



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 486

[CMS-3380-F2]

RIN 0938-AU02

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule; public comment period; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2021, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," this action temporarily delays for 60 days the effective date of part of the final rule entitled, "Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule" published in the **Federal Register** on December 2, 2020. We are also providing an additional 30-day public comment period.

DATES: The February 1, 2021, effective date of the rule amending 42 CFR part 486, published at 85 FR 77898 on December 2, 2020, is delayed to March 30, 2021.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: In commenting, please refer to file code CMS-3380-F2.

Comments, including mass comment submissions, must be submitted in one of

the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3380-F2
P.O. Box 8010,
Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3380-F2,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the

SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Diane Corning, (410) 786-8486; Jesse Roach, (410) 786-1000; Kristin Shifflett, (410) 786-4133; CAPT James Cowher, (410) 786-1948; or Alpha-Banu Wilson, (410) 786-8687.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

The January 20, 2021 memorandum from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” instructed Federal agencies to delay the effective date of rules published in the **Federal Register**, but which have not yet taken effect, for a period of 60 days. On December 2, 2020, we published a final rule in the **Federal Register** entitled “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule” (85 FR 77898). The December 2020 final rule revises the Organ Procurement Organizations Conditions for Coverage to increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures and increasing competition for open donation service areas. The effective date of that rule, except for amendment number 3, which would have been February 1, 2021, is now March 30, 2021. We are also providing a 30-day public comment period. The 60-day delay in effective date is necessary to give Department officials the opportunity for

further review of the issues of fact, law, and policy raised by this rule. In addition, this action provides a comment period on the policies set out in the December 2, 2020 final rule to allow interested parties to provide comments about issues of fact, law and policy raised by the rule.

II. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Norris Cochran,

Acting Secretary,

Department of Health and Human Services.

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