

Where:

$K_5 = 4.3209$ for metric units = 0.09450 for English units.

* * * *

16.1.1.4 Calculate flow rate, Q , for each run using the wet test meter volume, V_w , and the run time, θ . Calculate the DGM coefficient, Y_{ds} , for

each run. These calculations are as follows:

$$Q = K_1 \frac{P_{bar} V_w}{(T_w + T_{std}) \theta} \quad Eq. 5-9$$

$$Y_{ds} = \frac{V_w (T_{ds} + T_{std}) P_{bar}}{V_{ds} (T_w + T_{std}) (P_{bar} + \frac{\Delta p}{13.6})} \quad Eq. 5-10$$

Where:

$K_1 = 0.38572$ °K/mm Hg for metric units = 17.636 °R/in. Hg for English units.

V_w = Wet test meter volume, liter (ft3).

V_{ds} = Dry gas meter volume, liter (ft3).

T_{ds} = Average dry gas meter temperature, °C (°F).

$T_{adj} = 273.15$ °C for metric units = 459.67 °F for English units.

T_w = Average wet test meter temperature, °C (°F).

P_{bar} = Barometric pressure, mm Hg (in. Hg).

Δp = Dry gas meter inlet differential pressure, mm H₂O (in. H₂O).

θ = Run time, min.

* * * *

16.2.3.3 Calculate the standard volumes of air passed through the DGM and the critical orifices, and calculate the DGM calibration factor, Y , using the equations below:

$$V_{m(std)} = \frac{K_1 V_m [P_{bar} + (\frac{\Delta H}{13.6})]}{T_m} \quad Eq. 5-12$$

$$V_{cr(std)} = K' \frac{P_{bar} \theta}{\sqrt{T_{amb}}} \quad Eq. 5-13$$

$$Y = \frac{P_{bar} \theta}{V_{m(std)}} \quad Eq. 5-14$$

Where:

$V_{cr(std)}$ = Volume of gas sample passed through the critical orifice, corrected to standard conditions, dscm (dscf).

$K_1 = 0.38572$ °K/mm Hg for metric units = 17.636 °R/in. Hg for English units.

* * * *

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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; Final Rule; Delay of Effective Date

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

ACTION: Final rule; delay of effective date.

SUMMARY: This final rule implements a further delay until July 20, 2021, of 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. This rule was scheduled to take effect on March 22, 2021, after a delay from its original effective date of January 22, 2021. HHS is delaying the effective date of the rule to July 20, 2021, to ensure that implementation of the rule does not impede HHS’s and health centers’ immediate priority work, on a nationwide basis, of responding to and mitigating the spread of COVID-19, including ensuring widespread and equitable access to COVID-19 vaccines, and maintaining the delivery of comprehensive primary health services to medically underserved populations, while considering how to address administrative/implementation issues raised by commenters and further address comments regarding the impact of the rule.

DATES: As of March 22, 2021, the effective date of the final rule published at 85 FR 83822 (December 23, 2020), which was delayed at 86 FR 7059

(January 26, 2021), is further delayed until July 20, 2021.

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:

I. Public Participation

On March 9, 2021, the Office of the Federal Register placed a HHS notice of proposed rulemaking (NPRM) on file for public inspection. This NPRM was published in the **Federal Register** on March 11, 2021, proposing 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. The comment period closed on March 14, 2021, with HHS receiving 198 comments on the proposed delay.

Section 553(d) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et*

seq.) requires that Federal agencies provide at least 30 days after publication of a final rule in the **Federal Register** before making it effective, unless good cause can be found not to do so. HHS finds that there is good cause for making this final rule effective less than 30 days after publication in the **Federal Register** given that failure to do so would result in the final rule going into effect before the delay begins. Allowing for a 30-day delay between publication and the effective date is both unnecessary and impracticable, as it would undermine this rule's objective of delaying the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule so that HHS can fully review it for questions of law, policy, and fact.

HHS has considered all comments in finalizing this rule, as outlined in Section III below, and presents a summary of all significant comments and HHS responses.

II. Background

HHS published a NPRM in the **Federal Register** on September 28, 2020 (85 FR 60748), and a final rule on December 23, 2020 (85 FR 83822). The 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 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.

As stated in the NPRM, consistent with Regulatory Freeze Memorandum and OMB Memorandum M-21-14, a delay of the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule will 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 invited comments on 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.

After HHS review of submitted comments, HHS believes that this delay is reasonable, and will allow HHS to consider the impact that the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule may have. The delay will also ensure that, consistent with concerns raised by commenters, implementation of the rule does not impede HHS's and health centers' immediate priority work, on a nationwide basis, of responding to and mitigating the spread of COVID-19, including ensuring equitable access to COVID-19 vaccines, and maintaining the delivery of comprehensive primary health services to medically underserved populations, while considering how to address administrative/implementation issues raised by commenters and further address comments regarding the impact of the rule. In addition, the delay will not be disruptive since the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule has not yet taken effect and neither HHS nor health centers have undertaken the administrative changes associated with implementation of the rule.

III. Public Comments and Responses

Consistent with Regulatory Freeze Memorandum and OMB Memorandum M-21-14, HHS requested comment on whether a 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 stated that it would further consider comments regarding the impact of the rule's administrative requirements, costs of new processes and procedures that would be necessary under the "Implementation of Executive Order on Access to Affordable Life-saving Medications" 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 received a total of 198 comments. Commenters identified themselves as individuals requiring insulin or injectable epinephrine and their family members, health centers, associations and organizations representing health centers, a

professional organization, a diabetes research foundation, a pharmaceutical manufacturer, and clinical professionals. The vast majority of comments (187) favored a further delay in the effective date of the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule. Three comments opposed further delay of the effective date for the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule and supported implementation of the rule, though one commenter opposed to a further delay also urged HHS to take steps to limit administrative burden to health centers. The remaining comments did not explicitly support or oppose the delay.

Many commenters (175), including many health centers, primary care associations, and a number of other individuals and organizations, including a Health Care Controlled Network and a Medicaid Accountable Care Organization, also strongly urged that the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule be rescinded. Three commenters supported implementation of the "Implementation of Executive Order on Access to Affordable Life-saving Medications" rule, although one of those commenters also supported a delay to allow health centers time to come into compliance with the regulation.

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

1. Delay Implementation Based on "Regulatory Freeze Pending Review" Memo

Approximately 181 commenters supported the delay as consistent with the "Regulatory Freeze Pending Review" issued by the White House Chief of Staff on January 20, 2021. Specifically, commenters noted that this delay aligns with the Regulatory Freeze language to delay implementation "where necessary to continue to review these questions of fact, law, and policy," and acknowledged the effort required for HHS to address those questions.

Response: HHS appreciates these comments and agrees that delaying the

effective date of this final rule is consistent with the intent of the “Regulatory Freeze Pending Review” memorandum.

2. Delay Implementation Based on Health Centers’ Role in National COVID-19 Vaccination Campaign

Approximately 169 commenters suggested that the impact of implementing the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule on health centers’ efforts to vaccinate hard-to-reach populations against COVID-19 should be considered as a new issue of “fact, law, and policy,” necessitating a further delay. These commenters noted that since the rule was initially delayed in January, health centers have been requested to perform a critical role in the national efforts to vaccinate hard-to-reach populations. Commenters stated that, in taking on this responsibility, health centers’ staff and resources are being stretched to unprecedented levels, making the administrative and financial burden of implementing the rule even more challenging.

Response: HHS agrees that health centers’ need to focus efforts on expeditiously vaccinating their patient populations against COVID-19, including as part of the Health Center COVID-19 Vaccine Program, is a factor that supports a further delay in the effective date of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule. Health centers across the nation are engaging in mitigating and otherwise responding to the effects of COVID-19, and many health centers are participating in the Health Center COVID-19 Vaccine Program, to ensure the nation’s underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19. In addition, under the American Rescue Plan Act of 2021 (Pub. L. 117-2), HHS will soon be issuing additional funds for health centers to increase efforts to plan, prepare for, promote, distribute, administer, and track COVID-19 vaccines and to carry out a range of activities to further support detecting, diagnosing, tracing, and monitoring of COVID-19 infections necessary to mitigate the spread of COVID-19.

3. Delay Implementation Due to Administrative Procedure Act Concerns

One commenter urged HHS to rescind the rule implementing Executive Order 13937 or delay implementation until the rule could be adequately considered and “substantive shortcomings” under the Administrative Procedure Act (APA)

addressed. This commenter further noted that neither a rational basis nor legal authority was offered to target health centers for differential treatment nor to establish different policies for insulin and injectable epinephrine. In addition, the commenter expressed concern that the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule neither provided a rational basis for implementation of the new policy, nor addressed comments concerning the complexity and administrative challenges of implementation.

Response: HHS appreciates the commenter’s support for delaying the effective date of the rule. During the period of additional delay, HHS will consider whether potential APA issues were raised by the promulgation of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule. HHS plans to use the delay period to review and consider all questions of fact, law, and policy.

4. Delay Implementation for Duration of COVID-19 Public Health Emergency

One commenter requested HHS consider delaying the effective date of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule for the duration of the COVID-19 public health emergency.

Response: HHS appreciates the commenter’s support for delaying the effective date of the rule. This final rule will delay the effective date of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule for 120 days, until July 20, 2021. HHS plans to use the delay period to review and consider all questions of fact, law, and policy that would be presented by implementation of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule, including the ongoing COVID-19 public health emergency. As the NPRM for this delay specified the new effective date of July 20, 2021, and as the duration of the COVID-19 public health emergency is currently unknown, HHS declines at this time to change the period of delay to extend through the duration of the COVID-19 public health emergency.

5. Delay To Allow Health Centers Time To Come Into Compliance With the Regulation

One commenter, a patient with Type 1 diabetes who supported the underlying rule, requested HHS delay the effective date of the rule to allow health centers time and resources to come into compliance with the “Implementation of Executive Order on

Access to Affordable Life-Saving Medications” rule. The commenter also stated that implementing the new rule will take substantial time and resources for health centers who are currently playing a critical role leading the national COVID-19 vaccination campaign.

Response: HHS appreciates the commenter’s support for delaying the effective date of the rule. HHS agrees that health centers need to continue to focus efforts on the critical work of responding to the COVID-19 public health emergency while continuing to provide essential comprehensive primary care to medically underserved communities. HHS will continue during the delay period to further consider and review questions of fact, law, and policy that impact the implementation of the final rule.

6. Opposition to Proposed Delay

Three commenters opposed further delaying the effective date of the rule.

Two of the three commenters opposed to delaying the effective date of the rule, including the family member of a patient with diabetes, cited the importance of insulin to patients with Type 1 diabetes. One of the three commenters opposed to delaying the effective date, supported implementation of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule because access to affordable insulin is a top priority that can help those with Type 1 diabetes avoid emergency room visits, inpatient admissions, other complications, and save lives. The commenter cited the cost of insulin as a substantial economic burden for those living with Type 1 diabetes, and stated that the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule will benefit certain health center patients between 200% and 350% of the Federal Poverty Guidelines by helping them afford the insulin they need to survive. The commenter also encouraged HHS to limit any administrative burden to health centers subject to the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule. Another of the three commenters, a patient of a health center, expressed concern that further delaying of the effective date would keep much-needed pharmaceuticals out of the hands of certain patients, especially those with disabilities.

Response: HHS appreciates the commenters’ opposition to delaying the effective date of the rule, as well as the concern about limiting administrative burden to health centers associated with

implementing the rule. Given the overwhelming support by other commenters for delaying implementation of the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule, HHS is finalizing this rule to delay the effective date to July 20, 2021. HHS will use the delay period to review and consider the questions of fact, law, and policy posed by and the potential impact of the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule, including on access to affordable insulin for health center patients, including those with Type 1 diabetes, patients with disabilities, and those with incomes up to 350% of the Federal Poverty Guidelines.

Another commenter, a pharmaceutical manufacturer, opposed any further delay of the effective date, arguing that policymakers are operating under the erroneous assumption that 340B discounts directly benefit patient access to drugs. Instead, the commenter stated, covered entity middlemen pocket the discounts, rather than pass them on to patients. The commenter provided data suggesting that the markup charged by some covered entities on insulin is as much as 200,000%. However, the commenter noted that none of the covered entities examined were health centers. The commenter encouraged HHS to look at its own data to see if “spread pricing” on penny priced insulin is an appropriate policy solution for federal grantees. The commenter stated that they have implemented a program for 340B pass-through pricing where patients receive insulin at the 340B price at the point-of-sale, which five covered entities have instituted, as evidence that such a policy is operationally feasible. The commenter stated that the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule would dramatically lower the cost of insulin for many of the most vulnerable patients in the country.

Response: HHS appreciates the commenter’s opposition to delaying the effective date of the rule. However, given the overwhelming support by other commenters for delaying implementation of the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule, HHS is finalizing this rule to delay the effective date to July 20, 2021. HHS will use the delay period to review and consider the questions of fact, law, and policy posed by and the potential impact of the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule, whether

the rule would be likely to significantly lower the cost of insulin for the most vulnerable patients.

As stated in the NPRM for this delay, HHS will further consider and review comments submitted, including those made on the substance of the “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule.

7. Comments on the Underlying Rule

Most commenters raised issues that concerned the underlying rule, in particular, the high cost of these drugs, and the significant administrative costs associated with the rule. The nature of these comments suggests that a further delay of the “Implementation of Executive Order on Access to Affordable Life-saving Medications.” rule is warranted. This final rule does not address these substantive issues, but rather responds to concerns raised regarding the proposed delayed effective date. However, as stated in the NPRM, HHS will consider and review these comments on the substance of the underlying rule during the delay period.

8. Miscellaneous

Other commenters raised a variety of issues that do not pertain directly to either the delay period extended by this final rule or to the underlying “Implementation of Executive Order on Access to Affordable Life-saving Medications” rule. This final rule does not address those issues as they are outside of its scope.

IV. Regulatory Impact Analysis

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The Office of Information and Regulatory Affairs has determined that this rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866.

HHS has determined that no resources are required to implement the requirements in this rule because compensation will continue to be made consistent with the status quo. Therefore, in accordance with the

Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, HHS certifies that this rule will not have a significant impact on a substantial number of small entities.

HHS has also determined that this rule does not meet the criteria for a major rule under the Congressional Review Act or Executive Order 12866 and would have no major effect on the economy or federal expenditures. Similarly, it will not have effects on state, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995. Nor on the basis of family well-being will the provisions of this rule 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.

V. Impact of the New Rule

This final rule delays the effective date of the rule entitled “Implementation of Executive Order on Access to Affordable Life-saving Medications” until July 20, 2021, to allow HHS additional opportunity for review and consideration of the rule. This delay is reasonable and will not be disruptive because the underlying rule has not yet been implemented or taken effect.

VI. Paperwork Reduction Act of 1995

This rule has no information collection requirements.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

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