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 85 FR 70599, 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 josephb@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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