Furtheing the agency’s stated intention to pay for value over volume, the Centers for Medicare & Medicaid Services (CMS) recently issued a proposed rule representing the first expansion of mandatory hospital-centric bundled payment models to non-elective procedures and for a patient population with a large proportion of chronic conditions. It is apparent that CMS views bundled payments as a reimbursement paradigm of the future to promote better care coordination and improved patient outcomes, while also reducing costs for the overall Medicare program. Some 30 percent of Medicare payments already flow through alternative payment models, and when finalized this Rule will move CMS closer to its stated goal of achieving 50 percent by 2018.

The proposed rule, issued on July 25, contains three new components and also expands and revises certain aspects of the Comprehensive Care for Joint Replacement (CJR) payment model which began April 1. Major elements of the proposal include:

- A new retrospective bundled payment model for cardiac care (Cardiac Model), including acute myocardial infarction (AMI) and coronary artery bypass graft (CABG), in 98 randomly selected metropolitan statistical areas (MSAs) which will be named in the final rule;

- A new incentive payment model (Cardiac Incentives) to encourage increased use of cardiac rehabilitation in 90 MSAs (45 of which will be the same as those selected for the Cardiac Model);

- Proposed pathways for physicians participating in various CMS bundled payment models to qualify for payment incentives under the Quality
• **Expansion of the CJR payment model**, now applicable in 67 CJR MSAs, to include episodes for hip and femur fractures that do not require a lower extremity joint replacement already covered under CJR (SHFFT).

Comments on the Rule are due October 3 and, if finalized, the new episode payment models (EPMs), will begin July 1, 2017, and continue for five performance years through December 31, 2021. CMS has not yet identified the 98 MSAs required to participate in the Cardiac Model and will make that announcement when the Rule is finalized. Hospitals participating in other voluntary Medicare programs, such as the Medicare Shared Savings Program (MSSP), and other Accountable Care Organization (ACO) based models, are encouraged to continue participation in such programs but will still be required to participate in the new EPMs as applicable. However, certain hospitals will be excluded from participating in the Cardiac Model, including hospitals participating in BPCI Model 1 or Phase II of Models 2 or 4 for covered episodes. Like CJR, overlap with the Bundled Payments for Care Improvement (BPCI) program is intended to be minimized by exclusion of MSAs with high BPCI participation rates.

Many elements of the Cardiac Model mirror CJR, including significant inspiration from BPCI Model 2. As with BPCI Model 2 and CJR, participating hospitals and other providers will continue to receive standard fee-for-service (FFS) payments throughout EPM performance years. Thus, although all models represent alternative payment methodologies they do not require a reinvention of Medicare billing or payment infrastructure. Instead, use of retrospective bundled payments permits CMS to build on the existing FFS system, while also incentivizing performance in comparison to financial and quality benchmarks.

**Episode Payment Models**

Akin to CJR and certain BPCI models, the proposed EPMs make participant hospitals accountable for the financial performance and quality of care delivered during an inpatient stay related to an AMI or CABG episode as well as certain hip and femur fractures (applicable MSDRGs listed in the attached Table 1), in addition to the 90-day period following discharge (Episode). CMS will calculate the total costs incurred for all items and services from all providers or entities delivering care to a patient during an applicable Episode, and compare those costs and the quality of care achieved during the Episode to quality-adjusted target prices and benchmarks. Participating hospitals may then receive a Net Payment Reconciliation Amount (NPRA) if the charges in an Episode are lower than the target price or, alternatively, may be required to repay CMS the amount that the charges exceed the target price, subject to caps on gains and losses. Hospitals may also enter into financial arrangements with collaborating providers to distribute positive NPRA based on comparison to CMS target prices and Internal Cost Savings (ICS) based on comparison to past hospital costs of providing care, and can further allocate downside financial risk among a variety of providers in an effort to better incentivize care coordination during the course of an Episode.

Strict protocols related to program integrity must be followed, which include updating hospital compliance programs, ensuring governing body oversight over EPM participation, defining quality criteria for participation in gainsharing related to the EPMs, defining changes to care processes expected of participating providers, and prescribing the manner in which gainsharing amounts will be calculated and allocated. Details related to these program
integrity elements must be included in all agreements among collaborating providers prior to any care being applied to gainsharing or risk allocation calculations.

Similar to CJR, as the Cardiac Model progresses, target prices will move to a more regional, as opposed to individual hospital, calculation format, while quality targets will become more aggressive and larger percentages of total CMS payments related to Episodes will be put at risk for participant hospitals. Under the Cardiac Model, downside risk will also be phased in, so that hospital payments will not be put at risk until the second quarter of 2018. Unlike CJR, certain payment adjustments will be permitted for designated transfers and readmissions where higher acuity care is required than a participating hospital is capable of providing.

Proposed CMS program waivers in the Rule will largely mirror those under CJR in relation to telehealth, but may vary as applied to the waiver of skilled nursing facility (SNF) 3-day stay requirements. Additionally, under the Cardiac Model a further waiver is proposed to permit furnishing of rehabilitation services by various allied health professionals. While the Rule does address CMS program waivers, it does not propose fraud and abuse waivers but instead encourages comments regarding the necessity thereof. It is hoped that such waivers will be released by CMS and the Office of Inspector General in conjunction with any final rule, which would be consistent with the process earlier used under the BPCI and CJR programs. The need for such waivers again reflects the tension between existing fraud and abuse laws (Stark Law and Anti-Kickback Statute) and CMS’ current efforts to encourage provider collaboration.

Cardiac Rehabilitation Incentives

Cardiac Incentives proposed by the Rule involve payments to participating hospitals of $25 per cardiac rehabilitation service for the first 11 services paid by Medicare following AMI or CABG, increasing to $175 per service after the first 11. The payments will be available to hospitals in 45 MSAs that were selected. CMS notes that such services have been shown to improve outcomes, but currently only 15 percent of cardiac patients receive rehabilitation treatment. Significantly, sharing arrangements with other providers or entities related to the Cardiac Incentives are not explicitly defined under the proposal, and would instead have to comply with existing fraud and abuse laws, which may prove challenging to accomplish.

Quality Payment Program Pathway

MACRA describes two ways for clinicians to link quality to payments through Medicare in the Quality Payment Program: (1) the Merit-Based Incentive Payment System (MIPS), and (2) Advanced Alternative Payment Models (APM). Participating clinicians in the EPMs and CJR may qualify for additional incentives set forth under the Quality Payment Program by permitting such clinicians to meet the criteria for an Advanced APM if they use Certified Electronic Health Record Technology and bear financial risk for monetary losses in an applicable program. If clinicians do select to pursue Advanced APM qualification through participation in EPMs or CJR, they are permitted to opt out of more arduous MIPS requirements beginning in 2018.

CJR Changes

Finally, the Rule expands the current CJR model to hip and femur fractures not requiring a lower extremity joint replacement already covered under CJR, and also makes some minor revisions to the CJR Model. This expansion will apply to MSAs currently participating in CJR, but the timeline and performance years will be consistent with the
Cardiac Model. Revisions to CJR include clarification that ACOs may be collaborators with hospitals, and distribute incentives and downside risk to their participants, as well as clarification regarding overlap between MSSP, certain ACOs and CJR. Under the EPMs and CJR, beneficiaries in CMS’ Next Generation ACO Model and the Comprehensive ESRD Care Model are excluded from participation in either the EPMs or CJR. Several other changes to the CJR regulations, at 42 C.F.R. § 510, are also proposed.

In the Rule, CMS emphasizes that it wants hospitals to consider strategies for: (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating care across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the proposed Episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating care between providers and suppliers including hospitals, physicians and post-acute care providers. In this context, CMS expects hospitals to implement these strategies, so the increasing role that hospital-centric bundled payments will likely play may also influence hospitals to concentrate on infrastructure and related investments which better achieve these goals. For affected and potentially affected hospitals, the Rule is a shot across the bow that change is coming at a pace faster than many expected.

For more information regarding this topic and related developments, please contact any of the authors, a member of Polsinelli’s Health Care practice, or your Polsinelli attorney.

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