking is issued to the time the matter is no longer subject to Commission consideration or court review, *see* 47 CFR 1.1208. There are, however, exceptions to this prohibition, which can be found in Section 1.1204(a)