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CMS ISSUES NOTICE OF PROPOSED RULEMAKING FOR NEW BUNDLED PAYMENT MODELS

BACKGROUND

On August 2, 2016, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule (the "Proposed Rule") to create 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 would be held financially accountable not only for the cost and quality of care provided during the inpatient stay but also for the care provided during the 90 days following inpatient discharge. The goal of the proposed EPMs is to improve the quality of care provided to Medicare beneficiaries while reducing spending for the full episode of care.

The Proposed Rule would also implement 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 bypass surgery. The proposed EPMs and CR incentive program would be tested for a period of five performance years beginning July 1, 2017 and ending December 31, 2021[1].

The Proposed 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. Finally, the Proposed Rule would amend certain regulatory provisions applicable to the CJR Model.

EPISODE PAYMENT MODELS

Under the Proposed Rule, CMS would 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 noted that it chose to focus on these EPMs because it believes that hospitals have significant opportunity to redesign care, improve quality and control costs for episodic care provided for these conditions. Unlike the predominantly 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 participant 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 covered episodes.

Episode Initiation and Payment Under EPMs. Under the proposed EPMs, an episode would begin with an inpatient admission to an anchor hospital and would be triggered by a Medicare beneficiary's assignment to an EPM-designated Medicare Severity-Diagnosis Related Group upon discharge from the hospital. As in the CJR Model, the acute care participant hospital would be the episode initiator and would bear the financial risk under the proposed EPMs. An eligible Medicare beneficiary who receives care at a participant hospital would automatically be included in the applicable EPM.

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

CMS would set target prices annually for the three EPMs based upon factors including the following:

- Hospital-specific and regional historical costs for treating the condition during inpatient hospitalization and for the 90 days post-discharge;
- Complexity of the patient's condition; and
- For heart attack patients, whether the condition was treated medically (including use of percutaneous coronary intervention) or surgically.

Target prices for each year of the EPM will be calculated based on a blend of hospital-specific and regional historical spending data. Initially, this blend would be weighted more heavily on hospital-specific data and would gradually shift to pricing based entirely on regional data over the five years of the EPM.

At the end of each performance year, each hospital's aggregate actual episode payments would be reconciled against the aggregate QATP for all episodes within each EPM. Hospitals with positive episode cost and quality performance would be eligible to receive incentive payments (referred to in the Proposed Rule as "reconciliation payments") for the relevant performance year. Alternatively, beginning with the second EPM performance year, those participant hospitals whose actual aggregate episode payments exceed the aggregate QATP would be required to repay a portion of the difference to the Medicare program.

Participant Hospitals and Collaborators. CMS would implement both the AMI and CABG EPMs for hospitals in 98 Metropolitan Statistical Areas ("MSAs"), which CMS will select at random from among 294 MSAs identified in the Proposed Rule. Participation in the SHFFT bundle will be mandatory for hospitals in the same 67 MSAs covered by the CJR Model. Critical access hospitals ("CAHs") and hospitals in rural counties would be excluded from mandatory participation in the newly proposed EPMs.

Much like the CJR Model, CMS also proposed to allow EPM participant hospitals to enter into financial arrangements with other provider types to share reconciliation payments, cost savings and downside risk. CMS has stated that one of the major goals of these bundled payment models is to encourage coordination among all providers involved in a patient's care. Therefore, as in the CJR Model, CMS proposed to allow EPM hospital participants to enter into financial arrangements with other providers, such as physicians and skilled nursing facilities. Such financial sharing arrangements would be subject to numerous restrictions designed to protect quality, beneficiary choice and other aspects of Medicare program integrity.

In addition to the potential collaborators permitted under the existing CJR Model regulations, the Proposed Rule would also allow hospitals in the EPM and CJR Model to enter into financial sharing arrangements with other IPPS hospitals, CAHs 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) would benefit significantly from the care coordination and care redesign expertise of MSSP ACOs. However, as proposed, CMS would impose a number of requirements on financial sharing agreements between a hospital and a MSSP ACO. These requirements would be substantially similar to the requirements under which physician group practices ("PGPs") serve as collaborators under the CJR Model.

Advanced Payment Track Option. Under the Proposed Rule, CMS also seeks 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 Alternative Payment Models ("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 outlines 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.

For EPMs, CMS proposed to implement two different tracks: Track 1, an Advanced APM track; and Track 2, a non-Advanced APM track. Due to special protections applicable to rural hospitals, sole community hospitals, Medicare dependent hospitals and rural referral centers under the Proposed Rule, such hospitals would not be eligible to participate in Track 1. Other 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 ("CEHRT") functions (as set forth in the definition of CEHRT under CMS's proposed regulation at 42 CFR §414.1305) 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. 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. CMS did not issue waivers of fraud and abuse laws in connection with the Proposed Rule; however, CMS indicated that it would consider seeking such waivers as the EPMs develop. Providers can reasonably expect to see EPM waivers similar to those issued in connection with the CJR Model. It is likely that such waivers would be jointly issued by CMS and the Office of the Inspector General.

CARDIAC REHABILITATION INCENTIVE PAYMENT MODEL

The Proposed Rule introduces the Cardiac Rehabilitation Incentive Payment Model ("CR Incentive Model"), under which CMS would provide incentive payments to hospitals based on beneficiary utilization of cardiac rehabilitation 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 will establish the CR Incentive Model in a total of 90 MSAs: 45 of the CR Incentive Model MSAs will be selected from among the AMI and CABG EPM participating MSAs, and the remaining 45 MSAs will be selected from among MSAs that were not selected for EPM participation. Two levels of CR incentive payments would be available to CR participants (defined by the Proposed Rule as all hospitals participating in the CR Incentive Model). 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 would increase to $175 per CR/ICR service beginning with the 12th CR service provided to an individual beneficiary. CR Incentive Model payments would be in addition to the current Medicare FFSpayments for CR/ICR services and would 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 Proposed 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. Additionally, in recognition of potential barriers that may exist to beneficiary access to CR services, CMS proposed to allow hospitals to provide transportation to CR/ICR services, subject to restrictions designed to protect against overutilization and inappropriate beneficiary inducement. Finally, CMS proposed to waive certain requirements related to physician involvement in CR/ICR services. These waivers would allow non-physician practitioners (including nurse practitioners, clinical nurse specialists and physician assistants) to provide supervision, prescribe exercises, and establish, review and sign treatment plans for CR services provided under the CR Incentive Model.

CMS notes that many aspects of the proposed CR Incentive Model are without precedent among existing pay-for-performance programs and seeks comments on other types of financial arrangements that would advance the goals of increased CR/ICR utilization.

MODIFICATIONS TO CJR MODEL

Finally, the Proposed Rule also includes several significant changes to the recently implemented CJR Model. As very 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 Proposed Rule contains significant changes from the 2015 CJR Final Rule issued by CMS in November 2015 (click here to view a summary of the Final Rule). Perhaps most notable among the proposed revisions are provisions allowing ACOs and non-CJR participant hospitals to participate as CJR collaborators, revisions to requirements related to PGP distributions of gainsharing payments to PGP members and modification to episode target price calculations.

Potential CJR Collaborators. The Proposed Rule would modify the regulations governing permitted financial relationships under CJR. Under

the Proposed Rule, "CJR Collaborators" (previously defined as skilled nursing facilities, home health agencies, long-term care hospitals, inpatient rehabilitation facilities, physicians or PGPs, non-physician practitioners or outpatient therapy provider/suppliers) would also include MSSP ACOs, other IPPS hospitals and CAHs.

Distribution Payments to Individual Providers. Existing CJR regulations contain significant restrictions on PGP distributions of gainsharing payments to individual PGP members. For example, existing 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 Proposed Rule would permit 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 which meets the Group Practice exception to the federal Stark Law.

Calculation of Target Pricing. Finally, CMS proposes to change the 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 three through five. The Proposed Rule would also modify the calculation of certain quality measures for hospitals under the CJR Model.

For a more detailed analysis of the Proposed Rule's CJR modifications, click here.

PRACTICAL TAKEAWAYS

Although the Proposed Rule does not identify the hospitals that will be subject to mandatory participation in the new EPM bundled payment program, all health care providers should begin to prepare their organizations to move towards value-based payment models. CMS has previously announced a goal of moving 30 percent of Medicare payments to alternative payment models by the end of 2016 and to move 50 percent of payments to such models by the end of 2018. CMS is rapidly meeting and exceeding these goals, and providers must be in a position to align with new payment models.

Providers and other interested parties should also contact CMS with comments and concerns regarding the Proposed Rule. Comments must be received by CMS no later than **5:00 PM EDT on October 3, 2016**. CMS invites comments to the Proposed Rule, and it is critical that providers address their concerns before a final rule is implemented. Further, providers often must raise comments in the proposed rulemaking phase in order to appeal any issues under final rules.

If you have any questions, need assistance in formulating comments or would like additional information about this topic, please contact:

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[1] Note - the Proposed Rule defines July 1, 2017 through December 31, 2017 as performance year one.