# CMS ISSUES FINAL RULE FOR NEW BUNDLED PAYMENT MODELS

## BACKGROUND

On December 20, 2016, the Centers for Medicare & Medicaid Services ("CMS") published a final rule (the "Final Rule")[1] creating three new episode payment models ("EPMs") covering services provided to Medicare beneficiaries admitted to certain Inpatient Prospective Payment System ("IPPS") hospitals for heart attacks, coronary bypass surgery or surgical treatment of hip or femur fractures. For each of these three conditions, hospitals participating in the EPMs will be held financially accountable not only for the cost and quality of care provided during the inpatient stay, but also for care provided during the 90 days following inpatient discharge. The goal of the EPMs is to improve the quality of care provided to Medicare beneficiaries while reducing spending for the full episode of care.

The Final Rule also implements a model for testing the use of incentives to promote cardiac rehabilitation ("CR") services for Medicare beneficiaries discharged from hospital stays after heart attacks or coronary artery bypass surgery. The EPM and CR incentive programs will be tested for a period of five performance years, beginning July 1, 2017 and ending December 31, 2021.

The EPM Final Rule builds on concepts introduced by CMS through the Comprehensive Care for Joint Replacement Model ("CJR Model"), the first performance year of which began on April 1, 2016. The Final Rule also amends certain regulatory provisions applicable to the CJR Model.

## EPISODE PAYMENT MODELS

Under the Final Rule, CMS finalized its proposal to create EPMs for care episodes related to the following conditions:

- Acute Myocardial Infarction ("AMI");
- Coronary Artery Bypass Graft ("CABG"); and
- Surgical Hip/Femur Fracture Treatment Excluding Lower Extremity Joint Replacement ("SHFFT").

CMS believes that hospitals have a significant opportunity to redesign care, improve quality and control costs for episodic care provided for these conditions. Unlike predominately elective lower extremity joint replacement procedures covered by the CJR Model, most AMI, CABG and SHFFT hospitalizations are non-elective and tend to include patients with multiple chronic conditions that contribute to illness. Additionally, these episodes historically have significant variation in spending. The EPMs are designed to encourage participating hospitals to consider the most appropriate strategies for care design, including coordination of care across the spectrum, reducing readmissions and complications and effectively managing the chronic diseases and conditions that may be related to the covered episodes.

*Episode Initiation and Payment Under EPMs.* Under the finalized EPMs, an episode will begin with an inpatient hospital admission and will be triggered by a Medicare beneficiary's assignment to an EPM-designated Medicare Severity-Diagnosis Related Group ("MS-DRG") upon discharge from the hospital. The episode will extend to 90 days after the date of the beneficiary's discharge from the inpatient hospital stay. As in the CJR Model, the acute care participating hospital will be the episode initiator and will bear the financial risk under the EPMs. An eligible Medicare beneficiary who receives care at a participating hospital is automatically included in the applicable EPM.

Financial incentives available to participating hospitals under the EPMs are calculated using a methodology similar to that introduced in the CJR Model. During each performance year, participating hospitals and other providers involved in an episode of care are reimbursed according to the usual Medicare fee-for-service ("FFS") payment system. After the completion of a performance year, Medicare FFS payments for services furnished to each beneficiary during the 90-day episode are combined to calculate the actual episode payment for that beneficiary. The actual episode payment is then reconciled against an established EPM quality-adjusted target price ("QATP").

CMS will set QATPs annually based on a blend of hospital-specific and regional historical spending data. Initially, this blend will be weighted more heavily on hospital-specific data and will gradually shift to pricing based entirely on regional data (based on the relevant census regions) over the five years of the EPM.

For the AMI, CABG and SHFFT models, participating hospitals will also earn a composite quality score ("CQS"). The CQS will allow hospitals

with relatively high quality performance an increased opportunity for financial incentives within the EPM. Following completion of a performance year, a hospital that achieves actual episode spending below the QATP and achieves an acceptable or better CQS will be eligible to earn a reconciliation payment from Medicare for the performance year. The reconciliation payment will be the difference between the QATP and actual episode spending, up to a specified cap.

Conversely, participating hospitals whose actual aggregate FFS episode payments exceed the aggregate QATP will be required to assume downside risk by repaying a portion of such excess spending to the Medicare program. In response to comments on the Proposed Rule, however, CMS revised the downside risk model originally set forth in the Proposed Rule. Under the Final Rule, participating hospitals are not required to assume downside risk for new EPMs until performance year 3 (beginning January 1, 2019). Hospitals may elect to accept downside risk beginning in performance year 2 (beginning January 1, 2018) if the hospital wishes to have its EPM program qualify as an Advanced Alternative Payment Model ("Advanced APM") under the CMS Quality Payment Program.

*Participating Hospitals and Collaborators.* The AMI and CABG EPMs will apply to hospitals in 98 Metropolitan Statistical Areas ("MSAs"), which CMS selected at random from among 294 MSAs identified in the Proposed Rule. The MSAs selected for the new EPMs can be found here. Participation in the SHHFT EPM will be mandatory for hospitals in the same 67 MSAs covered by the CJR Model. Critical access hospitals and hospitals in rural counties are excluded from mandatory participation in the EPMs.

Much like hospitals participating in the CJR Model, EPM participating hospitals are also permitted to enter into financial arrangements with other providers to share reconciliation payments, cost savings and downside risk. CMS has stated that one of the major goals of both voluntary and mandatory bundled payment models is to encourage coordination among all providers involved in a patient's care. Therefore, as in the CJR Model, EPM hospital participants may enter into financial arrangements with other providers, such as physicians and skilled nursing facilities. Such financial sharing arrangements are subject to numerous restrictions designed to protect quality, beneficiary choice and other aspects of Medicare program integrity. A detailed summary of financial arrangements permitted under the EPMs is available here.

In addition to the potential collaborators permitted under the existing CJR Model regulations, the Final Rule also permits hospitals in the EPM and CJR models to enter into financial sharing arrangements with other IPPS hospitals, critical access hospitals and Medicare Shared Savings Program ("MSSP") accountable care organizations ("ACOs"). CMS believes hospitals participating in the new EPMs (as well as those already participating in the CJR Model) will benefit significantly from the care coordination and care redesign expertise of MSSP ACOs.

*Waiver of Payment Requirements.* The Final Rule waives certain existing payment system requirements in an effort to assist participant hospitals in providing efficient, high-quality care. These provisions include:

- A waiver of the requirement for a three-day inpatient hospital stay prior to admission for a covered skilled nursing facility stay;
- A waiver allowing payment for certain telehealth services provided to a beneficiary in his or her home; and
- A waiver allowing payment for certain types of physician-directed home visits for non-homebound beneficiaries.

*Advanced Payment Track Option.* In the Final Rule, CMS finalized provisions to align hospital-focused EPMs with other pay-for-performance models, including the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). Very briefly, the MACRA physician Quality Payment Program links quality to payment through, among other things, allowing clinicians to participate in Advanced APMs. Eligible clinicians who meet the requirements to participate as Qualified Providers ("QPs") in Advanced APMs can receive APM incentive payments and favorable payment updates under the Medicare Physician Fee Schedule. In the Proposed Rule, CMS outlined how the EPMs meet the requirements to be considered Advanced APMs, thus permitting clinicians collaborating with hospitals in these programs to be considered eligible for QP status under the Advanced APMs.

In the Final Rule, CMS finalized the implementation of two different tracks for EPMs, beginning as early as performance year 2 (January 1, 2018): Track 1, an Advanced APM track; and Track 2, a non-Advanced APM track. Participating hospitals interested in participating in Track 1, and thus qualifying their EPM programs as Advanced APMs, must attest to their use of certified electronic health information technology functions to document and communicate clinical care with patients and other health care professionals. In order to allow CMS to determine whether EPM collaborating clinicians are QPs for purposes of MACRA, EPM participant hospitals must also provide CMS a list of clinician financial arrangements that discloses each clinician's name, tax identification number and national provider identifier, as well as the start and end dates for the financial sharing agreement under which the clinician participates.

Hospitals wishing to qualify their EPMs as Advanced APMs may elect to do so effective as early as January 1, 2018. This will result in the hospital being subject to downside risk sharing under the EPMs effective January 1, 2018 rather than January 1, 2019. As a practical matter, CMS points out that participation in Track 1 does not otherwise change any EPM participant hospital's obligations (including obligations to make any required repayments) under the EPMs, nor does participation in Track 1 alter the hospital's opportunity to earn reconciliation payments under the EPMs. However, by providing an opportunity for physicians and other clinicians to meet QP requirements under MACRA, participation in Track 1 may provide an additional incentive for such clinicians to take an active role in collaborating with hospitals in EPMs.

*Potential Fraud and Abuse Waivers.* Notably, CMS and the Office of the Inspector General did not issue waivers of fraud and abuse laws in connection with the Final Rule; however, CMS indicated that it would consider seeking such waivers as the EPMs develop. Unless and until such waivers are issued, EPM participating hospitals and collaborators will be required to structure any sharing arrangements to comply with applicable requirements of the federal Stark Law and Anti-Kickback Statute. While CMS advised that federal regulatory agencies are considering fraud and abuse waivers applicable to the EPMs, it gave no assurance that such waivers will, in fact, be issued.

**CARDIAC REHABILITATION MODEL**

The Final Rule finalizes without modification the majority of the provisions related to the Proposed Rule's Cardiac Rehabilitation Incentive Payment Model ("CR Incentive Model"). Under the CR Incentive Model, CMS will provide incentive payments to hospitals based on beneficiary utilization of CR and intensive cardiac rehabilitation ("ICR") services in the 90-day period following hospital discharge of an AMI or CABG patient. According to CMS, studies show that while CR/ICR services significantly improve long-term outcomes for AMI and CABG patients, such services are currently widely underutilized. The goal of the CR Incentive Model is therefore to encourage use of CR/ICR services for AMI and CABG patients.

CMS established the CR Incentive Model in a total of 90 MSAs: 45 of the CR Incentive Model MSAs were selected from among the AMI and CABG EPM participating MSAs, and the remaining 45 MSAs were selected from among MSAs that were not selected for EPM participation. Two levels of CR incentive payments will be available to CR participants. CMS will pay an incentive of $25 per CR/ICR service for each of the first 11 services provided to an individual beneficiary during the 90-day post discharge care period. Because evidence shows that Medicare beneficiaries who complete at least 12 CR sessions have significantly reduced mortality rates as compared to those completing fewer than 12 sessions, the CR incentive payment will increase to $175 per CR/ICR service beginning with the twelfth CR service provided to an individual beneficiary. CR Incentive Model payments will be in addition to the current Medicare FFS payments for CR/ICR services and will also be separate and distinct from any Medicare reconciliation payments made to hospital participants under the AMI and CABG EPMs.

Unlike the incentive payments CMS will make under other bundled payment programs (including the Bundled Payment for Care Improvement program, the CJR Model and the proposed EPMs), payments made under the CR Incentive Model may not be included in financial sharing arrangements with other providers. However, the Final Rule does not appear to prohibit CR participant hospitals from entering into fair market value services agreements with other parties involved in providing CR services.

Finally, the Final Rule made noteworthy modifications with regard to beneficiary engagement incentives under the CR Incentive Program. The Proposed Rule limited permissible beneficiary engagement incentives to a relatively narrow range of transportation services; however, in response to comments, CMS expanded the range of beneficiary incentives permissible under the CR Incentive Program to essentially mirror those available under the CJR and EPM programs.

**MODIFICATIONS TO THE CJR MODEL**

The Final Rule also includes several significant changes to the recently implemented CJR Model. As brief background, the CJR Model is a retrospective bundled payment program limited to lower extremity joint replacement ("LEJR") procedures and is designed to encourage hospitals to collaborate with other providers in care redesign measures to improve quality and control costs in LEJR care episodes. The Final Rule contains significant changes from the 2015 CJR Final Rule issued by CMS in November 2015 (click here to view a summary of the 2015 CJR Final Rule). Notable revisions to the CJR regulations include: provisions allowing ACOs, non-CJR participant hospitals, outpatient rehabilitation facilities and therapy service providers to participate as CJR collaborators; revisions to requirements related to physician group practice ("PGP") distributions of gainsharing payments to PGP members; and modifications to episode target price calculations.

*CJR Collaborators.* Under the Final Rule, the term "CJR Collaborators" (previously defined as skilled nursing facilities, home health agencies, long-term care hospitals, inpatient rehabilitation facilities, physicians or PGPs, nonphysician practitioners or outpatient therapy provider/suppliers) now also includes:

- Therapists in private practice;
- Comprehensive outpatient rehabilitation facilities;
- Hospitals;
- Critical access hospitals;
- Nonphysician practitioner group practices; and
- Therapy group practices.

*Distribution Payments to Individual Providers.* The 2015 CJR regulations contained significant restrictions on PGP distributions of gainsharing payments to individual PGP members. For example, the 2015 regulations prohibit a PGP from distributing any portion of a gainsharing payment to any individual practitioner who has not provided a billable service to a CJR beneficiary during the relevant performance year. In addition, distribution payments to an individual practitioner may not exceed 50 percent of the professional fees paid to that practitioner by Medicare for care of CJR beneficiaries during the relevant performance year. The Final Rule permits PGPs to make distributions of gainsharing payments to any member of the PGP, regardless of whether the PGP member had any involvement in CJR episodes of care and regardless of the amount of professional fees received by the PGP member for care of CJR patients, so long as such distributions are made in a manner that meets the Group Practice exception to the federal Stark Law.

*Calculation of Target Pricing*. Finally, CMS changed the CJR term "episode target price" to "quality adjusted target price," or QATP, in order to align with the EPMs and to revise certain calculations related to the QATP for CJR performance years 3 through 5. The Final Rule also modified the calculation of certain quality measures for hospitals under the CJR Model.

For a more detailed analysis of the Final Rule's CJR amendments, click here.

**PRACTICAL TAKEAWAYS**

The future of value-based payment programs implemented by CMS's Center for Medicare and Medicare Innovation ("CMMI") remains uncertain under the new administration. President-elect Donald Trump's nominee for Secretary of Health and Human Services, Rep. Tom Price, M.D., has been critical of the EPMs and publicly spoke out against the Proposed Rule. Rep. Price has also called on CMS to halt all current and future planned mandatory CMMI initiatives.

Despite this uncertainty, those hospitals selected to participate in the EPMs should still begin to prepare for the July 1, 2017 EPM implementation date. Additionally, hospitals participating in the CJR Model should review the revisions to the CJR Model implemented by the Final Rule to ensure they remain in compliance.

If you have any questions or would like additional information about this topic, please contact:

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[1] Hall Render's previous alert on CMS's August 2016 proposed rule (the "Proposed Rule") is available here.

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