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Medicare Launches Its First Mandatory Bundled Payment Model for Joint Replacement Care – What You Need to Know to Get Ready

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On November 24, 2015, the Centers for Medicare & Medicaid Services (CMS) published a significant final rule that will *require* hospitals in selected geographic areas to participate in a new Medicare Comprehensive Care for Joint Replacement (CJR[1]) model beginning April 1, 2016.[2] CMS estimates that approximately 800 hospitals will participate in the model, and that about 23 percent of all lower extremity joint replacement (LEJR) episodes nationally will be covered by the program.

In brief, under this model, CMS will provide a "bundled" payment to participant hospitals for an "episode of care" for LEJR surgery, covering all services provided during the inpatient admission through 90 days post-discharge. The bundled payment will be paid retrospectively through a reconciliation process; hospitals and other providers and suppliers will continue to submit claims and receive payment via the usual Medicare fee-for-service (FFS) payment systems, with the reconciliation occurring later. Most hospitals in 67 metropolitan statistical areas (MSAs) will be covered.

CMS intends for this initiative to improve quality of care and reduce costs associated with LEJR procedures by promoting coordination among hospitals, physicians, and post-acute care (PAC) providers from the initial hospitalization through recovery – although hospitals ultimately will be held responsible for the episode spending. 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 both for the procedures and the associated PAC. The CJR model is part of a broader CMS initiative that seeks to accelerate the share of Medicare FFS payments that are tied to quality and value, and are reimbursed through alternative payment models.

The final 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 final rule, highlighting significant changes from the July 14, 2015 proposed rule.[3]

I. Model Period

Under the final rule, the CJR program begins April 1, 2016 and runs through December 31, 2020. Although CMS had initially proposed a January 1, 2016 start date, the agency agreed with commenters' requests to delay the program to "provide hospitals with more time to prepare for participation by identifying care redesign opportunities, beginning to form financial and clinical partnerships with other providers and suppliers, and using data to assess financial opportunities under the model."[4]

The first year of the model will have a performance period of nine months; all other performance years of the model will begin January 1 and have a performance period of 12 months.

II. Hospitals and Beneficiaries Subject to CJR Model

In contrast to the CMS Bundled Payments for Care Improvement (BPCI) model on which this initiative is based, participation in the CJR model is *mandatory* for inpatient prospective payment system (IPPS) hospitals in selected geographic areas, with limited exceptions (such as hospitals participating in BPCI Model 1, or Phase II of Models 2 or 4 for LEJR episodes).[5] Conversely, hospitals outside of the selected MSAs may not elect to participate in the CJR program.

CMS used complex criteria to determine the geographic areas to be included in the model. The final methodology results in 67 MSAs being selected for mandatory participation in the CJR model, compared with 75 MSAs in the proposed rule, reflecting updated data on BPCI participation levels. The final list of selected MSAs is as follows:

10420	Akron, OH
10740	Albuquerque, NM
11700	Asheville, NC
12020	Athens-Clarke County, GA
12420	Austin-Round Rock, TX
13140	Beaumont-Port Arthur, TX
13900	Bismarck, ND
14500	Boulder, CO
15380	Buffalo-Cheektowaga-Niagara Falls, NY
16020	Cape Girardeau, MO-IL
16180	Carson City, NV
16740	Charlotte-Concord-Gastonia, NC-SC
17140	Cincinnati, OH-KY-IN
17860	Columbia, MO
18580	Corpus Christi, TX
19500	Decatur, IL
19740	Denver-Aurora-Lakewood, CO
20020	Dothan, AL
20500	Durham-Chapel Hill, NC
22420	Flint, MI
22500	Florence, SC
23540	Gainesville, FL
23580	Gainesville, GA
24780	Greenville, NC
25420	Harrisburg-Carlisle, PA
26300	Hot Springs, AR
26900	Indianapolis-Carmel-Anderson, IN
28140	Kansas City, MO-KS
28660	Killeen-Temple, TX
30700	Lincoln, NE
31080	Los Angeles-Long Beach-Anaheim, CA
31180	Lubbock, TX

31540	Madison, WI
32820	Memphis, TN-MS-AR
33100	Miami-Fort Lauderdale-West Palm Beach, FL
33340	Milwaukee-Waukesha-West Allis, WI
33700	Modesto, CA
33740	Monroe, LA
33860	Montgomery, AL
34940	Naples-Immokalee-Marco Island, FL
34980	Nashville-Davidson-Murfreesboro-Franklin, TN
35300	New Haven-Milford, CT
35380	New Orleans-Metairie, LA
35620	New York-Newark-Jersey City, NY-NJ-PA
35980	Norwich-New London, CT
36260	Ogden-Clearfield, UT
36420	Oklahoma City, OK
36740	Orlando-Kissimmee-Sanford, FL
37860	Pensacola-Ferry Pass-Brent, FL
38300	Pittsburgh, PA
38940	Port St. Lucie, FL
38900	Portland-Vancouver-Hillsboro, OR-WA
39340	Provo-Orem, UT
39740	Reading, PA
40980	Saginaw, MI
41860	San Francisco-Oakland-Hayward, CA
42660	Seattle-Tacoma-Bellevue, WA
42680	Sebastian-Vero Beach, FL
43780	South Bend-Mishawaka, IN-MI
41180	St. Louis, MO-IL
44420	Staunton-Waynesboro, VA
45300	Tampa-St. Petersburg-Clearwater, FL
45780	Toledo, OH
45820	Topeka, KS
46220	Tuscaloosa, AL
46340	Tyler, TX
48620	Wichita, KS

According to CMS, approximately 800 hospitals are required to participate in the CJR model; the list of hospital is posted at https://innovation.cms.gov/initiatives/cjr/index.html.

CMS notes that some commenters requested that hospital participation in the CJR model be voluntary, as is participation in the BPCI. CMS cites a number of reasons for selecting a mandatory model, including that it avoids the "selection bias" inherent in voluntary models and leads to a more robust evaluation of the model's effect on all types of hospitals. This will, in turn, enable CMS to assess whether LEJR episode payment models are appropriate for potential national expansion. Moreover, CMS contends that "[t]he coexistence of voluntary initiatives such as BPCI alongside new models in which providers are required to participate will provide CMS, providers, and beneficiaries with multiple opportunities to benefit from various care redesign and payment reform initiatives."[6]

Eligible beneficiaries who receive care at a CJR hospital will automatically be included in the model, although Medicare Advantage and other managed care plan enrollees and beneficiaries eligible for Medicare on the basis of End Stage Renal Disease will be excluded (along with other limited exclusions). Beneficiaries retain their full rights to choose their providers and suppliers. While physicians and hospitals may recommend "preferred providers" (to the extent permitted under current laws and regulations), the final rule prevents participant hospitals from restricting beneficiaries to any such list of recommended providers/suppliers. The final rule also requires participant hospitals to advise beneficiaries that their choices are not constrained, and to inform beneficiaries of financial arrangements between the participant hospital and the preferred providers/suppliers.

III. Covered Episodes and Services

Under the CJR model, an LEJR "episode of care" begins with admission to an IPPS hospital for an LEJR procedure assigned to either:

- 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 CJR initiative is often 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. Despite commenters' requests to limit the CJR model to only elective total hip and total knee replacement cases, CMS declined to exclude the other low-volume, lower extremity procedures. CMS expects there to be a small number of surgeries for these less common clinical conditions at any one hospital, and therefore it believes the model will not put hospitals at undue financial risk. Moreover, CMS includes outlier policies in the final rule that it believes will limit exposure resulting from outlier episodes, as discussed below. Finally, CMS asserts that such patients will benefit from the improved care coordination and quality improvement goals under the CJR model. CMS did agree with commenters, however, on the need to recognize the higher costs associated with beneficiaries with *hip* fractures; rather than exclude such patients from the CJR program altogether, however, CMS will risk stratify hospital target prices based on the patient's hip fracture status.

The LEJR episode of care *ends* on the 90th day after the date of discharge from the anchor hospitalization, with the day of discharge itself being counted as the first day of the 90-day post-discharge period.

Under the final rule, the following extensive list of Medicare Part A and Part B items and services are included in the LEJR episode of care (subject to certain exclusions):

- Physicians' services
- Inpatient hospital services (including hospital readmissions)
- Inpatient psychiatric facility services
- Long-term care hospital (LTCH) services
- Inpatient rehabilitation facility (IRF) services
- Skilled nursing facility (SNF) services
- Home health agency (HHA) services
- Hospital outpatient services
- Outpatient therapy services
- Clinical laboratory services
- Durable medical equipment
- Part B drugs
- Hospice

- Certain per-beneficiary per-month care management payments under CMS innovation models

The final rule excludes items and services unrelated to the anchor LEJR hospitalization, such as care related to oncology, trauma medical, and certain chronic diseases. Also excluded are new technology add-on payments, transitional pass-through payments for medical devices, hemophilia clotting factors, and certain other enumerated payments. The complete list of episode exclusions is posted on the CMS website;[7] CMS will periodically update this list.

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

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

CMS is finalizing its proposal to allow only IPPS hospitals to be designated as "episode initiators" that are financially responsible for episode cost. 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) will not be permitted in the CJR model, nor can physicians or PAC or other providers be episode initiators, despite numerous requests by commenters. CMS will share data, including beneficiary claims data, with hospital participants to help hospitals understand care patterns and identify opportunities for care redesign and savings (CMS did not finalize a proposal that would have allowed beneficiaries to decline having their data shared).

Every year during the model, participant hospitals will receive separate episode target prices for MS-DRGs 469 and 470. In response to commenters who noted the higher costs associated with hip fracture cases, CMS will set different target prices for patients with hip fractures within each MS-DRG. Targets will be based on three years of historical data. The target initially will be based on a blend of hospital-specific and regional episode data, transitioning to wholly regional pricing according to the following framework:

- Years 1 and 2: two-thirds hospital-specific, one-third regional data
- Year 3: one-third hospital-specific, two-thirds regional data
- Years 4 and 5: 100 percent regional pricing

CMS has posted[8] the following data regarding the regional historical average episode payments on which the regional portion of the target will be based:

Region	Regional historical average CJR payments for MS-DRG 469 CJR episodes	Regional historical average CJR payments for MS-DRG 470 CJR episodes	Regional high payment ceiling for MS-DRG 469 CJR episodes	Regional high payment ceiling for MS-DRG 470 CJR episodes
New England	$47,928	$24,858	$93,682	$48,433
Middle Atlantic	$52,028	$27,406	$102,359	$55,615
East North Central	$50,954	$25,480	$102,222	$53,548
West North Central	$46,189	$23,800	$100,992	$51,357
South Atlantic	$51,239	$25,989	$106,332	$53,516
East South Central	$50,328	$26,345	$101,762	$55,965
West South Central	$55,448	$27,464	$113,995	$61,418
Mountain	$47,925	$23,734	$99,425	$50,841
Pacific	$48,874	$23,425	$110,168	$50,527

After a performance year, a hospital's actual episode spending will be compared with the episode target prices. A participant hospital will receive a "reconciliation payment" if its actual episode payments (combined Medicare Part A and B claims payments for services furnished to the beneficiary during the episode) are below the target price for the episode and certain quality thresholds are met (discussed below). Note that there are limits on the reconciliation payments; hospital participants will be eligible to earn up to:

- 5 percent of their target price in performance years 1 and 2
- 10 percent in performance year 3
- 20 percent in performance years 4 and 5

Beginning with the second performance year, a hospital will be *required* to repay Medicare for a portion of spending that exceeds the target price (CMS will not impose any repayment responsibility in performance year 1). For participant hospitals other than rural hospitals, CMS will apply a stop-loss limit of:

- 5 percent in performance year 2
- 10 percent in performance year 3
- 20 percent in performance years 4 and 5

Note that certain hospitals will have different limits: Medicare-dependent hospitals, rural referral centers, and sole community hospitals will all have a 3 percent stop loss limit in performance year 2, and a 5 percent limit in performance years 3 through 5.

Importantly, CMS will apply other limitations and adjustments to repayment and reconciliation payments. For instance, each hospital's target prices will incorporate an applicable "discount factor" to allow Medicare to achieve savings from the CJR model. The discount factor for *reconciliation* payments in all performance years is 3 percent. The applicable discount factor for *repayment* amounts is not applicable in performance year 1, and is 2 percent in performance years 2 and 3. In all performance years, the discount factor may be reduced based on achieving certain quality thresholds.

In addition, to help hospitals manage the risk associated with certain exceptionally costly cases, CMS will apply high episode payment ceilings (two standard deviations above the mean episode payment amount) when calculating actual episode payments, setting episode target prices, and calculating reconciliation and repayment amounts. (Note that this does not have the effect of capping *payments* to providers and suppliers under the episode.) CMS also has adopted an appeals process through which CJR participant hospitals can contest various payment and reconciliation calculations.

While acknowledging that its estimates "contain a significant amount of uncertainty," CMS projects that CJR participant hospitals will receive $170 million in reconciliation payment over the five years of the model, but will be subject to repayment of $513 million, for total savings to the Medicare program of $343 million over five years (out of $12.299 billion in total episode spending), as illustrated in the following table[9]:

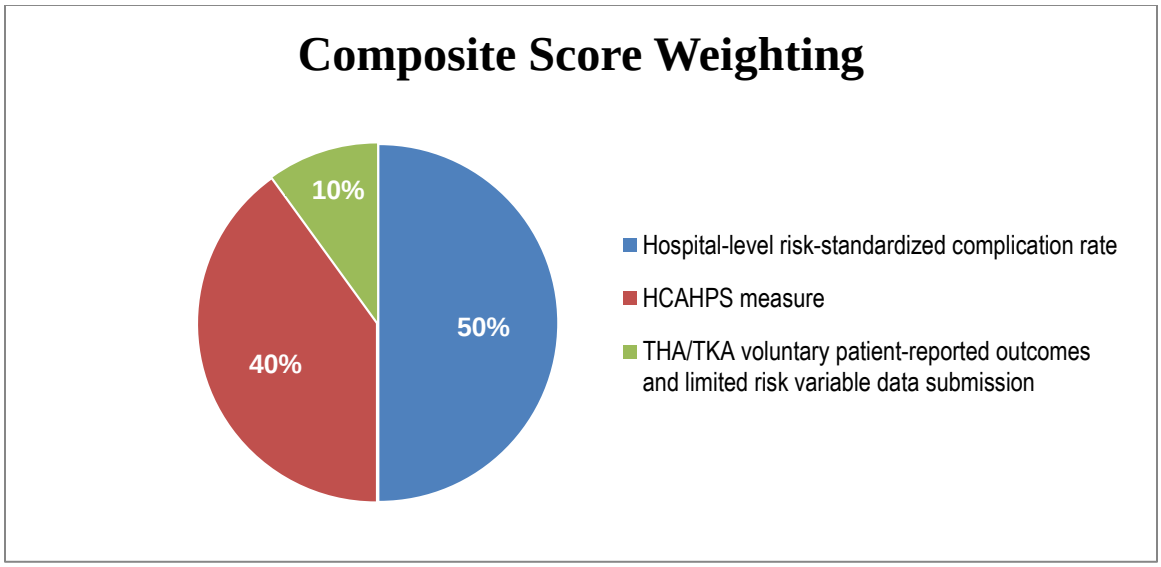
	Performance Year of the Model					Across all 5 years of the Model
	2016	2017	2018	2019	2020	
Total episode spending	$1,247	$2,562	$2,688	$2,821	$2,980	$12,299
Net reconciliation payments**	$11	$(36)	$(71)	$(120)	$(127)	$(343)
Reconciliation amounts	$11	$23	$30	$52	$55	$170
Repayment amounts	$-	$(58)	$(101)	$(172)	$(182)	$(513)
Net reconciliation as a percentage of total episode spend	0.8%	-1.4%	-2.6%	-4.2%	-4.2%	-2.8%

*Impact for 67 selected MSAs. All numbers rounded to closest million.
**Sum of reconciliation amount and repayment amount may not add to net reconciliation payment due to rounding.

V. Tying Payment To Quality

Adding to the complexity of the final rule, CMS will use a composite quality score methodology to link payment to quality (rather than to the proposed performance percentile thresholds). The composite quality score methodology will be used to determine hospital eligibility for reconciliation payments and a reduced discount factor. Based on its composite quality score, a hospital may qualify for an effective discount factor at reconciliation of 2 percent or 1.5 percent instead of 3 percent, which would increase the overall Medicare payment to the hospital.

This composite quality score is a hospital-level summary quality score measuring the hospital's performance and improvement on two quality measures, and its successful voluntary reporting of certain patient-reported outcomes data and limited risk variable data. The composite score is weighted as follows:



- 50 percent for the hospital's quality performance on the hospital-level risk-standardized complication rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) measure (NQF #1550)

- 40 percent for the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) measure (NQF #0166) – a survey instrument and data collection methodology for measuring patients' perceptions of their hospital experience

- 10 percent for the THA/TKA voluntary patient-reported outcomes and limited risk variable data submission

CMS did not finalize inclusion of a TKA/THA readmissions measure (NQF #1551) as proposed. Note that the application of the quality score to hospital payments is extremely complex; CMS has posted a detailed description of its quality methodology at https://innovation.cms.gov/Files/x/cjr-qualstrat.pdf.

VI. Beneficiary Incentives and Financial Arrangements with Collaborators

The final rule defines how participant hospitals may enter into financial arrangements with other providers involved in a beneficiary's care, to share the participant hospital's risks and rewards under the CJR model.

A. Beneficiary/Patient Engagement Incentives

CMS will permit participant hospitals to offer to beneficiaries certain "patient engagement incentives" to encourage beneficiaries to participate in their own recoveries (i.e., by encouraging beneficiary adherence to drug regimens or incentivizing control of a chronic condition such as diabetes that might be affected by the LEJR procedure). The fraud and abuse waiver needed to permit such incentives is discussed further below.

Beneficiary incentives must be reasonably connected to medical care that is provided during a CJR episode, and can be preventive in nature, or an item to advance a clinical goal.[10] CMS clarified that services for chronic conditions are included in CJR episodes, and therefore, under the final rule, it would be appropriate for participant hospitals to offer beneficiary incentives to manage these chronic diseases and conditions during the episode.[11] By way of example, CMS identifies as a permissible incentive post-surgical monitoring equipment to track weight and vital signs at home; however, it states theater tickets would not be permissible as they would not bear a reasonable connection to the patient's medical care. CMS also stated in the final rule that beneficiary incentives must not serve as inducements to beneficiaries to seek care from the participant hospital or other specific suppliers and providers, and they cannot be advertised or promoted. To further reduce the potential for a hospital to steer a beneficiary toward a particular supplier or provider, CMS has added a new requirement in the final rule that beneficiary incentives not be tied to the receipt of items or services from a particular provider or supplier.[12]

CMS specifies in the final rule that only participant hospitals may offer beneficiary incentives, but notes that the incentives may be provided through an agent under the participant hospital's direction and control. However, if a reasonable beneficiary would perceive the item or service as being from the agent rather than the hospital, CMS would not consider the incentive to have been provided by the hospital.[13]

Despite comments to the contrary, CMS also maintained from the proposed rule the requirement that participant hospitals contemporaneously document beneficiary incentive items and services valued at or above a certain amount, although it has raised the threshold from $10 to $25.[14] Similarly, despite opposition from commenters, CMS maintained its proposal to require items of technology of a certain value to remain the property of the participant hospital and be returned at the episode of care, but raised the threshold from $50 to $100.[15] Finally, CMS limits to $1,000 the retail value of items and services involving technology that may be provided to any one beneficiary during a CJR episode.

B. Collaborators

CMS will permit participant hospitals to partner with other providers furnishing care to beneficiaries in CJR episodes, in order to align the financial incentives with the goal of improving quality and efficiency. Referred to as "CJR collaborators," CMS identified these providers as:

- SNFs, HHAs, LTCHs, and IRFs
- Physician group practices (PGPs)

- Physicians, non-physician practitioners
- Outpatient therapy providers

CMS rejected requests to expand this list, stating that "we expect enrolled providers and suppliers to be most directly and specifically engaged with participant hospitals in care redesign and episode care…."[16] A consequence of this decision is that, subject to any future rulemaking to the contrary, only those providers specifically identified by CMS as CJR collaborators are eligible for gainsharing payments; the parameters for such gainsharing payments are discussed below.

Among the multiple requirements that CMS imposes on participant hospitals and collaborators are the following:

- Participant hospitals must develop and maintain a written set of policies for selecting their CJR collaborators, including criteria related to the quality of care to be delivered to beneficiaries during a CJR episode. The selection criteria cannot be based directly or indirectly on the volume or value of referrals or business otherwise generated by, between, or among the participant hospital and CJR collaborators or affiliated individuals or entities.
- In order for a physician or nonphysician practitioner to be a CJR collaborator, the physician or nonphysician practitioner must not have opted out of Medicare.[17]
- Participant hospitals must publish on their websites current and historical lists of CJR collaborators.
- Sharing arrangements (discussed further below), which are included in collaborator arrangements, must be entered before care is furnished to CJR beneficiaries.[18]

C. Other Non-Provider Entities

In the final rule, CMS asserts that many of the potential reasons commenters provided in support of an argument to expand the list of CJR collaborators – such as data analytics and general program support – can be accomplished outside the context of gainsharing. Thus, in declining to expand the list of CJR collaborators, CMS reiterated in the final rule that participant hospitals may choose to engage with organizations that are neither providers nor suppliers to assist with certain care redesign, data analysis, care coordination, and related efforts.[19]

All relationships established between participant hospitals and these organizations for purposes of the CJR model are only those permitted under existing law and regulation, meaning that gainsharing agreements between hospitals and organizations that are neither providers nor suppliers are not permitted. For instance, a hospital may pay an accountable care organization (ACO) for care coordination services that the ACO provides during or after a beneficiary's stay in the hospital, in the event that a hospital and the ACO are collaborating and agree to that arrangement.[20] According to the final rule, this payment is outside of the context of the CJR model and does not fall under the categories of a gainsharing payment or alignment payment. Nothing in the final rule alters the applicable laws, rules, and regulations that apply to such arrangements.

VII. Parameters for Financial Arrangements Between Participant Hospitals and Collaborators

CMS will permit "sharing arrangements" to be set forth within collaborator agreements: specifically, financial arrangements between participant hospitals and CJR collaborators, subject to a variety of requirements. As discussed further below, these can include both "gainsharing payments," in which participant hospitals pay CJR collaborators, and "alignment payments," in which CJR collaborators pay participant hospitals.

CMS specifies that CJR collaborators must, with the exception of PGPs that are CJR collaborators, actually furnish a billable service to CJR beneficiaries during CJR episodes in the calendar year in which the savings or loss was created.[21] PGPs must either (1) have billed for an item or service that was rendered by one or more members of the PGP to a CJR beneficiary during a CJR episode that occurred during the calendar year in which the participant hospital's internal cost savings was generated, or (2) contribute to a participant hospital's care redesign in the CJR model and be clinically involved in the care of CJR beneficiaries.[22] The rule provides several examples of how a PGP might be clinically involved in the care of CJR beneficiaries.

CMS imposes specific and highly detailed requirements on both collaborator agreements and sharing arrangements within those agreements, applicable to participant hospitals and CJR collaborators. **Collaborator agreements** are to set forth, among other elements:

- Specifics of the parties' sharing arrangement
- Details on care redesign and changes in care coordination and delivery
- Specifics regarding the quality criteria used to determine gainsharing payments to collaborators
- A requirement that collaborators have a compliance program and be in compliance with all Medicare enrollment requirements

Specific requirements of **sharing arrangements** to be set forth within the collaborator agreements include the following:

- Neither gainsharing payments nor alignment payments may be conditioned on the volume or value of referrals between the parties
- The arrangement may not induce participant hospitals, collaborators, or any employees or contractors to reduce or limit medically necessary services to beneficiaries
- The agreement must define the methodology the participant hospital will use to determine gainsharing payments, which must be based, at least in part, on criteria related to, and inclusive of, the quality of care to be delivered to beneficiaries during a CJR episode, and not directly on the volume or value of referrals
- The agreement cannot restrict the ability of a physician or CJR collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments. Furthermore, beneficiaries must retain their full rights to choose their providers and suppliers.[23]

"**Gainsharing payments**" from hospitals to collaborators may only be comprised of (1) CJR reconciliation payments, and/or (2) the participant hospital's internal cost savings.[24]

Gainsharing payments must be actually and proportionally related to the care of beneficiaries in a CJR episode. The final rule prohibits participant hospitals from making a gainsharing payment to a CJR collaborator that is subject to any action for noncompliance with the CJR rules or the fraud and abuse laws, or for the provision of substandard care in CJR episodes or other integrity problems. In a calendar year, the aggregate amount of all gainsharing payments distributed by a participant hospital that are derived from a CJR reconciliation payment may not exceed the amount of the reconciliation payment the participant hospital receives from CMS.[25] Further, the total amount of gainsharing payments for a calendar year paid to an individual physician or nonphysician practitioner who is a CJR collaborator must not exceed 50 percent of the total Medicare approved amounts under the Medicare Physician Fee Schedule (MPFS) for services furnished to the participant hospital's CJR beneficiaries during a CJR episode by that physician or nonphysician practitioner.[26] Likewise, PGPs that are CJR collaborators are subject to a cap equal to 50 percent of the sum of the total Medicare approved amounts under the MPFS for services furnished by physician or nonphysician practitioner members of the PGP to the participant hospital's CJR beneficiaries during a CJR episode.[27]

With respect to gainsharing payments received by PGPs, CMS removed the proposed provision that would have prohibited a PGP that is a CJR collaborator from retaining any portion of a gainsharing payment. Instead of requiring a PGP to distribute 100 percent of the gainsharing payment to the PGP's member physicians and nonphysician practitioners that actually furnished the services to the CJR beneficiaries, as was proposed, PGPs will be permitted to retain all or a portion of a gainsharing payment.[28]

Regarding "**alignment payments"** from CJR collaborators to participant hospitals, CMS rejected requests from commenters that CJR collaborators assume greater financial risk. Specifically, CMS retained its proposed cap on alignment payments, providing that in a calendar year, the aggregate amount of all alignment payments received by a participant hospital may not exceed 50 percent of the participant hospital's Medicare repayment amount.[29] Further, the aggregate amounts of all alignment payments from any one CJR collaborator to a participant hospital must not be greater than 25 percent of the participant hospital's repayment amount.[30]

Note that, notwithstanding any sharing arrangements between the hospital and CJR collaborators, CMS ultimately holds the participant hospital responsible for fully complying with all provisions of the CJR model.

VIII. Waiver of Medicare Program Rules

The CJR retrospective bundled payment model requires CMS to waive certain existing Medicare payment and related requirements. In addition to waiving various Medicare Part A and Part B payment rules, CMS proposed to waive specific program requirements to assist participant hospitals in caring for beneficiaries in the most effective, convenient setting in order to encourage timely, accessible care, and to facilitate improved communication and treatment adherence. As discussed further below, these waivers include:

- Allowing payment for two types of physician-directed home visits for non-homebound beneficiaries

- Allowing payment for certain types of physician visits to beneficiaries in the home via telehealth
- Waiving the requirement for a three-day hospital stay prior to admission to a SNF

A. Waivers of Medicare Program Rules to Allow Reconciliation Payment or Repayment Actions

CMS finalized, without modification, its proposal to waive requirements for Medicare Part A and Part B systems to the extent necessary to make reconciliation payments or receive repayments (i.e., alignment payments) to reflect the episode payment methodology for CJR participant hospitals. Under the final rule, reconciliation payments or repayments will not change beneficiary cost-sharing obligations that otherwise would have applied outside of the CJR program.

CMS declined to waive any additional Medicare program rules not specifically discussed in the sections below.

B. Waivers Related to Post-Discharge Home Visits

In the proposed rule, CMS stated that it was considering whether to waive the existing home health "homebound" requirement under the CJR model, particularly beginning in performance year 2, when hospitals begin to bear repayment responsibility for excess episode spending. Under the homebound requirement, before Medicare will pay for home health services, a physician must have certified that home health services are required because of an individual being "confined to the home" and needing skilled nursing care. Notwithstanding requests from commenters for such a waiver, CMS *declined* to waive this requirement, and the existing homebound Medicare requirements for home health services will apply to beneficiaries in CJR program-covered LEJR episodes.

On the other hand, CMS finalized its proposal to waive the "incident to" direct physician supervision requirement set forth in 42 C.F.R. section 410.26(b)(5), as CMS elected to do in the BPCI Initiative. Under the final rule, CMS will permit billing for up to nine post-discharge home visits during each 90-day post-anchor hospitalization CJR episode. CMS reasoned that nine visits would represent a home visit on average of once per week for a majority of the 90-day episode duration – the period of time when the typical beneficiary may have concluded post-acute care. The waiver applies to non-homebound beneficiaries, i.e., it will not apply for beneficiaries who otherwise would qualify for Medicare home health services by reason of their homebound status. Only licensed clinicians, such as nurses, either employed by a hospital or not, will be allowed to furnish the service under the general supervision of a physician, who may be either an employee or a contractor of the hospital.

Services that are furnished under this waiver may be billed under Medicare Part B by the physician or nonphysician practitioner or entity, including a hospital, to which the supervising physician or nonphysician practitioner has reassigned their billing rights.

In a separate section, CMS further waives certain global surgery billing requirements to permit separate billing for up to nine post-operative visits provided by the beneficiary's

physician, or nonphysician practitioner, or by the participant hospital to which those billing rights have been reassigned.[31]

C. Waiver of Certain Telehealth Requirements

Medicare currently pays for telehealth services furnished by a physician or practitioner even though the physician or practitioner is not in the same location as the beneficiary, subject to specific geographic site and originating site requirements, among others. While the CJR model was designed to permit participant hospitals to engage health care professionals in furnishing timely visits to homebound or non-homebound CJR beneficiaries in their homes or residences to address concerning symptoms or observations raised by beneficiaries or others, CMS recognizes that home visits are not always feasible. Hence, it will permit waiver of some existing telehealth requirements.

The final rule waives the geographic site requirements that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000, with the exception of the existing geographic site requirements for a face-to-face encounter for home health certification. All services that are Medicare-approved telehealth services and reported on a claim with an ICD-10-CM principal diagnosis code not excluded from the CJR episode definition may be furnished to a CJR beneficiary, regardless of geographic location.

Additionally, the final rule waives the originating site requirements that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. Further, all services that are Medicare-approved telehealth services and reported on a claim with an ICD-10-CM principal diagnosis code that is not excluded from the CJR episode definition may be furnished to the CJR beneficiary in their home or residence, unless the service's HCPCS code descriptor specifically precludes delivering the service in the home or residence.

CMS rejected proposals to apply the telehealth waiver beyond the beneficiary's home or place of residence, as CMS does not believe that providing telehealth services would be necessary in other locations. Furthermore, CMS rejected proposals to extend the proposed telehealth waiver to furnishing additional services to CJR model beneficiaries via telehealth, reasoning that the CJR model is itself the focal testing model, not telehealth services.

Even though CMS is waiving the geographic site and originating site requirements, it will not permit additional payment to be made to cover set-up costs, technology purchases, training and education, or other related costs. The facility fee paid by Medicare to an originating site for telehealth services will be waived if the service is originated in the beneficiary's home. All other current requirements for Medicare coverage and payment of telehealth services not waived in the final rule will continue to apply, including the list of services approved to be furnished by telehealth and the eligible distant site requirements.

D. Waiver of SNF 3-Day Prior Hospitalization Rule

Under current rules, in order to be eligible for Medicare coverage of inpatient SNF care, beneficiaries must have a prior inpatient hospital stay of no fewer than three consecutive days.

Given that the CJR model was designed to encourage participating hospitals and their provider and supplier partners to develop and refine the most efficient care pathways for beneficiaries to receive the lowest intensity, clinically appropriate care at each point throughout the episode, CMS proposed to waive the SNF three-day rule for beneficiaries in the CJR model, as it had done in prior CMS models and programs, including the BPCI Model 2. Under the proposed rule, beneficiaries would be eligible to receive services furnished under the three-day rule waiver only during the CJR episode. Additionally, CMS proposed to require that participant hospitals only discharge CJR beneficiaries to an SNF with an overall rating of three stars or better by CMS at the time of discharge.

CMS finalized its proposal to waive the SNF three-day rule for episodes being tested in the CJR model in performance years two through five, but it slightly modified the proposed rule with regard to the SNF quality requirements. Under the final rule, the SNF three-day rule will be waived for a CJR beneficiary following the anchor hospitalization only if the SNF is "qualified" at the time of the CJR beneficiary's SNF admission. CMS defines a qualified SNF as one that has an overall rating of three starts or better in the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website for at least seven of the 12 preceding months. CMS will further post the list of qualified SNFs quarterly on the CMS website.

IX. Waivers of Certain Fraud and Abuse Laws in Connection with the CJR Model

Pursuant to the proposed rule, CMS and the Health and Human Services Office of the Inspector General (OIG), on November 16, 2015, jointly issued limited waivers of the Stark physician self-referral and federal anti-kickback laws, as well as the beneficiary inducement civil monetary penalty (CMP) provisions, for the purpose of testing the CJR model.[32]

Each waiver described below applies only to arrangements that squarely meet each of its applicable conditions. Additionally, arrangements that do not fit within a waiver have no special protection and must be evaluated on an independent basis. The waivers below do not provide retrospective protection; an arrangement must meet each of the waiver conditions during the period for which waiver protection is sought.

A. Waiver for Distribution of Gainsharing Payments and Payment of Alignment Payments under Sharing Arrangements (Payments Waiver)

The Payments Waiver applies to the Stark and anti-kickback statutes with regard to distributions of gainsharing payments and payment of alignment payments (as defined in the final rule). The Payments Waiver protects only gainsharing and alignment payments, and does not protect any other arrangements that may be included in the collaborator agreement or any other agreement between a participant hospital and a CJR collaborator.

To be protected by the Payments Waiver, gainsharing and alignment payments must meet the requirements of 42 C.F.R. section 510.500, including all requirements related to the calculation and distribution of payments; the quality criteria for selecting CJR Collaborators and determining payments to CJR collaborators; and the creation and retention of records.

To qualify for the waiver protection, no additional conditions, limitations, or restrictions, other than those permitted or required by the final rule of the waiver, may be added to the

sharing arrangements set forth in collaborator agreements or imposed on the receipt of gainsharing and alignment payments. The Payments Waiver does not protect any payment solicited or received by a participant hospital for including a particular provider or supplier on the participant hospital's preferred provider list. Further, the Payments Waiver does not protect arrangements that incentivize reductions in the amount or quality of medically necessary care furnished to beneficiaries.

Under the final rule and the Payments Waiver, gainsharing and alignment payments must be made by electronic funds transfer for the purpose of increasing transparency. The Payments Waiver also requires documentation that identifies key information related to the payments for which waiver protection is sought, including documentation of payment and receipt.

B. Waiver for Distribution Payments from a PGP to Practice Collaboration Agent (PGP Waiver)

The PGP Wavier applies to the Stark and anti-kickback statutes for distribution payments made by a PGP that is a CJR collaborator to a practice collaboration agent who is entitled to receive such a distribution (as defined in the final rule).

Under the PGP Waiver, the distribution payments must be derived solely from a gainsharing payment made by a participant hospital to a PGP under the CJR model. Additionally, the distribution of the gainsharing payment must comply with the Payments Waiver as described above. Further, the distribution payments must be made pursuant to a written distribution arrangement between the PGP and the practice collaboration agent that sets forth the terms and conditions of the distribution arrangement. No conditions, limits, or restrictions may be added beyond those required or permitted by the final rule or the PGP Waiver. All distribution payments must be made by electronic funds transfer.

C. Waiver for Beneficiary/Patient Engagement Incentives (PEI) Provided by Participant Hospitals to Medicare Beneficiaries in Episodes (PEI Waiver)

The waiver notice waives the beneficiary inducements CMP law and the anti-kickback statute for items or services provided to a Medicare beneficiary under the patient engagement incentives (PEI) provision discussed above. The PEI Waiver only protects items and services provided by the participant hospital directly or through an agent under the hospital's direction and control. The PEI Waiver does not protect an item or service that a reasonable beneficiary would perceive as being from an agent of the participant hospital, rather than from the participant hospital itself.

The PEI Waiver will allow participant hospitals to offer and provide to beneficiaries preventive items and care services that advance clinical goals by engaging patients in managing their care. All items covered under the PEI Waiver must be provided in-kind. The PEI Waiver specifically does not cover gift cards, coupons, cash, or cash equivalents. Additionally, the PEI Waiver does not protect waivers of cost-sharing amounts, such as copayments or deductibles. The in-kind requirement means that the beneficiary must receive the actual item or service, as opposed to funds to purchase the item or service. Last, the item or service must be reasonably related to the medical care provided to a beneficiary during an episode.

X. Conclusion

The CJR initiative is particularly significant given that it is the first bundled payment model in which providers will be required to participate. As such, CMS has committed to conducting a thorough evaluation of the CJR model, examining the impact of the program on quality of care, utilization, outcomes, Medicare expenditures, access, referral patterns, and various "unintended consequences" (e.g., whether the model will lead to adverse selection of patients, access problems, cost shifting beyond the agreed-upon episode, evidence of stinting on appropriate care, anti-competitive effects on local health care markets, or evidence of inappropriate referral practices). If the model is determined to be successful, CMS could expand the program nationally, or apply mandatory bundled payments to other procedures.

CMS believes that the CJR model can benefit the Medicare program and its beneficiaries by improving care coordination and care transitions; encouraging provider investment in infrastructure and redesigned care processes to improve the efficiency and quality of service delivery; and incentivizing higher-value care across an episode of care. It remains to be seen, however, whether the payment provisions and framework for collaboration among providers will be sufficient to support the type of system transformation that CMS envisions.

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1 Note that while CMS abbreviated the program name as *CCJR* in the July 14, 2015 proposed rule, CMS is using the abbreviation *CJR* in the final rule.
2 The text of the rule is available at http://www.gpo.gov/fdsys/pkg/FR-2015-11-24/pdf/2015-29438.pdf.
3 A Reed Smith analysis of the proposed rule is available at http://www.healthindustrywashingtonwatch.com/wp-content/uploads/sites/620/2015/07/CMS-CCJR.pdf.
4 80 Fed. Reg. at 73286.
5 For more information on the BPCI, see https://innovation.cms.gov/initiatives/Bundled-Payments/. (Note that the final rule includes special rules for CJR episodes that involve a BPCI participant other than an acute care hospital, such as PGPs or PAC providers).
6 80 Fed. Reg. at 73287.
7 *See* https://innovation.cms.gov/initiatives/cjr.
8 *See* "Average Regional Historical Episodes from Proposed Rule" at https://innovation.cms.gov/initiatives/cjr.
9 80 Fed. Reg. at 73536
10 80 Fed. Reg. at 73434.
11 *Id.*
12 *Id.*
13 80 Fed. Reg. at 73435.
14 *Id.*
15 80 Fed. Reg. at 73436.
16 80 Fed. Reg. at 73417.
17 80 Fed. Reg. at 73418.
18 80 Fed. Reg. at 73429.
19 80 Fed. Reg. at 73286.
20 80 Fed. Reg. at 73418.
21 80 Fed. Reg. at 73417.
22 42 C.F.R. § 510.500(b)(5)(iii).

[23] 42 C.F.R. § 510.505(2)(b).
[24] 42 C.F.R. § 510.500(b)(7)(i).
[25] 80 Fed. Reg. at 73430.
[26] 80 Fed. Reg. at 73431.
[27] *Id.*
[28] 80 Fed. Reg. at 73422.
[29] 80 Fed. Reg. at 73430.
[30] *Id.*
[31] 42 C.F.R. § 510.615.
[32] *See* "Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model," available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2015-CJR-Model-Waivers.pdf.