

The business of relationships.™

Life Sciences Health Industry Group

Client Alert



CMS Proposes "Comprehensive Care for Joint Replacement" Model; Would Mandate Bundled Acute/Post-Acute Medicare Payment in 75 MSAs, 25% of U.S. Hip/Knee Replacement Surgeries

Written by Gail L. Daubert, Elizabeth Carder-Thompson and Debra A. McCurdy

July 2015

IF YOU HAVE QUESTIONS OR WOULD LIKE ADDITIONAL INFORMATION ON THE MATERIAL COVERED IN THIS WHITE PAPER, PLEASE CONTACT ONE OF THE AUTHORS:

Gail L. Daubert Partner, Washington, D.C. +1 202 414 9241 gdaubert@reedsmith.com

Elizabeth Carder-Thompson Partner, Washington, D.C. & Princeton +1 202 414 9241 +1 609 524 2054 ecarder@reedsmith.com

Debra A. McCurdy

Senior Health Policy Analyst, Northern Virginia +1 703 641 4283 dmccurdy@reedsmith.com

Table of Contents

CMS Proposes "Comprehensive Care for Joint Replacement" Model; Would Mandate Bundled Acute/Post-Acute Medicare Payment in 75 MSAs, 25% of U.S. Hip/Knee	
Hospitals and Beneficiaries Subject to the CCJR Model	2
Covered Episodes and Services	2
Hospitals as Episode Initiators Would Bear Financial Risk (Upside and Downside)	3
Beneficiary Incentives and Financial Arrangements with Collaborators	5
Parameters for Gainsharing Payments involving Collaborators	6
Medicare Waivers	8
Comment Opportunity	8

Page

CMS Proposes "Comprehensive Care for Joint Replacement" Model; Would Mandate Bundled Acute/Post-Acute Medicare Payment in 75 MSAs, 25% of U.S. Hip/Knee Replacement Surgeries

Written by Gail L. Daubert, Elizabeth Carder-Thompson and Debra A. McCurdy

On July 14, 2015, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule to establish a Medicare Comprehensive Care for Joint Replacement (CCJR) model.¹ Under the proposed rule, CMS would provide a bundled payment to hospitals in selected geographic areas for an episode of care for lower extremity joint replacement (LEJR) surgery, covering all services provided during the inpatient admission through 90 days post-discharge. CMS proposes that the bundled payment would be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers would continue to submit claims and receive payment via the usual Medicare fee-for-service (FFS) payment systems, with the reconciliation occurring later. CMS estimates that the five-year CCJR model (beginning January 1, 2016, and ending December 31, 2020) would cover about 25 percent of all lower extremity joint replacement procedures nationally, and would involve about \$2.26 billion in episode-spending in 2016, rising to \$2.71 billion by 2020.

This proposal represents the next step in CMS' goal of accelerating the share of Medicare FFS payments that are tied to quality and value, and are reimbursed through alternative payment models.² CMS notes that the current FFS payment system is tied to the volume of services delivered by multiple providers and suppliers during the course of a treatment, hence "creat[ing] incentives for care that are fragmented, unnecessary or duplicative, while impeding the investment in quality improvement or care coordination that would maximize patient benefit." CMS hopes to transform those incentives by focusing on a single-payment arrangement for an episode of care that provides incentives for:

improving the coordination and transition of care, improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incentivizing higher value care across the inpatient and post-acute care spectrum spanning the episode of care.

² For background information, see <u>http://www.healthindustrywashingtonwatch.com/2015/01/articles/other-hhs-</u> <u>developments/hhs-sets-ambitious-goals-for-medicare-qualityvalue-based-purchasing-alternative-payment-</u> <u>models/</u>.

¹ The text of the proposed rule is available at <u>http://www.gpo.gov/fdsys/pkg/FR-2015-07-14/pdf/2015-17190.pdf</u>, and CMS has posted supplemental information at <u>http://innovation.cms.gov/initiatives/ccjr/</u>.



Unlike other voluntary episode-based, bundled payment models currently being tested by CMS, this model would *require* providers in certain geographies to participate. CMS is pursuing this approach because it believes that "realizing the full potential of new payment models will require the engagement of an even broader set of providers than have participated to date, providers who may only be reached when new payment models are applied to an entire class of providers of a service." CMS is focusing on LEJR procedures for this model because they are high-expenditure, high-utilization procedures in which there is significant variation in spending for both the procedures and the associated post-acute care. CMS expects the lessons learned from the model to inform future Medicare payment policy.

The proposed rule is extremely complex, both in terms of the implications for Medicare payment to participant hospitals, and the parameters for relationships between hospitals and other providers that may furnish care to beneficiaries under the model. The following is an overview of the proposed rule.

Hospitals and Beneficiaries Subject to the CCJR Model

In contrast to the CMS Bundled Payments for Care Improvement (BPCI) model on which this initiative is based, participation in the CCJR model would be mandatory for all hospitals paid under the Medicare inpatient prospective payment system (IPPS) and physically located in the CMS-designated geographic areas, with limited exceptions (such as for hospitals participating in risk-bearing BPCI models). CMS identifies in the proposed rule the 75 Metropolitan Statistical Areas (MSAs) in 33 states that it proposes to include in the model.

Eligible beneficiaries who receive care at these hospitals in the 75 MSAs would automatically be included in the model, although Medicare Advantage enrollees and beneficiaries eligible for Medicare on the basis of End Stage Renal Disease would be excluded (along with other limited exclusions).

Covered Episodes and Services

Under the CCJR model, LEJR episodes would *begin* with admission to an acute care hospital for a procedure that is assigned to the following Medicare Severity-Diagnosis Related Groups (MS-DRGs):

- MS-DRG 469 (Major joint replacement or reattachment of lower extremity with Major Complications or Comorbidities (MCC)) or
- MS-DRG 470 (Major joint replacement or reattachment of lower extremity without MCC)

Note that while the initiative is described as a hip/knee replacement model, these MS-DRGs also include total ankle replacement, partial hip replacement and hip resurfacing, and certain reattachment cases that may involve different resources than total hip and total knee replacement alone.

The episode would *end* 90 days after the actual date of discharge from the admitting acute care hospital. CMS proposes including the following services in the episode:

- All physician services
- Inpatient hospital services including readmissions where a patient is assigned to all medical MS-DRGs, with the exception of oncology and trauma medical MS-DRGs
- Inpatient psychiatric services
- Long-term care hospital, inpatient rehabilitation facility, and skilled nursing facility (SNF) services
- Home health services
- Hospital outpatient services
- Outpatient therapy services
- Clinical lab services
- Durable medical equipment
- Part B drugs
- Hospice care

A limited number of items and services would be excluded, including certain specified hospital readmissions and admissions for acute disease surgical procedures (e.g., appendectomy), or oncology and trauma admissions.

As noted, the admitting hospital, and other hospitals and providers, furnishing services during the covered episode, would continue to be reimbursed according to current Medicare payment methodologies at the time of service. That is, the admitting hospital would *not* serve as a "gatekeeper" for payment of all services during the episode. As discussed below, that hospital *would*, however, be accountable for overall spending attributable to the episode (although there would be opportunities for the hospital to share risk and reward with other providers in certain circumstances).

Hospitals as Episode Initiators Would Bear Financial Risk (Upside and Downside)

CMS proposes that admitting hospitals, as defined above, would be the "episode initiators" and bear financial risk under the proposed CCJR model (except there would be no downside risk for the first year). Unlike the BPCI model, third-party conveners (i.e., non-provider business entities that bear risk related to multiple health care providers' participation in a bundled payment model) would not be permitted in the CCJR model, nor could physicians or post-acute care or other providers be episode initiators.

After the completion of a performance year (PY), CMS would use claims data to sum into an actual "episode payment" the combined Medicare payments for all hospital and related services furnished to the beneficiary during the episode. The episode payment would be reconciled against an established CCJR target price, which would be set using a blend of hospital-specific and regional data, transitioning to full regional pricing in PYs 4 and 5. CMS would communicate target prices to hospitals prior to the applicable performance period.

CMS proposes that Medicare would require the admitting hospital to repay the difference between the actual episode payments and the CCJR target price, if actual payments *exceeded* the CCJR target price (except that CMS would not require repayment in PY 1). On the other hand, if the episode payment were *less than* the target price, CMS would make a reconciliation payment to the admitting hospital.

CMS would apply certain limitations and adjustments to repayment and reconciliation payments, including the following:

- Eligibility for reconciliation payment would be conditioned upon attaining certain quality performance thresholds based on three hospital-level quality measures (a complication measure, a readmission measure, and a patient experience measure).
- Notably, in recognition that hospitals may have limited ability to moderate spending for certain high-cost cases, CMS proposes to set a high outlier limit to target prices at two standard deviations above the regional average episode cost. Individual episode costs would be capped at the high outlier limit to manage hospitals' downside risk.
- CMS intends to apply a 2 percent discount factor when setting an episode target price for a participant hospital, which would guarantee that the Medicare program achieved savings from the CCJR model. In order to help hospitals transition to taking on repayment risk in PY 2, CMS proposes to apply a reduced discount of 1 percent in PY 2 for purposes of determining the hospital's responsibility for excess episode spending, but maintain the 2 percent discount for purposes of determining the hospital's opportunity to receive reconciliation payment for actual episode spending below the target price. CMS would reduce to 1.7 percent the discount for hospitals that voluntarily tracked patient-reported outcome measures (CMS estimates the value of this discount reduction to be about \$75 per LEJR episode, which the agency believes is sufficient to pay hospitals for the resources required to survey patients).
- CMS proposes to exclude special payment provisions (e.g., various quality program payments, low-volume add-ons, new-technology payments, disproportionate share hospital, and rural hospital adjustments) when calculating actual episode payments, setting episode target prices, comparing actual episode payments with target prices, and determining whether a reconciliation payment should be made to the hospital, or funds should be repaid by the hospital.

- For certain rural hospitals, CMS proposes a "stop-loss" limit of 3 percent of episode payments in year two and a stop-loss limit of 5 percent for years three to five.
- CMS proposes to limit reconciliation payments to 20 percent of the hospital's target prices for each MS-DRG, multiplied by the number of the hospital's episodes for that MS-DRG (called the "stop-gain" limit).

CMS intends to calculate retrospectively the participant hospital's actual episode performance two months after a PY ends. CMS proposes an appeals process if a participant believes there is an error in CMS payment calculations/determinations.

Beneficiary Incentives and Financial Arrangements with Collaborators

Participant hospitals under the proposal would be subject to financial risks and rewards impacted by beneficiaries themselves, as well as by other downstream providers involved in the beneficiaries' care, including post-acute care providers and physicians. As a result, such hospitals are likely to seek financial arrangements with these individuals and entities to improve the provision of care, decrease the cost of care, and/or share the risk. Accordingly, CMS sets forth proposed guidelines on how participant hospitals may involve these other parties.

(a) Beneficiary Incentives

CMS expects that hospitals may want to offer beneficiaries incentives to adhere to recommended treatment, and generally to encourage active patient engagement in recovery. CMS specifies that such incentives should be closely related to the provision of high-quality care during the episode and advance a beneficiary's *clinical* goal. Such incentives should *not* serve as inducements to beneficiaries to seek care from the participant hospital or other specific suppliers and providers. CMS expresses its belief that such incentives could "help participant hospitals reach their quality and efficiency goals for CCJR episodes, while benefitting beneficiaries' health and the Medicare Trust Fund if hospital readmissions and complications are reduced while recovery continues uninterrupted or accelerates."

(b) Collaborators

Likewise, CMS observes that participant hospitals may wish to partner with other providers furnishing care to beneficiaries in CCJR episodes in order to align the financial incentives with the goal of improving quality and efficiency for LEJR episodes. Such providers may include:

- SNFs, home health agencies, long-term care hospitals; and inpatient rehabilitation facilities
- Physician practice groups

- Physicians, non-physician practitioners
- Outpatient therapy providers

CMS refers to such providers and suppliers as "CCJR collaborators." CMS recognizes that these providers/suppliers may invest substantial time and resources in patient care activities, yet they would neither be direct recipients of Medicare reconciliation payments nor be directly responsible for repaying Medicare for excess spending. Therefore, CMS believes that participant hospitals may seek to enter into financial arrangements with other providers and suppliers to share risks and rewards under the CCJR.

Notably, the proposed CCJR model could have a significant impact on the relationships and arrangements between participant hospitals and downstream providers, including the providers noted above. Since participant hospitals would seek to reduce the costs of care furnished to CCJR model beneficiaries in the 90 days after the patient's discharge, while ensuring the achievement of certain quality performance thresholds, participant hospitals would likely be incentivized to collaborate with lower-cost providers who have a proven quality track record.

(c) Other Entities

Further, CMS notes that participant hospitals may choose to engage organizations that are neither providers nor suppliers to assist with matters such as: episode data analysis; care redesign planning and implementation; beneficiary outreach; CCJR beneficiary care coordination and management; monitoring hospital compliance with terms of CCJR model; or other model activities. Such non-provider organizations are not covered by the proposed definition of "CCJR collaborator," however. CMS states that all relationships established between participant hospitals and these organizations for purposes of the CCJR model – including relationships involving sharing of risks and rewards – "would only be those permitted under existing law and regulation." CMS also would expect that such relationships would solely be based on the level of engagement of the organization's resources to directly support the participant hospitals' CCJR model implementation.

Parameters for Gainsharing Payments involving Collaborators

CMS believes that participant hospitals should be able, on the one hand, to share internal cost savings with CCJR collaborators, and on the other, to share the responsibility for repaying Medicare. Specifically, the collaborators would be required to:

- Directly furnish related items or services to a CCJR beneficiary, and/or
- Participate in CCJR model LEJR episode care redesign activities, such as attending CCJR meetings and learning activities; drafting LEJR episode care pathways; reviewing CCJR beneficiaries' clinical courses;

developing episode analytics; or preparing reports of episode performance, under the direction of the participant hospital or another CCJR collaborator that directly furnishes related items and services to CCJR beneficiaries.

If a participant hospital sought to have a financial arrangement with a CCJR collaborator, specific written documents would have to be drafted and signed, including a Participation Agreement that spelled out any CCJR Sharing Arrangement and defined the arrangements both for sharing in savings and repayment responsibilities.

If a payment *from* a participant hospital were made *to* a CCJR collaborator, CMS defines that payment as a "**Gainsharing Payment**." Such a "gainsharing payment" could only be comprised of (1) CCJR reconciliation payments; and/or (2) the participant hospital's *internal cost savings*. Gainsharing Payment would be available only to CCJR collaborators that *directly furnished* services to CCJR beneficiaries. CMS defines **internal cost savings** as:

the measurable, actual, and verifiable cost savings realized by the participant hospital resulting from care redesign undertaken by the participant hospital in connection with providing items and services to beneficiaries within specific CCJR episodes of care. Internal cost savings would include savings realized by any individual or entity that is not the participant hospital.

CMS sets forth specific requirements for calculating internal cost savings of the participant hospital, where the hospital intends to share internal cost savings through a CCJR Sharing Arrangement with a CCJR collaborator.

If a payment *from* a CCJR collaborator *to* a participant hospital were made pursuant to a CCJR Sharing Arrangement, CMS proposes to define that payment as an "**Alignment Payment**." CCJR Sharing Arrangements that provide for Alignment Payments would not relieve the participant hospital of its ultimate responsibility for repayment to CMS.

CCJR Sharing Arrangements between hospitals and collaborators would have to be solely related to the contributions of the collaborators to redesign and achieve quality and efficiency improvements under the CCJR model. CMS proposes a series of program integrity safeguards related to such arrangements, including that no gainsharing payments could be based on the volume or value of past or anticipated referrals or other business. All Gainsharing Payments and Alignment Payments would have to be auditable by HHS to ensure their financial and programmatic integrity. CMS emphasizes that any CCJR collaborator that receiving or making a payment **must have furnished services included in the episode to CCJR beneficiaries**. These payments would have to be proportionally related to the care of the beneficiaries in a CCJR episode, and the CCJR collaborator would have to contribute to the care redesign strategies of the participant hospital. CMS also provides that total

Gainsharing Payments could not exceed 50 percent of the reconciliation payment that the hospital received from CMS, and likewise total Alignment Payments could not exceed 50 percent of the repayment amount due to CMS.

CMS notes that certain arrangements could implicate various fraud and abuse authorities, including the civil monetary penalty law, the Federal Anti-kickback statute, or the physician self-referral prohibition. CMS observes that in many cases, arrangements that implicate these laws could be structured to comply with them by using existing safe harbors and exceptions. While CMS is authorized to waive certain specified fraud and abuse laws as may be necessary solely for purposes of testing of payment models, CMS states that a waiver is not needed for an arrangement that does not implicate the fraud and abuse laws, or that implicates the fraud and abuse laws but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. The HHS Secretary will consider whether waivers of certain fraud and abuse laws are necessary to test the CCJR model as the model develops. Such waivers, if any, would be promulgated separately.

Medicare Waivers

CMS acknowledges that some current Medicare rules may impede effective care management under CCJR. For instance, CMS proposes waiving the three-day inpatient hospital stay requirement prior to a covered SNF stay, beginning in PY 2 (CMS is not proposing to waive this rule in PY 1 when hospitals are not responsible for excess spending). CMS also proposes waivers to allow expanded use of telemedicine.

Comment Opportunity

CMS is accepting comments on the proposed rule until September 8, 2015. CMS specifically requests comments on numerous aspects of the proposal, which provides stakeholders an opportunity to help shape the final framework of the model. Specific areas subject to comment include, among many others:

- The proposed methodology for determining the geographic areas to be included in the model
- The scope of diagnoses and services to be covered in the episode bundle
- The limitation of the episode initiator/risk-bearing role to hospitals
- Calculation of the episode target and the payment reconciliation methodology
- Thresholds for measuring quality attainment
- The proposed definition and role of CCJR collaborators
- The parameters for gainsharing payments and alignment payments
- Waivers of current statutory provisions

About Reed Smith

Reed Smith is a global relationship law firm with more than 1,800 lawyers in 26 offices throughout the United States, Europe, Asia and the Middle East. Founded in 1877, the firm represents leading international businesses, from Fortune 100 corporations to mid-market and emerging enterprises. Its lawyers provide litigation and other dispute-resolution services in multi-jurisdictional and other high-stakes matters; deliver regulatory counsel; and execute the full range of strategic domestic and cross-border transactions. Reed Smith is a preeminent advisor to industries including health care, life sciences, financial services, advertising, technology and media, shipping, energy and natural resources, real estate, manufacturing, and education. For more information, visit reedsmith.com.

This Alert is presented for informational purposes only and is not intended to constitute legal advice.