The Beginning of Mandatory Bundled Payment Programs: CMS' Proposed Comprehensive Care for Joint Replacement Model

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On July 14, 2015, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule (Proposed Rule) which, if finalized, will establish a retrospective bundled payment program for lower extremity joint replacement (LEJR) procedures performed for fee-for-service Medicare beneficiaries. Under the Proposed Rule, which is set to become effective January 1, 2016, CMS establishes the Comprehensive Care for Joint Replacement (CCJR) model, which will be mandatory for many acute care hospitals throughout the country. CMS solicited comments from stakeholders regarding the implementation of the Proposed Rule and, as of the September 8, 2015 comment submission deadline, received nearly 300 comments. Many providers and interest groups are paying special attention to the Proposed Rule because the CCJR model is likely just the first of many mandatory bundled payment programs CMS will initiate as it implements its promised transition from fee-for-service payment to value-based payment methodologies.

Overview of Proposed Rule

The Proposed Rule is viewed by health care providers, interest groups, and attorneys alike as the first step in implementation of CMS' aggressive plan to shift Medicare reimbursement away from a program that focuses primarily on compensating providers for the volume or quantity of care provided toward a program that compensates providers for the value or quality of care provided. Today, many providers are familiar with the voluntary Bundled Payments for Care Improvement (BPCI) initiative, many elements of which are also reflected in the Proposed Rule. Through the CCJR model, CMS is taking the BPCI concept a step further, imposing financial consequences and other requirements that will force hospitals to engage in care redesign efforts with other health care providers involved in episodes of care for LEJR procedures.

As proposed, the CCJR model is a retrospective bundled payment program limited to LEJR procedures grouped under MS-DRG 469 (major joint replacement or reattachment of lower extremity with major complications or comorbidities) or MS-DRG 470 (major joint replacement or reattachment of lower extremity without major complications or comorbidities). The Proposed Rule mandates participation by all inpatient prospective payment system hospitals located in one of 75 specified metropolitan statistical areas (MSAs); however, hospitals that on or after July 15, 2015 are participating in the BPCI initiative under BPCI Model 1 or serving as episode initiators in the risk-bearing period of BPCI Models 2 or 4 for LEJR episodes are exempt from participating in the CCJR model.[1]

An episode of care, for purposes of the CCJR model, begins with the beneficiary's admission to a hospital for a LEJR procedure and ends 90 days after discharge from the hospital. Services included in the episode of care are all Medicare Part A and Part B items and services furnished to a fee-for-service beneficiary unless expressly excluded by the Proposed Rule.[2] Because participation in CCJR is mandatory for all hospitals within a covered MSA, beneficiaries residing in a MSA covered by the CCJR model will, with a few exceptions, also be required to either participate in the CCJR model or travel outside the MSA for their LEJR procedures. The Proposed Rule nonetheless explicitly states that all existing beneficiary protections, including patient choice of providers and services, remain available for beneficiaries involved in CCJR episodes of care. While beneficiaries are not permitted to opt out of the CCJR model itself, the Proposed Rule perplexingly permits beneficiaries to opt out of CCJR data sharing, creating a potential conundrum for participating hospitals, which could be required to manage episodes of care for which they have no patient data.

The CCJR model will cover five performance years beginning January 1, 2016 and ending December 31, 2020. If a participant hospital fails to comply with any of the requirements outlined in the Proposed Rule, CMS may: (1) issue a warning letter to the participant hospital; (2) require the participant hospital to develop a corrective action plan; (3) reduce or eliminate a participant hospital's financial incentive payment (described below); or (4) terminate the participant hospital's participation in the CCJR model.

CCJR Effect on Reimbursement

The CCJR bundled payment methodology is based on a series of calculations for: (1) fee-for-service expenditures during a performance year; (2) "episode target prices"; (3) "reconciliation payments"; and (4) "repayment amounts."

1. *Fee-for-Service Expenditures*. All services provided to beneficiaries covered by the CCJR model are billed under the standard fee-for-service model.
2. *Episode Target Prices*. For each performance year, CMS will calculate a participant hospital's "episode target price" for episodes of care anchored by MS-DRG 469 and MS-DRG 470. CMS will communicate the hospital's episode target price before or shortly after the start of the first performance year and before the beginning of each performance year thereafter. The episode target price will be based on a blend of: (1) the participant hospital's "historical episode payment," which includes

Medicare payments for the Part A and Part B items and services provided in episodes of care for LEJR procedures performed at the hospital during the three prior years;[3] and (2) the "historical episode payment" for the region in which the participant hospital is physically located. In performance years one and two of the CCJR model, each hospital's episode target price will be based two-thirds on the hospital's historical episode payment and one-third on the regional historical episode payment. In performance year three, the hospital's episode target price will be based one-third on the hospital's historical episode payment and two-thirds on the regional historical episode payment. In performance years four and five, each hospital's episode target price will be entirely based on the regional historical episode payment.

3. *Calculation of NPRA*. For each participant hospital in each performance year, CMS will calculate a Net Payment Reconciliation Amount (NPRA) for episodes of care anchored by MS-DRG 469 and MS-DRG 470. The NPRA is calculated as follows:
   - Step 1—Medicare's actual Part A and Part B payments for all episodes of care for LEJR procedures performed at the hospital during the performance year is aggregated;
   - Step 2—The hospital's episode target price is multiplied by the number of episodes attributable to the hospital during the performance year; and
   - Step 3—The amount determined in Step 1 is subtracted from the amount determined in Step 2.
4. *Reconciliation Payments*. If the NPRA for a performance year is a positive number, the participant hospital will be entitled to a "reconciliation" payment from Medicare. Any reconciliation payment owed by Medicare to a hospital is subject to certain quality reporting requirements for the performance year. Specifically, hospitals must report the following:
   - Hospital-level, 30-day, all-cause risk standardized readmission rate following elective primary total hip arthroplasty or total knee arthroplasty. (National Quality Forum Measure #1551);
   - Hospital-level, risk-standardized complication rate following elective primary total hip arthroplasty or total knee arthroplasty. (National Quality Forum Measure #1550); and
   - Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results. (National Quality Forum Measure #0166).

   In order to receive any reconciliation payment, hospitals must meet or exceed the 30th percentile for each of the above performance measures in performance years one through three and must meet or exceed the 40th percentile for each performance measure in performance years four and five.

   The Proposed Rule also contemplates voluntary submission of patient-reported outcomes. Additional financial incentives are available for hospitals that voluntarily submit data for at least 80% of beneficiaries within 60 days of the most recent performance period.
5. *Repayment Amounts*. If the applicable NPRA as calculated above is a negative number, the hospital will be required to make a "repayment" to Medicare equal to that amount. However, the Proposed Rule provides certain caps on repayment amounts. In performance year one, regardless of whether the NPRA is a negative amount, the hospital will not be required to make any repayment to Medicare. In performance year two, the repayment amount will be capped at 10% of the amount calculated in Step 2 of the NPRA calculation. In performance years three through five, the repayment amount will be capped at 20% of the amount calculated in Step 2 of the NPRA calculation.

Permitted Financial Arrangements

In addressing hospital relationships with other providers under the CCJR model, the Proposed Rule discusses potential "Participation Agreements," "CCJR Sharing Arrangements," "Gainsharing Payments," and "Alignment Payments." Many of the components of these permitted arrangements, particularly the structure of permitted gainsharing and alignment payments, are similar to structures permitted under the BPCI program.

1. *Participation Agreements and CCJR Collaborators*. The Proposed Rule authorizes the use of "Participation Agreements" to organize and memorialize the terms of agreements between a hospital and "CCJR Collaborators" with regard to care redesign and the alignment of financial incentives under the CCJR model. A CCJR Collaborator may be any of the following:
   - Skilled nursing facility;
   - Home health agency;
   - Long term care hospital;
   - Inpatient rehabilitation facility;
   - Physician;
   - Non-physician practitioner;
   - Outpatient therapy provider; and
   - Physician group practice.

However, Participation Agreements are not required under the Proposed Rule unless the activities of the CCJR Collaborator involve a "CCJR sharing arrangement."

2. *CCJR Sharing Arrangements*. The Proposed Rule defines a CCJR sharing arrangement as a financial arrangement between a participant hospital and a CCJR Collaborator for the sole purpose of sharing: (1) any reconciliation payments the hospital receives from Medicare; (2) the hospital's internal cost savings generated by the CCJR model; or (3) the hospital's responsibility for repayment to Medicare. All CCJR sharing arrangements must be memorialized in a written Participation Agreement. If the sharing arrangement involves paying the CCJR Collaborator a portion of the hospital's internal cost savings, the Participation Agreement must include specific methodologies for accruing and calculating the internal cost savings. Such methodologies must be transparent, measurable, and verifiable in accordance with Generally Accepted Accounting Principles and federal government auditing standards. Further, the Participation Agreement must describe the methodology and accounting formula for calculating the percentage or dollar amount of a reconciliation payment that the hospital will pay to the CCJR Collaborator.
3. *Gainsharing Payments*. Under the Proposed Rule, CMS also permits a CCJR sharing arrangement to provide for gainsharing payments made from a participant hospital to a CCJR Collaborator. Any Participation Agreement involving a gainsharing payment must include a description of the calculation methodology, frequency of payments, accounting formula, care redesign plan, changes in care coordination, and success measures. In addition, gainsharing payments:
    - May only be paid from the hospital's reconciliation payment from Medicare and/or the hospital's internal cost savings;
    - May only be made on an annual basis;
    - May not in the aggregate exceed the reconciliation payment received by the hospital from Medicare for that year;
    - Must not induce any party to limit medically necessary services;
    - May not be made or conditioned on the volume or value of referrals or other business generated between the parties; and
    - Must allow individual physician and non-physician practitioners to make decisions in the patient's best interest, including selection of devices, supplies, and treatments.

    In addition to the above requirements, the total amount of gainsharing payments for a calendar year paid to a physician or non-physician practitioner who is a CCJR Collaborator may not exceed 50% of the total Medicare-approved amounts under Medicare's physician fee schedule for services furnished by physician or non-physician practitioners to the hospital's CCJR beneficiaries. The preamble to the Proposed Rule also provides that if gainsharing payments are made to a CCJR Collaborator that is a physician group practice, all monies contained in such a gainsharing payment must be shared only with physicians or non-physician practitioners who furnished a service to a CCJR beneficiary during an episode of care in the calendar year for which a reconciliation payment, and/or internal cost savings, was generated. The physician group may not retain any portion of the gainsharing payment.[4]
4. *Alignment Payments*. Alignment payments are those made from a CCJR Collaborator to a participating hospital if care redesign goals are not met and the hospital is therefore required to make repayment to Medicare. The Proposed Rule sets forth substantial requirements that must be met before alignment payments may be made, including requirements that alignment payments:
    - Must be clearly identified and comply with all provisions in the Proposed Rule, as well as all applicable laws, statutes, and rules;
    - Must not be issued, distributed, or paid prior to the calculation by CMS of the hospital's NPRA;
    - Must not be loans, advance payments, or payments for referrals or other business.
    - Must be made by electronic funds transfer; and
    - May not be made or conditioned on the volume or value of referrals or other business generated between the parties.

    Total alignment payments received by a participant hospital may not exceed 50% of the repayment amount owed by the hospital to Medicare. Further, a single CCJR Collaborator may not make an alignment payment to a hospital in any calendar year that exceeds 25% of the repayment amount owed by the participant hospital to CMS.

Reimbursement and Beneficiary Inducement Waivers

CMS acknowledges that various reimbursement requirements will inhibit the successful implementation of the CCJR model. As such, the Proposed Rule provides for the following reimbursement requirement waivers:

- Waiver of the direct physician/qualified practitioner supervision requirement for certain post-discharge home visits;

- Waiver of certain geographic site requirements, including the originating site requirements, for telehealth;
- Waiver of the skilled nursing facility (SNF) three-day rule for performance years two through five, but only if the beneficiary is admitted to a SNF that is rated three stars or better; and
- Waiver to permit certain services to be billed separately during the 90-day post-operative global surgical period.

Further, the Proposed Rule provides that participant hospitals may provide in-kind patient engagement incentives free or at charges below fair market value without violating federal beneficiary inducement prohibitions. Such incentives must be:

- Provided to a beneficiary during a CCJR episode of care;
- Reasonably connected to the beneficiary's medical care; and
- Either a preventive care item/service or an item/service that advances a clinical goal by engaging the beneficiary in better managing his/her own health.

Permissible clinical goals include beneficiary adherence to drug regimens, adherence to a follow-up care plan, reduction of readmissions and complications from LEJR procedures, and management of chronic conditions that may be affected by LEJR. A participant hospital must maintain a list of beneficiary incentive items/services that exceed $10, and any item/service that exceeds $50 must remain the property of the hospital and be retrieved from the beneficiary at the end of the CCJR episode.

Fraud and Abuse Law Implications

CMS specifically acknowledged in the Proposed Rule that certain arrangements between and among participant hospitals and other health care providers may implicate the fraud and abuse laws, and stated that it will collaborate with the Office of Inspector General in considering whether waivers of certain fraud and abuse laws are necessary with regard to the CCJR model. CMS indicated that any such waivers would be proposed and issued separately from the final CCJR rule. Many of the comments received by CMS on the Proposed Rule expressed concern over the application of the Stark Law and the Anti-Kickback Statute (AKS) to the CCJR model and stressed the critical need for fraud and abuse waivers similar to those contained in other BPCI programs. Without such waivers specific to the CCJR model, it will be difficult for participating hospitals and CCJR Collaborators to enter into financial relationships that comply with the AKS and the strict liability standards of the Stark Law.

Hospital Preparation for Mandatory Bundled Payment

The mandatory CCJR model is likely to be the first of many of its kind as CMS continues its push toward value-based payment methodologies. CMS is expected to issue the final rule establishing the CCJR model in November or December 2015. If the final rule adheres to a January 1, 2016 implementation date, affected hospitals will have little time before commencement of the CCJR model to finalize preparations for receiving bundled payments for LEJR procedures, including care redesign and coordination initiatives as well as any related gainsharing or other agreements with physicians and other providers. Hospitals subject to mandatory participation in the CCJR model should therefore immediately begin to assess and develop relationships with post-acute care providers and key physician stakeholders. Hospitals should also consider initiating discussions regarding participation agreements with likely CCJR Collaborators (including orthopedists, hospitalists, SNFs, and home care agencies) and forming interdisciplinary teams to respond to successes and failures of CCJR processes. Further, hospitals should immediately undertake assessment of such things as quality measurement readiness, information technology and data sharing capabilities, preadmission educational programs, and options for payment mechanisms, all of which will be required for hospitals to thrive under the CCJR model and other future bundled payment initiatives.

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1 The preamble to the Proposed Rule suggests that in cases where a hospital is not participating or serving as an episode initiator in the BPCI initiative, but a physician or group practice serving as an episode initiator in the BPCI initiative admits Medicare beneficiaries to the hospital for LEJR procedures, CMS will exclude the individual procedures from the CCJR model.

2 Services excluded from the CCJR episode of care include hemophilia clotting factors, new technology add-on payments, items and services unrelated to the hospitalization, and certain per-beneficiary, per-month payments under other Affordable Care Act models. Notably, payments related to chronic conditions likely to be affected by LEJR (e.g., diabetes or CHF) are included in the episode of care.

3 CMS would not include special payment provisions (e.g., Indirect Medical Education payments, Medicare DSH payments or other add-on payments or incentives) when calculating a hospital's episode target price for a performance year.

4 This limitation is discussed only in the preamble to the Proposed Rule and is not included in the Proposed Rule itself.