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CMS Proposes Sweeping 'Episode Payment Models' for Cardiac Care, Hip/Femur Fracture Cases, Plus Changes to 'Comprehensive Care for Joint Replacement' Model

Proposed Rule to Impact Hundreds of Hospitals and Post-Acute Providers

The Centers for Medicare & Medicaid Services (CMS) has announced proposals for three new "episode payment models" that, like the Comprehensive Care for Joint Replacement (CJR) model, would mandate provider participation in selected geographic areas. The episodes included in these payment models would address care for heart attacks, coronary artery bypass graft, and surgical hip/femur fracture treatment (excluding lower-extremity joint replacement). The performance period for these proposed episode payment models would begin July 1, 2017, giving hospitals and other providers a very short amount of time to prepare for these new payment methods. Comments are due October 3, 2016. Reed Smith is available to assist clients with preparation of comments or questions related to the proposed rule.

I. Overview Building on the current mandatory Comprehensive Care for Joint Replacement (CJR) bundled payment initiative, the Centers for Medicare & Medicaid Services (CMS) has announced ambitious and expansive proposals for three new "episode payment models" (EPMs) that, like the CJR model, would mandate provider participation in selected geographic areas.[1] The episodes included in these EPMs address care for (1) heart attacks (acute myocardial infarction (AMI)), (2) coronary artery bypass graft (CABG), and (3) surgical hip/femur fracture treatment (SHFFT), excluding lower-extremity joint replacement (LEJR). As under the current CJR model, CMS proposes to provide a bundled payment to hospitals in selected geographic areas for an episode, covering all services provided during the inpatient admission through 90 days post-discharge.

CMS proposes that the bundled payment 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. The proposal also includes provisions for episode-based gainsharing and alignment payments, as well as certain financial sharing and distribution arrangements among participants providing care. The performance period for these proposed EPMs would begin July 1, 2017, giving hospitals and other providers a very short amount of time to prepare for these new payment methods.

In the waning weeks of the Obama administration, CMS is moving full-steam ahead toward its goal of transitioning Medicare from FFS to payments that are tied to quality and value, and that are reimbursed through alternative payment models. The three new EPM proposals are particularly controversial, given:

- The CJR model is not even a year old, and there is no analysis yet on how it is working
- CMS has not identified the hospitals that would be subject to the AMI/CABG cardiac bundle
- CMS plans to "randomly" select the affected geographic areas of those hospitals subject to the cardiac bundle, potentially leading to very different results given the wide array of facilities that may be selected, from small rural or community hospitals to tertiary care hospitals with dedicated cardiac programs
- Hospitals in the CJR bundle would have to participate in the SHFFT EPM, although treatment and post-operative care are very different from elective LEJR, as noted by CMS
- CMS is proposing complex and complicated experimental programs at a time when hospitals and other providers are grappling to implement many other payment reforms (e.g., extensive quality measure reporting)
- These EPM bundles involve complex patients with multiple comorbidities; these patients and the care they need will likely be harder to manage across the continuum of care

It appears that CMS is trying to accomplish a great deal – perhaps too much – with multiple contemporaneous payment experiments across multiple disease states involving numerous treatment regimes. In addition to the EPM bundles, the proposed rule includes a new payment model for cardiac rehabilitation and provisions to enable physicians who are involved in the EPMs to qualify for the Advanced Alternative Payment model track under the Medicare Physician Fee Schedule (MPFS).

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 and collaborators that may furnish care to beneficiaries under these new payment models. The following is our initial overview of the proposed rule. Given the multiple new acronyms used in CMS' proposal, we have included a glossary of terms at the end. We will continue our assessment of this lengthy proposal and update clients who have an interest in these proposed policies and wish to submit comments. Comments on the proposed rule are due October 3, 2016.

II. Scope of EPM Initiative CMS recommends testing the proposed EPMs for five performance years (PYs), starting July 2017. The AMI and CABG EPMs would be tested in 98 randomly selected metropolitan statistical areas (MSAs), and the SHFFT EPM would be tested in the 67 MSAs currently involved in the CJR model.

SHFFT Model: The SHFFT model would be tested in the same hospitals participating in the CJR model, so that all surgical treatments for Medicare beneficiaries with hip fractures would be included in EPMs. The existing CJR model tests payment for LEJR procedures, whereas the SHFFT model would test payment for hip fixation.

SHFFT episodes would include procedures covered by Medicare Severity-Diagnosis Related Groups (MS-DRGs) 480-482.

AMI & CABG Models: The AMI and CABG models would be tested at a single set of hospitals and would include all beneficiaries who have AMI treated medically or with revascularization, as well as beneficiaries who undergo CABG. CMS proposes to include any patients who undergo a CABG during the care of AMI in the CABG model. Likewise, CMS would only include AMI beneficiaries whose AMI diagnosis appeared in the primary position of the claim.

CMS notes that the AMI EPM model is the first Center for Medicare & Medicaid Innovation (CMMI) episode payment model that includes substantially different clinical pathways (e.g., medical, surgical) for a single clinical condition. As such, CMS views this as a step toward testing EPMs for clinical conditions that involve a range of approaches and treatment management.

AMI episodes would include:

- AMI MS-DRGs 280-282
- Percutaneous Coronary Intervention (PCI) MS-DRGs 246-251

CABG episodes would include:

- MS-DRG 231-236 representing a Medicare acute Inpatient Prospective Payment System (IPPS) admission for coronary revascularization procedure irrespective of AMI diagnosis

Because beneficiaries in the AMI and CABG models all have coronary artery disease (CAD), CMS also takes the ambitious step of proposing to test

concurrently a cardiac rehabilitation (CR)/intensive cardiac rehabilitation (ICR) incentive payment. CMS intends to evaluate the effects of a CR incentive payment in the context of an EPM, as well as short-term and longer-term outcomes.

CMS expects the EPMs to result in Medicare savings of $170 million over five years.

Advanced APMs: CMS proposes two different tracks for the EPMs. Track 1 EPMs would be considered to meet the Advanced Alternative Payment Model (APM) requirements set forth in CMS' May 9, 2016, Quality Payment Program Rule (QPP Rule), whereas Track 2 EPMs would not meet the proposed criteria. As set out in the QPP Rule, an APM must meet three general criteria to be considered an Advanced APM: (1) an APM must provide for payment for covered professional services based on quality measures comparable to the Merit-based Incentive Payment System (MIPS) measures; (2) an APM must require that the participating APM entities bear risk for monetary losses of more than a nominal amount under the APM; and (3) the APM must require participants to use certified electronic health record technology (CEHRT).

First, CMS asserts that the proposed EPM quality measures would meet the proposed Advanced APM quality measures and thus satisfy the first criterion above.

Second, CMS states that the EPM financial risk component generally meets the QPP risk standards, with limited exceptions. For example, certain EPM participants (e.g., rural hospitals) are subject to a stop-loss limit that caps downside risk below the proposed QPP threshold. CMS is considering allowing these participants to elect a higher stop-loss limit to qualify as a Track 1 EPMs.

Third, CMS proposes to leave it to the EPM participants to decide whether to meet the CEHRT requirements. Note, however, that only those EPM participants electing to meet the CEHRT requirement would qualify for Track 1. CMS would require these Track 1 participants to attest that their use of CEHRT meets the QPP standards.

Notably, any Track 1 PM participant that entered into financial arrangements with an EPM collaborator would be required to submit to CMS a "clinician financial arrangements list" on at least a quarterly basis. In accordance with the QPP, CMS would assess those practitioners included on the Affiliated Practitioner list as of December 31 to determine whether they qualify for APM Incentive Payments. CMS also proposes that the EPM participant would have to maintain documentation of CEHRT use and the clinician financial arrangements.

III. EPM Participants: Hospitals and Beneficiaries The proposed EPMs would be implemented in all IPPS hospitals in the geographic areas selected, subject to certain exclusions.

CMS proposes that the geographic selection unit be based on MSAs. As noted, the SHFFT model would be implemented in the MSAs in which the CJR model already is being implemented. The AMI and CABG models would be tested together in the same geographic areas, although not necessarily in the same areas as the CJR model. Although MSAs are periodically revised, CMS proposes to maintain the same hospital cohort throughout the five-year performance period, with limited exceptions. Thus, CMS would only consider changing the cohort if a new hospital were opened within the MSA during the performance period.

CMS proposes to exclude the following MSAs from the EPM program:

- MSAs with fewer than 75 AMI episodes in the reference year
- MSAs with fewer than 75 non-Bundled Payments for Care Improvement (BPCI) AMI episodes in the reference year
- MSAs in which the number of non-BPCI episodes is less than 50 percent of the total number of AMI episodes in a reference year

Pursuant to these rules, CMS would select 98 MSAs for the AMI and CABG EPMs through random selection from the 294 eligible MSAs. CMS would require all IPPS hospitals physically located in an MSA to participate, with the determination of physical location based on the CMS Certification Number (CCN) at the time of an EPM start.

CMS proposes to include in the relevant model all Medicare beneficiaries meeting certain general Medicare Part A coverage criteria, who are not specifically excluded, and who are hospitalized for an EPM episode. Proposed excluded beneficiaries would be those enrolled in a Medicare Advantage, health care prepayment plan, or HMO; those aligned to a Next Generation Accountable Care Organization (ACO); or those in an ACO in a track of the Comprehensive ESRD Care Initiative, in a BPCI model, or already in one of the other proposed EPMs, among other exclusions.

IV. Defining EPM Episodes Generally speaking, the definition of an episode would have two significant components: (1) a clinical definition, and (2) a time component.

Clinical Definitions: The proposed clinical definitions for each episode are discussed above in section II. CMS proposes a sub-regulatory process for periodically updating the clinical episode definition list based on updates to the ICD-10-CM. This process would mirror the existing CJR model process and would occur at least annually. CMS would post these updates to the CMS website for public input.

Time Definitions: Each new EPM episode would begin at the time of hospitalization and extend 90 days after hospital discharge. Special consideration would be given to triggering an EPM episode and setting target prices for AMI

beneficiaries based on the complexity of treating a heart attack, and because of the likelihood of patients being transferred to a different hospital as a result of the uneven distribution of cardiac care units. The proposed definition of the initiation of an AMI EPM episode is as follows:

EPM Payment Transfer Status	EPM Initiation
No transfer	Episode begins upon admission to the sole treating hospital
Inpatient-to-inpatient (non-EPM hospital to EPM hospital)	Episode begins at transfer hospital
Inpatient-to-inpatient (EPM hospital to non-EPM hospital)	Episode begins at initial treating hospital; only cancelled if beneficiaries discharged from inpatient-to-inpatient transfer hospital under MS-DRGs that are not anchor MS-DRGs for AMI/CABG model episodes
Inpatient-to-inpatient (both EPM hospitals)	Episode begins at initial treating hospital
Outpatient-to-inpatient (beneficiary with AMI transferred from emergency department without admission)	Episode begins at transfer hospital

Generally, once an EPM episode began, it would continue until the end of the episode, unless certain circumstances arose. The following circumstances would cancel an episode:

- Beneficiary ceases to meet general inclusion criteria (see 81 Fed. Reg. 50,834)
- Beneficiary initiates any BPCI model episode
- Beneficiary dies during the anchor hospitalization

Of note, the cancellation of an episode based on death during an anchor hospitalization differs from existing CJR model policy, which cancels the episode if the beneficiary dies at any time during the episode. The proposed change reflects the fact that beneficiaries in AMI, CABG, and SHFFT models are at significant risk of death during these episodes that extend 90 days post-hospital discharge; thus CMS is interested in including reduced mortality as targeted outcome improvement. When an episode is cancelled, Medicare would pay for the services and items furnished prior to and following cancellation, but these payments would not be considered actual EPM spending.

The determination of the end of the 90-day post-hospital discharge period, and thus the end of the EPM episode, would depend on the triggering episode. As in the CJR, CMS proposes that for the SHFFT model episode, the day of discharge from the anchor hospitalization would count as day 1 of the 90-day post-hospital discharge period. Conversely, for an AMI model episode that includes a "chained anchor hospitalization," CMS proposes counting the day of discharge from the

final hospitalization in the chained anchor hospitalization as day 1 of the post-hospital discharge period. A chained anchor hospitalization refers to situations in which a patient is admitted to an EPM anchor hospital, and is subsequently transferred to another inpatient EMP hospital for the purposes of further inpatient episode treatment.

EPM Related Services: As in the CJR model, CMS proposes to include all items and services paid under Medicare Part A and Part B during the episode. Related services in the EPM episode would include, among others:

- Physician services
- Inpatient hospital services, such as operating and capital payments
- Long-term care hospital services
- Skilled nursing facility services
- Home health services
- Hospital outpatient services
- Independent outpatient therapy services
- Clinical lab services
- Part B drugs
- Durable medical equipment
- Hospice

Also similar to CJR, CMS would exclude the following:

- Items and services that are unrelated to the EPM diagnosis code and procedure
- Drugs paid outside of the MS-DRGs included in the EPM episode definition
- IPPS new technology add-on payments for drugs, technologies and services
- Transitional pass-through payments for medical devices

The anchor MS-DRG initiating the EPM episode would determine the specific exclusion list. The exclusion lists would be updated via sub-regulatory guidance at least annually to changes to the ICD-10-CM and MS-DRGs. CMS would post these updates to the CMS website to allow for public input.

Limitation on Concurrent Participation in Multiple Payment Models: There are instances in which an episode could trigger several bundled payment models. CMS proposes the following resolution, with a guiding principle that a beneficiary can never be simultaneously in more than one model:

- **BPCI Overlap:** AMI, CABG, and SHFFT episodes currently are being tested in BPCI models. In cases where an episode qualified under both a BPCI and an EPM, CMS generally intends to give priority to the BPCI, regardless of qualifying episode.

- **AMI/CABG Overlap:** If a beneficiary is admitted to an initial treating hospital for an AMI episode and subsequently is transferred to a chained AMI/CABG EPM hospital, all related care should be attributed to the initial AMI model episode.

V. EPM Pricing & Payment CMS proposes that the acute care hospital in which an eligible beneficiary has an initial hospitalization (anchor hospital) for a specific MS-DRG would be the accountable financial entity.

Performance Period: CMS proposes using the general payment and pricing parameters under the CJR model for the new EPMs, with certain modifications. Consistent with methodology from the CJR model, CMS proposes five performance years (PYs) for the EPMs, which would include EPM episodes for the periods displayed in the following table:

Performance Year (PY)	Calendar Year	EPM Episodes Included in Performance Year
1	2017	EPM episodes that start on or after July 1, 2017 and end on or before December 31, 2017
2	2018	EPM episodes that end between January 1, 2018 and December 31, 2018, inclusive
3	2019	EPM episodes that end between January 1, 2019 and December 31, 2019, inclusive
4	2020	EPM episodes that end between January 1, 2020 and December 31, 2020, inclusive
5	2021	EPM episodes that end between January 1, 2021 and December 31, 2021, inclusive

Because this proposed timeline would only allow six months of EPM episodes for PY1, compared with nine months for CJR, CMS proposes to delay the downside risk requirement (discussed below) until the second quarter of PY2.

Payment Methodology: Consistent with the CJR model, CMS proposes to use a retrospective payment methodology for the EPMs. Under this proposal, all participating providers would bill and be paid as usual by Medicare. At the end of the PY, CMS would group claims for EPM beneficiaries into EPM episodes and aggregate actual payments. These aggregated actual payments would be compared with quality-adjusted target prices, which would determine whether Medicare would make a reconciliation payment, or whether the participant would owe a Medicare repayment.

The two-sided risk methodology would be phased as follows:

Downside Risk (possible repayments to Medicare)	
July 2017 – March 2018 (PY1 and Q1 of PY2)	No repayment
April 2018 – December 2018 (Q2 – Q4 of PY2)	Capped at 5%
2019 (PY3)	Capped at 10%
2020 – 2021 (PY4 and PY5)	Capped at 20%

Gains (possible reconciliation payments from Medicare)	
July 2017 – December 2018 (PY1 and PY2)	Capped at 5%
2019 (PY3)	Capped at 10%
2020 – 2021 (PY4 and PY5)	Capped at 20%

There would be an exception to these stop-loss and stop-gain limits for participants that have lower risk tolerance, less infrastructure, and larger vulnerable populations.

In addition, consistent with the CJR model, CMS proposes to include certain payment adjustments for:

- **Special payment provisions under Medicare payment systems:** CMS would exclude special payments (e.g., rural add-on payments) from price and payment calculations.
- **Payments for services that straddle episodes:** For services that straddle an EPM episode (i.e., begin before the start of or continue beyond EPM episode), CMS would apply CJR methodologies for prorating payments and calculating historical payments.
- **High-payment episodes:** CMS proposes applying a high-payment ceiling when calculating payments and historical payments for high-payment episodes (i.e., at least two standard deviations above the regional mean level).

Further, CMS proposes an adjustment for reconciliation payments and Medicare repayments when updating benchmarks and quality-adjusted target prices, and proposes to implement this adjustment in the CJR model. Similarly, CMS proposes to include BPCI Net Payment Reconciliation Amounts in the benchmark and target price calculation.

EPM Episode – Setting Target Price CMS proposes to use the same pricing methodologies to calculate EPM-episode benchmark and quality-adjusted target prices for each EPM model episode. Specifically, consistent with the CJR model, CMS proposes to use three years of historical episodes for calculating benchmark prices, with each set of historical data updated every other year. Further, CMS proposes trending the first two years' historical data to the most recent year.

In these calculations, CMS proposes blending hospital-specific and regional historic average episode payments. The precise data blend would be two-thirds hospital-specific and one-third regional historic data for the first three PYs. CMS plans to phase out hospital-specific data such that only regional historical data would be considered in PY4 and PY5, with exceptions detailed at 81 Fed. Reg. 50,856. CMS also proposes (1) normalizing wage indices and (2) combining episodes to set stable benchmark and quality-adjusted target prices. The detailed methodology is set forth at 81 Fed. Reg. 50,858.

Finally, CMS proposes making participants accountable for episode payments in relation to the quality-adjusted target price by applying an effective discount factor to hospital-specific and regional blended historical payments for a performance period. In other words, participating hospitals would be required to offer some level of savings or "discount" to Medicare, with the discount level varying based on the hospital's quality score. The following discount factors would be applied:

- 3 percent for EPM participants in the "below acceptable" and "acceptable" quality categories
- 2 percent for participants in the "good" category
- 1.5 percent for the "excellent" category

Reconciliation At the end of each PY, CMS would retrospectively calculate a participant's actual payment for an episode compared with the quality-adjusted target price. The difference between actual payment and the quality-adjusted target price would be aggregated for all episodes in each EPM for a participant within the PY, representing the Net Payment Reconciliation Amount (NPRA) for each participant. Specifically, CMS would capture claims submitted by March 1 and calculate the NPRA. CMS would annually issue a reconciliation report to all participants for review.

During the following PY's reconciliation process, CMS would calculate the prior PY's actual EPM episode payments a second time (called a "subsequent reconciliation") to account for final claims run-out and any cancelled EPM episodes, due to overlap with other models. This amount would be applied to the NPRA for the subsequent performance year, as well as the post-episode spending and ACO overlap calculation.

Appeal Process CMS proposes to allow participants to appeal matters related to payment, cardiac rehabilitation (CR) incentive payments, reconciliation amounts, repayment amounts, quality measure determinations affecting payment, and certain non-payment-related issues.

VI. EPM Quality Measures As noted above, CMS proposes establishing an effective discount factor based on the EPM participant's overall quality performance and improvement on the EPM's quality measures as reflected in the EPM composite quality score (similar to the CJR model). CMS would calculate this composite quality score for each PY at the time of reconciliation, using a methodology that is similar to the CJR methodology.

Specifically, the EPM composite score would be a combination of the composite performance score and an improvement score. The actual level of quality performance would be valued more highly, with the improvement component representing a smaller contribution. CMS would exclude certain participants (e.g., low volume participants without a reportable measure value) from this process,

and would automatically assign these participants to the 50th performance percentile.

In determining quality improvement, CMS proposes adding into the composite quality score, up to 10 percent of the maximum value for each applicable quality measure for those participants that demonstrate substantial improvement from the prior PY. The definition of quality measure improvement would vary between the AMI/CABG models and the SHFFT/CJR models. These definitions are detailed in the proposed rule at 81 Fed. Reg. 50,883.

VII. EPM Monitoring and Beneficiary Notification CMS would assign any Medicare beneficiary receiving care for an EPM episode in a participant hospital to the respective EPM. These beneficiaries would not be permitted to opt out of EPM participation, but beneficiaries would retain their freedom of choice of Medicare providers. As with CJR, CMS would require hospitals to notify beneficiaries of their participation in an EPM.

VIII. EPM Financial Arrangements CMS anticipates that EPM hospitals would enter into financial arrangements that allow EPM participants to share financial risk with EPM "collaborators" that are engaged in providing care to EPM beneficiaries, and that have a role in the EPM participant's episode spending or quality performance. The EPM rules for financial arrangements among health providers and other entities reflect changes from the current CJR model regulations, including streamlining language, providing additional flexibility, and expanding the scope of permissible financial arrangements under the EPM. Likewise, CMS proposes changes to the CJR model that parallel the EPM proposed rule.

The proposed definition of EPM collaborator includes skilled nursing facilities (SNFs), home health agencies (HHAs), long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), physicians, non-physician practitioners, providers or supplies of outpatient therapy, physician group practices (PGPs), hospitals, critical access hospitals (CAHs), and accountable care organizations (ACOs) participating in the Medicare Shared Savings Program. Notably, hospitals, CAHs, and ACOs would be additions to the entities permitted to be EPM collaborators under the existing CJR model. For collaborators other than PGPs and ACOs, the collaborator must have directly furnished the item or service, meaning that that entity billed for it. For PGPs and ACOs, the collaborator not only must have a PGP member or ACO provider/supplier that billed for an EPM service or item, but it also must have contributed to the EPM activities and been clinically involved in beneficiary care.

Requirements for Selection of Collaborators and Compliance CMS would require an EPM participant to develop written criteria for selecting EPM collaborators, which must include consideration of quality of care but may not consider the volume or value of referrals, either past or anticipated. CMS also

proposes that an EPM participant hospital must have a compliance program and a governing body to provide oversight of the participant hospital's participation in the EPM, its arrangements with collaborators, and its provision of gainsharing payments, among other things.

Types of EPM Financial Arrangements CMS provides for three different types of financial arrangements between different entities participating in and collaborating with EPMs: (1) sharing arrangements, (2) distribution arrangements, and (3) downstream distribution agreements.

Sharing Arrangements: The first financial arrangement proposed by CMS is a "sharing arrangement," which would be an arrangement between an EPM participant and an EPM collaborator. Under the terms of this arrangement, the participant and collaborator must only share (1) EPM reconciliation payments, (2) the EPM participant's internal cost savings, and (3) the EPM participant's Medicare repayment.

Any payment from an EPM participant to an EPM collaborator pursuant to a sharing arrangement would be known as a "gainsharing payment," which could be composed only of (1) EPM reconciliation payments, (2) the EPM participant's internal cost savings, or (3) both. The "internal cost savings" would have to be measurable, actual and verifiable cost savings realized by the EPM participant resulting from any care design. Conversely, any payment from an EPM collaborator to an EPM participant would be known as an "alignment payment," and could only consist of a portion of the Medicare repayment to the EPM participant.

CMS would require participants to distribute these payments in accordance with the following conditions and limitations: (1) payments must be distributed annually and not more than once per calendar year; (2) payments must not be a loan, an advanced payment, or a payment for referrals; and (3) any gainsharing payments must be clearly identified as such at the time of payment.

These payments would be conditioned on the meeting of quality of care criteria, and upon the rendering of items and services to an EPM beneficiary during an EPM episode that occurred in the same PY for which the participant accrued the internal cost savings or earned the reconciliation payment. CMS proposes a limit on total gainsharing payments for a PY to physician, nonphysician practitioners and PGPs such that these payments could not exceed 50 percent of the Medicare-approved amounts under the Physician Fee Schedule (PFS). Likewise, the aggregate amount of all alignment payments could not exceed 50 percent of the EPM participant's repayment amount.

With respect to CJR, CMS seeks comments on a proposal for gainsharing payments that would take into account the number of CJR activities provided by

a CJR collaborator relative to other CJR collaborators. In addition, CMS invites comment on whether additional safeguards or a different standard is needed to allow for greater flexibility to provide certain performance-based payments consistent with the goals of program integrity, protecting against abuse and advancing this payment model.

Distribution Arrangements: The second financial arrangement proposed by CMS is a "distribution arrangement," which is an arrangement between an EPM collaborator and another individual or entity termed a "collaboration agent." A payment from a collaborator to a collaboration agent pursuant to a distribution arrangement would be termed a "distribution payment." The requirements for distribution arrangements would largely parallel those for sharing arrangements and gainsharing payments. Note that CMS is proposing a more flexible standard for determining the amount of distribution payments from ACOs and PGPs under CJR. Specifically, for ACOs, CMS proposes that the amount of any distribution payments must be determined in accordance with a methodology that is substantially based on quality of care and the provision of CJR activities, and that may take into account the amount of such CJR activities provided by a collaboration agent relative to other collaboration agents. CMS observes that the amount of a collaboration agent's provision of CJR activities (including direct care) to CJR beneficiaries during a CJR episode may contribute to the participant hospital's internal cost savings and reconciliation payment that may be available for making a gainsharing payment to the CJR collaborator with which the collaboration agent has a distribution arrangement. Greater contributions of CJR activities by one collaboration agent versus another collaboration agent that result in different contributions to the gainsharing payment made to the CJR collaborator with which those collaboration agents both have a distribution arrangement, may be appropriately valued in the methodology used to make distribution payments to those collaboration agents.

Downstream Distribution Arrangements: The final financial arrangement proposed by CMS is a "downstream distribution arrangement," which is an arrangement between a collaboration agent that is both a PGP and an ACO participant, and other individuals termed downstream collaboration agents. A downstream distribution agent would be an individual (1) who is neither an EPM collaborator nor a collaboration agent, and (2) who is a PGP member that has entered into a downstream distribution arrangement with the same PGP in which he or she is an owner or an employee, and where the PGP is a collaboration agent. The requirements for downstream distribution arrangements largely parallel those for sharing and other distribution arrangements.

Procedural Requirements for Financial Arrangements In addition to these general requirements, CMS proposes a number of specific requirements, including: (1) the sharing arrangement must be in writing, signed, and entered into

before care is furnished; (2) participation must be voluntary; (3) the collaborator must comply with certain program integrity requirements; (4) the sharing arrangement must not pose a risk to beneficiary access, freedom of choice or quality of care; and (5) the sharing arrangement terms must not induce either the EPM participant or the collaborator to reduce or limit medically necessary services.

Beneficiary Engagement Incentives CMS acknowledges that engaging beneficiaries throughout the episodes may lead to higher quality care and lower spending. CMS believes that one mechanism that participants may use in achieving these goals is providing beneficiaries with certain items and services as in-kind patient engagement incentives. Under this approach, the costs of patient engagement incentives would be borne by the participant. CMS proposes conditions to ensure that the sole purpose for these incentives is to improve quality and efficiency. For example, CMS proposes that the incentive must be provided directly by the EPM participant (or its agent) to the EPM beneficiary during the episode. The item or service must be reasonably connected to the medical care provided to an EPM beneficiary during the episode and it must not be tied to the receipt of items or services outside the EPM episode. Further, the availability of the items or services provided as incentives must not be advertised or promoted. As with the CJR model, CMS proposes specific enhanced safeguards for items or services involving technology, specifically that these items or services (1) may not exceed $1,000 in value for any one beneficiary in one episode, and (2) must be the minimum necessary to advance clinical goals.

IX. Waivers of Medicare Program Requirements CMS proposes providing certain waivers, similar to those adopted under the CJR model, which would provide additional flexibility to participating hospitals. For instance, CMS proposes waiving the three-day inpatient hospital stay requirement prior to a covered SNF stay, beginning in PY2. CMS also proposes waivers to allow expanded use of telemedicine and use of non-physician practitioners in the cardiac care bundle. It is unclear whether CJR hospitals in SHFFT EPM models would need to wait for PY2 for the three-day hospital inpatient stay.

X. Comment Opportunity and Conclusion CMS is accepting comments on the proposed rule **until October 3, 2016**. CMS specifically requests comments on numerous significant aspects of the proposal, thus providing stakeholders an opportunity to help shape the final framework of the model. Specific areas subject to comment include, among many others:

- Calculation of the episode target and the payment reconciliation methodology
- The inclusion of both reconciliation payments and Medicare repayments in the calculation of historical EPM-episode payments to update EPM-episode benchmark and quality-adjusted target prices

- Sharing beneficiary-level claims data, as CMS does under the CJR model
- 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
- Thresholds for measuring quality attainment and proposals for quality measures
- The proposed definition and role of collaborators
- The parameters for gainsharing payments and alignment payments
- Changes in the gainsharing methodology to allow alignment/gainsharing payments to be based on the volume or value of services and be commensurate with participants' level of effort
- Waivers of current statutory provisions, including the proposed Medicare waivers, waiving the physician definition to allow a qualified non-physician practitioner to perform specific physician functions, and any additional waivers that CMS could consider

While the proposed rule is lengthy and complex, it is important to note that CMS did consider and incorporate stakeholders' comments in the final CJR rule. For this EPM proposal, moreover, CMS is considering and evaluating many "refinements" to its bundled payment model after further consideration of comments received on the CJR Final Rule. Therefore, we urge clients to consider carefully the current CMS proposal and provide timely comments to CMS.

Please contact us with any questions.

Glossary of Terms in Cardiac CJR EPM Rule

ACO	Accountable Care Organization
AMI	Acute Myocardial Infarction
APM	Advanced Alternative Payment Model
BPCI	Bundled Payments for Care Improvement
CABG	Coronary Artery Bypass Graft
CAD	Coronary Artery Disease
CAHs	Critical Access Hospitals
CCN	CMS Certification Number
CEHRT	Certified Electronic Health Record Technology
CJR	Comprehensive Care for Joint Replacement
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CR	Cardiac Rehabilitation
EPMs	Episode Payment Models

ESRD	End-Stage Renal Disease
FFS	Fee-For-Service
HHAs	Home Health Agencies
HMO	Health Maintenance Organization
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
ICR	Intensive Cardiac Rehabilitation
IPPS	Inpatient Prospective Payment System
IRFs	Inpatient Rehabilitation Facilities
LEJR	Lower-Extremity Joint Replacement
LTCHs	Long-Term Care Hospitals
MIPS	Merit-Based Incentive Payment System
MPFS	Medicare Physician Fee Schedule
MSAs	Metropolitan Statistical Areas
MS-DRGs	Medicare Severity-Diagnosis Related Groups
NPRA	Net Payment Reconciliation Amount
PCI	Percutaneous Coronary Intervention
PGPs	Physician Group Practices
PYs	Performance Years
QPP Rule	Quality Payment Program Rule
SHFFT	Surgical Hip/Femur Fracture Treatment
SNFs	Skilled Nursing Facilities