



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS-5519-IFC]

RIN 0938-AS90

Medicare Program; Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model; Delay of Effective Date

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

ACTION: Interim final rule with comment period; delay of effective date.

SUMMARY: This interim final rule with comment period (IFC) further delays the effective date of the final rule entitled "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model" published in the January 3, 2017 **Federal Register** (82 FR 180) from March 21, 2017 until May 20, 2017. This IFC also delays the applicability date of the regulations at 42 CFR part 512 from July 1, 2017 to October 1, 2017 and effective date of the specific CJR regulations itemized in the DATES section from July 1, 2017 to October 1, 2017. We seek comment on the appropriateness of this delay, as well as a further applicability date delay until January 1, 2018.

DATES: Effective date: As of [Insert date of filing for public inspection at the Office of the Federal Register], the effective date for the provisions of the final rule published in the January 3, 2017 **Federal Register** (82 FR 180), which was delayed until March 21, 2017 on February 18, 2017 (82 FR 10961), is further delayed to May 20, 2017. Additionally, the effective date of the provisions of the final rule contained in the following amendatory instructions is delayed from July 1, 2017 to October 1, 2017: number 3 amending 42 CFR 510.2; number 4 adding 42 CFR 510.110; number 6 amending 42 CFR 510.120; number 14 amending 42 CFR 510.405; number 15 amending 42 CFR 510.410; number 16 revising 42 CFR 510.500; number 17 revising 42 CFR 510.505; number 18 adding 42 CFR 510.506; and number 19 amending 42 CFR 510.515.

Applicability date: The applicability date of the regulations at 42 CFR part 512 is delayed from their

current applicability date of July 1, 2017 until October 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert 30 days after the date of filing for public inspection at the Office of the Federal Register].

ADDRESSES: In commenting, please refer to file code CMS-5519-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four 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-5519-IFC,

P.O. Box 8013,

Baltimore, MD 21244-8013.

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-5519-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments

ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Sean Harris (410) 786-0812.

For questions related to the EPMs: *EPMRULE@cms.hhs.gov*. For questions related to the CJR model: *CJR@cms.hhs.gov*.

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 Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Provisions of the Interim Final Rule with Comment Period

In the January 3, 2017 **Federal Register** (82 FR 180), we published a final rule entitled "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model" which implements three new Medicare Parts A and B EPMs and a Cardiac Rehabilitation (CR) Incentive Payment model, and implements changes to the existing Comprehensive Care for Joint Replacement model under section 1115A of the Social Security Act (the Act). Under the three new episode payment models, acute care hospitals in certain selected geographic areas will participate in retrospective EPMs targeting care for Medicare fee-for-service beneficiaries receiving services during acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes. All related care within 90 days of hospital discharge will be included in the episode of care. Under the CR Incentive Payment model, acute care hospitals in certain selected geographic areas will receive retrospective incentive payments for beneficiary utilization of cardiac rehabilitation/intensive cardiac rehabilitation services during the 90 days following discharge from a hospitalization treatment of an acute myocardial infarction or coronary artery bypass graft surgery.

The January 3, 2017 final rule (82 FR 180) included an effective date of February 18, 2017 for all provisions except those contained in the following amendatory instructions, which were to become effective on July 1, 2017: number 3 amending 42 CFR 510.2; number 4 adding 42 CFR 510.110; number 6

amending 42 CFR 510.120; number 14 amending 42 CFR 510.405; number 15 amending 42 CFR 510.410; number 16 revising 42 CFR 510.500; number 17 revising 42 CFR 510.505; number 18 adding 42 CFR 510.506; and number 19 amending 42 CFR 510.515.

In the February 17, 2017 **Federal Register** (82 FR 10961), as directed by the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review", we published a final rule that delayed the effective date of the final rule published in the January 3, 2017 **Federal Register** (82 FR 180) for provisions that were to become effective on February 18, 2017, to an effective date of March 21, 2017. In the February 17, 2017 final rule (82 FR 10961), we stated that the provisions contained in the amendatory instructions summarized in the previous paragraph remained effective July 1, 2017. The January 20, 2017 "Regulatory Freeze Pending Review" memorandum encourages agencies to consider proposing for notice and comment a rule to delay the effective date for regulations beyond that 60-day period. As explained below, this interim final rule with comment period (IFC) further delays the effective date of the final rule published in the January 3, 2017 **Federal Register** (82 FR 180), from March 21, 2017 (as provided in the final rule published in the February 17, 2017 **Federal Register** (82 FR 10961)) to May 20, 2017. This IFC also delays the applicability date of the regulations that were to be applicable on July 1, 2017 to an applicability date of October 1, 2017 and delays the effective date of conforming changes to CJR provisions that were to be effective July 1, 2017 to October 1, 2017. These delays postpone the applicability of the EPMs and the CR Incentive Payment model, as well as the date on which conforming changes to the CJR model regulations take effect, for an additional 3 months. This additional 3-month delay is necessary to allow time for additional review, to ensure that the agency has adequate time to undertake notice and comment rulemaking to modify the policy if modifications are warranted, and to ensure that in such a case participants have a clear understanding of the governing rules and are not required to take needless compliance steps due to the rule taking effect for a short duration before any potential modifications are effectuated. We note that, in light of this potential need for further notice and comment rulemaking prior to the start of the models, it would be problematic not to adjust the start date for EPMs from July 1, 2017. Given the need for advanced notice of the terms of the models by participants, and the fact that the episodes

in the models involved exceed 90 days in duration, we believe that immediately moving the start date of the model to October 1, 2017 is appropriate. Moreover, in the January 3, 2017 final rule, payment year one for the EPMs is currently established to cover the 6-month period from July 1, 2017 through December 31, 2017. Subsequent EPM model years run a full 12 months in accordance with the calendar year.

Considering the length of episodes in the models, we believe it would be preferable to maintain a duration of at least 6 months for payment year 1 and it would be less burdensome for participants to adhere as closely to the calendar year as possible when defining model payment years. Further, to the extent that we propose and finalize revisions to the model, should we determine modifications are warranted, participants should have reasonable time to prepare. We remain committed to providing some period of time between establishing final model parameters and beginning the model to allow participants to prepare for the unique attributes of this model. Therefore, we seek comment on a longer delay of the applicability (model start) date, including to January 1, 2018, and we will address these comments and effectuate any additional delay in the model start date when we finalize this IFC. If we effectuate any additional delay in the model start date, we also would delay the effective date of the conforming CJR regulation changes so that the effective date of those changes remains aligned with the applicability (model start) date of the EPMs.

To the extent that section 553 of the Administrative Procedure Act (APA) applies to this action to further delay the rule's effective date for the purpose of ensuring adequate time for subsequent notice and comment rulemaking if that is warranted, this IFC is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Furthermore, 5 U.S.C. 553(b)(B) permits a waiver of prior notice and comment if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest. Similarly, section 1871 of the Act, which normally requires prior notice and a 60-day public comment period for rules that establish or change a substantive legal standard, permits waiver of prior notice and comment when there is good cause for an exception under 5 U.S.C. 553(b)(B). In addition, the requirement under section 553(d) of the APA for a 30-day delay in the effective date of a rule can be waived for good cause. The January 20, 2017 "Regulatory Freeze Pending Review" executive memorandum stated that the rules under review should be delayed 60 days from the date of the memorandum. In addition, that memorandum provided that agencies

should consider issuing a notice of proposed rulemaking and solicit public comment if they believed that a delay beyond 60 days from the date of the memorandum was necessary. Given that the provisions of the final rule that provide for a start date for the EPMs and CR Incentive Payment model of July 1, 2017 will take effect on March 21, 2017, there is insufficient time to undertake full notice and comment rulemaking ahead of the March 21, 2017 effective date. We have determined that issuing this IFC as a proposed rule, such that it would not become effective until after public comments are submitted, considered and responded to in a final rule, would be contrary to the public interest, since the models would begin July 1, 2017 as originally set forth in the January 3, 2017 final rule, which could lead to a good deal of confusion for the public. In setting forth revised effective and applicability dates, we seek to ensure that all parties could participate in any rulemaking resulting from further review as requested in the January 20, 2017 presidential memorandum. Therefore, we are publishing this IFC to delay the effective date of the rule to May 20, 2017 and to move the applicability date for the EPM provisions from July 1, 2017 to October 1, 2017. We are also delaying the effective date of the CJR regulation amendments that were to take effect July 1, 2017 to October 1, 2017, to maintain our policy of aligning these changes with EPMs and to avoid confusion. Because we are immediately adjusting the effective and applicability dates of the EPMs by 3 months but believe a 6-month delay in the applicability (model start) date to be warranted, in this IFC we are soliciting public comment on the appropriateness of a further delay in the applicability (model start) date and will take those comments into consideration. For these same reasons, we find good cause to waive the 30-day delay in effective date provided for in 5 U.S.C. 553(d). Based on these findings, this rule is effective immediately upon publication in the **Federal Register**.

As discussed previously, timing considerations support an immediate delay to the effective and applicability dates and necessitate that the delay operate on a quarterly basis. Moreover, our ongoing review of the policy, consistent with the January 20, 2017 presidential memorandum, and our identification of the possibility of additional notice and comment rulemaking to make any warranted modifications to the policy, further necessitate immediate delay. As discussed in the January 3, 2017 final rule (82 FR 184), under the 5-year models governed by the rule, participants will have a significant opportunity to redesign care. Delaying the effective and applicability (model start) dates will prevent participant confusion and

corresponding disruption to these efforts, ensure that the agency has adequate time to undertake notice and comment rulemaking to modify the policy if modifications are warranted, and ensure that in the case of policy modifications, participants have a clear understanding of the governing rules and are not required to take needless compliance steps due to the rule taking effect for a short duration before any potential modifications are effectuated.

II. Responses to Public 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.

CMS-5519-IFC

Dated: March 16, 2017

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: March 17, 2017

Thomas E. Price,

Secretary,

Department of Health and Human Services.

BILLING CODE 4120-01-P

[FR Doc. 2017-05692 Filed: 3/20/2017 8:45 am; Publication Date: 3/21/2017]