



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 510 and 512

[CMS-5524-P]

RIN 0938-AT16

Medicare Program; Cancellation of Advancing Care Coordination through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model (CMS-5524-P)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes to cancel the Episode Payment Models (EPMs) and Cardiac Rehabilitation (CR) incentive payment model and to rescind the regulations governing these models. It also proposes to revise certain aspects of the Comprehensive Care for Joint Replacement (CJR) model, including: giving certain hospitals selected for participation in the CJR model a one-time option to choose whether to continue their participation in the model; technical refinements and clarifications for certain payment, reconciliation and quality provisions; and a change to increase the pool of eligible clinicians that qualify as affiliated practitioners under the Advanced Alternative Payment Model (APM) track.

DATES: Comment period: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EDT on **[Insert date 60 days from date of publication in the Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-5524-P. 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-5524-P,

P.O. Box 8013,

Baltimore, MD 21244-1850. 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-5524-P,

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) 786-7195 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:

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

For questions related to the EPMs: EPMRULE@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://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received prior to the submission deadline will also be available for public inspection as they are received, generally beginning approximately three 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.

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Acronyms

ACE	Acute Care Episode Demonstration
ACO	Accountable Care Organization
AMI	Acute Myocardial Infarction
APM	Alternative Payment Model
BPCI	Bundled Payments for Care Improvement
CABG	Coronary Artery Bypass Graft
CCN	CMS Certification Number
CCSQ	Center for Clinical Standards and Quality
CEHRT	Certified Electronic Health Record Technology
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CJR	Comprehensive Care for Joint Replacement
CMS	Centers for Medicare & Medicaid Services
CR	Cardiac rehabilitation
CY	Calendar Year
E/M	Evaluation and Management
EPM	Episode payment model

FFS	Fee-for-service
FR	Federal Register
HACRP	Hospital-Acquired Condition Reduction Program
HHS	U.S. Department of Health and Human Services
HVBP	Hospital Value-Based Purchasing Program
ICD-CM	International Classification of Diseases, Clinical Modification
IFC	Interim Final Rule with Comment Period
IPPS	Inpatient Prospective Payment System
LEJR	Lower-extremity joint replacement
MPFS	Medicare Physician Fee Schedule
MP	Malpractice
MSA	Metropolitan Statistical Area
MS-DRG	Medical Severity Diagnosis-Related Group
NPI	National Provider Identifier
NPRA	Net Payment Reconciliation Amount
NQF	National Quality Forum
OMB	Office of Management and Budget
PE	Practice Expense
PGP	Physician Group Practice
PRO	Patient-Reported Outcome
PY	Performance year
QP	Qualifying APM Participant

RFA	Regulatory Flexibility Act
RSCR	Risk-Standardized Complication Rate
RVU	Relative Value Unit
SHFFT	Surgical hip/femur fracture treatment
THA	Total hip arthroplasty
TIN	Taxpayer Identification Number
TKA	Total knee arthroplasty
UMRA	Unfunded Mandates Reform Act

I. Executive Summary

A. Purpose

The purpose of this proposed rule is to propose to cancel the Episode Payment Models (EPMs) and the Cardiac Rehabilitation (CR) incentive payment model, established by the Center for Medicare and Medicaid Innovation (Innovation Center) under the authority of section 1115A of the Social Security Act (the Act), and to rescind the regulations at 42 CFR part 512. Additionally, this proposed rule proposes to prospectively make participation voluntary for all hospitals in approximately half of the geographic areas selected for participation in the Comprehensive Care for Joint Replacement (CJR) model (that is, in 33 of the 67 Metropolitan Statistical Areas (MSAs) selected; (see 80 FR 73299 Table 4)) and for low-volume and rural hospitals in all of the geographic areas selected for participation in the CJR model. We are also proposing several technical refinements and clarifications for certain CJR model payment, reconciliation, and quality provisions, and a change to the criteria for the Affiliated

Practitioner List to broaden the CJR Advanced Alternative Payment Model (APM) track to additional eligible clinicians.

We note that review and reevaluation of policies and programs, as well as revised rulemaking, are within an agency's discretion, and that discretion is often exercised after a change in administration occurs. The EPMs and the CR incentive models were designed as mandatory payment models and implemented via notice and comment rulemaking to test the effects of bundling cardiac and orthopedic care beginning in 2018 and further incentivizing higher value care. The CJR model was also designed as a mandatory payment model established via notice and comment rulemaking to test the effects of bundling on orthopedic episodes involving lower extremity joint replacements; we note that the CJR model began on April 1, 2016 and is currently in its second performance year.

While we continue to believe that cardiac and orthopedic episode models offer opportunities to redesign care processes and improve quality and care coordination across the inpatient and post-acute care spectrum while lowering spending, after careful review, we have determined that it is appropriate to propose to rescind the regulations at 42 CFR part 512, which relate to the EPMs and CR incentive payment model, and reduce the geographic scope of the CJR model for the following reasons. First, we believe that requiring hospitals to participate in additional episode payment models at this time is not in the best interest of the agency or the affected providers. Many providers are currently engaged in voluntary initiatives with CMS, and we expect to continue to offer opportunities for providers to participate in voluntary initiatives, including episode-based

payment models. We are concerned that engaging in large mandatory episode payment model efforts at this time may impede our ability to engage providers, such as hospitals, in future voluntary efforts. Similarly, we also believe that reducing the number of providers required to participate in the CJR model will allow us to continue to evaluate the effects of such a model while limiting the geographic reach of our current mandatory models. We considered altering the design of the EPMS and the CR incentive payment model to allow for voluntary participation and to take into account other feedback on the models, but as this would potentially involve restructuring the model design, payment methodologies, financial arrangement provisions and/or quality measures, we did not believe that such alterations would offer providers enough time to prepare for such changes, given the planned January 1, 2018 start date. In addition, if at a later date we decide to test these models, or similar models, on a voluntary basis, we would not expect to implement them through rulemaking, but rather would use methods of soliciting applications and securing participants' agreement to participate consistent with how we have implemented other voluntary models. Finally, we believe that canceling the EPMS and CR incentive payment model, as well as altering the scope of the CJR model, offers CMS greater flexibility to design and test other episode-based payment models, while still allowing us to test and evaluate the impact of the ongoing CJR model on enhancing the quality of care while reducing costs. Hospitals in the CJR model have been participating for more than a year and a half, and we have begun to give hospitals in the model financial and quality results from the first performance year. In many cases, CJR hospitals have made investments in care redesign, and we want to recognize such

investments and commitments to improvement while reducing the overall number of hospitals that are required to participate.

We seek public comment on the proposals contained in this proposed rule, and also on any alternatives considered.

B. Summary of Economic Effects

We do not anticipate that our proposal to cancel the EPMs and CR incentive payment model prior to the start of those models will have any costs to providers. As shown in our impact analysis in section V. of this proposed rule, we estimate that the CJR model changes we are proposing will reduce the previously projected CJR model savings (82 FR 603) by approximately \$90 million. Therefore, we estimate that the total CJR model impact after the changes in this proposed rule will save the Medicare program \$204 million, instead of \$294 million, over the remaining 3-year performance period (2018 through 2020) of the CJR model. Our impact analysis has some degree of uncertainty and makes assumptions as discussed in section V. of this proposed rule. In addition to these estimated impacts, as with many of the Innovation Center models, the goals that participants are attempting to achieve include improving overall quality of care, enhancing participating provider infrastructure to support better care management and reducing costs. We anticipate there will continue to be a broader focus on care coordination and quality improvement through the CJR model among hospitals and other providers and suppliers within the Medicare program that may lead to better care management and improved quality of care for beneficiaries.

II. Statutory Authority and Background

Under the authority of section 1115A of the Social Security Act (the Act), through notice-and-comment rulemaking, CMS' Center for Medicare and Medicaid Innovation (Innovation Center) established the Comprehensive Care for Joint Replacement model in a final rule titled "Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services" published in the November 24, 2015 **Federal Register** (80 FR 73274 through 73554) (referred to in this proposed rule as the "CJR model final rule"). We established three new models for acute myocardial infarction, coronary artery bypass graft, and surgical hip/femur fracture treatment episodes of care, which are collectively called the Episode Payment Models (EPMs), created a Cardiac Rehabilitation incentive payment model (CR incentive payment model), and revised several existing provisions for the CJR model, in 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" published in the January 3, 2017 **Federal Register** (82 FR 180) (referred to in this proposed rule as the "EPM final rule").

The effective date for most of the provisions of the EPM final rule was February 18, 2017, and in the EPM final rule we specified an effective date of July 1, 2017 for certain CJR model regulatory changes intended to align with a July 1, 2017 applicability, or start, date for the EPMs and CR incentive payment model. On January 20, 2017, the Assistant to the President and Chief of Staff issued a memorandum titled "Regulatory Freeze Pending Review" that instructed Federal agencies to temporarily postpone the effective date for 60 days from the date of the memorandum

for regulations that had been published in the **Federal Register** but had not taken effect, for purposes of reviewing the rules and considering potentially proposing further notice-and-comment rulemaking. Accordingly, on February 17, 2017, we issued a final rule in the **Federal Register** (82 FR 10961) to delay until March 21, 2017 the effective date of any provisions of the EPM final rule that were to become effective on February 18, 2017. We subsequently issued an interim final rule with comment (IFC) period in the **Federal Register** on March 21, 2017 (referred to in this proposed rule as the "March 21, 2017 IFC") (82 FR 14464). The March 21, 2017 IFC further delayed the effective date of the provisions that were to take effect March 21, 2017 until May 20, 2017, further delayed the applicability date of the EPMs and CR incentive payment model provisions until October 1, 2017, and further delayed the effective date of the conforming CJR model changes until October 1, 2017. In the March 21, 2017 IFC, we also solicited public comment on further delaying the applicability date for the EPMs and CR incentive payment provisions, as well as the effective date for the conforming changes to the CJR model from October 1, 2017 until January 1, 2018 to allow for additional notice-and-comment rulemaking. Based on the public comments we received in response to the March 21, 2017 IFC, we published a final rule (referred to in this proposed rule as the "May 19, 2017 final delay rule") on May 19, 2017 (82 FR 22895) to finalize a January 1, 2018 applicability date for the EPMs and CR incentive payment provisions, as well as to finalize a January 1, 2018 effective date for the conforming changes to the CJR model (specifically amending §510.2; adding §510.110; amending §510.120; amending §510.405; amending §510.410; revising §510.500; revising §510.505;

adding §510.506; and amending §510.515). Additional changes to the CJR model, in accordance with the March 21, 2017 IFC, took effect May 20, 2017.

As we stated in the May 19, 2017 final delay rule (82 FR 22897), we 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, many of these comments suggested that we should make participation in the models voluntary instead of mandatory. We did not respond to these comments in the May 19, 2017 final delay rule, as the comments were out of scope of that rulemaking, but we stated that we might take them into consideration in future rulemaking.

Our specific proposals are discussed in the following sections of this proposed rule.

III. Provisions of the Proposed Regulations

A. Proposed Cancellation of EPMs and Cardiac Rehabilitation Incentive Payment Model

In the January 3, 2017 EPM final rule, we established three bundled payment models for acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT) episodes, and a Cardiac Rehabilitation (CR) incentive payment model. These models are similar to other Innovation Center models and focus on more complex cases where we believe improvements in care coordination and other care redesign efforts offer the potential for improved patient outcomes and more efficient use of resources. Many stakeholders, including commenters responding to the March 21, 2017 IFC, have expressed concerns about the provider

burden and challenges these new models present. As we noted in the May 19, 2017 final delay rule (82 FR 22896), which finalized a January 1, 2018 start date for the EPMs and the CR incentive payment model, we would engage in notice and comment rulemaking on these models if we believed it to be warranted. We also noted that we received 47 submissions in response to the March 21, 2017 IFC. These responses contained a mix of in- and out-of-scope comments (82 FR 22899). In the May 19, 2017 final delay rule (82 FR 22897), we noted that in addition to commenting on the change to the effective date for the EPMs and CR incentive payment model and certain provisions of the CJR model, commenters highlighted concerns with the models' design, including but not limited to participation requirements, data, pricing, quality measures, episode length, CR and skilled nursing facility (SNF) waivers, beneficiary exclusions and notification requirements, repayment, coding, and model overlap issues. Specifically, many commenters were opposed to the mandatory participation requirements, arguing that the mandatory nature of these models would force many providers who lack familiarity, experience, or proper infrastructure to quickly support care redesign efforts for a new bundled payment system. Many commenters were concerned that the mandatory nature of these models might harm patients and providers before CMS knows how these models might affect access to care, quality or outcomes in various locations. Additionally, commenters were concerned that unrelated services would be incorporated into episode prices under the finalized price setting methodology, which bases prices on MS-DRGs and identifies excluded, unrelated services rather than included, related services based on clinical review. Commenters also expressed concern that this pricing approach would

result in diagnosis codes that would be classified as included services, when in fact these services have no clinical relevance to the episode(s). Commenters were further concerned with the fact that CMS will progressively incorporate regional data into EPM target prices, where 100 percent of the EPM target price would be based on regional data by performance year 4. Commenters also took issue with the quality measures established for the SHFFT model, stating that these measures are not clinically related to the target population and are inappropriate for use in assessing the care provided to beneficiaries in the SHFFT model. In addition, commenters requested revisions to the CABG EPM to allow participants the option to use a CABG composite score developed by the Society of Thoracic Surgeons (STS) rather than the all-cause mortality measure.

Commenters also expressed concerns about the design of the CR incentive payment model waivers. Commenters stated that current direct supervision requirements would continue to contribute to a lack of access to cardiac rehabilitation services and would inhibit providers' ability to redesign care for the CR incentive payment model. Commenters suggested broadening the CR physician supervision waiver because the current waivers would not cover non-model beneficiaries who might be obtaining services concurrently with model participants and are therefore not sufficient. Other commenters were concerned with the precedence rules for model overlap with Models 2, 3 and 4 of the Innovation Center's Bundled Payments for Care Improvement (BPCI) initiative.

In the May 19, 2017 final delay rule (82 FR 22895), we stated that we might consider these public comments in future rulemaking. Based on our additional review

and consideration of this stakeholder feedback, we have concluded that certain aspects of the design of the EPMs and the CR incentive payment model should be improved and more fully developed prior to the start of the models, and that moving forward with the implementation of the EPMs and CR incentive payment model as put forth in the January 3, 2017 EPM final rule would not be in the best interest of beneficiaries or providers at this time. Based on our acknowledgment of the many concerns about the design of these models articulated by stakeholders, we are proposing to cancel the EPMs and CR incentive payment model before they begin. Accordingly, we propose to rescind 42 CFR Part 512 in its entirety.

We seek public comment on our proposal to cancel the EPMs and CR incentive payment model.

We note that, if the proposal to cancel the EPMs and CR incentive payment model is finalized, providers interested in participating in bundled payment models may still have an opportunity to do so during calendar year (CY) 2018 via new voluntary bundled payment models. Building on the BPCI initiative, the Innovation Center expects to develop new voluntary bundled payment model(s) during CY 2018 that would be designed to meet the criteria to be an Advanced APM. We also note the strong evidence base and other positive stakeholder feedback that we have received regarding the CR incentive payment model. As we further develop the Innovation Center's portfolio of models, we may revisit this model and will consider stakeholder feedback for a potential new voluntary initiative.

B. Proposed Changes to the CJR Model Participation Requirements

1. Proposed Voluntary Participation Election (Opt-in) for Certain MSAs and Low-Volume and Rural Hospitals

The CJR model began on April 1, 2016. The CJR model is currently in the second performance year, which includes episodes ending on or after January 1, 2017 and on or before December 31, 2017. The third performance year, which includes all CJR episodes ending on or after January 1, 2018 and on or before December 31, 2018, would necessarily incorporate episodes beginning before January 2018. The fifth, and last, performance year would end on December 31, 2020. Currently, with limited exceptions, hospitals located in the 67 geographic areas selected for participation in the CJR model must participate in the model through December 31, 2020; that is, their participation in the CJR model is mandatory unless the hospital is an episode initiator for a lower-extremity joint replacement (LEJR) episode in the risk-bearing period of Models 2 or 4 of the BPCI initiative. Hospitals with a CCN primary address in the 67 selected geographic areas that participated in Model 1 of the BPCI initiative, which ended on December 31, 2016, began participating in the CJR model when their participation in the BPCI initiative ended.

Based on smaller, voluntary tests of episode-based payment models and demonstrations, such as the Acute Care Episode (ACE) demonstration and the BPCI initiative, that have indicated a potential to improve beneficiaries' care while reducing costs (see ACE evaluation at: <https://downloads.cms.gov/files/cmimi/ace-evaluationreport-final-5-2-14.pdf> and BPCI evaluation at:

<https://innovation.cms.gov/Files/reports/BPCI-EvalRpt1.pdf>), we finalized the CJR model with mandatory participation in the 67 selected geographic areas so that we could further test delivery of better care at a lower cost across a wide range of hospitals, including some hospitals that may not otherwise participate, in many locations across the country. In the CJR model final rule (80 FR 73276), we stated that we believed that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model would result in a robust data set for evaluation of this bundled payment approach, and would stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner would also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes.

After further consideration of stakeholder feedback, including responses we received on the March 21, 2017 IFC, we are proposing certain revisions to the mandatory participation requirements for the CJR model to allow us to continue to evaluate the effects of the model while limiting the geographic reach of our current mandatory models. Specifically, we are proposing that the CJR model would continue on a mandatory basis in approximately half of the selected geographic areas (that is, 34 of the 67 selected geographic areas), with an exception for low-volume and rural hospitals, and continue on a voluntary basis in the other areas (that is, 33 of the 67 selected geographic areas).

The geographic areas for the CJR model are certain Metropolitan Statistical Areas (MSAs) that were selected following the requirements in § 510.105 as discussed in the

CJR model final rule (80 FR 73297 through 73299). In § 510.2, an MSA is defined as a core-based statistical area associated with at least one urbanized area that has a population of at least 50,000. In selecting the 67 MSAs for inclusion in the CJR model, the 196 eligible MSAs were stratified into 8 groups based on MSA average wage adjusted historic LEJR episode payments and MSA population size (80 FR 41207). Specifically, we classified MSAs according to their average LEJR episode payment into four categories based on the 25th, 50th and 75th percentiles of the distribution of the 196 potentially selectable MSAs as determined in the exclusion rules as applied in the CJR model proposed rule (80 FR 41198). This approach ranked the MSAs relative to one another and created four equally sized groups of 49. The population distribution was divided at the median point for the MSAs eligible for potential selection, creating 8 groups. Of the 196 eligible MSAs, we chose 67 MSAs via a stratified random selection process as discussed in the CJR model final rule (80 FR 73291). In reviewing our discussion of the MSA selection and the MSA volume needed to provide adequate statistical power to evaluate the impact of the model in the CJR model final rule (80 FR 73297), we have determined that reducing the mandatory MSA volume in half by selecting the 34 MSAs with the highest average wage-adjusted historic LEJR episode payments for continued mandatory participation could still allow us to evaluate the effects of the CJR model across a wide range of providers, including some that might not otherwise participate in the model. Higher payment areas are most likely to have significant room for improvement in creating efficiencies and greater variations in practice patterns. Thus, the selection of more expensive MSAs is the most appropriate

approach to fulfilling the overall priorities of the CJR model to increase efficiencies and savings for LEJR episodes while maintaining or improving the overall quality of care.

The original determination of the sample size need in the CJR model final rule was constructed to be able to observe a 2-percent reduction in wage-adjusted episode spending after 1 year. This amount was chosen based on the anticipated amount of the discount applied in the target price. In considering the degree of certainty that would be needed to generate reliable statistical estimates, we assumed a 20 percent chance of false positive and a 30 percent chance of a false negative. Using these parameters, we determined that the number of MSAs needed ranged from 50 to 150. In order to allow for some degree of flexibility, we selected 75 MSAs, which were narrowed to 67 due to final exclusion criteria.

As we reviewed the CJR model for this proposed rule, we noted that, excluding quarterly reconciliation amounts, evaluation results from BPCI Model 2 have indicated possible reductions in fee-for-service spending of approximately 3 percent on orthopedic surgery episodes for hospitals participating in the LEJR episode bundle. (<https://innovation.cms.gov/Files/reports/bpci-models2-4-yr2evalrpt.pdf>). We examined the sample size needed to detect a 3-percent reduction in CJR model episode spending after 1 year using the same methodology as described in the CJR model final rule. We determined that we would be able to meet this standard with 34 MSAs from the higher cost groups. We expect that hospitals in the higher cost MSAs will be able to achieve similar 3 percent savings given their MSA's relatively high historic episode spending and thus greater opportunities for improvements, and their experience in optimizing clinical

care pathways to produce greater efficacies over the first two performance years of the CJR model. We note that the proposed changes to the model, including the focus on higher cost MSAs and the reduced number of mandatory MSAs, will cause changes to the nature of the evaluation.

To select the 34 MSAs that would continue to have mandatory participation (except for low-volume and rural hospitals), we took the distribution of average wage-adjusted historic LEJR episode payments for the 67 MSAs using the definition described in the CJR model final rule, ordered them sequentially by average wage-adjusted historic LEJR episode payments, and then selected the 34 MSAs with the highest average payments. Under this proposal to reduce the number of MSAs with mandatory participation, the remaining 33 MSAs would no longer be subject to the CJR model's mandatory participation requirements; that is, hospital participation would be voluntary in these 33 MSAs.

After dividing the 67 MSAs into 34 mandatory and 33 voluntary MSAs as described previously, we examined selected MSA characteristics. In order to determine whether a good balance was maintained across MSA population size, we examined the number of MSAs below and above the median population point of the 196 MSAs eligible for potential selection. We observed that a good balance of MSA population size was maintained (17 out of 34 mandatory and 17 out of 33 voluntary MSAs had a population above the median population). While the 34 MSAs that would continue to have mandatory participation have higher spending on average, these MSAs all include providers with average cost episodes in addition to providers with high cost episodes. In

general, we note that hospitals located in higher cost areas have a greater potential to demonstrate significant decreases in episode spending. However, within the higher cost MSAs, there is still significant variation in characteristics and experiences of the included hospitals. We anticipate the evaluation will be able to assess the generalizability of the findings of the CJR model by examining variations of performance within the participating hospitals who represent a wide range of hospital and market characteristics. Therefore, we are proposing that the CJR model would have 34 mandatory participation MSAs (identified in Table 1) and 33 voluntary participation MSAs (identified in Table 2) for performance years 3, 4, and 5.

Specifically, we are proposing that, unless an exclusion in § 510.100(b) applies (that is, for certain hospitals that participate in the BPCI initiative), participant hospitals in the proposed 34 mandatory participation MSAs that are not low-volume or rural (as defined in § 510.2 and discussed in the following paragraphs) would continue to be required to participate in the CJR model. We are also proposing that hospitals in the proposed 33 voluntary participation MSAs and hospitals that are low-volume or rural (as defined in § 510.2 and discussed in the following paragraphs) would have a one-time opportunity to notify CMS, in the form and manner specified by CMS, of their election to continue their participation in the CJR model on a voluntary basis (opt-in) for performance years 3, 4, and 5. Hospitals that choose to participate in the CJR model and make a participation election that complies with proposed § 510.115 would be subject to all model requirements. Hospitals in the proposed 33 voluntary participation MSAs and low-volume and rural hospitals (as defined in § 510.2 and discussed in the following

paragraphs) that do not make a participation election would be withdrawn from the CJR model as described later in this section of this proposed rule.

We are proposing to exclude and automatically withdraw low-volume hospitals in the proposed 34 mandatory participation MSAs, as identified by CMS (see Table 3), from participation in the CJR model effective February 1, 2018. Since some low-volume hospitals may want to continue their participation in the CJR model, we are proposing to allow low-volume hospitals to make a one-time, voluntary participation election that complies with the proposed § 510.115 in order for the low-volume hospital to continue its participation in the CJR model. We are proposing to define a low-volume hospital in § 510.2 as a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices. Note that under this definition, all hospitals listed in Table 3 would meet the definition of a low-volume hospital, but this list would not be inclusive of all hospitals that could be identified by CMS as a low-volume hospital. For example, a new hospital (with a new CCN) that opens in a mandatory MSA during the remaining years of the CJR model would not have any LEJR episodes during the historical years of data used to calculate the performance year 1 CJR episode target prices. Under our proposal, we intend that any hospital with a new CCN that comes into existence after the proposed voluntary participation election period would not be required and/or eligible to join the CJR model. Note that our proposed policy for new hospitals would not be applicable in the case of a reorganization event where the remaining entity is a hospital with a CCN that was participating in the CJR model prior to the reorganization event; consistent with

our current policy, such hospital would continue participation in the CJR model regardless of whether all predecessor hospitals were participant hospitals prior to the reorganization event.

We are also proposing to exclude and automatically withdraw rural hospitals from participation in the CJR model effective February 1, 2018. Since some rural hospitals may want to continue their participation in the CJR model, we are proposing to allow rural hospitals to make a one-time, voluntary participation election that complies with the proposed § 510.115 in order for the rural hospital to continue its participation in the CJR model. Specifically, we are proposing that rural hospitals (as defined in § 510.2) with a CCN primary address in the 34 mandatory participation MSAs would have a one-time opportunity to opt-in to continue its participation in the CJR model during the proposed voluntary participation election period. We are proposing that a hospital's change in rural status after the end of the voluntary participation election period would not change the hospital's CJR model participation requirements. Specifically, we are proposing that hospitals in the proposed 34 mandatory participation MSAs that are neither low-volume or rural hospitals during the proposed voluntary participation election period would be required to participate in the CJR model for performance years 3, 4, and 5, and that these hospitals would continue to be required to participate in the CJR model even if they subsequently become a rural hospital. Similarly, we are proposing that a rural hospital that makes a voluntary participation election during the one-time opportunity would be required to continue participating in the CJR model if that hospital no longer meets the definition of rural hospital in § 510.2. We are proposing this approach so that CMS can

identify the hospitals, by CCN, that would participate in the model for the remainder of performance year 3 and performance years 4 and 5 at the conclusion of the proposed voluntary participation election period and so that there would be less confusion about which hospitals are CJR model participants. We seek comment on this proposal.

TABLE 1: CJR MANDATORY PARTICIPATION MSAs

MSA	MSA Name	Wage-adjusted Episode Payments (in \$)
10420	Akron, OH	28,081
11700	Asheville, NC	27,617
12420	Austin-Round Rock, TX	28,960
13140	Beaumont-Port Arthur, TX	32,544
17140	Cincinnati, OH-KY-IN	28,074
18580	Corpus Christi, TX	30,700
20020	Dothan, AL	30,710
22500	Florence, SC	27,901
23540	Gainesville, FL	29,370
24780	Greenville, NC	27,446
25420	Harrisburg-Carlisle, PA	28,360
26300	Hot Springs, AR	29,621
28660	Killeen-Temple, TX	27,355
31080	Los Angeles-Long Beach-Anaheim, CA	28,219
31180	Lubbock, TX	29,524
32820	Memphis, TN-MS-AR	28,916
33100	Miami-Fort Lauderdale-West Palm Beach, FL	33,072
33740	Monroe, LA	30,431
33860	Montgomery, AL	30,817
35300	New Haven-Milford, CT	27,529
35380	New Orleans-Metairie, LA	29,562
35620	New York-Newark-Jersey City, NY-NJ-PA	31,076
36420	Oklahoma City, OK	27,267
36740	Orlando-Kissimmee-Sanford, FL	29,259
37860	Pensacola-Ferry Pass-Brent, FL	29,485
38300	Pittsburgh, PA	30,886
38940	Port St. Lucie, FL	30,423
39340	Provo-Orem, UT	28,852
39740	Reading, PA	28,679
42680	Sebastian-Vero Beach, FL	28,015
45300	Tampa-St. Petersburg-Clearwater, FL	32,424
45780	Toledo, OH	28,658
46220	Tuscaloosa, AL	31,789
46340	Tyler, TX	30,955

TABLE 2: CJR VOLUNTARY PARTICIPATION MSAs

MSA	MSA Name	Wage-adjusted Episode Payments (in \$)
10740	Albuquerque, NM	25,892
12020	Athens-Clarke County, GA	25,394
13900	Bismarck, ND	22,479
14500	Boulder, CO	24,115
15380	Buffalo-Cheektowaga-Niagara Falls, NY	26,037
16020	Cape Girardeau, MO-IL	24,564
16180	Carson City, NV	26,128
16740	Charlotte-Concord-Gastonia, NC-SC	26,736
17860	Columbia, MO	25,558
19500	Decatur, IL	24,846
19740	Denver-Aurora-Lakewood, CO	26,119
20500	Durham-Chapel Hill, NC	25,151
22420	Flint, MI	24,807
23580	Gainesville, GA	23,009
26900	Indianapolis-Carmel-Anderson, IN	25,841
28140	Kansas City, MO-KS	27,261
30700	Lincoln, NE	27,173
31540	Madison, WI	24,442
33340	Milwaukee-Waukesha-West Allis, WI	25,698
33700	Modesto, CA	24,819
34940	Naples-Immokalee-Marco Island, FL	27,120
34980	Nashville-Davidson--Murfreesboro--Franklin, TN	26,880
35980	Norwich-New London, CT	25,780
36260	Ogden-Clearfield, UT	25,472
38900	Portland-Vancouver-Hillsboro, OR-WA	22,604
40980	Saginaw, MI	25,488
41180	St. Louis, MO-IL	26,425
41860	San Francisco-Oakland-Hayward, CA	23,716
42660	Seattle-Tacoma-Bellevue, WA	23,669
43780	South Bend-Mishawaka, IN-MI	23,143
44420	Staunton-Waynesboro, VA	25,539
45820	Topeka, KS	24,273
48620	Wichita, KS	25,945

TABLE 3: LOW-VOLUME HOSPITALS LOCATED IN THE MANDATORY MSAs ELIGIBLE TO OPT-IN DURING VOLUNTARY ELECTION PERIOD

CCN	Hospital Name	MSA	MSA TITLE
010034	Community Hospital, Inc.	33860	Montgomery, AL
010062	Wiregrass Medical Center	20020	Dothan, AL
010095	Hale County Hospital	46220	Tuscaloosa, AL
010097	Elmore Community Hospital	33860	Montgomery, AL
010108	Prattville Baptist Hospital	33860	Montgomery, AL
010109	Pickens County Medical Center	46220	Tuscaloosa, AL
010149	Baptist Medical Center East	33860	Montgomery, AL

CCN	Hospital Name	MSA	MSA TITLE
040132	Leo N. Levi National Arthritis Hospital	26300	Hot Springs, AR
050040	LAC-Olive View-UCLA Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050091	Community Hospital of Huntington Park	31080	Los Angeles-Long Beach-Anaheim, CA
050137	Kaiser Foundation Hospital-Panorama City	31080	Los Angeles-Long Beach-Anaheim, CA
050138	Kaiser Foundation Hospital-Los Angeles	31080	Los Angeles-Long Beach-Anaheim, CA
050139	Kaiser Foundation Hospital-Downey	31080	Los Angeles-Long Beach-Anaheim, CA
050158	Encino Hospital Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050205	Glendora Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050373	LAC+USC Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050378	Pacifica Hospital of the Valley	31080	Los Angeles-Long Beach-Anaheim, CA
050411	Kaiser Foundation Hospital-South Bay	31080	Los Angeles-Long Beach-Anaheim, CA
050468	Memorial Hospital of Gardena	31080	Los Angeles-Long Beach-Anaheim, CA
050543	College Hospital Costa Mesa	31080	Los Angeles-Long Beach-Anaheim, CA
050548	Fairview Developmental Center	31080	Los Angeles-Long Beach-Anaheim, CA
050552	Motion Picture & Television Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050561	Kaiser Foundation Hospital-West Los Angeles	31080	Los Angeles-Long Beach-Anaheim, CA
050609	Kaiser Foundation Hospital-Orange County-Anaheim	31080	Los Angeles-Long Beach-Anaheim, CA
050641	East Los Angeles Doctors Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050677	Kaiser Foundation Hospital-Woodland Hills	31080	Los Angeles-Long Beach-Anaheim, CA
050723	Kaiser Foundation Hospital-Baldwin Park	31080	Los Angeles-Long Beach-Anaheim, CA
050738	Greater El Monte Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050744	Anaheim Global Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050747	South Coast Global Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050751	Miracle Mile Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050771	Coast Plaza Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050776	College Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050779	Martin Luther King Jr. Community Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
050780	Foothill Medical Center	31080	Los Angeles-Long Beach-Anaheim, CA
050782	Casa Colina Hospital	31080	Los Angeles-Long Beach-Anaheim, CA
070038	Connecticut Hospice Inc.	35300	New Haven-Milford, CT
070039	Masonic Home and Hospital	35300	New Haven-Milford, CT
100048	Jay Hospital	37860	Pensacola-Ferry Pass-Brent, FL
100130	Lakeside Medical Center	33100	Miami-Fort Lauderdale-West Palm Beach, FL
100240	Anne Bates Leach Eye Hospital	33100	Miami-Fort Lauderdale-West Palm Beach, FL
100277	Douglas Gardens Hospital	33100	Miami-Fort Lauderdale-West Palm Beach, FL
100320	Poinciana Medical Center	36740	Orlando-Kissimmee-Sanford, FL
100326	Promise Hospital of Miami	33100	Miami-Fort Lauderdale-West Palm Beach, FL
190005	University Medical Center New Orleans	35380	New Orleans-Metairie, LA
190011	University Health Conway	33740	Monroe, LA
190079	St. Charles Parish Hospital	35380	New Orleans-Metairie, LA
190245	Monroe Surgical Hospital	33740	Monroe, LA
190300	St. Charles Surgical Hospital LLC	35380	New Orleans-Metairie, LA
190302	Omega Hospital LLC	35380	New Orleans-Metairie, LA
190308	St. Bernard Parish Hospital	35380	New Orleans-Metairie, LA
190313	New Orleans East Hospital	35380	New Orleans-Metairie, LA
250012	Alliance Healthcare System	32820	Memphis, TN-MS-AR
250126	North Oak Regional Medical Center	32820	Memphis, TN-MS-AR
250167	Methodist Olive Branch Hospital	32820	Memphis, TN-MS-AR
310058	Bergen Regional Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330080	Lincoln Medical & Mental Health Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330086	Montefiore Mount Vernon Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA
330100	New York Eye and Ear Infirmary	35620	New York-Newark-Jersey City, NY-NJ-PA
330199	Metropolitan Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330231	Queens Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330233	Brookdale Hospital Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330240	Harlem Hospital Center	35620	New York-Newark-Jersey City, NY-NJ-PA

CCN	Hospital Name	MSA	MSA TITLE
330385	North Central Bronx Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA
330396	Woodhull Medical and Mental Health Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330397	Interfaith Medical Center	35620	New York-Newark-Jersey City, NY-NJ-PA
330399	St. Barnabas Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA
330405	Helen Hayes Hospital	35620	New York-Newark-Jersey City, NY-NJ-PA
360241	Edwin Shaw Rehab Institute	10420	Akron, OH
370011	Mercy Hospital El Reno Inc.	36420	Oklahoma City, OK
370158	Purcell Municipal Hospital	36420	Oklahoma City, OK
370199	Lakeside Women's Hospital A Member of INTEGRIS Health	36420	Oklahoma City, OK
370206	Oklahoma Spine Hospital	36420	Oklahoma City, OK
370215	Oklahoma Heart Hospital	36420	Oklahoma City, OK
370234	Oklahoma Heart Hospital South	36420	Oklahoma City, OK
390184	Highlands Hospital	38300	Pittsburgh, PA
390217	Excelsa Health Frick Hospital	38300	Pittsburgh, PA
420057	McLeod Medical Center-Darlington	22500	Florence, SC
420066	Lake City Community Hospital	22500	Florence, SC
440131	Baptist Memorial Hospital Tipton	32820	Memphis, TN-MS-AR
450143	Seton Smithville Regional Hospital	12420	Austin-Round Rock, TX
450605	Care Regional Medical Center	18580	Corpus Christi, TX
450690	University of Texas Health Science Center at Tyler	46340	Tyler, TX
450865	Seton Southwest Hospital	12420	Austin-Round Rock, TX
460043	Orem Community Hospital	39340	Provo-Orem, UT
670087	Baylor Scott & White Emergency Medical Center-Cedar Park	12420	Austin-Round Rock, TX

As stated previously in this section, we are proposing a one-time participation election period for hospitals with a CCN primary address located in the voluntary participation MSAs listed in Table 2, low-volume hospitals specified in Table 3, and rural hospitals in the mandatory participation MSAs. Based on the anticipated timing for when the final rule implementing this proposal would be published, we propose that the voluntary participation election period would begin January 1, 2018, and would end January 31, 2018. We must receive the participation election letter no later than January 31, 2018. We are proposing that the hospital’s participation election letter would serve as the model participant agreement. Voluntary participation would begin February 1, 2018, and continue through the end of the CJR model, unless sooner terminated. Thus, participant hospitals located in the voluntary participation MSAs listed in Table 2, the low-volume hospitals specified in Table 3, and the rural hospitals in the 34 mandatory

participation MSAs that elect voluntary participation would continue in the CJR model without any disruption to episodes attributed to performance year 3, which begins January 1, 2018. Participant hospitals located in the voluntary participation MSAs listed in Table 2, the low-volume hospitals specified in Table 3, and the rural hospitals in the 34 mandatory participation MSAs that do not elect voluntary participation would be withdrawn from the model effective February 1, 2018, and all of their performance year 3 episodes up to and including that date would be canceled, so that these hospitals would not be subject to a reconciliation payment or repayment amount for performance year 3. We are proposing to implement our proposed opt-in approach in this manner as a way to balance several goals, including establishing a uniform time period for hospitals to make a voluntary participation election, avoiding disruption of episodes for hospitals that elect to continue their participation in the CJR model, and preventing confusion about whether a hospital is participating in performance year 3 of the model. Specifically, we considered whether adopting a voluntary election period that ended prior to the start of performance year 3 would be less confusing and less administratively burdensome in terms of whether a hospital is participating in performance year 3. To implement this approach, the voluntary participation election period would have to close by December 31, 2017, such that each hospital would have made its determination regarding participation in performance year 3 before the start of performance year 3 (note that episodes attributed to performance year 3 would still be canceled under this alternative approach for eligible hospitals that do not make a participation election). Because the voluntary election period under this approach would conclude in advance of the relevant

CJR model performance year, this approach could simplify our administration of performance year 3 by establishing in advance of performance year 3 whether a hospital would be a participant hospital for the totality of performance year 3. However, given the timing of this proposed rulemaking, we were not confident that hospitals would have sufficient time to make a voluntary participation election by December 31, 2017. Thus, we are proposing that the voluntary participation election period would occur during the first month of performance year 3 (that is, throughout January 2018) and would apply prospectively beginning on February 1, 2018. We believe this approach will best ensure adequate time for hospitals to make a participation election while minimizing the time period during which participation in performance year 3 remains mandatory for all eligible hospitals in the 67 selected MSAs. We note that based on timing considerations, including potential changes to the anticipated date of publication of the final rule, we may modify the dates of the voluntary participation election period and make conforming changes to the dates for voluntary participation in performance year 3. We seek comment on the proposed voluntary participation election period, including whether we should instead require the participation election to be made by December 31, 2017 (that is, prior to the start of performance year 3) or if a different or later voluntary election period may be preferable.

To specify their participation election, we are proposing that hospitals would submit a written participation election letter to CMS in a form and manner specified by CMS. We intend to provide templates that can easily be completed and submitted in order to limit the burden on hospitals seeking to opt-in. If a hospital with a CCN primary

address located in the voluntary participation MSAs or a low-volume or rural hospital in the mandatory participation MSAs does not submit a written participation election letter by January 31, 2018, the hospital's participation in performance year 3 would end, all of its performance year 3 episodes would be canceled, and it would not be included in the CJR model for performance years 4 and 5.

We are proposing a number of requirements for the participation election letter and that the hospital's participation election letter would serve as the model participant agreement. First, we are proposing that the participation election letter must include all of the following:

- Hospital Name.
- Hospital Address.
- Hospital CCN.
- Hospital contact name, telephone number, and email address.
- If selecting the Advanced APM track, attestation of CEHRT use as defined in § 414.1305.

Second, we are proposing that the participation election letter must include a certification in a form and manner specific by CMS that--

- The hospital will comply with all requirements of the CJR model (that is, 42 CFR 510) and all other laws and regulations that are applicable to its participation in the CJR model; and
- Any data or information submitted to CMS will be accurate, complete and truthful, including, but not limited to, the participation election letter and any quality data

or other information that CMS uses in reconciliation processes or payment calculations or both.

We solicit feedback on this proposed certification requirement, including whether the certification should include different or additional attestations.

Finally, we are proposing that the participation election letter be signed by the hospital administrator, chief financial officer (CFO) or chief executive officer (CEO).

We are proposing that, if the hospital's participation election letter meets these criteria, we would accept the hospital's participation election. Once a participation election for the CJR model is made and is effective, the participant hospital would be required to participate in all activities related to the CJR model for the remainder of the CJR model unless the hospital's participation is terminated sooner.

We note that episodes end 90 days after discharge for the CJR model and episodes that do not start and end in the same calendar year will be attributed to the following performance year. For example, episodes that start in October 2017 and do not end on or before December 31, 2017 are attributed to performance year 3. Our methodology for attributing these episodes to the subsequent performance year would be problematic in cases where a hospital with a CCN primary address located in a voluntary participation MSA or a rural hospital or a low-volume hospital, as specified by CMS, has not elected to voluntarily continue participating in the model. Therefore, for a hospital with a CCN primary address located in a voluntary participation MSA, or a rural hospital or a low-volume hospital, as specified by CMS, that does not elect voluntary participation during the one-time voluntary participation election period, we are proposing that all episodes

attributed to performance year 3 for that hospital would be canceled and would not be included in payment reconciliation. Such hospitals would have their participation in the CJR model withdrawn effective February 1, 2018. We note that this proposal is consistent with our policy for treatment of episodes that have not ended by or on the last day of performance year 5 and cannot be included in performance year 5 reconciliation due to the end of the model (see Table 8 of the CJR model final rule (80 FR 73326)).

We are proposing to define a low-volume hospital, mandatory MSA, and voluntary MSA, to change the definition of participant hospital in § 510.2, and to amend the specification of the geographic areas in §510.105(a) to reflect the establishment of mandatory and voluntary participation MSAs. We are proposing to codify the opt-in proposal in new §510.115. In addition, we are proposing to post the list of mandatory participation MSAs, voluntary participation MSAs, and low-volume hospitals on the CJR model website.

We believe our proposed opt-in approach to allow for voluntary participation in the CJR model by certain hospitals would be less burdensome on such hospitals than a potential alternative approach of requiring hospitals to opt-out of the model. In developing the proposal to allow eligible hospitals located in the proposed 33 voluntary participation MSAs and low-volume and rural hospitals located in the 34 mandatory participation MSAs to elect voluntary participation, we considered whether to propose that hospitals would have to make an affirmative voluntary participation election (that is, an opt-in approach) or to propose that these hospitals would continue to be required to participate in the CJR model unless written notification was given to CMS to withdraw

the hospital from the CJR model (that is, an opt-out approach). We believe an opt-in approach would be less burdensome on hospitals, because it would not require participation in the CJR model for hospitals located in the proposed 33 voluntary participation MSAs and for low-volume and rural hospitals located in the 34 mandatory participation MSAs unless the hospital affirmatively chose it. Further, we believe requiring an affirmative opt-in election would result in less ambiguity about a hospital's participation intentions as compared to an opt-out approach. Specifically, with an opt-in approach, a hospital's participation election would document each hospital's choice, whereas under an opt-out approach there could be instances where hospitals fail to timely notify CMS of their desire to withdraw from participation and are thus included in the model and subject to potential repayment amounts. For these reasons, we have proposed an opt-in approach. We seek comment on this proposal and the alternative considered.

We also believe that our proposed approach to make the CJR model primarily concentrated in the higher cost MSAs where the opportunity for further efficiencies and care redesign may be more likely and allow voluntary participation in the lower cost MSAs and for low-volume and rural hospitals allows the Innovation Center to focus on areas where the opportunity for further efficiencies and care redesign may be more likely, while still allowing hospitals in the voluntary MSAs the opportunity to participate in the model. In developing this proposed rule, we considered that hospitals in the CJR model have been participating for over a year and a half as of the timing of this proposed rule, and we have begun to give hospitals in the model financial and quality results from the first performance year. In many cases, participant hospitals have made investments in

care redesign, and we want to recognize such investments and commitments to improvement while reducing the overall number of hospitals that are required to participate. We also considered stakeholder feedback that suggested we make participation in the CJR model voluntary, and the model size necessary to detect at least a 3-percent reduction in LEJR episode spending. Taking these considerations into account, we considered whether revising the model to allow for voluntary participation in all, some, or none of the 67 selected MSAs would be feasible.

As discussed in section V. of this proposed rule, the estimated impact of the changes to the CJR model proposed in this proposed rule reduces the overall estimated savings for performance years 3, 4, and 5 by \$90 million. If voluntary participation was allowed in all of the 67 selected MSAs, the overall estimated model impact would no longer show savings, and would likely result in additional costs to the Medicare program. If participation was limited to the proposed 34 mandatory participation MSAs and voluntary participation was not allowed in any MSA, the impact to the overall estimated model savings over the last three years of the model would be closer to \$30 million than the \$90 million estimate presented in section V. of this proposed rule, because our modeling, which does not include assumptions about behavioral changes that might lower fee-for-service spending, estimates that 60 to 80 hospitals will choose voluntary participation. Since we estimate that these potential voluntary participants would be expected to earn only positive reconciliation payments under the model, these positive reconciliation payments would offset some of the savings garnered from mandatory participants. However, as many current hospital participants in all of the 67 MSAs are

actively invested in the CJR model, we are proposing to allow voluntary participation in the 33 MSAs that were not selected for mandatory participation and for low-volume and rural hospitals. We seek comment on our proposed approach and the alternatives considered.

A summary of the proposed changes to the CJR model participation requirements is shown in Table 4.

TABLE 4: PROPOSED PARTICIPATION REQUIREMENTS FOR HOSPITALS IN THE CJR MODEL

	REQUIRED TO PARTICIPATE AS OF FEBRUARY 1, 2018	MAY ELECT VOLUNTARY PARTICIPATION	PARTICIPATION ELECTION PERIOD	ELECTION EFFECTIVE DATE
<i>Mandatory Participation MSAs</i>				
All IPPS participant hospitals, except rural and low-volume*	Yes	No	n/a	n/a
Rural hospitals *	No	Yes	1/1/2018-1/31/2018	2/1/2018
Low-volume hospitals (see Table 3)	No	Yes	1/1/2018-1/31/2018	2/1/2018
<i>Voluntary Participation MSAs</i>				
All IPPS participant hospitals	No	Yes	1/1/2018-1/31/2018	2/1/2018

*Note: Participation requirements are based on the CCN status of the hospital as of January 31, 2018. A change in rural status after the voluntary election period does not affect the participation requirements.

2. Proposed Codification of CJR Model-related Evaluation Participation Requirements

We note that for the CJR model evaluation, the data collection methods and key evaluation research questions under the proposed reformulated approach (that is, the proposal for voluntary opt-in elections discussed in section III.B.1 of this proposed rule) would remain similar to the approach presented in the CJR model final rule. The evaluation methodology for the CJR model would be consistent with the standard Innovation Center approaches we have taken in other voluntary models such as the Pioneer Accountable Care Organization (ACO) Model. Cooperation and participation in

model-related activities by all hospitals that participate in the CJR model would continue to be extremely important to the evaluation. Therefore, with respect to model-related evaluation activities, we propose to add provisions in § 510.410(b)(1)(i)(G) to specify that CMS may take remedial action if a participant hospital, or one of its collaborator, collaboration agent, or downstream collaboration agent fails to participate in model-related evaluation activities conducted by CMS and/or its contractors for any performance year in which the hospital participates. We believe the addition of this provision would make participation and collaboration requirements for the CJR model evaluation clear to all participant hospitals and in particular to hospitals that are eligible to elect voluntary participation. We seek comment on our proposed regulatory change.

3. Comment Solicitation: Incentivizing Participation in the CJR Model

In this proposed rule, we are proposing to make participation in the CJR model voluntary in 33 MSAs and for low-volume and rural hospitals in the remaining 34 MSAs via the proposed opt-in election policy discussed in section III.B.1 of this proposed rule. In order to keep hospitals in all MSAs selected for participation in the CJR model actively participating in the model, we are soliciting comment on ways to further incentivize eligible hospitals to elect to continue participating in the CJR model for the remaining years of the model and to further incentivize all participant hospitals to advance care improvements, innovation, and quality for beneficiaries throughout LEJR episodes.

Additionally, we note that, under the CJR refinements established in the January 3, 2017 EPM final rule, the total amount of gainsharing payments for a

performance year paid to physicians, non-physician practitioners, physician group practices (PGPs), and non-physician practitioner group practices (NPPGPs) must not exceed 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services that are furnished to beneficiaries during episodes that occurred during the same performance year for which the CJR participant hospital accrued the internal cost savings or earned the reconciliation payment that comprises the gainsharing payment being made (§ 510.500(c)(4)). Similarly, distribution arrangements are limited as specified in § 510.505(b)(8), and downstream distribution arrangements are limited as specified in § 510.506(b)(8). These program integrity safeguards, which are consistent with the gainsharing caps in other Innovation Center models, were included to avoid setting an inappropriate financial incentive that may result in stinting, steering or denial of medically necessary care (80 FR 73415 and 73416). While we are not proposing in this rule any changes to the gainsharing caps for these models, we have heard various opinions from stakeholders, including the Medicare Payment Advisory Commission (MedPAC), on the relative benefit of such limitations on gainsharing and in this proposed rule we are soliciting comment on this requirement and any alternative gainsharing caps that may be appropriate to apply to physicians, non-physician practitioners, PGPs, and NPPGPs.

C. Maintaining ICD-CM codes for Quality Measures

In the CJR model final rule (80 FR 73474), we discussed how specific International Classification of Diseases (ICD)—Clinical Modifications (CM) procedure codes define group of procedures included in the Hospital-level risk-standardized

complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF #1550) (Hip/Knee Complications) measure. In discussing quality measures in general, the ICD-CM codes relative to defining a measure cohort are updated annually and are subject to change. For example, in the EPM final rule (82 FR 389), we itemized specific ICD-9-CM and ICD-10-CM codes for Hip/Knee Complications measure. As quality measures are refined and maintained, the ICD-CM code values used to identify the relevant diagnosis and/or procedures included in quality measures can be updated. For example, CMS' Center for Clinical Standards and Quality (CCSQ) has recently updated the list of ICD-10 codes used to identify procedures included in the Hip/Knee Complications measure. We did not intend for our preamble discussions of certain ICD-CM codes used, for example, to identify procedures included in the Hip/Knee Complications measures, and therefore the PRO cohorts for the CJR model, to set a policy that would define the relevant cohorts for the entirety of the CJR model. We should have also directed readers to look for the most current codes on the CMS quality website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>. To ensure that model participants are aware of periodic ICD-CM code updates to the Hip/Knee Complications measure, we are proposing to clarify that participants must use the applicable ICD-CM code set that is updated and released to the public each calendar year in April by CCSQ and posted on the Hospital Quality Initiative Measure Methodology web site (<https://www.cms.gov/medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>) for purposes of reporting

each of those measures. CMS relies on the National Quality Forum (NQF) measure maintenance update and review processes to update substantive aspects of measures every 3 years. Through NQF's measure maintenance process, NQF endorsed measures are sometimes updated to incorporate changes that we believe do not substantially change the nature of the measures. Examples of such changes include updated diagnosis or procedures codes, changes to patient population, definitions, or extension of the measure endorsement to apply to other settings. We believe these types of maintenance changes are distinct from more substantive changes and do not require the use of the agency's regulatory process used to update more detailed aspects of quality measures.

D. Clarification of CJR Reconciliation Following Hospital Reorganization Event

In the CJR model final rule (80 FR 73348) rule, we discussed our method of setting target prices using all historical episodes that would represent our best estimate of historical volume and payments for participant hospitals when an acquisition, merger, divestiture, or other reorganization results in a hospital with a new CCN. When a reorganization event occurs during a performance year, CMS updates the quality-adjusted episode target prices for the new or surviving participant hospital (§ 510.300(b)(4)). Following the end of a performance year, CMS performs annual reconciliation calculations in accordance with the provisions established in § 510.305. The annual reconciliation calculations are specific to the episodes attributable to each participant hospital entity for that performance year. The applicable quality-adjusted episode target price for such episodes is the quality-adjusted episode target price that applies to the episode type as of the anchor hospitalization admission date (§ 510.300(a)(3)). For

example, if during a performance year, two participant hospitals (Hospital A and Hospital B) merge under the CCN of one of those two participant hospital's CCN (Hospital B's CCN), (assuming no other considerations apply) three initial (and three subsequent) annual reconciliation calculations for that performance year are performed: an initial (and subsequent) reconciliation for Hospital A for the episodes where the anchor hospitalization admission occurred prior to the merger (as determined by the CCN on the IPPS claim), using Hospital A's episode target price for that time period; an initial (and subsequent) reconciliation for Hospital B for the episodes where anchor hospitalization admission occurred before the merger (as determined by the CCN on the IPPS claim), using Hospital B's episode target price for that time period; and an initial (and subsequent) reconciliation for the post-merger entity (merged Hospitals A and B) for the episodes where anchor hospitalization admission occurred on or after the merger's effective date, using the episode target price that time period. Reorganization events that involve a CJR model participant hospital and a hospital that is not participating in the CJR model and result in the new organization operating under the CJR participant hospital's CCN, would not affect the reconciliation for the CJR participant hospital for episodes that initiate before the effective date of the reorganization event. Episodes that initiate after such reorganization event would be subject to an updated quality-adjusted episode target price that is based on historical episodes for the CJR participant hospital which would include historical episode expenditures for all hospitals that are integrated under the surviving CCN. These policies have been in effect since the start of the CJR model on April 1, 2016. To further clarify this policy for the CJR model, we propose to

add a provision specifying that separate reconciliation calculations are performed for episodes that occur before and after a reorganization that results in a hospital with a new CCN at § 510.305(d)(1). We believe this clarification would increase transparency and understanding of the payment reconciliation processes for the CJR model. We seek comment on this proposal.

E. Proposed Adjustment to the Pricing Calculation for the CJR Telehealth HCPCS Codes to Include the Facility PE Values

In the CJR model final rule (80 FR 73450), we established 9 HCPCS G-codes to report home telehealth evaluation and management (E/M) visits furnished under the CJR telehealth waiver as displayed in Table 5. These codes have been payable for CJR model beneficiaries since the CJR model began on April 1, 2016. Pricing for these 9 codes is updated each calendar year to reflect the work and malpractice (MP) relative value units (RVUs) for the comparable office and other outpatient E/M visit codes on the Medicare Physician Fee Schedule (MPFS). As we stated in the CJR model final rule (80 FR 73450), in finalizing this pricing method for these codes, we did not include the practice expense (PE) RVUs of the comparable office and other outpatient E/M visit codes in the payment rate for these unique CJR model services, based on the belief that practice expenses incurred to furnish these services are marginal or are paid for through other MPFS services. However, since the publication of the CJR model final rule, stakeholders have expressed concern that the zero value assigned to the PE RVUs for these codes results in inaccurate pricing. Stakeholders assert that there are additional costs related to the delivery of telehealth services under the CJR model such as maintaining the

telecommunications equipment, software and security and that, while these practice expense costs are not equivalent to in-person service delivery costs, they are greater than zero. In considering the pricing concerns voiced by stakeholders, we recognize that there are resource costs in practice expense for telehealth services furnished remotely, however, we do not believe the current PE methodology and data accurately account for these costs relative to the PE resource costs for other services. This belief previously led us to assign zero PE RVUs in valuing these services, but because we recognize that there are some costs that are not being accounted for by the current pricing for these CJR model codes, we believe an alternative to assigning zero PE RVUs would be to use the facility PE RVUs for the analogous in-person services. While we acknowledge that assigning the facility PE RVUs would not provide a perfect reflection of practice resource costs for remote telehealth services under the CJR model, in the absence of more specific information, we believe it is likely a better proxy for such PE costs than zero. Therefore, we are proposing to use the facility PE RVUs for the analogous services in pricing the 9 CJR HCPCS G codes shown in Table 5. Additionally, we are proposing to revise § 510.605(c)(2) to reflect the addition of the RVUs for comparable codes for the facility PE to the work and MP RVUs we are currently using for the basis for payment of the CJR telehealth waiver G codes.

TABLE 5: HCPCS CODES FOR TELEHEALTH VISITS FOR CJR MODEL BENEFICIARIES IN HOME OR PLACE OF RESIDENCE

HCPCS Code Number	Long Descriptor	Short Descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/Outpatient E/M Visit CPT Code for Same Calendar Year under the PFS; PE RVUs Equal to the Facility Values for Each
G9481	<p>Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:</p> <ul style="list-style-type: none"> • A problem focused history. • A problem focused examination. • Straightforward medical decision making, furnished in real time using interactive audio and video technology. <p>Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.</p>	Remote E/M new pt 10mins	99201
G9482	<p>Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:</p> <ul style="list-style-type: none"> • An expanded problem focused history. • An expanded problem focused examination. • Straightforward medical decision making, furnished in real time using interactive audio and video technology. <p>Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology.</p>	Remote E/M new pt 20mins	99202

HCPCS Code Number	Long Descriptor	Short Descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/Outpatient E/M Visit CPT Code for Same Calendar Year under the PFS; PE RVUs Equal to the Facility Values for Each
G9483	<p>Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:</p> <ul style="list-style-type: none"> • A detailed history. • A detailed examination. • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M new pt 30 mins	99203
G9484	<p>Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:</p> <ul style="list-style-type: none"> • A comprehensive history. • A comprehensive examination. • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M new pt 45mins	99204

HCPCS Code Number	Long Descriptor	Short Descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/Outpatient E/M Visit CPT Code for Same Calendar Year under the PFS; PE RVUs Equal to the Facility Values for Each
G9485	<p>Remote in-home visit for the evaluation and management of a new patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires these 3 key components:</p> <ul style="list-style-type: none"> • A comprehensive history. • A comprehensive examination. • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M new pt 60mins	99205
G9486	<p>Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components:</p> <ul style="list-style-type: none"> • A problem focused history. • A problem focused examination. • Straightforward medical decision making, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M est. pt 10mins	99212

HCPCS Code Number	Long Descriptor	Short Descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/Outpatient E/M Visit CPT Code for Same Calendar Year under the PFS; PE RVUs Equal to the Facility Values for Each
G9487	<p>Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components:</p> <ul style="list-style-type: none"> • An expanded problem focused history. • An expanded problem focused examination. • Medical decision making of low complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M est. pt 15mins	99213

HCPCS Code Number	Long Descriptor	Short Descriptor	Work and MP RVUs Equal to Those of the Corresponding Office/Outpatient E/M Visit CPT Code for Same Calendar Year under the PFS; PE RVUs Equal to the Facility Values for Each
G9488	<p>Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components:</p> <ul style="list-style-type: none"> • A detailed history. • A detailed examination. • Medical decision making of moderate complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M est. pt 25mins	99214
G9489	<p>Remote in-home visit for the evaluation and management of an established patient for use only in the Medicare-approved Comprehensive Care for Joint Replacement model, which requires at least 2 of the following 3 key components:</p> <ul style="list-style-type: none"> • A comprehensive history. • A comprehensive examination. • Medical decision making of high complexity, furnished in real time using interactive audio and video technology. Counseling and coordination of care with other physicians, other qualified health care professionals or agencies are provided consistent with the nature of the problem(s) and the needs of the patient or the family or both. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient or family or both via real time, audio and video intercommunications technology. 	Remote E/M est. pt 40mins	99215

F. Clinician Engagement Lists

1. Background for Submission of Clinician Engagement Lists

Under the Quality Payment Program, the Advanced APM track of the CJR model does not include eligible clinicians on a Participation List; rather the CJR Advanced APM track currently includes eligible clinicians on an Affiliated Practitioner List as defined under § 414.1305 and described under § 414.1425(a)(2) of the agency's Quality Payment Program regulations. As such, the Affiliated Practitioner List for the CJR model is the "CMS-maintained list" of eligible clinicians that have "a contractual relationship with the Advanced APM Entity [for CJR, the participant hospital] for the purposes of supporting the Advanced APM Entity's quality or cost goals under the Advanced APM." As specified in our regulations at §414.1425(a)(2), CMS will use this list to identify the eligible clinicians who will be assessed as Qualifying APM Participants (QPs) for the year. CMS will make QP determinations individually for these eligible clinicians as specified in §§ 414.1425(b)(2), (c)(4), and 414.1435.

In the EPM final rule, we stated that a list of physicians, nonphysician practitioners, or therapists in a sharing arrangement, distribution arrangement, or downstream distribution arrangement, as applicable, would be considered an Affiliated Practitioner List of eligible clinicians who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM for purposes of the Quality Payment Program. An in-depth discussion of how the clinician financial arrangement list is considered an Affiliated Practitioner List can be found in section V.O. of the EPM final rule (82 FR 558 through 563). The clinician financial arrangements list (§ 510.120(b))

will be used by CMS to identify eligible clinicians for whom we would make a QP determination based on services furnished through the Advanced APM track of the CJR model.

Stakeholders have expressed a desire for model changes that would also include in the clinician financial arrangement list physicians, non-physician practitioners, and therapists without a financial arrangement under the CJR model, but who are affiliated with and support the Advanced APM Entity in its participation in the Advanced APM for purposes of the Quality Payment Program.

We agree with stakeholders that these physicians, non-physician practitioners, and therapists should have their contributions to the Advanced APM Entity's participation in the Advanced APM recognized under the Quality Payment Program; however, since these individuals do not have financial arrangements with the participant hospital, to also include them on the clinician financial arrangement list would be misleading, and could create confusion when CJR model participant hospitals submit lists to CMS.

2. Proposed Clinician Engagement List Requirements

To increase opportunities for eligible clinicians supporting CJR model participant hospitals by performing CJR model activities and who are affiliated with participant hospitals to be considered QPs, we are proposing that each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS, but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's

quality or cost goals under the CJR model during the period of the performance year specified by CMS, would be added to a clinician engagement list.

In addition to the clinician financial arrangement list that is considered an Affiliated Practitioner List for purposes of the Quality Payment Program, we propose the clinician engagement list would also be considered an Affiliated Practitioner List. The clinician engagement list and the clinician financial arrangement list would be considered together an Affiliated Practitioner List and would be used by CMS to identify eligible clinicians for whom we would make a QP determination based on services furnished through the Advanced APM track of the CJR model. As specified in § 414.1425, as of our regulations, adopted in the Calendar Year (CY) 2017 Quality Payment Program final rule (81 FR 77551) (hereinafter referred to as the 2017 QPP final rule), those physicians, nonphysician practitioners, or therapists who are included on the CJR model Affiliated Practitioner List as of March 31, June 30, or August 31 of a QP performance period would be assessed to determine their QP status for the year. As discussed in the 2017 QPP final rule (81 FR 77439 and 77440), for clinicians on an Affiliated Practitioner List, we determine whether clinicians meet the payment amount or patient count thresholds to be considered QPs (or Partial QPs) for a year by evaluating whether individual clinicians on an Affiliated Practitioner List have sufficient payments or patients flowing through the Advanced APM; we do not make any determination at the APM Entity level for Advanced APMs in which eligible clinicians are not identified on a Participation List, but are identified on an Affiliated Practitioner List. CMS makes the QP determination based

on Part B claims data, so clinicians need not track or report payment amount or patient count information to CMS.

This proposal would broaden the scope of eligible clinicians that are considered Affiliated Practitioners under the CJR model to include those without a financial arrangement under the CJR model but who are either directly employed by or contractually engaged with a participant hospital to perform clinical work for the participant hospital when that clinical work, at least in part, supports the cost and quality goals of the CJR model. We propose that the cost and quality goals of the additional affiliated practitioners who are identified on a clinician engagement list because they are contracted with a participant hospital must include activities related to CJR model activities, that is, activities related to promoting accountability for the quality, cost, and overall care for beneficiaries during LEJR episodes included in the CJR model, including managing and coordinating care; encouraging investment in infrastructure, enabling technologies, and redesigned care processes for high quality and efficient service delivery; the provision of items and services during a CJR episode in a manner that reduces costs and improves quality; or carrying out any other obligation or duty under the CJR model.

Like the requirements of the clinician financial arrangement lists specified at § 510.120(b), for CMS to make QP determinations for eligible clinicians based on services furnished through the CJR Advanced APM track, we would require that accurate information about each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by

CMS, but who is included on a clinician engagement list, be provided to CMS in a form and manner specified by CMS on a no more than quarterly basis. Thus, we propose that each participant hospital in the Advanced APM track of the CJR model submit to CMS a clinician engagement list in a form and manner specified by CMS on a no more than quarterly basis. We propose this list must include the following information on eligible clinicians for the period of the CJR model performance year specified by CMS:

- For each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS but who does have a contractual relationship with a participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the CJR model performance year specified by CMS:

- ++ The name, TIN, and NPI of the individual.

- ++ The start date and, if applicable, the end date for the contractual relationship between the individual and participant hospital.

Further, we propose that if there are no individuals that meet the requirements to be reported, as specified in any of § 510.120 (b)(1) through (3) of the EPM final rule or § 510.120(c) as proposed here, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report.

Given that this proposal would require submission of a clinician engagement list, or an attestation that there are no eligible clinicians to be included on such a list, to reduce burden on participant hospitals, we would collect information for the clinician engagement list and clinician financial arrangement list at the same time.

We seek comments on the proposal for submission of this information. We are especially interested in comments about approaches to information submission, including the periodicity and method of submission to CMS that would minimize the reporting burden on participant hospitals while providing CMS with sufficient information about eligible clinicians to facilitate QP determinations.

For each participant hospital in the CJR Advanced APM track, we propose that the participant hospital must maintain copies of its clinician engagement lists and supporting documentation (that is, copies of employment letters or contracts) of its clinical engagement lists submitted to CMS. Because we would use these lists to develop Affiliated Practitioner Lists used for purposes of making QP determinations, these documents would be necessary to assess the completeness and accuracy of materials submitted by a participant hospital and to facilitate monitoring and audits. For the same reason, we further propose that the participant hospital must retain and provide access to the required documentation in accordance with § 510.110.

G. Clarification of Use of Amended Composite Quality Score Methodology During CJR Model Performance Year 1 Subsequent Reconciliation

We conducted the initial reconciliation for performance year 1 of the CJR model in early 2017, and expect to make reconciliation payments to CJR participant hospitals by the end of September 2017 to accommodate the performance year 1 appeals process timelines. We will conduct the subsequent reconciliation calculation for performance year 1 of the CJR model beginning in the first quarter of 2018, which may result in additional amounts to be paid to participant hospitals or a reduction to the amount that

was paid for performance year 1. However, the results of the performance year 1 subsequent reconciliation calculations will be combined with the performance year 2 initial reconciliation results before reconciliation payment or repayment amounts are processed for payment or collection. Changes to the CJR model established in the EPM final rule impact this process.

The improvements to the CJR model quality measures and composite quality score methodology, which were finalized in the EPM final rule (82 FR 524 through 526), were intended to be effective before the CJR model's performance year 1 initial reconciliation. However, as noted in section II. of this proposed rule, the effective date for certain EPM final rule provisions, including those amending §§ 510.305 and 510.315 to improve the quality measures and composite quality score methodology, were delayed until May 20, 2017. As a result, the CJR reconciliation reports issued in April 2017 were created in accordance with the provisions of §§ 510.305 and 510.315 in effect as of April 2017; that is, the provisions finalized in the CJR model final rule. In early 2018, we would perform the performance year 1 subsequent reconciliation calculation in accordance with the provisions §§ 510.305 and 510.315 in effect as of early 2018, that is, established in the EPM final rule. Applying the provisions established in the EPM final rule to the performance year 1 subsequent reconciliation calculation may result in significant differences between the reconciliation payments calculated during the performance year 1 initial reconciliation and the performance year 1 subsequent reconciliation. We anticipate that these differences will be greater than those that would be expected as a result of using more complete claims and programmatic data that will be

available for the subsequent reconciliation (due to the additional 12 months of time that will occur between the initial and subsequent reconciliation calculations), more accurate identification of model overlap and exclusion of episodes, as well as factoring in adjustments to account for shared savings payments, and post-episode spending, as specified in § 510.305(i). Specifically, the methodology used to determine the quality-adjusted target price for the performance year 1 subsequent reconciliation calculation will differ from the methodology used to determine the quality-adjusted target price for the performance year 1 initial reconciliation calculation as follows: the quality-adjusted target price would be recalculated to apply the amended reductions to the effective discount factors (§ 510.315(f)), which would be determined after recalculating the composite quality scores, including applying more generous criteria for earning quality improvement points (that is, a 2 decile improvement rather than 3 decile improvement as specified in amended § 510.315(d)). Using the recalculated quality-adjusted target price, the net payment reconciliation amount (NPRA) would be recalculated and will include application of post-episode spending reductions (§ 510.305(j)), as necessary, after determining the limitations on loss or gain. Thus, calculating performance year 1 reconciliation payments using these two different provisions may result in a range of upward or downward adjustments to participant hospitals' performance year 1 payment amounts. We note that a downward adjustment to the performance year 1 payment amounts would require payment recoupment, if offset against a performance year 2 initial reconciliation payment amount is not feasible, which may be burdensome for participant hospitals.

In developing this proposed rule, we also considered whether there might be benefit in further delaying the amendments to §§ 510.305 and 510.315 such that the same calculations would be used for both the performance year 1 initial reconciliation and the subsequent performance year 1 reconciliation, and the use of the amended calculations would begin with the performance year 2 initial reconciliation. We believe such an approach would impact future CJR model implementation and evaluation activities. Because determining the performance year 2 composite quality score considers the hospital's quality score improvement from its performance year 1 score, using different methodologies across performance years would require a mechanism to account for differences in the quality score methodology, for example we would have to develop a reliable crosswalk approach. If we were to develop and use a crosswalk approach, participants and other stakeholders would need to be informed about the crosswalk methodology in order to validate data analyses across performance years and that usage of the crosswalk would be ongoing throughout the model's duration for consistency across performance years. This methodology could add substantial complexity to this time-limited model. We also considered that the composite quality score for some participant hospitals may be higher under the revised scoring methodology. Delaying use of the revised scoring methodology may disadvantage these participants if their composite quality score would be higher and result in a more favorable discount percentage or allow the hospital to qualify for a reconciliation payment. Therefore, we believe the best approach is to apply the quality specifications as established in the EPM final rule (that is, the amendments to §§ 510.305 and 510.315 that became effective May

20, 2017) to performance year 1 subsequent reconciliation calculations to ensure that reconciliation calculations for subsequent performance years will be calculated using the same methodology and to improve consistency across performance years for quality improvement measurement. Thus, for the reasons noted previously, we are not proposing to change the amendments to §§ 510.305 and 510.315 that became effective May 20, 2017. We seek comment on whether using an alternative approach, such as the quality composite score methodology from the CJR model final rule for the performance year 1 subsequent reconciliation, would ensure better consistency for analyses across CJR performance years.

H. Clarifying and Technical Changes Regarding the Use of the CMS Price (Payment)

Standardization Detailed Methodology

Based on questions we received from participant hospitals during the performance year 1 reconciliation process, we are proposing to make two technical changes to the CJR model regulations to clarify the use of the CMS Price (Payment) Standardization Detailed Methodology, posted on the QualityNet Web site at

<http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage>

[%2FQnetTier4&cid=1228772057350](http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350), in the calculation of target prices and actual

episode spending. This pricing standardization approach is the same as that used for the Hospital Value-Based Purchasing Program's (HVBP) Medicare spending per beneficiary metric. In section III.C.3.a. of the CJR model final rule (80 FR 73331 through 73333), we finalized how we would operationalize the exclusion of the various special payment provisions in calculating CJR model episode expenditures, both historical episode

spending and performance year episode spending, by relying upon the CMS Price (Payment) Standardization Detailed Methodology with modifications. However, we did not clearly articulate this finalized policy in the regulations at 42 CFR part 510. Thus, we are proposing the following technical changes to bring the regulatory text into conformity with our intended policy and to reduce potential stakeholder uncertainty about how the price (payment) standardization methodology is used. We are proposing to insert “standardized” into the definition of actual episode payment in § 510.2, and insert “with certain modifications” into § 510.300(b)(6) to account for the modifications we must make to the standardization methodology to ensure all pricing calculations are consistent with our finalized policies.

IV. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget. However, we have, summarized the anticipated cost burden associated with the information collection requirements in the Regulatory Impact Analysis section of this proposed rule.

V. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory

Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule proposes to cancel the EPMS and the CR incentive payment model in advance of their start date and proposes several revisions to the design of the CJR model; these proposals impact a subset of hospitals under the IPPS. Therefore, it would have a relatively small economic impact; as a result, this proposed rule does not reach the \$100 million threshold and thus is neither an “economically significant” rule under E.O. 12866, nor a “major rule” under the Congressional Review Act.

B. Statement of Need

As discussed previously, review and reevaluation of policies and programs, as well as revised rulemaking, are within an agency’s discretion, especially after a change in administration occurs. After review and reevaluation of the CJR model final rule, the EPM final rule and the public comments we received in response to the March 21, 2017

IFC, in addition to other considerations, we have determined that it is necessary to propose to rescind the regulations at 42 CFR part 512 and to reduce the geographic scope of the CJR model for the following reasons. First, we believe that requiring hospitals to participate in additional episode models at this time is not in the best interest of the agency or affected providers. We are concerned that engaging in large mandatory episode payment model efforts at this time may impede our ability to pursue and engage providers, such as hospitals, in future voluntary efforts. Similarly, we also believe that reducing the number of providers required to participate in the CJR model would allow us to continue to evaluate the effects of such a model while limiting the geographic reach of our current mandatory models. Finally, we believe that canceling the EPMs and CR incentive payment model, as well as altering the scope of the CJR model, offers CMS maximum flexibility to design alternative episode-based models and make potential improvements to these models as suggested by stakeholders, while still allowing us to test and evaluate the impact of the CJR model on the quality of care and expenditures.

This proposed rule is also necessary to propose improvements to the CJR model for performance years 3, 4, and 5. We are proposing a few technical refinements and clarifications for certain payment, reconciliation and quality provisions, and a change to the criteria for the Affiliated Practitioner List to broaden the CJR Advanced APM track to additional eligible clinicians. We believe these proposed refinements would address operational issues identified since the start of the CJR model.

C. Anticipated Effects

In section III. of the preamble to this proposed rule, we discuss our proposals to amend the regulations governing the CJR model. We present the following estimated overall impact of these proposed changes to the CJR model. Table 6 summarizes the newly calculated estimated impact for the CJR model for the last 3 years of the model. The modeling methodology for provider performance and participation is consistent with the methodology used in modeling the CJR impacts in the EPM final rule (82 FR 596). However, we updated our analysis to include an opt-in option for hospitals in 33 of the 67 MSAs selected for participation in the CJR model (all but 4 of these MSAs are from the lower cost groups), while maintaining mandatory participation for the remaining 34 MSAs (all of which are from the higher cost groups), and allowing for the exclusion of low-volume and rural hospitals in these 34 MSAs from mandatory participation and allowing them to choose voluntary participation (opt-in). We would expect the number of mandatory participating hospitals from year 3 forward to decrease from approximately 700, which is approximately the number of current CJR participants, to approximately 393. We assumed that if a hospital would exceed its target pricing such that it would incur an obligation of repayment to CMS of 3 percent or more in a given year, that hospital would not elect voluntary participation in the model for the final three performance years. We assumed no low-volume providers would participate, noting that including them in impacts would not have any noticeable effects due to their low claims volume. For purposes of identifying CJR rural hospitals for this impact, we used the 2017 IPPS § 412.103 rural reclassification list. We found only one provider in the 34 mandatory MSAs with an active rural reclassification and this provider was also on the

low-volume hospital list and was not included in the impacts. The likelihood of voluntary participation linearly increases based on an upper bound of 3 percent bonus, but the modeling assumes that 25 percent of hospitals in the voluntary MSAs would not consider participation so that the likelihood of participation for each hospital is capped at 75 percent; we expect 60 to 80 hospitals to elect voluntary participation in the model. We seek comment on our assumptions about the number of hospitals that would elect voluntary participation in the CJR model. Due to a lack of available data, we did not account for participant investment in the impact analysis model we used for this proposed rule. However, we would expect that those who choose to voluntarily participate would have made investments in the CJR model that enable them to perform well and that they would anticipate earning positive reconciliation payments. For those hospitals choosing not to voluntarily participate, we would expect that the cost of any investments they may have made based on their participation in performance years 1 and 2 of the CJR model would be outweighed by the reconciliation payment obligations they would expect to incur if they continued to participate. The 60 to 80 participants we expect to continue participating in the model through the voluntary election process are not included in our previous estimate of 393 CJR participants in the mandatory MSAs. Thus, in total we expect approximately 450 to 470 participants in the CJR model for the final three performance years. The participation parameters were chosen to reflect both the anticipated risk aversion of providers, and an expectation that many participants do not remain in an optional model or demonstration when there is an expectation that the hospital would incur an obligation of repayment to CMS. These assumptions reflect the

experience with other models and demonstrations. The value of 3 percent may be somewhat larger than the level of repayment at which providers would opt-in, but the value was chosen to allow for the uncertainty of expected claims. We note that the possibility of shifting episodes from CJR model participant hospitals to low-volume or other non-participating hospitals exists and that we did not include any assumptions of this potential behavior in our financial impact modeling. We seek comment on our model assumptions that shifting of episodes will not occur. The new calculations estimate that the CJR model would result in a net Medicare program savings of approximately \$204 million over the 3 remaining performance years (2018 through 2020). This represents a reduction in savings of approximately \$90 million from the estimated net financial impacts of the CJR model in the EPM final rule (82 FR 603).

Our previous analyses of the CJR model did not explicitly model for utilization changes, such as improvements in the efficiency of service during episodes. However, these behavioral changes would have minimal effect on the Medicare financial impacts. If the actual costs for an episode are below the discounted bundled payment amount, then CMS distributes the difference between these two amounts to the participant hospital, up to a capped amount. Similarly, if actual costs for an episode are above the discounted bundled payment amount, then the participant hospital pays CMS the difference between these amounts, up to a capped amount. Due to the uncertainty of estimating the impacts of this model, actual results could be higher or lower than this estimate.

TABLE 6: COMPARISON OF INITIAL ESTIMATE OF THE IMPACT ON THE MEDICARE PROGRAM OF THE CJR MODEL WITH REVISED ESTIMATES
(Figures are in \$ millions, negative values represent savings)

Year	2018	2019	2020	Total
Initial CJR Estimate	-61	-109	-125	-294
Revised CJR Estimate	-38	-77	-88	-204
Change	22	32	36	90

Note: The initial estimate includes the changes to the CJR model finalized in the EPM final rule (82 FR 603). The 2016 and 2017 initial estimate is not impacted by the proposed changes to the CJR model in this proposed rule. The total column reflects 2018 through 2020. Totals do not necessarily equal the sums of rounded components

Our analysis presents the cost and transfer payment effects of this proposed rule to the best of our ability.

D. Effects on Beneficiaries

We believe that the proposal to cancel the EPMs and CR incentive payment model would not affect beneficiaries' freedom of choice to obtain healthcare services from any individual or organization qualified to participate in the Medicare program, including providers that are making care improvements within their communities.

Although these models seek to incentivize care redesign and collaboration throughout the inpatient and post-acute care spectrum, the models have not yet begun. As the current baseline assumes these models would become effective on January 1, 2018, and that these models would incentivize care improvements that would likely result in an increase in quality of care for beneficiaries, it is possible that the proposal to cancel these models could cause hospitals that potentially made improvements in care in anticipation of the start of these models to delay or cease these investments, which could result in a reversal of any recent quality improvements. However, we believe the concerns raised by

stakeholders and the lack of time to consider design improvements for these models prior to the January 1, 2018 start date outweigh potential reversal of any recent improvements in care potentially made by some hospitals and warrant cancellation of these models at this time while we engage with stakeholders to identify future tests for bundled payments and incentivizing high value care.

We believe that the proposed changes to the CJR model discussed in this proposed rule, specifically focusing the model on higher cost MSAs in which participation would continue to be mandatory and allowing low-volume and rural hospitals and all participant hospitals in lower cost MSAs to choose voluntary participation, would maintain the potential benefits of the CJR model for beneficiaries in many areas while providing a substantial number of hospitals with increased flexibility to better focus on priority needs of the beneficiaries they serve. Specifically, low-volume and rural hospitals as well as other hospitals in the 33 voluntary participation MSAs (which are relatively more efficient areas) could elect to participate in the CJR model if they believe that doing so best meets their organization's strategic priorities for serving the beneficiaries in their community. Alternatively, if these hospitals do not believe continued participation in the CJR model would benefit their organizational goals and local patient care priorities, they can elect not to opt-in for the remainder of the model. We believe that beneficiaries in the service areas of the hospitals that would be allowed to choose to participate in the CJR model under our proposal may have an ongoing benefit from the care redesign investments these hospitals have already made during the first 2 years of the CJR model. Overall, we believe the refinements to the CJR model

proposed in this proposed rule do not materially alter the potential effects of the model on beneficiaries. However, we acknowledge the possibility that the improved quality of care that was likely to have occurred during performance years 1 and 2 of the CJR model may be curtailed for beneficiaries that receive care at hospitals that do not elect to continue participation in the CJR model.

E. Effects on Small Rural Hospitals

The changes to the CJR model proposed in this proposed rule do not substantially alter our previous impacts of the impact on small, geographically rural hospitals specified in either the EPM final rule (82 FR 606) and the CJR model final rule (80 FR 73538) because we continue to believe that few geographically rural hospitals will be included in the CJR model. In addition, the proposal to allow all rural hospitals (as defined in § 510.2) that are not otherwise excluded the opportunity to elect to opt-in to the CJR model instead of having a mandatory participation requirement may further reduce the likelihood that rural hospitals would be included in the model. We solicit public comment on our estimates and analysis of the impact of our proposals on small rural hospitals.

F. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities, either by virtue of their nonprofit status or by

qualifying as small businesses under the Small Business Administration's size standards (revenues of less than \$7.5 to \$38.5 million in any 1 year; NAIC Sector–62 series).

States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at

<http://www.sba.gov/content/smallbusiness-size-standards>.

For purposes of the RFA, we generally consider all hospitals and other providers and suppliers to be small entities. We believe that the provisions of this proposed rule relating to acute care hospitals would have some effects on a substantial number of other providers involved in these episodes of care including surgeons and other physicians, skilled nursing facilities, physical therapists, and other providers. Although we acknowledge that many of the affected entities are small entities, and the analysis discussed throughout this proposed rule discusses aspects of episode payment models that may or would affect them, we have no reason to assume that these effects would reach the threshold level of 3 percent of revenues used by HHS to identify what are likely to be "significant" impacts. We assume that all or almost all of these entities would continue to serve these patients, and to receive payments commensurate with their cost of care. Hospitals currently experience frequent changes to payment (for example, as both hospital affiliations and preferred provider networks change) that may impact revenue, and we have no reason to assume that this would change significantly under the changes proposed in this rule.

Accordingly, we have determined that this proposed rule will not have a significant impact on a substantial number of small entities. We solicit public comments on our estimates and analysis of the impact of our proposals on those small entities.

G. Effects of Information Collection

The changes proposed in this proposed rule would have a minimal additional burden of information collection for CJR model participant hospitals. The two areas which this proposed rule may increase participant burden include providing clinician engagement lists and submitting opt-in documentation (for eligible hospitals who choose to opt-in to the CJR model)

Clinician engagement list submission for the CJR model would require that participants submit on a no more than quarterly basis a list of physicians, nonphysician practitioners, or therapists who are not a CJR model collaborator during the period of the CJR model performance year specified by CMS but who do have a contractual relationship with a CJR model participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS.

For hospitals eligible to opt-in to the CJR model that elect to participate in the model, CMS intends to provide a template that can be completed and submitted prior to the proposed January 31, 2018 submission deadline. As stated previously, we estimate that the number of hospitals that will elect voluntary participation in CJR is 60 to 80. As stated previously, this template would be designed to minimize burden on participants, particularly since all necessary information required to effectively opt-in will be included

within the template. Using wage information from the Bureau of Labor Statistics for medical and health service managers (Code 11-9111), we assumed a rate of \$105.16 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm) and estimated that the time to complete the opt-in template would be, on average, approximately 30 minutes per hospital. Thus, total costs associated with completing opt-in templates for all 60 to 80 hospitals projected to elect voluntary participation is expected to range between \$3,150 (60 hospitals) and \$4,200 (80 hospitals).

We seek comment on our assumptions and information on any costs associated with this work.

H. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on the EPM proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the precedent rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters on the EPM proposed rule would be a fair estimate of the number of reviewers of this rule. We

welcome any comments on the approach in estimating the number of entities that would review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, however for the purposes of our estimate we assume that each reviewer reads approximately 100 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is \$105.16 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed, we estimate that it would take approximately 1.6 hours for the staff to review this proposed rule. For each entity that reviews the rule, the estimated cost is \$168.26 (1.6 hours x \$105.16). Therefore, we estimate that the total cost of reviewing this regulation is \$29,445 (\$105.16 x 175 reviewers).

I. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2017, that is approximately \$148 million. This proposed rule does not include any mandate that would result in spending by state, local or tribal governments, in the aggregate, or by the private sector in the amount of \$148 million in any 1 year.

J. Federalism

We do not believe that there is anything in this proposed rule that either explicitly or implicitly preempts any state law, and furthermore we do not believe that this proposed rule would have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication.

K. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule, if finalized as proposed, is not expected to be subject to the requirements of E.O. 13771 because it is estimated to result in no more than *de minimis* costs.

L. Alternatives Considered

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered, and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. We considered but did not propose to allow voluntary participation in all of the 67 selected MSAs in the CJR model because the overall estimated CJR model impact would no longer show savings, and would likely result in costs. An entirely voluntary CJR model would likely result in costs due to the assumption that, in aggregate, hospitals that expect to receive a positive reconciliation payment from Medicare would elect to opt-in to the model while hospitals that expect to owe Medicare a reconciliation amount would not likely elect to participate in the model. We also considered but did not propose limiting participation to the proposed 34 mandatory participation MSAs and not allowing voluntary participation in

any of the 67 selected MSAs. If participation was limited to the proposed 34 mandatory participation MSAs and voluntary participation was not allowed in any MSA, the impact to the overall estimated model savings over the last three years of the model would be closer to \$30 million than the \$90 million estimate presented in section V. of this proposed rule, because our modeling does not include assumptions about behavioral changes that might lower fee-for-service spending. Since our impact model estimates that 60 to 80 hospitals would choose voluntary participation and that these potential voluntary participants would be expected to earn only positive reconciliation payments under the model, these positive payments to the voluntary participants would offset some of the savings garnered from mandatory participants. However, we are proposing to allow voluntary participation in the proposed 33 voluntary participation MSAs and for low-volume and rural hospitals to permit hospitals that have made investments in care redesign and commitments to improvement to continue to participate in the model for the remaining 3 years. We believe our proposal would benefit a greater number of beneficiaries because a greater number of hospitals would be included in the CJR model.

Instead of proposing to cancel the EPMs and CR incentive payment model, we considered altering the design of these models to allow for voluntary participation but as this would potentially involve restructuring the model design, payment methodologies, financial arrangement provisions and/or quality measures, we did not believe that such alterations would offer providers enough time to prepare for such changes, given the planned January 1, 2018 start date. In addition, if at a later date we decide to offer these models, or similar models, on a voluntary basis, we would not expect to implement them

through rulemaking, but rather would establish them consistent with the manner in which we have implemented other voluntary models.

We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider, as well as on the costs, benefits, or other effects of these.

M. Accounting Statement and Table

As required by OMB Circular A–4 under Executive Order 12866 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4) in Table 7, we have prepared an accounting statement showing the classification of transfers associated with the provisions in this proposed rule. The accounting statement is based on estimates provided in this regulatory impact analysis. As described in Table 6, we estimate the proposed changes to the CJR model would continue to result in savings to the federal government of approximately \$204 million over the 3 remaining performance years of the model from 2018 to 2020, noting these changes do reduce the original CJR estimated savings by approximately \$90 million. In Table 7, the overall annualized change in payments (for all provisions in this proposed rule relative to the CJR model as originally finalized) based on a 7-percent and 3-percent discount rate, results in net federal monetary transfer from the federal government to participant IPPS hospitals of \$73.2 million and \$82.4 million in 2017 dollars, respectively, over the period of 2018 to 2020.

**TABLE 7: ACCOUNTING STATEMENT
CHANGES TO COMPREHENSIVE CARE FOR JOINT REPLACEMENT
MODEL FOR PERFORMANCE YEARS 2018 TO 2020**

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs*				
Upfront cost of regulation (\$million)	0.03	2017	7%	–2018 upfront cost
	0.03	2017	3%	–2018 upfront cost
From Whom to Whom	Incurred by IPPS Hospitals as a result of this regulation.			
Transfers				
Annualized/Monetized (\$million/year)	27.90	2017	7%	2018 - 2020
	29.14	2017	3%	2018 - 2020
From Whom To Whom	From the Federal Government to Participating IPPS Hospitals			

* The cost includes the regulatory familiarization and completing opt-in templates for up to 80 hospitals to join the CJR model.

M. Conclusion

This analysis, together with the remainder of this preamble, provides the Regulatory Impact Analysis of a rule. As a result of this proposed rule, we estimate that the financial impact of the changes to the CJR model proposed here would result in a reduction to previously estimated savings by \$90 million over the 3 remaining performance years (2018 through 2020) although we note that the CJR model would still be estimated to save the Medicare program approximately \$204 million over the remaining three performance years.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget.

VI. 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.

List of Subjects**42 CFR Part 510**

Administrative Practice and Procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative Practice and Procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at section 1115A of the Social Security Act, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV, as follows:

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

1. The authority citation for part 510 continues to read as follows:

Authority: Secs. 1102, 1115A, and 1871 of the Social Security Act (42 U.S.C. 1302, 1315(a), and 1395hh).

2. Section 510.2 is amended by—

- a. Revising the definition of “Actual episode payment”;
- b. Adding, in alphabetical order, definitions of “Low-volume hospital” and “mandatory MSA”.
- c. Revising the definition of “participant hospital”; and
- d. Adding the definition of “voluntary MSA”.

The revisions and additions read as follows:

§ 510.2 Definitions.

* * * * *

Actual episode payment means the sum of standardized Medicare claims payments for the items and services that are included in the episode in accordance with § 510.200(b), excluding the items and services described in § 510.200(d).

* * * * *

Low-volume hospital means a hospital identified by CMS as having fewer than 20 LEJR episodes in total across the 3 historical years of data used to calculate the performance year 1 CJR episode target prices.

* * * * *

Mandatory MSA means an MSA designated by CMS as a mandatory participation MSA in accordance with §510.105(a).

* * * * *

Participant hospital means one of the following:

(1) During performance years 1 and 2 of the CJR model and the period from January 1, 2018 to January 31, 2018 of performance year 3, a hospital (other than a hospital excepted under §510.100(b)) with a CCN primary address located in one of the geographic areas selected for participation in the CJR model in accordance with §510.105.

(2) Beginning February 1, 2018, a hospital (other than a hospital excepted under §510.100(b)) that is one of the following:

(i) A hospital with a CCN primary address located in a mandatory MSA as of February 1, 2018 that is not a rural hospital or a low-volume hospital on that date.

(ii) A hospital that is a rural hospital or low-volume hospital with a CCN primary address located in a mandatory MSA that makes an election to participate in the CJR model in accordance with §510.115.

(iii) A hospital with a CCN primary address located in a voluntary MSA that makes an election to participate in the CJR model in accordance with §510.115.

* * * * *

Voluntary MSA means an MSA designated by CMS as a voluntary participation MSA in accordance with §510.105(a).

3. Section 510.105 is amended by revising paragraph (a) to read as follows:

§ 510.105 Geographic areas.

(a) *General.* The geographic areas for inclusion in the CJR model are obtained based on a stratified random sampling of certain MSAs in the United States.

(1) All counties within each of the selected MSAs are selected for inclusion in the CJR model.

(2) Beginning with performance year 3, the selected MSAs are designated as either mandatory participation MSAs or voluntary participation MSAs.

* * * * *

4. Section 510.115 is added to read as follows:

§ 510.115 Voluntary participation election.

(a) *General.* To continue participation in performance year 3 and participate in performance year 4 and performance year 5, the following hospitals must submit a

written participation election letter as described in paragraph (c) of this section during the voluntary participation election period specified in paragraph (b) of this section:

(1) Hospitals (other than those excluded under §510.100(b)) with a CCN primary address in a voluntary MSA.

(2) Low-volume hospitals with a CCN primary address in a mandatory MSA.

(3) Rural hospitals with a CCN primary address in a mandatory MSA.

(b) *Voluntary participation election period.* The voluntary participation election period begins on January 1, 2018 and ends on January 31, 2018.

(c) *Voluntary participation election letter.* The voluntary participation election letter serves as the model participation agreement. CMS accepts the voluntary participation election letter if the letter meets all of the following criteria:

(1) Includes the following:

(i) Hospital name.

(ii) Hospital address.

(iii) Hospital CCN.

(iv) Hospital contact name, telephone number, and email address.

(v) Model name (that is, CJR model).

(vi) Attestation of CEHRT use as specified in §510.120(a)(1) (if the hospital is choosing to participate in the Advanced APM track).

(2) Includes a certification that the hospital will --

(i) Comply with all applicable requirements of this part and all other laws and regulations applicable to its participation in the CJR model; and

(ii) Submit data or information to CMS that is accurate, complete and truthful, including, but not limited to, the participation election letter and any quality data or other information that CMS uses in its reconciliation processes.

(3) Is signed by the hospital administrator, CFO or CEO.

(4) Is submitted in the form and manner specified by CMS.

5. Section 510.120, as added January 3, 2017 (82 FR 180), delayed until October 1, 2017, on March 21, 2017 (82 FR 14464), further delayed until January 1, 2018, on May 19, 2017 (82 FR 22895), is amended by removing paragraph (b)(4), revising paragraph (c), and adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 510.120 CJR participant hospital CEHRT track requirements.

* * * * *

(c) *Clinician engagement list.* Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must submit to CMS a clinician engagement list in a form and manner specified by CMS on a no more than quarterly basis. This list must include the following information on individuals for the period of the performance year specified by CMS:

(1) For each physician, nonphysician practitioner, or therapist who is not a CJR collaborator during the period of the CJR model performance year specified by CMS but who does have a contractual relationship with the participant hospital based at least in part on supporting the participant hospital's quality or cost goals under the CJR model during the period of the performance year specified by CMS:

(i) The name, TIN, and NPI of the individual.

(ii) The start date and, if applicable, the end date for the contractual relationship between the individual and participant hospital.

(2) [Reserved]

(d) *Attestation to no individuals.* If there are no individuals that meet the requirements to be reported, as specified in paragraphs (b)(1) through (3) or paragraph (c) of this section, the participant hospital must attest in a form and manner required by CMS that there are no individuals to report.

(e) *Documentation requirements.* (1) Each participant hospital that chooses CEHRT use as provided in paragraph (a)(1) of this section must maintain documentation of their attestation to CEHRT use, clinician financial arrangements lists, and clinician engagement lists.

(2) The participant hospital must retain and provide access to the required documentation in accordance with §510.110.

6. Section 510.210 is amended by revising paragraph (b) to read as follows:

§ 510.210 Determination of the episode.

* * * * *

(b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in §510.305 if any of the following occur:

(1) The beneficiary does any of the following during the episode:

(i) Ceases to meet any criterion listed in §510.205.

(ii) Is readmitted to any participant hospital for another anchor hospitalization.

(iii) Initiates an LEJR episode under BPCI.

(iv) Dies.

(2) For performance year 3, the participant hospital did not submit a participation election letter that was accepted by CMS to continue participation in the model.

7. Section 510.300 is amended by revising paragraph (b)(6) to read as follows:

§ 510.300 Determination of quality-adjusted episode target prices.

* * * * *

(b) * * *

(6) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain incentive programs and add-on payments are excluded from historical episode payments by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

* * * * *

8. Section 510.305 is amended by revising paragraph (d)(1) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(d) * * *

(1) Beginning 2 months after the end of each performance year, CMS does all of the following:

(i) Performs a reconciliation calculation to establish an NPRA for each participant hospital.

(ii) For participant hospitals that experience a reorganization event in which one or more hospitals reorganize under the CCN of a participant hospital performs--

(A) Separate reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each predecessor participant hospital for episodes where anchor hospitalization admission occurred before the effective date of the reorganization event; and

(B) Reconciliation calculations (during both initial and subsequent reconciliations for a performance year) for each new or surviving participant hospital for episodes where the anchor hospitalization admission occurred on or after the effective date of the reorganization event.

* * * * *

9. Section 510.410 is amended by adding paragraph (b)(1)(i)(G) to read as follows:

§ 510.410 Compliance enforcement.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(G) Failing to participate in CJR model-related evaluation activities conducted by CMS or its contractors or both.

* * * * *

10. Section 510.605 is amended by revising paragraph (c)(2) to read as follows:

§ 510.65 Waiver of certain telehealth requirements.

* * * * *

(c) * * *

(2) CMS waives the payment requirements under section 1834(m)(2)(B) of the Act to allow the distant site payment for telehealth home visit HCPCS codes unique to this model.

* * * * *

PART 512—[REMOVED AND RESERVED]

11. Part 512, as added January 3, 2017 (82 FR 180), delayed until October 1, 2017, on March 21, 2017 (82 FR 14464), further delayed until January 1, 2018, on May 19, 2017 (82 FR 22895), is removed and reserved.

CMS-5524-P

Dated: August 10, 2017.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: August 11, 2017.

Thomas E. Price,

Secretary,

Department of Health and Human Services.

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