



A Passionate Voice for Compassionate Care

October 3, 2016

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G
Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington DC 20201

RE: CMS-5519-P - Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) (81 FR 50793-51040), August 2, 2016.

Dear Acting Administrator Slavitt:

On behalf of the Catholic Health Association of the United States, the national leadership organization of the Catholic health ministry, representing the largest group of not-for-profit providers of health care services in the nation, I would like to offer the following comments on the referenced proposal by the Centers for Medicare and Medicaid Services (CMS) to create new episode payment models (EPMs) for acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT), a new Cardiac Rehabilitation Incentive Payment Model (CR), and changes to the Comprehensive Care for Joint Replacement Model (CJR).

The Catholic health ministry is committed to providing safe, effective, patient-centered, timely, efficient and equitable care to all patients. We strive to improve the quality and safety of the care that we provide every day. **CHA welcomes the continued movement of our health care systems towards one that rewards providers for high-quality patient care in a manner that focuses on quality and outcome rather than volume.** CHA has consistently been a willing partner with CMS in support of programs such as CJR, the Medicare Shared Savings Program/Accountable Care Organizations, Value Based Purchasing and Readmission Reductions. **CHA has become increasingly concerned, however, about the complexity and pace of change CMS has asked of hospitals, given the other regulatory and statutory requirements our members' hospital staff and physicians face.** This confluence of new requirements is putting increasing stress on our hospital staff and physicians as well as the financial resources of our member hospitals to implement these programs successfully and to the greatest benefit to beneficiaries. In this light, our goal in offering comments to the current

proposal is to contribute to its successful implementation in a way that avoids unintended consequences such as increasing disparities in care or creating disincentives to serve low-income or vulnerable patients.

- **Start Dates of Payment Models/Downside Risk**

CMS proposes to test the proposed episode payment bundles for AMI, CABG, and SHFFT and the CR incentive payment model beginning in July 1, 2017. This allows for eight months, at most, for hospitals to prepare to be successful in these models. CHA believes this is insufficient time given the number and complexity of the models CMS proposes. **CHA urges CMS not to finalize this timeframe and instead to delay the implementation six months to begin on January 1, 2018.** Our members' experience have shown that that the pre-implementation administrative work and data analysis needed to be successful in episode payment bundles inevitably takes more time than initially anticipated. Hospitals need sufficient time to better understand the clinical and financial risk of their patient populations, establish collaborator relationships and establish the internal organization structure to manage payment bundles. There is considerable variation in hospital preparedness and capabilities and many hospitals will face considerable staffing and financial challenges in implementing these models without a delay.

The implementation of these models within this timeframe is simply too much, too fast and too soon. CMS needs additional time to learn from hospitals' CJR experience (a model with only four months of history when CMS issued this proposed rule) and from the Bundled Payments for Care Improvement (BPCI) initiative Model 2 results. BPCI Model 2 is analogous to the EPM approach, as the BPCI Model 2 design includes the triggering hospital stay and all concurrent professional services for a chosen episode length of 30, 60, or 90 days. CMS only recently released the BPCI Year 2 evaluation and monitoring report and this report raises questions, in particular, about the cardiac models.¹ Results from the evaluation of year two results showed no statistically significant difference in the change of Medicare payments for the cardiovascular surgical episodes between the BPCI and the comparison groups. This is surprising given that BPCI hospitals volunteered to participate in this program and should have been well-prepared to succeed and achieve cost savings, while maintaining quality. Of most concern, researchers found a statistically significant increase in mortality for beneficiaries with cardiovascular surgery episodes in BPCI-participating hospitals relative to comparison hospitals. Although the most recent BPCI results did not show a statistically significant increase in mortality between the comparison and BPCI groups, the initial increased mortality findings are concerning. Moreover, while there was a significant reduction in utilization of institutional post-acute care settings, there were instances where BPCI patients exhibited less improvement in functioning suggesting that work is needed in determining optimal sites of post-acute care and in establishing effective transitions to appropriate home health care.

¹ The Lewin Group. (August 2016). CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report. Prepared for the Centers for Medicare and Medicaid Services.

We are also concerned about the start date for when hospitals will begin to face downside risk. Under the current proposal, downside risk would be in effect after six months. **CHA urges that the start of downside risk be delayed until after the third quarter of performance year two (which ends September 30, 2108) to give participants a full year without down side risk.**

- **Episode of Care Definition/Risk Adjustment/Exclusions**

An episode of care in the EPM models would be triggered by an admission to an acute hospitals paid under one of the MS-DRGs specified by CMS in the proposed rule. The episode of care would end 90 days after discharge from the hospitals and include all related care under Medicare Parts A and B, including inpatient, outpatient, physician, in-patient rehabilitation, skilled-nursing and home-health services. Certain unrelated services (e.g., unrelated hospital admissions and IPPS new technology add-on payments) would be excluded. The model would last for five years, beginning July 1, 2017 and ending December 31, 2021.

CHA is concerned about the complexity of the proposed AMI model, which includes multiple treatment pathways and in which inter-hospital transfers of patients are likely to occur in at least 20 percent of cases. Hospitals that admit the patient for cardiac care and then transfer the patient are accountable for the episode costs. While this may be appropriate in most instances, we are concerned that this could create incentives either to immediately transfer ED patients with AMI symptoms or to fail to transfer admitted patients to another facility. This would be an unfortunate distraction from what should be the goal of making sure every patient has access to the right place for the care they need. We are especially concerned about the possible impact on smaller hospitals unable to provide sophisticated cardiac care. The transfer of the sickest patients to a larger, higher level hospital that can provide the appropriate care should not trigger a penalty for these hospitals.

In general, we are also concerned about the lack of risk adjustment for patient-specific clinical indicators or differentiation within a given DRG. In particular, we remain concerned about the need to appropriately account for variation in treating fractures and trauma cases. The SHFFT model includes no quality measures or risk stratification that are targeted to the hip fracture fixation population. CMS states it continues to believe that no standard risk adjustment approach is widely accepted and that CMS Hierarchical Condition Categories (HCC) used to adjust for risk in the Medicare Advantage program would not be appropriate for risk adjusting EPM episodes, despite proposing EPM quality measures that incorporate HCC risk scoring. We believe that failure to properly risk adjust is a significant limitation of the proposed approach, and our concerns are buttressed by a recent September 2016 articles published in *Health Affairs*.² Specifically the authors found that the new bundled payment for joint replacement penalizes hospitals that treat medically complex patients. Reliance upon region-based target pricing led to

²Ellimoottil C, Ryan AM, Hou H, Dupree J, Hallstrom B, and Miller DC. Medicare's new bundled payment for joint replacement may penalize hospitals that treat medically complex patients. *Health Aff (Millwood)*. 2016;35(9):1651-1657.

reduced reconciliation payments to such hospitals, and failure to risk adjust produced wide swings in reconciliation payments. The authors found that CMS-HCC risk scores controlled for much of this variation and cite a number of advantages in using this approach, including that CMS-HCC risk scores are currently used in number of other performance programs; can be computed from administrative claims with minimal burden; and factors that comprise the HCC-risk score have independently been shown to affect expenditures. We agree with these conclusions. **CHA strongly urges CMS to use CMS-HCC risk scores as an approach to risk adjust EPM target prices. For future consideration, CHA also urges CMS to examine and consider incorporating other important risk-adjustment variables such as socioeconomic status or functional status.**

- **Stop-Loss and Stop-Gain Limits**

CMS proposes that an EPM participant's responsibility for post-episode payment spending would not be subject to the stop-loss and stop-gain limits proposed. CMS expressed concern that some EPM participants may have an incentive to withhold or delay medically-necessary care until after an EPM episode ends to reduce its actual EPM-episode payments. As a protection against stinting of care, CMS proposes that an EPM participant would repay Medicare for the amount of 30-day post-episode spending that exceeded three standard deviations above the regional average. CMS made a similar proposal for the CJR model that would modify its current application of the stop-loss and stop-gain limits.

CHA believes, as CMS states in the proposed rule, that inappropriate shifting would not be typical given the relatively long EPM episode duration. We believe this proposal to address potential stinting of care is not necessary and that in almost cases where 30-day post-episode spending exceeded a certain threshold these expenditures instead were necessary for treatment of a patient's clinical needs rather than representing an intentional delay in providing care to Medicare beneficiaries to game the system for financial rewards. CMS has other enforcement mechanisms to address hospitals that are willfully committing potential fraud and abuse, and we find this proposal unnecessary. **CHA strongly urges CMS to not finalize its proposal to exclude post-episode spending from the stop-loss and stop-gain limits for the proposed EPM models and the CJR model.**

- **Quality Measures**

In order to be eligible to receive reconciliation payments, hospitals must first meet or exceed a minimum performance threshold on certain specified quality measures currently used in the hospital IQR program. As part of its proposal, CMS proposes to use the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measure (NQF #0166) as a measure common to all models to assess quality performance and patient experience for the EPMs. We are concerned that HCAHPS survey responses from patients treated under the new EPM models will be diluted in the much larger pool of HCAHPS responses from patients

hospitalized for all causes and will not accurately capture the experience of patients under these new models, and thus could have little to no relevant, model-specific, impact upon EPM participant behavior. **CHA urges CMS to develop a model-specific HCAHPS metrics by developing an alternative approach that more directly links HCAHPS feedback to the new models.** This could include, for example, conducting subgroup analysis of HCAHPS survey responses by diagnoses or MS-DRGs that are used to define the EPMs.

Second, as with CJR, none of the proposed quality measures include adjustment for sociodemographic factors such as income, education, race, homelessness, and language proficiency, which have been shown to have a significant relationship to health outcomes. **We strongly support incorporating sociodemographic adjustments in quality measures used in reporting or pay for performance programs, and again urge CMS to do so.** Such an adjustment is particularly important when, as is proposed here, a hospital is held accountable for what happens to the patient post-discharge. Many factors beyond the control of the hospital can affect the recovery and health of patients, such as whether a patient can afford medications, has access to healthy food and safe places to exercise, and has housing and living conditions conducive to healing. Failing to adjust for these factors in performance-based payment incentive programs can result in unnecessary and inappropriate payment reductions for providers that serve a high percentage of disadvantaged patients, harming both the patients and the providers by depriving them of the resources they need to make sure every patient receives quality care.

- **Waivers**

CHA supports CMS' proposal to waive certain Medicare program rules. These waivers include the "incident to" direct supervision requirement for home health visits and the geographic site limitations on telehealth payments.

CMS proposes to waive the skilled nursing facility (SNF) three-day rule only for the AMI model, and not for the CABG and SHFFT model, and only beginning in the second performance year beginning on or after April 1, 2018 (when hospitals are subject to financial risk). **CHA urges CMS to waive the SNF three-day rule at the inception of the program (the first six months of PY1 and first quarter of PY2) as well as apply the three-day SNF rule more broadly to incorporate all of the proposed EPM models including CABG and SHFFT models.** While hospitals do not face downside risk in the first nine months, they will be setting up their program procedures including discharge procedures and relationships. It makes better sense to have this rule in place from the beginning than to wait to introduce this when downside risk begins. In addition, we believe the waiver of the SNF three-day rule should apply more broadly than just the AMI model. While the average lengths of stay for CABG and SHFFT may be more than three days that does mean that no patient is ever ready to move to a SNF in a shorter time period. CHA believes that treating physicians should be allowed to exercise their best judgment as to the most appropriate mode of treatment and place of service for individual patients.

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CMS also proposes to permit use of this waiver only for discharges with overall rating of three stars or better (on the CMS Five-Star Quality Rating System) based on information publicly available at the time of hospital discharge. **We strongly support efforts to ensure that patients receive high-quality SNF care. However, we continue to be concerned that in some areas there may not be a sufficient number of SNFs with three-stars or more.** Thus some patients who could be safely released to SNF care in fewer than three days would have nowhere to go for appropriate care. The lack of a three-star SNF in the area means the patient either stays in the hospital longer than necessary, which runs counter to the goals the model is seeking to achieve, or is denied access to Medicare-covered SNF services. We ask CMS to consider this possibility and propose an alternative solution that both emphasizes quality and allows for exceptions when necessary.

CHA urges CMS to work with the Office of the Inspector General (OIG) to waive provisions of the civil money penalty (CMP) law, the federal anti-kickback statute and the physician self-referral law that could inhibit the formation of financial relationships need to make these model succeed. Alternative payment models, such as accountable care organizations (ACOs) and bundled payments, require substantial clinical and financial integration among institutional providers of services, physicians and other practitioners. Some of these financial arrangement either run afoul of the physician self-referral law or do not clearly fit into an existing exception to the law, especially in the case of provider groups who provide the continuum of care across settings.

In order for these alternative payment models to be successful, CMS has in the past recognized that certain provisions of Title XI and Title XVIII of the Social Security Act must be waived to permit the parties to form the arrangements required to provide quality care and better manage the conditions of the Medicare beneficiary population. While these waivers have been helpful in establishing some of the arrangements under the alternative payment models, the self-referral law still imposes substantial barriers for hospitals, other institutional providers of services and physicians to create the legal relationships and arrangements necessary to improve care quality, care coordination and efficiency for the Medicare population.

Additionally, we are concerned that the proposed start date of July 1, 2017 is insufficient time and poses an unreasonable burden on providers, physicians and practitioners who must negotiate arrangements that meet the many regulatory and sub-regulatory requirements of the model. Without some certainty as to what CMS intends to provide in the form of waivers (be they waivers currently in effect under an ACO model or additional waivers to alleviate the burden of self-referral law barriers to integration), participating hospitals and EPM collaborators will be entering into agreements for purposes of a mandatory program without fully understanding the legal landscape in which they must operate. This lack of information and planning could very well stifle the very innovation CMS and CMMI hope to encourage, and puts providers and physicians at risk of inadvertently violating fraud and abuse laws in their efforts to coordinate and improve care quality and efficiency under the Medicare program.

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CMS should also waive discharge planning requirements that prevent hospitals from recommending preferred high-quality post-acute care settings. While beneficiary choice is a very important principle, in the context of these models it must be considered in light of the hospital's financial accountability for the entire episode of care. Hospitals must have reliable guidelines giving them the flexibility to help patients choose high-quality post-acute care.

- **Timing and Data**

CMS proposes to begin the three EPMs and the CR/ICR models July 1, 2017, after presumably finalizing its rule in November 2016. Consistent with its practice for the CJR model, CMS proposes to make the three years of baseline data available to EPM participants upon request and prior to the start of the first episode payment model performance year. Similar to our concerns with CJR and based on feedback from our member hospitals, we are concerned about the timing of when this data will be made available to participants. For CJR, this information was provided much too late given that CMS is using historical baseline data from prior years to determine price targets and other measurements. **We strongly urge CMS to release this data to EPM-participating hospitals as soon as the rule is finalized.** Providing historical claims data before the effective implementation date of the EPM models will enable hospitals to engage in the critical analysis necessary to focus their efforts more effectively than happened with respect to CJR. Timely data provision will also provide our members with an improved ability to undertake re-design, identify system weaknesses and plan improvements.

In closing, thank you for the opportunity to share these comments on this proposed rule. We look forward to working with you on these and other issues that continue to strengthen the country's hospitals and health care system. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,



Michael Rodgers
Senior Vice President
Public Policy and Advocacy