



CMS-5519-F3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS-5519-F3]

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 (CJR); Delay of Effective Date

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

ACTION: Final rule; delay of effective date.

SUMMARY: This final rule finalizes May 20, 2017 as the effective date of the final rule titled "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)" originally published in the January 3, 2017 **Federal Register**. This final rule also finalizes a delay of the applicability date of the regulations at 42 CFR part 512 from July 1, 2017 to January 1, 2018 and delays the effective date of the specific CJR regulations listed in the DATES section from July 1, 2017 to January 1, 2018.

DATES: Effective date: The final rule published in the January 3, 2017 **Federal Register** (82 FR 180)) is effective May 20, 2017, except for the provisions of the final rule contained in the following amendatory instructions, which are effective January 1,

2018: 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 January 1, 2018.

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SUPPLEMENTARY INFORMATION:

I. Background

In the interim final rule with comment period published on March 21, 2017 (82 FR 14464), we delayed the effective date of the final rule titled "Advancing Care Coordination Through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)" to May 20, 2017, the applicability date of the regulations at 42 CFR part 512 to October 1, 2017, and the effective date of the **specific CJR regulations itemized in the DATES section to October 1, 2017**. The 30-day comment period for that rule closed on April 19, 2017. We received 47 submissions in response to our comment solicitation on the start date for the EPMs and Cardiac Rehabilitation (CR) incentive payment model, and we have summarized and responded to comments related

to the appropriateness of this delay as well as a further delay until January 1, 2018, in the following section.

II. Provisions of the Interim Final Rule with Comment Period and Analysis of and Responses to Public Comments

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

The EPM final rule 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. For the EPMs and CR incentive payment model, the provisions in the EPM final rule regarding the regulations at 42 CFR Part 512 were to become effective February 18, 2017, but the applicability date was July 1, 2017, meaning that the episodes for those models would not start until July 1, 2017.

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, titled "Regulatory Freeze Pending Review", we published a final rule that delayed the effective date of the EPM final rule 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. In addition, the applicability dates for the EPMs and CR incentive payment model remained 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. In the interim final rule with comment period published on March 21, 2017 (hereafter called the March 21, 2017 IFC), we further delayed the effective date of the EPM final rule 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; delayed the applicability date of the regulations that were to be applicable on July 1, 2017 to an applicability date of October 1, 2017; and delayed the effective date of certain conforming changes to CJR provisions that were to be effective July 1, 2017 to October 1, 2017. These delays postponed 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, until October 1, 2017. This additional 3-month delay was necessary to allow time for additional review, to ensure that the agency had adequate time to undertake notice and comment rulemaking to propose changes to the policy as warranted, and to ensure that participants have a clear understanding of the models and are not required to take needless compliance steps due to the rule taking effect for a short duration before any potential changes are effectuated. We noted that, in light of the 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 the EPMs and CR incentive payment model from July 1, 2017. Given participants' need for advance notice of the terms of the models, and the fact that the episodes being tested in these models exceed 90 days in duration because they initiate with a hospitalization and end 90 days after discharge, we believed that immediately moving the start date of the EPMs and CR incentive payment model to October 1, 2017 was appropriate.

Moreover, in the January 3, 2017 final rule, payment year one for the EPMs was originally 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 believed it would be preferable to

maintain a duration of at least 6 months for payment year one and that 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 would propose and finalize revisions to the model, should we determine changes are warranted, we noted that participants should have reasonable time to prepare. Therefore, we sought comment on a longer delay of the start date, including to January 1, 2018, and noted that we would address the comments and effectuate any additional delay in the models' start date when we finalized the March 21, 2017 IFC. In addition, we noted that if we effectuated any additional delay in the models' start date, we also would delay the effective date of certain conforming CJR regulation changes (that is, the changes listed in the DATES section of the EPM final rule that originally were to take effect July 1, 2017) so that the effective date of those changes remained aligned with the start date of the EPMs.

The 30-day comment period for the March 21, 2017 IFC closed on April 19, 2017. We received multiple comments on the models' start date change on which we solicited comment in the IFC and those comments and our responses are discussed in the following paragraphs. We also received a number of comments on the models that did not relate to the start date change comment solicitation. These additional comments suggested that we reconsider or revise various model aspects, policies and design components; in particular these comments suggested that we should make participation in the models voluntary instead of mandatory. We will not respond to these comments in this final rule as they are out of scope of this rulemaking, but we may take them into consideration in future rulemaking.

Comment: Many commenters supported CMS' further delay of the start date from October 1, 2017 to January 1, 2018 for the EPMs and CR incentive payment model. Commenters requested at least 6 months of preparation time after the EPM final rule takes effect, stating that the EPM episodes are complex, involve sick patients with many entry points into acute care settings, and require the establishment of networks for coordination across numerous specialists. Commenters stated that participants need time to evaluate the final model provisions, to develop specific EPM care plans, and to update health information technology, quality metrics, patient and family education, care management and discharge planning. Commenters stated that more lead time is needed to redesign clinical care in a manner that ensures beneficiaries receive the most appropriate and optimal care, including increasing referrals to cardiac rehabilitation. Some commenters requested that we provide historic claims data as scheduled and do not delay sharing data so that hospital can identify opportunities for care redesign in advance of the models' start date. Additionally, commenters noted that January 1, 2018 would be better than October 1, 2017 to start the models, as a 3-month payment year one would not allow for meaningful performance outcomes. Commenters also noted that a model start date of January 1, 2018 would allow CMS to engage in additional rulemaking on the specific EPM structure and overall model design.

A few commenters suggested that the October 1, 2017 start date should be retained, and hospitals should have the option to delay their participation in the EPMs until January 1, 2018. This option would allow hospitals with no prior experience operating under risk-based models more time to prepare while other hospitals could begin participating sooner. One commenter did not support further delay until January 1, 2018,

stating that continued uncertainty around the start date of the EPMs and CR incentive payment model may penalize proactive providers who have been preparing for implementation of the EPMs and CR incentive payment model since they were notified of their participation in the model at the time of the publication of the EPM final rule in early 2017. Several commenters suggested that rather than delaying the EPMs, CMS should withdraw these models all together. Other commenters suggested that these models be delayed indefinitely until further evaluation can be done to determine consequences of these models on the health care marketplace in the selected geographic areas and on other Innovation Center models.

Response: We thank commenters for their feedback. Based on this feedback, we agree with the majority of commenters that an additional delay prior to the start of the EPMs and CR incentive payment model is necessary. Delaying the EPMs' and CR incentive payment model's start date dates until January 1, 2018 will ensure that CMS has adequate time to undertake notice and comment rulemaking, if modifications are warranted. This would ensure that, in the case of any policy changes, participants would have a clear understanding of the governing rules before episodes begin and have the opportunity to take additional steps to adjust to any potential changes that may be effectuated.

Moreover, in the EPM final rule, payment year one for the EPMs was 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 that the length of episodes in the EPMs includes the duration of the hospitalization and the 90 day post-discharge period and therefore exceeds 90 days in

duration, we believe it would be preferable to maintain a duration of at least 6 months for payment year one, which also would also give participant hospitals 6 additional months of experience in the models before downside risk begins for all participants.

Additionally, we believe it would be less burdensome for participants to adhere as closely to the calendar year as possible when defining model payment years.

We disagree with commenters who were opposed to further delaying the models until January 1, 2018 on the basis that a delay would penalize those participants who may be ready for an October 1, 2017 implementation date. Additionally, we are respectfully rejecting the suggestion that optional model start dates of October and January should be allowed due to the additional operational and administrative burden that would arise from creating two sets of model timeframes. We believe that all model participants should have time to consider proposed changes to these models, operate under the same model timeframe, and have time between the establishment of the final model parameters and the start date of the models.

We also note that we disagree with commenters who suggested that CMS withdraw these models altogether and/or delay them indefinitely. As we stated in the January 3, 2017 EPM final rule, we believe these models will further our goals of improving the efficiency and quality of care for Medicare beneficiaries receiving care for these common clinical conditions and procedures.

Comment: Several commenters did not support the delay of the establishment of an Alternative Payment Models Beneficiary Ombudsman, which they believe would result from a delay of the EPM final rule. These commenters stated that beneficiaries whose care is provided through alternative payment models have unique questions and

may face a variety of issues, and a centralized, expert resource with information about all of the Alternative Payment Models will support CMS's existing information networks and allow for robust tracking of complaints and problems. Commenters stated that focused ombudsman programs work well both in protecting beneficiaries and helping demonstrations stay on track by identifying issues early. Commenters stated that an ombudsman can help ensure consumer understanding, identify systemic issues with implementation, and solve many problems without the need to use formal appeals processes.

Response: As we stated in the January 3, 2017 EPM final rule (82 FR 430), we intend to establish an Alternative Payment Models Beneficiary Ombudsman within CMS who will complement the Medicare Beneficiary Ombudsman in responding to beneficiary inquiries and concerns arising from care under the EPMs, CR incentive payment model and CJR model, as well as other Innovation Center models, under the existing Medicare processes. We agree with the commenters that ombudsman programs are helpful to resolve beneficiary concerns and in tracking model issues. We note that delaying the start date of the EPMs and CR incentive payment model will allow CMS additional time to establish ombudsman support for these models.

For the CJR model, there are already numerous model-specific processes in place and in the Medicare program generally to protect beneficiary choice. We have established similar protections for beneficiary choice in the EPM regulations. In the EPMs and CJR model, beneficiaries retain their right to choose the provider or supplier for medically necessary, covered services. Under these models, the beneficiary retains the benefits of the doctor-patient relationship and is provided additional notification of any sharing

arrangements the participant hospital may have with EPM and CJR collaborators that could create a potential conflict of interest. In addition, the beneficiary must be provided with a notice for continuing services that are not covered under the models or Medicare, such as a continued stay in an EPM participant or a skilled nursing facility (SNF), and the beneficiary has access to the existing expedited review process in these cases. At any time during these models, the beneficiary retains the right to also voice concerns or grievances using currently available resources, by calling their local Quality Improvement Organization (QIO) contractor or by calling the 1-800-MEDICARE helpline.

Comment: Several commenters strongly urged CMS to refrain from delaying implementation of the CR incentive payment model. Citing multiple research studies on cardiac rehabilitation data, commenters stated that cardiac rehabilitation has health benefits as well as financial advantages, including reduced hospitalizations and use of medical resources. Commenters stated that the incentive payments may be used to better coordinate cardiac rehabilitation and to support beneficiary adherence to the CR treatment plans by removing barriers to participation.

Response: Although we appreciate the commenters' support for the CR incentive payment model, we note that the CR incentive payment model that will run in the EPM MSAs is designed to incentivize CR utilization by beneficiaries in active EPM AMI and CABG episodes. The CR incentive payment model is being tested in EPM model MSAs and in other FFS MSAs concurrently. Prior to January 1, 2018 there will be no active EPM episodes in the EPM MSAs. We believe it would be confusing and operationally challenging to start the CR incentive payment model on October 1, 2017, which is 3

months before the EPM cardiac models start. We believe that existing Medicare FFS provisions sufficiently allow beneficiaries access to appropriate cardiac rehabilitation services prior to the start of the CR incentive payment model. Thus, we do not agree that we should begin the CR incentive payment model prior to the EPMs, and will start the CR incentive payment model in conjunction with the AMI and CABG EPMs on January 1, 2018.

Comment: Some commenters expressed concerns about delaying the conforming changes to the CJR model that were originally intended to take effect July 1, 2017 to October. These commenters also objected to a further delay of those same CJR model changes to January 1, 2018. One commenter expressed support for delaying these CJR conforming changes to allow participants ample time to implement changes within their healthcare systems, even though there could be some impact on clinicians' participation in the 2017 Advanced APM track. Commenters expressed concern regarding the ability of orthopedic surgeons to achieve qualified provider status for participating in an Advanced APM for 2017 should the models be delayed beyond October 1, 2017. Commenters stated that changes to CJR requirements for beneficiary notification and sharing arrangements provide clarity, help ensure compliance with timely beneficiary notification, and enhance hospitals' ability to engage with additional crucial care partners through the use of financial incentives. Commenters expressed concern that without these changes to beneficiary notification and sharing agreements, there will continue to be beneficiary confusion and distress regarding the notification requirement and an increased burden for participants. Commenters also expressed concern that a further delay of changes to the types of entities that can be CJR collaborators would prevent non-

physician practitioner group practices, therapy group practices, therapists in private practice, and comprehensive outpatient rehabilitation facilities from becoming CJR collaborators during 2017.

Response: We thank the commenters for their feedback. The purpose of making conforming changes to certain aspects of the CJR model was to align the established EPM policies with CJR policies that are similar, which we believe would decrease burden, particularly for CJR hospitals participating in the SHFFT model. We note that several changes to the CJR beneficiary notification requirements will take effect on May 20, 2017, most notably the changes at § 510.405(a) and (b) changes that recognize that the beneficiary's condition may affect the timing of notification about the CJR model and that cover notification by collaborators about applicable sharing arrangements (82 FR 616). We are only delaying changes to the beneficiary notification provisions (that is, revisions to § 510.405(b)(1), (2), and (4)) that add non-physician practitioner group practices (NPPGPs) and therapy group practices (TGPs) to the collaborators responsible for compliance with § 510.405 because the conforming provisions that add NPPGPs and TGPs to the list of eligible collaborators are being delayed until January to align collaborator requirements across the CJR and SHFFT models.

We note that the provisions in the EPM final rule that allow hospitals to join the Advanced APM option under the CJR model are effective May 20, 2017, and will allow eligible clinicians on a CJR affiliated practitioner list to potentially qualify as Qualifying APM Participants (QPs) under the Quality Payment Program in 2017. In response to commenters' concern regarding the ability of orthopedic surgeons to achieve QP status for participating in an Advanced APM for 2017, we would like to clarify that the delay

until January 1, 2018 of certain conforming changes to the CJR regulations is unlikely to have an effect on most eligible clinicians to achieve QP status for participating in an Advanced APM for 2017. We understand that the conforming changes to the types of CJR collaborators, including the change that permits ACOs to be CJR collaborators, will not become effective until January 1, 2018. However, physicians and physician group practices have been valid CJR collaborator types since the CJR model began, and therefore we believe that most orthopedic surgeons furnishing services to beneficiaries included in CJR in 2017 would already have arranged to be CJR collaborators under these existing categories. Therefore, we believe orthopedic surgeons' ability to qualify for QP status in 2017 is unlikely to be significantly affected by the delay of regulations that broaden the scope of CJR collaborator provider types.

Final Decision: After careful consideration of the public comments received, we are finalizing a further delay of the start date of the EPMs and CR incentive payment model until January 1, 2018, such that these models' performance year 1 would start on January 1, 2018 and end on December 31, 2018. Additionally, we are finalizing a further delay of the effective date of the CJR regulation amendments that were to take effect October 1, 2017. These CJR regulation amendments will now be effective as of January 1, 2018, to maintain our policy of aligning these changes with the EPMs.

III. Out of Scope Public Comments Received

We received public comments suggesting changes to the overall design of the EPMs, CR incentive payment model and CJR model that were outside of the scope of the March 21, 2017 IFC. These comments touched on participation requirements, data, pricing, quality measures, episode length, CR and SNF waivers, beneficiary exclusions

and notification requirements, repayment, coding, and model overlap issues. We consider these public comments to be outside of the scope of the March 21, 2017 IFC; and therefore, we are not addressing them in this final rule. We may consider these public comments in future rulemaking.

IV. Waiver of the Delay in Effective Date

Section 553(d) of the Administrative Procedure Act (APA) normally requires a 30-day delay in the effective date of a rule, but this delay can be waived for good cause. Because in the March 21, 2017 IFC we immediately adjusted the applicability dates of the EPMs and CR incentive payment model (and the effective date of certain conforming CJR model changes) by 3 months, but believed a 6-month delay might be warranted, in the March 21, 2017 IFC we solicited public comment on the appropriateness of a further delay in the applicability (model start) date of the EPMs and CR incentive payment model, and took those comments into consideration in this final rule. In light of the comments, we are implementing a further delay in the applicability (model start) date for the EPMs and CR incentive payment model (as well as a further delay in the effective date of the conforming CJR model changes specified in the DATES section of this final rule). We believe that a 30-day delay in the effective date of this final rule would be contrary to the public interest because it would cause confusion for affected participants. Specifically, as of May 20, 2017, the EPM final rule would become effective and would specify an October 1, 2017 start date for the EPMs and CR incentive payment model, and then this final rule would subsequently specify a January 1, 2018 start date for the EPMs and CR incentive payment model. Such an outcome could cause participants to take needless compliance steps in anticipation of an October 1, 2017 start date, and before any

potential modifications, if warranted, can be effectuated. For these 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 final rule is effective upon publication in the **Federal Register**.

Dated: May 12, 2017.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: May 15, 2017.

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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