Revision 4.4, EMMC Version, 1994. Available on the internet at *https://www.epa.gov/esam/method-2007-determination-metals-and-trace-elements-water-and-wastes-inductively-coupled-plasma.*

(ii) Method 537.1 ''Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry,'' Version 2.0, 2020. Available on the internet at *https://www.epa.gov/water-research/epa-drinking-water-research-methods.*

(iii) Method 533 ''Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry,'' November 2019, EPA 815–B–19–020. Available on the internet at *https://www.epa.gov/dwanalyticalmethods.*

(2) American Public Health Association, 800 I Street NW, Washington, DC 20001–3710.

(i) ''Standard Methods for the Examination of Water & Wastewater,'' 23rd edition (2017).

(A) SM 3120 B ''Metals by Plasma Emission Spectroscopy (2017): Inductively Coupled Plasma (ICP) Method.''

(B) [Reserved]

(ii) The following methods are from ''Standard Methods Online.'' Available for purchase on the internet at *https://www.standardmethods.org.*

(A) SM 3120 B ''Metals by Plasma Emission Spectroscopy: Inductively Coupled Plasma (ICP) Method (Editorial Revisions, 2011),'' (SM 3120 B–99)

(B) [Reserved]

(3) ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959.

(i) ASTM D1976–20 ''Standard Test Method for Elements in Water by Inductively-Coupled Plasma Atomic Emission Spectroscopy,'' approved May 1, 2020. Available for purchase on the internet at *https://www.astm.org/Standards/D1976.htm.*

(ii) [Reserved]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906–AB25

Implementation of Executive Order on Access to Affordable Life-Saving Medications; Delay of Effective Date

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

ACTION: Proposed delay of effective date; request for comments.

SUMMARY: In accordance with the Presidential directive as expressed in the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' this action proposes, following a 5-day public comment period, to further delay until July 20, 2021, the effective date of the rule entitled ''Implementation of Executive Order on Access to Affordable Life-saving Medications'' published in the **Federal Register** on December 23, 2020. That final rule is currently scheduled to take effect on March 22, 2021, after an initial delay from its original effective date of January 22, 2021. HHS seeks comments on this proposed delay of the effective date to July 20, 2021, which would allow it additional opportunity for review and consideration of the new rule. HHS will take comments about issues of fact, law, and policy raised by rule into account as the rule is reviewed during the delay period.

DATES: The effective date for the final rule published December 23, 2020, at 85 FR 83822, delayed January 26, 2021, at 86 FR 7059, is proposed to be further delayed until July 20, 2021. Written comments and related material to this proposal must be received to the online docket via *https://www.regulations.gov* on or before March 14, 2021.

ADDRESSES: You may submit written comments electronically by the following method: *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the website for submitting comments.

Instructions. Include the HHS Docket No. HRSA–2021–0002 in your comments. All comments received will be posted without change to *http://www.regulations.gov.* Please do not include any personally identifiable or confidential business information you do not want publicly disclosed.

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

SUPPLEMENTARY INFORMATION: HHS published a notice of proposed rulemaking in the **Federal Register** on September 28, 2020 (85 FR 60748), and a final rule on December 23, 2020 (85 FR 83822), delayed on January 26, 2021, at 86 FR 7069. The final rule, ''Implementation of Executive Order on Access to Affordable Life-Saving Medications,'' 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 Drug Pricing Program (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 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.

The January 20, 2021, memorandum from the Assistant to the President and Chief of Staff, entitled ''Regulatory Freeze Pending Review,'' instructed Federal agencies to consider delaying the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days so that the new Administration may review recently published rules for ''any questions of fact, law, and policy the rule may raise.'' The ''Implementation of Executive Order on Access to Affordable Life-Saving Medications'' rule falls within this category. On January 20, 2021, the Office of Management and Budget (OMB) also published OMB Memorandum M–21–14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, which provides guidance regarding the Regulatory Freeze Memorandum. See M–21–14, Implementation of Memorandum Concerning Regulatory Freeze Pending Review, *https://www.whitehouse.gov/wp-content/uploads/2021/01/M-21-14-Regulatory-Review.pdf.* OMB Memorandum M–21–14 explains that pursuant to the Regulatory Freeze Memorandum, agencies ''should

consider postponing the effective dates for 60 days and reopening the rulemaking process'' for ''rules that have not yet taken effect and about which questions involving law, fact, or policy have been raised.'' *Id.* In accordance with the Regulatory Freeze Memorandum and OMB M–21–14, HHS proposes to delay the effective date of the December 23, 2020, final rule entitled ''Implementation of Executive Order on Access to Affordable Life-saving Medications'' to July 20, 2021.

In addition, consistent with Regulatory Freeze Memorandum and OMB Memorandum M–21–14, the delay of the final rule would provide HHS additional time to review and consider further, questions of fact, law, and policy the rule may raise, including whether revision or withdrawal of the rule may be warranted. HHS is particularly interested in further consideration of previous comments regarding the impact of the rule's administrative requirements, costs of new processes and procedures that would be necessary under the rule, the impact of the establishment of a new income eligibility threshold for health center operations, and the overall impact on care delivery and service levels for health center patients. HHS is also interested in further review of the comments acknowledged in the final rule and additional information regarding these areas received by HHS subsequent to the issuance of the final rule. Specifically, comments acknowledged in the final rule expressed the concern that the rule would 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 Federal Poverty Level (FPL), a different income threshold than the 200 percent of FPL used by the Health Center Program to apply statutory requirements for sliding fee discount schedules under the Health Center Program's authorizing statute.

HHS believes that the proposed delay is reasonable, would allow HHS time to receive public comment, and would not be disruptive since the underlying rule has not yet taken effect, and since neither HHS nor health centers have undertaken the administrative costs associated with implementation of the final rule.

HHS seeks comment on the proposed delay, including the proposed delay's impact on any legal, factual, or policy issues raised by the underlying rule and whether further review of those issues warrants such a delay. HHS also will consider comments on the substance of the rule as the rule is reviewed during the delay period. HHS therefore seeks comment by March 14, 2021, on its proposal to extend the effective date to July 20, 2021.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

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