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CMS Finalizes Mandatory Bundled Payment Model for Lower Extremity Joint Replacements

+Insights

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CMS's final regulations implementing the Comprehensive Care for Joint Replacement Model open up a new frontier for Medicare payment and delivery system reform

On November 16, 2015, the Centers for Medicare & Medicaid Services (CMS) released final regulations implementing the Comprehensive Care for Joint Replacement Model, its five-year mandatory bundled payment program for hip and knee replacements (CJR Model or Model). All acute care hospitals in 67 designated metropolitan service areas (MSAs), with limited exceptions, will be required to participate in the Model. The bundled episode will consist of virtually all related care from a beneficiary's admission to a participant hospital for a lower extremity joint replacement or reattachment of lower extremity (LEJR) procedure to 90 days following hospital discharge.

The Model offers further evidence of the expansive statutory authority of the Center for Medicare & Medicaid Innovation (CMMI) under section 1115A of the Social Security Act and provides a critical lens into one method available to the Secretary of the U.S. Department of Health and Human Services to achieve the Department's ambitious goal to shift 50 percent of Medicare fee-for-service payments into value-based alternative payment models by the end of 2018.

Strategically, the Model underscores the imperative for hospitals to begin developing strategies outside the "four walls" of their institutions, particularly with post-acute care providers, in order to successfully respond to the new Medicare payment and service delivery expectations and perform under the attendant accountability requirements.

These regulations go into effect January 15, 2016, although the first performance period will begin on April 1, 2016.

Key Changes from the July 2015 Proposed Rule

Although the final rule largely adheres to the July 2015 proposed rule, it departs from that proposal in a few important ways. (Figure 1: Key Changes from the July 2015 Proposed Rule.)

Payment Model Overview

A Hospital-Centered Model

Under the Model, subject to limited exceptions, all Inpatient Prospective Payment System (IPPS) hospitals physically located in 67 designated MSAs will be held financially accountable for the quality and cost of care

Figure 1: Key Changes from the July 2015 Proposed Rule

Key Changes from the July 2015 Proposed Rule

- **Delay** of the Model's start date from January 1, 2016, to **April 1, 2016**
- **Reduction** in the number of participating geographic regions from 75 to **67 MSAs**
- Use of a composite quality score to link quality to payment, and removal of the mandatory all-cause risk-standardized readmission measure (NQF #1551)
- Phase-in of downside risk from a 2 percent discount up to a **maximum 3 percent discount**
- More gradual increase of stop-loss limits, providing greater protection against losses in early performance years
- Stratification of the CJR target prices based on beneficiary's fracture status

during the entire LEJR episode of care. Only hospitals already participating in CMMI's Bundled Payment for Care Improvement (BPCI) Model 1 or the risk-bearing phase of BPCI Models 2 and 4 for LEJR episodes will be exempt from participation. Hospitals located outside of the designated MSAs are excluded from, and will not be permitted to apply for, the Model. The list of the 67 designated MSAs, which were selected through a stratified random sampling, and the hospitals in those areas that are expected to participate is available on the CMS website.

Consistent with the proposed rule, hospitals in the designated MSAs that also participate in other CMMI models and CMS programs, including the Medicare Shared Savings Program and other accountable care organization (ACO) models, will not be exempted from required participation in the Model.

In total, CMS estimates that almost 800 hospitals will be required to participate in the CJR Model.

Table 1: Performance Periods

PY 1	PY 2	PY 3	PY 4	PY 5
April 1–Dec 31, 2016	Jan 1–Dec 31, 2017	Jan 1–Dec 31, 2018	Jan 1–Dec 31, 2019	Jan 1–Dec 31, 2020
Upside risk only	Partial downside risk		Full downside risk	

Episode Description

CMS selected LEJR as an entry into mandatory bundled payments because (i) LEJR is a high expenditure, high utilization procedure commonly furnished to Medicare beneficiaries, and (ii) it is subject to significant variation in spending.

The episode construction shows significant structural similarities to BPCI. Under the Model, the LEJR episode will be triggered by an admission to the IPPS hospital resulting in a discharge assigned to either MS-DRG 469 (Major joint replacement or reattachment of lower extremity with MCC) or MS-DRG 470 (Major joint replacement or reattachment of lower extremity w/out MCC). As a general matter, an episode may be triggered by any beneficiary who, for the duration of the episode, is enrolled in Medicare Parts A and B, whose eligibility for Medicare is not on the basis of end stage renal disease, and who is not enrolled in a managed care plan.

The episode of care will be defined to consist of all related care covered under Medicare Part A and Part B that is furnished to a CJR beneficiary from the beginning of the beneficiary's admission to the anchor hospital through the 90 days following hospital discharge. The 90-day period stands in notable contrast to BPCI, which afforded participants with the opportunity to select an episode length of 30, 60 or 90 days following hospital discharge.

Episodes of care will include, but are not limited to, (i) physicians' services, (ii) inpatient hospital services (including hospital readmissions), (iii) inpatient psychiatric facility services, (iv) long-term care hospital (LTCH) services, (v) inpatient rehabilitation facility services, (vi) skilled nursing facility (SNF) services, (vii) home health agency (HHA) services, (viii) hospital outpatient services, (ix) outpatient therapy services, (x) clinical laboratory services, (xi) durable medical equipment, (xii) Part B drugs, (xiii) hospice and (xiv) per-beneficiary per-month care management payments under CMMI models, with certain exceptions.

The inclusion of hospice services in the episode stands in contrast to BPCI. Items and services unrelated to the anchor hospitalization itself, as determined by CMS, are excluded from the episode.

Table 2: Episode Description

Episode Initiator	Time Period	Services Included
MS-DRG 469	From admission for episode through 90 days after the date of hospital discharge	Part A
MS-DRG 470		Part B

Payment Methodology

The Model is organized around a retrospective bundled payment. Hospitals and other providers will continue to be paid for all care delivered during the performance year consistent with existing Medicare payment rules. Following the applicable performance year, however, CMS will conduct a retrospective reconciliation to compare the payments made to providers relative to an established target price. If the participant hospital's episodes fall under the established target price, the hospital will be eligible for a reconciliation payment. By contrast, if the cost of episodes falls above the established target price, the hospital will be required to repay an overage to CMS.

CMS will provide each participant hospital with its own specific target price for MS-DRGs 469 and 470, stratified by whether a hip fracture is present or not. CMS will calculate such episodic target prices using a blend of historical hospital-specific and regional spending for the pertinent episode, applying a discount factor of up to 2.0 percent in performance years two and three and up to 3 percent in performance years four and five. To determine historical expenditures, CMS will use a three-year baseline period, which it will rebase every other year. The regional component of the blend will increase over time, moving from two-thirds hospital-specific and one-third regional for performance years one and two, to one-third hospital-specific and two-thirds regional for performance year three, to entirely regional for performance years four and five. This methodology could result in participant hospitals facing differing incentives based on whether they have historically been more or

less efficient compared to other hospitals in their region.

Limitations on Loss and Gains

To limit financial risk to both participant hospitals and CMS, the Model applies stop-loss limits (repayment limits) and stop-gain limits (reward limits). All participant hospitals that achieve LEJR actual spending below the target price and meet a minimum composite quality score may earn up to 5 percent of their target price in performance years one and two, 10 percent in performance year three, and 20 percent in performance years four and five. By contrast, beginning in performance year two, participant hospitals must repay Medicare up to a symmetrical repayment limit for spending in excess of the target price. In recognition of their lower risk tolerance and infrastructure and support, CMS has provided Rural Referral Centers, Sole Community Hospitals and Medicare Dependent Hospitals with greater stop-loss protection.

Table 3: Gain Limits

	Performance Year 1	Performance Year 2	Performance Year 3	Performance Year 4	Performance Year 5
Standard Limit	5%	5%	10%	20%	20%

Table 4: Stop-Loss Limits

	Performance Year 1	Performance Year 2	Performance Year 3	Performance Year 4	Performance Year 5
Standard Limit	N/A	5%	10%	20%	20%
Limit for RRCs, SCHs and MDHs	N/A	3%	5%	5%	5%

Quality Methodology

Consistent with CMS's goal to decrease health care costs while improving the quality of care through bundled payment initiatives, the Model includes specific and significant quality-related requirements. As finalized, the quality methodology represents a significant deviation from the proposed rule, whereby receipt of reconciliation payments was bluntly conditioned upon achieving a minimum quality threshold.

Under the final rule, CMS will factor a participant hospital's measure performance relative to the national distribution of all hospitals' performance when calculating the hospital's reconciliation payment amounts. Participant hospitals may reduce the effective discount percentage applied to reconciliation payments from 3 percent to as low as 1.5 percent in performance years four and five depending on performance in a composite quality score. The composite quality score is determined based on relative percentile

performance and, if substantial, hospital-specific improvement in two mandatory quality measures:

- Hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) (NQF# 1550) (50 percent weighting)
- Hospital Consumer Assessment of Healthcare Providers and Systems Survey (NQF# 0166) (40 percent weighting)

The composite quality score methodology also allocates additional points for hospitals that voluntarily report designated THA/TKA patient-reported outcomes and limited risk variable data (10 percent weighting).

Based on their composite quality scores, participant hospitals will be graded "Excellent," "Good," "Acceptable" or "Below Acceptable," which will result in application of varying effective discount percentages to reconciliation payments. Practically speaking, this grading will allow participating hospitals with excellent quality scores to receive easier episodic targets, while low-performing hospitals will face significant discounts of up to 3 percent. If a participant hospital receives a below acceptable grade or is found to be engaged in an inappropriate and systemic under-provision of care, it will not be eligible to receive or retain reconciliation payments.

Overlap with ACO Models

Addressing and reconciling overlaps among payment and service delivery models likely will become one of the most challenging and important issues in Medicare's emerging payment landscape. Acknowledging certain challenges created by overlapping payment models, CMS finalized its decision to account for reconciliation payments prior to paying out shared savings or other payments earned by participants in other models and programs. It further indicated its intent to recoup the applicable discount required under CJR from participant hospitals that are also ACO participants or ACO providers/suppliers, when a CJR beneficiary is assigned to the Pioneer ACO Model, Medicare Shared Savings Program, Next Generation ACO or Comprehensive ESRD Care initiative. Although CMS highlights certain meritorious arguments for its ACO overlap policy, the policy may limit an important avenue for ACOs to achieve shared savings, as ACOs will be limited to the discount factor reflected in the CJR target price, rather than the full savings achievable during beneficiaries' episodes of care.

Beneficiary Protections

The Model preserves Medicare beneficiaries' right to obtain health services from any Medicare-enrolled provider or supplier. While Medicare beneficiaries will not have the option to opt out of the Model, CMS will require participant hospitals to supply beneficiaries with detailed written information regarding the design of the Model, their continued access to all Medicare protections and freedom of provider choice, their ability to access their own patient data, and a list of all providers and suppliers with whom the participant hospital has "collaborator" agreements, discussed further below. While participant hospitals may recommend preferred providers and suppliers, consistent with applicable law, they may not unlawfully limit beneficiary choice.

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Regulatory Flexibilities
Gainsharing and Risk Sharing, Patient Incentives and Payment Policy Waivers

Gainsharing and Risk Sharing

The final CJR Model provides various regulatory flexibilities to assist providers in delivering high quality care at lower costs within the Model. As a general matter, these payment and fraud and abuse waivers demonstrate close similarities to those offered under the BPCI Models.

Under the Model, CMS will permit participant hospitals to make gainsharing payments to CJR "collaborators." These payments may consist only of reconciliation payments or internal cost savings (i.e., measurable, actual and verifiable cost savings realized by the participant hospital in connect with items or services to beneficiaries within CJR episodes) or both. Medicare-enrolled SNFs, HHAs, LTCHs, IRFs, physicians, non-physician practitioners, providers/suppliers of outpatient therapy services, and PGPs are considered eligible to serve as CJR collaborators.

The parameters around the provision of gainsharing payments and related documentation requirements are strictly prescribed, and participant hospitals should closely review the requirements set forth at 42 C.F.R. § 510.500 et seq. and in the fraud and abuse waivers issued for the CJR Model to ensure full compliance and, as applicable, protection of an applicable financial arrangement under the relevant waivers.

Among these requirements, participant hospitals should be aware of the need to establish written policies pertaining to the selection of CJR collaborators (the criteria of which may not be based, directly or indirectly, on the volume or value of referrals or business other generated), that sharing arrangements must be memorialized through detailed signed collaborator agreements, and that the participant hospital and its governing body must assume ultimate responsibility for full compliance with all Model provisions.

CMS also conditions a CJR collaborator's eligibility for gainsharing payments on requirements that include (i) meeting quality criteria established by the participant hospital; (ii) directly furnishing a billable service to a CJR beneficiary during a CJR episode; and (iii) if a physician group practice, having one or more PGP members bill for an item or service furnished during a CJR episode and the PGP's contribution to CJR care redesign and clinical involvement in the care of CJR beneficiaries.

The Model imposes specific financial limitations on gainsharing distributions and risk sharing allocation. Gainsharing payments must be derived solely from reconciliation payments and/or internal cost savings. Gainsharing payments to individual CJR collaborator physicians and practitioners are capped at 50 percent of the respective physician fee schedule payments for CJR episode services and, for PGPs, at 50 percent of the total aggregate Medicare fee schedule amount billed and furnished by PGP members during CJR episodes. A PGP may distribute all or a portion of any gainsharing payment it receives to "practice collaboration agents" only in accordance with a written distribution arrangement, the parameters for which are set forth in the final rule and associated fraud and abuse waivers.

The Model also permits participant hospitals to share responsibility with its CJR

collaborators for any required Medicare repayment through "alignment payments," but stipulates that (i) a hospital must retain responsibility for at least 50 percent of any repayment amount and (ii) an individual CJR collaborator may not pay more than 25 percent of the repayment amount.

Notwithstanding the above, CMS clarifies that financial arrangements between non-Medicare providers and suppliers, such as ACOs or other third parties, are permitted assuming they would be allowed under existing laws, rules and regulations outside of the context of the Model.

Patient Engagement Incentives

To enable heightened engagement with CJR beneficiaries, the Model permits participant hospitals and their agents to provide in-kind patient engagement incentives to CJR beneficiaries during a CJR episode. The final rule stipulates seven conditional requirements, including that the item or service be a preventive care item or service, or advance a clinical goal, and be reasonably connected to the medical care provided during the CJR episode. CMS stipulates that any item or service involving technology that has a retail value of more than $100 must be retrieved from the beneficiary at the end of the CJR episode and that aggregate retail value may not exceed $1,000 per-patient, per-episode.

Hospitals must document any patient incentives that exceed $25 and maintain such records for 10 years.

Post-Acute Care Services as a Key Variable for Success

CMS selected LEJR for this first mandatory bundled payment demonstration because of

Figure 2: Payment Policy Waivers

Payment Policy Waivers

CMS also finalized five payment policy waivers that offer critical tools for participant hospitals to enhance the quality and efficiency of patient care. These waivers include the following:

Waiver of the three-day SNF rule

Beginning in performance year two, the Model permits coverage of a SNF stay following discharge from an anchor hospital stay of less than three days, but stipulates that a receiving SNF must have at least a three-star rating and must be identified on the applicable list of qualified SNFs at the time of CJR beneficiary's admission to the SNF.

Post-discharge home visits

The Model waives the direct supervision requirement, enabling clinical staff to provide home visits to CJR beneficiaries under general supervision. It also permits up to nine visits during an episode to be billed to Medicare.

Telehealth

With the limited exception for the face-to-face requirement for home health certification, the Model waives the geographic site and originating site requirements for telehealth services, thereby allowing telehealth services to be provided in a CJR beneficiary's home or place of residence. The Model also designates HCPCS codes unique to the Model for such remote in-home visits.

significant volume of procedures, the associated expenses and the cost variation across the country. Hip and knee replacements are among the most common surgeries for Medicare beneficiaries. In 2013, there were more than 400,000 inpatient primary LEJR procedures amounting to more than $7 billion in hospitalization alone. Further, the quality and cost of care for these hip and knee replacement surgeries vary substantially among providers.

The 90-day episode length and financial accountability for care outside of the four walls of the hospital under the Model underscore a key strategic opportunity under the Model: reducing variation in post-acute care use. Because post-acute care providers have such a significant effect on cost of care within the 90-day post-discharge period, hospitals will need to strategically engage with post-acute providers to establish more efficient care and avoid hospital readmissions, both of which will be critical for financial performance and quality measures.

CMS and other policy makers anticipate opportunities for savings in the post-acute care space. In a recent analysis of Medicare claims data by episode of care, for example, the Medicare Payment Advisory Commission (MedPAC) found that while post-acute care accounts for a minority of episode spending, it comprises the majority of variation in spending. MedPAC concluded that hospitals have opportunities to improve episode spending efficiency by guiding patients to high-value post-acute care services. In the final rule, CMS also documents substantial regional variation in post-acute care referral patterns and the intensity of post-acute care services, reiterating the opportunities created by the Model to incentivize hospitals to manage the post-acute care decisions.

Key Takeaways

The CJR Model will be an important tool for CMS as it works to achieve the ambitious targets set by the Secretary to shift 30 percent of Medicare fee-for-service payments into alternative payment models by the end of 2016, and 50 percent by the end of 2018.

Heretofore, with the exception of several low-profile models such as the Prior Authorization of Power Mobility Devices Demonstration (which was not implemented through Section 1115A authority), CMS's payment and service delivery models have remained voluntary in nature. The CJR Model and Home Health Value-Based Purchasing Model, recently finalized in the 2016 Home Health Prospective Payment System final rule, evidence a critical shift in CMS's strategy. The use of CMMI's authority under Section 1115A of the Social Security Act is notable for its broader implications: beyond the wide latitude afforded under Section 1115A to test a broad, non-limited list of payment and service delivery models, Section 1115A also authorizes the Secretary to expand the scope or scale of models and demonstrations through rulemaking that the Secretary determines, and the CMS Actuary certifies, will (i) maintain quality and reduce net expenditure, (ii) improve quality and not increase net expenditure, or, ideally, (iii) simultaneously improve quality and reduce net expenditure. In turn, the information gained from testing CJR across a wide variety of hospitals nationally, without selection bias, could enable CMS to judiciously assess whether a national expansion of LEJR episodic payments is prudent.

There are equally valuable lessons for Medicare providers within and outside of the 67 selected MSAs. With the start date of the CJR Model less than six months away, hospitals in the 67 selected MSAs must begin planning immediately. Preparations should include establishing partnerships with the appropriate providers (physician and post-acute care providers) and building the internal infrastructure to properly manage participation in the program.

Medicare providers outside of the 67 selected MSAs should carefully observe the implementation and experience of participants, in case CMS pursues future scaling or additional mandatory bundled payment models. CMS may not wait until the end of this model to scale it to other areas. If CMS sees progress and adaptability, it may add more areas or more services sooner.

More broadly, as CMS becomes more aggressive in payment and delivery reform efforts, Medicare providers may benefit from gaining exposure to alternative payment models and population health management approaches in low-risk, voluntary settings. Early participants acquire a head start in developing the necessary infrastructure for care redesign and critical experience implementing the processes and cultural shifts foundational to success. Further, as CJR demonstrates, ratifying one factor motivating certain early adopters' participation in CMMI models, participation in voluntary models could facilitate exemptions from future mandatory models.

As new models and programs continue to multiply, providers and other stakeholders should seek to understand these initiatives individually, while keeping in view the broader reimbursement and patient care implications of multiple Medicare alternative payment programs operating in one marketplace.

Additional information and a link to the final rule is available on the CMMI website. Fraud and abuse waivers for specified arrangements involving CJR Model participants are available on the CMS website.

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