



October 3, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5519-P
P.O. Box 8013
Baltimore, MD 21244-1850
File Code: CMS-5519-P

Re: 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)

Dear Mr. Slavitt:

The Healthcare Financial Management Association (HFMA) would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the CMS's 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) proposed rule (hereafter referred to as the EPM Proposed Rule) published in the August 2, 2016 *Federal Register*.

HFMA is a professional organization of more than 40,000 individuals involved in various aspects of healthcare financial management. HFMA is committed to helping its members improve the management of and compliance with the numerous rules and regulations that govern the industry.

Introduction

HFMA fully supports CMS's goal of transitioning 50 percent of Medicare fee-for-service (FFS) payments to value-based arrangements (such as the payment models proposed in the EPM rule) by the end of 2018 that encompass the HFMA's principles¹ of a fair and rational payment. Over the past five years, HFMA has invested significant resources in our Value Project and BPCI-CJR Council in an effort to help our members and the industry at large prepare for the transition to value-based payments as envisioned by CMS. In addition to these efforts, we have collaborated with our members to submit comment letters proactively suggesting improvements to the Bundled Payment for Care Improvement (BPCI) model and responding to CMS's request for information in the 2016 Inpatient Prospective Payment System (IPPS) proposed rule and the CJR proposed rule (links included below).

HFMA would like to commend CMS for the detailed discussion of its choices in designing new cardiac (AMI and CABG) and orthopedic (SHFFT) episodic payment models and proposed changes to the CJR

¹ <http://www.hfma.org/Content.aspx?id=1017>

model. There are components of the proposed rule HFMA's members strongly support. In particular, our members are pleased CMS, in response to feedback from HFMA and other industry stakeholders, is proposing to:

- Add Net Payment Reconciliation Amounts (NPRA) achieved based on prior years' performance for both CJR and BPCI into future years' benchmarks so that participating providers are not constantly competing unfairly against their prior success.
- Create a "Track 2" that would allow physicians participating in CJR (and in future years BPCI) to qualify for the Advanced Alternative Payment Model (AAPM) Incentive Program so physicians will be encouraged to accept gainsharing agreements that include downside risk.
- Pilot financial incentives, which can be used to address a socioeconomic barrier (access to transportation) to care, for providers who expand the use of Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Services.

While HFMA's members were encouraged by some of the provisions of the proposed rule, we believe implementing three new EPMs is premature. Our members believe that CMS needs to delay the CABG and AMI models for the following reasons:

- The model design for cardiac episodes violates basic principles set forth in a recent white paper² by the Health Care Payment Learning & Action Network (LAN). The white paper was authored by the Clinical Episode Payment (CEP) Work Group, which includes representatives from health plans, physician practices, and health systems who have deep expertise in designing and operationalizing episodic payment models in a variety of settings. **Specifically, the proposed AMI and CABG models violate the CEP white paper's principles related to risk adjustment, minimum volume thresholds, comprehensiveness of payment, and episode exclusions. Each of these issues will be discussed in detail below. We ask that CMS adequately address these design deficiencies before implementing the new cardiac episodes of care.**
- These models are based on CMS's experience with the BPCI program – model two in particular. We ask that CMS give providers time to understand the findings from the second BPCI report and implement operational changes before it implements additional episodic payment models. **We believe stakeholders and the broader public need to understand the impact on both beneficiary and provider financial outcomes of these three models and have an opportunity to analyze the lessons learned so they can be broadly applied.**
- Many of the episode design features for the AMI and CABG payment models mimic the CJR model. We believe it is premature to use this "chassis" for additional payment models until we have evidence that bundles based on these features result in equitable payments to providers for medically necessary services across a 90-day period and improve outcomes for patients. **We ask that CMS allow for sufficient time to evaluate the results of the CJR program and incorporate the design lessons it learns from a thorough analysis into any new episodic payment model.**

We strongly encourage CMS to delay the AMI and CABG bundles for 24 to 36 months. We believe this provides sufficient time to incorporate both known best practice (as articulated by the CEP Work Group) and lessons from both the BPCI and CJR programs into the cardiac bundles. Otherwise, HFMA's members are concerned that CMS's episodic payment models will both put beneficiaries at risk and

² <https://hcp-lan.org/groups/cep/clinical-episode-payment/>

disadvantage providers as the episodes will be built using designs that are not supported by CMS's own panel of industry experts.

Further, our members do not support the development of a mandatory SHFFT episodic payment model until the issues discussed below are resolved. In addition to prematurely creating new episodes that do not incorporate the lessons learned from the CJR and BPCI programs (as discussed above), the SHFFT model has two technical flaws.

- First, it is not a value-based payment model. The clinical outcome quality measures that are proposed³ do not capture fracture patients. CMS asserts in the proposed rule that despite not capturing the patient population targeted by this episode in the SHFFT quality measures, they are adequate. CMS rationalizes that the same orthopedic surgeons and surgical teams whose patient population will likely be captured in this measure will likely be performing surgical fracture fixation. First, this is not true in all instances – particularly in large teaching hospitals. Second, while it may be true these measures capture the same surgeons and surgical teams in some hospitals, they do not capture the same patient population and therefore cannot provide an accurate picture of the value of care provided by the facility responsible for the episode. As currently designed, the episode only evaluates a hospital's performance against a price target, not the actual quality of care provided. Further, the model uses these measures to adjust the target price. **Until CMS can develop and gain National Quality Forum (NQF) approval for SHFFT episode-specific outcome measures, we believe it is inappropriate to create a 90-day episode of care targeting this non-elective procedure.**
- Second, feedback from HFMA's members suggests that hip fractures are operationally different from elective joint replacements. The patients are typically frail, experience higher utilization of post-acute care (both in terms of length of stay and intensity of setting), and have highly variable outcomes. Further, because SHFFT patients are emergent, there is no opportunity to implement pre-procedure protocols (e.g. weight management) to decrease recovery times, improve outcomes, and decrease cost. CMS itself acknowledges that the elective and non-elective patient populations are significantly different and that these differences cannot yet be accounted for with risk adjustment, as non-elective procedures are excluded when measuring joint replacement quality. For example, the agency's 30-day LEJR readmission measure excludes non-elective patients, because they "have a higher mortality, complication, and readmission rates," and "are typically performed on patients who are older, frailer, and who have more comorbid conditions."⁴ The agency's hip and knee complications measure excludes non-elective patients for the same reasons.⁵ Lastly, CMS's recently finalized measure of hip and knee episode spending also excludes non-elective patients.⁶ **HFMA's members strongly believe that, like the cardiac bundles, until an adequate risk-adjustment mechanism is developed for episode**

³ Mandatory: Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary THA and/or TKA - NQF #1550; Voluntary: Total Hip Arthroplasty (THA)/Total Knee Arthroplasty (TKA) voluntary patient-reported outcome (PRO) and limited risk variable data submission (Patient-reported outcomes and limited risk variable data following elective primary THA/TKA)

⁴ 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) – Version 4.0 and Isolated Coronary Artery Bypass Graft (CABG) Surgery – Version 2.0.

⁵ 2015 Procedure-Specific Complication Measure Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure – Version 4.0.

⁶ Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0) 2014 Measure Methodology Report.

prices, it is inappropriate to make hospitals responsible for a 90-day episode of care. Otherwise, CMS will be exposing hospitals to insurance risk, which is not the purpose of an episodic payment model. We ask that CMS delay implementation of an episode of care targeting SHFFT procedures until appropriate risk-adjusted quality measures and price risk-adjustment mechanisms are developed.

Finally, beyond the specific design challenges mentioned above and discussed in detail below, HFMA's members are deeply concerned with the rapidly increasing number of regulatory requirements that hospitals, physicians, and health systems must respond to and comply with. Even our most sophisticated and best resourced organizations report that the sheer volume of significant mandatory requirements that have been promulgated over the past 24 months (e.g., MACRA, CRJ, proposed part B payment rule, changes to outpatient department status as a result of section 603 of BIPA) and voluntary programs (e.g., MSSP, Next Gen, BPCI, OCM) coupled with state level initiatives is making it difficult to understand how the myriad of programs will interact with each other and impact individual delivery systems. Given that the only constant in the current environment is that these programs will change (and likely significantly), it makes it difficult for organizations to efficiently invest in the capabilities necessary to improve care delivery and reduce cost. Due to the relatively short implementation times, many organizations are responding by adding significant administrative cost to manage this torrent of change. The volume and velocity of change make it extremely difficult to engage, educate, and provide front-line caregivers with the tools they need to focus on the most significant opportunities to improve individual delivery systems' performances. **HFMA's members believe this is further evidence of the need to delay the EPM proposed rule and other new CMS/CMMI payment initiatives.**

When CMS elects to move forward with the cardiac and fracture repair bundles HFMA's member's believe the following elements of the proposed rule need to be modified:

- 1) Episode exclusions and other design attributes
- 2) Lack of sufficient risk-adjustment mechanisms
- 3) Transition to risk
- 4) Inadequate stop-loss provisions
- 5) Episode pricing
- 6) Episode assignment
- 7) Quality measurement
- 8) Data provided to support care redesign
- 9) Gainsharing models
- 10) Beneficiary notification
- 11) Expansion of waivers from outdated fraud and abuse regulations
- 12) Dispute resolution process
- 13) Alignment with ongoing state level efforts
- 14) Proposed cardiac rehabilitation incentive payments

Episode Exclusions and Other Design Attributes:

HFMA's members believe that CMS needs to significantly expand exclusions to the EPM at both the case level and the facility level.

At the case level, our members are deeply concerned that what CMS has proposed, similar to the finalized CJR model, is less a condition-specific episodic payment model and more of a 90-day global capitated model. The proposed EPM rule excludes certain Part A and B services from the calculation of the target price and calculation of the actual episode cost. The list of exclusions in the proposed rule is the same as the list used in BPCI. Based on feedback from our members, HFMA recommends that CMS make the following changes to the exclusions list.

Exclude “Salvage” CABG Procedures: HFMA’s members believe that any salvage CABG (whether part of a single admission episode or performed during an episode that includes subsequent readmission) from a failed or aborted PCI should not only cancel the initial episode but also not trigger a new CABG episode if it is part of a subsequent readmission as proposed below. Our members report that patients following this care pathway are clinically frail, resulting in extremely high-cost episodes. Further, most hospitals do not have sufficient volume to balance out the asymmetric risk associated with these cases. In recognition of this risk, both Arkansas⁷ and Tennessee⁸ have excluded “salvage” CABGs from their episode of care payment models.

Unrelated Chronic Conditions: Similar to BPCI and CJR, the proposed new EPMs include inpatient admissions, post-acute admissions, and Part B services for unrelated chronic conditions in both setting the target price and calculating actual performance. The rule proposes to exclude Part A services “unrelated hospital admissions for MS-DRGs that group to the following categories of diagnosis: oncology, trauma medical admissions, surgery for chronic conditions unrelated to a condition likely to have been affected by care furnished during the EPM episode, and surgery for acute conditions unrelated to a condition resulting from or likely to have been affected by care during the EPM episode.” **HFMA’s members strongly believe that CMS needs to also exclude medical MS-DRGs for unrelated chronic and acute conditions from both the calculation of the historical episode target price and actual episode spending.**

For Part B Services, the EPM rule proposes to “exclude acute disease diagnoses unrelated to a condition resulting from or likely to have been affected by care during the EPM episode, and certain chronic disease diagnoses, as specified by CMS on a diagnosis-by-diagnosis basis, depending on whether substantial services were likely to be provided for the chronic condition during the EPM episode.” CMS further states that it would include claims for diagnoses that are unrelated to preexisting chronic conditions such as diabetes. **HFMA’s members strongly believe that Part B claims should be limited to those that are directly related to the EPM episode.**

Further, in the proposed rule, CMS states that it believes that any spending (except for the explicitly excluded items) that occurs during the 90-day episode window is directly related to the proposed episode and symptomatic of uncoordinated care. However, our members report that the surgeons they work with believe a 30-day window for exacerbations of existing, unrelated chronic conditions is more appropriate. **If CMS will not expand the exclusions as recommended above, HFMA asks that CMS reduce the length of the episode to 30 days for CABG and SHFT episodes.** HFMA believes it is

⁷ <http://www.paymentinitiative.org/referenceMaterials/Documents/CABGEpisode%20Design%20Summary%20-%202016-06-02%20-%20Final.pdf>

⁸ <https://www.tn.gov/assets/entities/hcfa/attachments/CoronaryArteryBypassGraft.pdf>

important to note that in both Tennessee⁹ and Arkansas¹⁰ CABG episodes are only 30 days in duration, given that the longer the episode lasts, the more insurance risk (as opposed to performance risk) is transferred to the accountable provider.

Post-Acute Spending for an Excluded Admission: In the circumstance when an acute hospital readmission occurs during the episode with an excluded MS-DRG (e.g., an excluded readmission), the cost of the readmission is not counted toward the episode cost. However, similar to CJR, costs for any post-acute care that follows the excluded readmission are included in the cost of the episode, because there is no exclusion for payments associated with post-acute care provided as a result of unrelated services. **HFMA urges CMS to exclude post-acute care following an excluded readmission.** Holding a CJR and EPM participants accountable for all patient pathways is unreasonable given how little is known about the causal relationship between an unrelated hospital readmission and subsequent post-acute care services.

Implement Minimum Volume Thresholds: Like the CJR final rule, the proposed EPM rule does not have minimum volume thresholds for a facility to be included as a participant in each of the three episodes. As HFMA understands the proposed rule, if a hospital subject to the inpatient prospective payment system (IPPS) is located in one of the selected regions, it is compelled to participate even if it does only one EPM procedure a year. HFMA's members find this deeply concerning, especially considering that a key recommendation in the CEP Work Group white paper is that minimum-volume standards are a key factor in determining whether or not a facility is ready for undertaking bundled payments.

The proposed rule defines low-volume facilities as having over three years:

- 1) Fewer than 50 SHFFT model episodes
- 2) Fewer than 75 AMI episodes anchored by MS-DRGs 280-282
- 3) Fewer than 125 AMI episodes anchored by PCI MS-DRGs 246-251
- 4) Fewer than 50 CABG episodes

CMS attempts to address the statistical stability of price targets for these low volume-hospitals by using 100 percent regional data to calculate the target price for all five performance years.

HFMA is extremely concerned by the proposed rule's lack of a minimum volume criteria for hospitals within selected markets to be included in the EPM model. CMS's proposal to address the statistical stability issue for extremely low-volume hospitals is inadequate. Comparing these hospitals to the regional average may actually disadvantage them as they are likely to have cases that are more expensive than the regional average.

Additionally, HFMA continues to hear from its members that minimum scale is necessary to successfully re-engineer care. First, there needs to be a sufficient volume of claims to identify systematic unwarranted variance. Second, the opportunity to improve patient outcomes needs to be significant enough to engage physicians – both those managing the acute phase of the admission and primary care physicians managing the ongoing chronic condition(s) – and post-acute partners for redesign. From the standpoint of making the best use of scarce resources, Medicare beneficiaries are best served when

⁹ <https://www.tn.gov/assets/entities/hcfa/attachments/CoronaryArteryBypassGraft.pdf>

¹⁰ <http://www.paymentinitiative.org/referenceMaterials/Documents/CABGEpisode%20Design%20Summary%20-%202016-06-02%20-%20Final.pdf>

hospitals, physicians, and post-acute providers focus their efforts on improving outcomes on the highest volume conditions that exhibit the greatest variation. While CJR and EPM episodes as a rule fit this criterion nationally, that will not be the case for every hospital.

Further, in the proposed CJR rule, CMS seems to acknowledge this issue of sufficient volume as it relates to physicians:

*“If we were to assign financial responsibility to the operating physician, it is likely that there would be significant variation in the number of relevant episodes that could be assigned to an individual person. Where the physician was included in a physician group practice, episodes could be aggregated to this group level but this would not be possible for all cases and would likely still have low volume concerns. **We believe that the small sample sizes accruing to individual physician and physician group practices would make systematic care redesign inefficient and more burdensome.**” ¹¹*

HFMA is unsure as to why this would also not hold true for hospitals with low volumes as well. Therefore, HFMA recommends that CMS take the following steps:

- **Institute a minimum historic volume requirement for mandatory hospital inclusion in the CJR and EPM.** HFMA continues to believe that to be included in the CJR model, a hospital should have at least 100 LEJR eligible cases per year that would have been attributed to the hospital. Our members believe that the definition of “low volume” as calculated in the proposed rule is sufficient for the proposed EPMs and thus believe CMS needs to exclude any hospital from the proposed EPMs that does not meet the volume criteria for that particular episode. Any cases that would have been attributed to a BPCI-participating hospital, physician group, or post-acute care provider should be removed from the calculation of the threshold. Should CMS add additional cohorts to the BPCI program once the EPM program starts, if the number of CJR or EPM episodes attributed to the hospitals falls below the threshold due to precedence rules attributing the case to a physician group or post-acute provider participating in BPCI, the CJR or EPM hospital should have the option of quitting the program.
- **Work with state Medicaid programs and commercial health plans to implement the CJR and EPM programs¹² to help hospitals generate sufficient volume for inclusion in the program.** Assuming the changes discussed in this proposed rule are implemented, HFMA believes it would be appropriate for CMS to count Medicaid and commercial cases toward the minimum volume threshold if these plans were using a model that mimics CJR or the proposed EPMs in its construction of the episode and assignment of responsibility to the hospital. In particular, there should be a significant opportunity for CMS to align this model with Medicare Advantage plans and work with the Office of Personnel Management (OPM) to implement this model in the Federal Employee Health Benefit Plans (FEHBP). If CMS is able to do this, it would be a significant step toward its goal of aligning incentives across payers, accelerating care redesign, and encouraging more physicians to participate in the MACRA APM Incentive by increasing the availability of qualifying specialist-specific payment models.

¹¹ Emphasis added

¹² As modified by recommendations contained in this comment letter

HFMA believes that if CMS implements a minimum volume threshold, as recommended above, there is no need to calculate a specific benchmark for low-volume hospitals.

Lack of sufficient risk-adjustment mechanisms:

As stated above in the introduction, HFMA believes that CMS needs to delay implementation of additional EPMs until a sufficient risk-adjustment mechanism is developed. HFMA appreciates CMS’s efforts to adjust episode prices for cardiac episodes based on the final discharge MS-DRG in a chained AMI episode, adjusting CABG episodes based on the presence of an AMI diagnosis, and adjusting an AMI episode for a subsequent CABG readmission. **While HFMA believes these are significant improvements for these select episodes over the pricing model in the final CJR rule, we still believe these measures are an insufficient substitute for an adequate risk-adjustment methodology.** Further, each of the proposed price adjustments poses a concern for HFMA’s membership that will be addressed in the pricing section (below).

Similar to the CJR rule, CMS states in the EPM rule that there is no standard national risk-adjustment approach that is widely accepted for the EPM episodes. HFMA attributes the lack of a “current standard” to CMS’s failure to work with physicians, the broader health plan community, and other purchasers to identify one. Without CMS’s leadership, neither DRGs nor APCs would be as widely used by the payer community as they are today. **And we are deeply concerned that if CMS continues to implement episodic payment models without sufficient risk adjustment, other purchasers will follow-suit, undermining both providers’ willingness to participate in outcome-based payment models and the financial viability of these models, as they will inappropriately transfer insurance risk to providers.** We believe CMS has a number of risk-adjustment options from which to choose. Below are several examples:

- 1) CMS has developed an episode grouper, as mandated by the ACA. That grouper includes a method for adjusting for patient severity at the episode level.
- 2) Health Care Incentives Improvement Institute’s evidence-based case rates create a variety of patient-specific episodes that recalibrate based on various patient-specific severity factors.
- 3) The Society for Thoracic Surgeons’ (STS) National Database includes more than 5.4 million patient records. The database contributes to the STS Risk Calculator, which allows users to calculate outcomes such as a patient’s risk of mortality and length of stay.

HFMA notes the last two examples were cited in the CEP Work Group white paper. Further, many of the quality measures used for the proposed EPMs are risk adjusted using prior claims experience. For these measures, the proposed rule states “additional comorbidities prior to the index admission are assessed as Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to the index (initial) admission.” Given that CMS already has a regression model built to adjust quality measures based on prior utilization using administrative data, **HFMA’s members suggest that CMS explore the feasibility of using a similar model to risk adjust the episode price by making the price the dependent variable.**

Given this range of options, HFMA believes using an MS-DRG to risk adjust payment for a 90-day episode of care is highly inappropriate. We remind CMS that even with the pricing tweaks made in the proposed rule, an MS-DRG is only designed to predict hospital spending and therefore not valid for

predicting expenditure in the post-discharge period. Analysis by MedPAC supports this. A recent report to Congress found that only 8 percent of the variation in charges for 30-day post-acute care-only episodes could be explained by the MS-DRG from the prior acute care hospital stay.¹³

Additionally, HFMA continues to hear from BPCI participants (both those in Phase II and those who opted not to continue into Phase II) whose patient populations include a larger share of dual-eligible patients that their organizations are disadvantaged due to a lack of socioeconomic status adjustment. As research has shown, dual-eligible patients typically incur higher cost, particularly across longer episodes. This is particularly true for non-elective bundles such as AMI and CABG given that socioeconomically challenged patients are more likely to have an exacerbation of the underlying chronic condition that leads to an acute admission. Their lack of resources puts them at greater risk of readmission as has been shown by MedPAC research for heart failure patients¹⁴ (among other studies).

HFMA believes CMS should incorporate some level of adjustment for socioeconomic security (SES) factors into the CJR model and EPM target prices. As a long-term solution, HFMA encourages CMS to explore incorporating the NQF SES risk-adjustment measure once it is adopted. However, since the CJR model and proposed EPMs are hospital-specific, we believe an appropriate interim solution would be to base SES risk adjustment on a hospital's Supplemental Security Income (SSI) ratio as a proxy for SES factors as has been suggested by MedPAC and proposed in legislation that has passed the U.S. House of Representatives to address inequities in the Hospital Readmissions Reduction Program.

In summary, HFMA agrees with CMS's assertion that there currently isn't a widely accepted methodology for risk-adjusting episodic payments. If CMS moves forward with the proposed EPMs as a mandatory model absent a more sophisticated risk-adjustment mechanism that better accounts for cost variation related to patient-specific factors, it will knowingly shift insurance risk to hospitals as opposed to performance risk. This is especially true for lower volume hospitals and those that serve economically challenged populations. **We believe that, until CMS implements a "widely accepted" approach for episode risk adjustment that accounts for socioeconomic security factors, it should delay implementation of additional mandatory bundles focused on emergent conditions like AMI, CABG, and SHFFT.**

Transition to Risk:

HFMA fully supports transitioning hospitals to downside risk assuming they have sufficient volume, an adequate risk-adjustment methodology is implemented, they are provided sufficient time to redesign care, and they are provided sufficient data (discussed below). We especially appreciate the additional protections CMS has afforded SCHs, MDHs, and RRCs. However, HFMA believes CMS needs to improve the transition to risk in the CJR model and proposed EPMs by:

- Increasing the upside-only period to two years for hospitals other than SCHs, MDHs, and RRCs.
- Limiting SCHs, MDHs, RRCs, and low-volume hospitals (if CMS does not exclude them) to an upside-only for the duration of the model.

¹³ "Report to the Congress: Medicare and the Health Care Delivery System," MedPAC, June 2013.

¹⁴ <http://www.medpac.gov/docs/default-source/meeting-materials/september-2012-meeting-presentation-refining-the-hospital-readmissions-reduction-program.pdf>

- Retaining the protections afforded to hospitals currently classified as MDHs in the final rule, if MDH status expires. While the special payment mechanism afforded to MDHs due to their unique circumstances may expire, their ability to bear risk, which is to say their access to capital and smaller sample size that leaves them more exposed to random outcomes, will not expire.

Inadequate Stop-Loss Provisions:

HFMA generally supports the use of stop-loss provisions in outcome based payment models that incorporate downside risk. However, several of the provisions in the proposed EPM rule cause our members significant concern.

First, we are concerned that CMS is applying a blanket stop-loss to all of its episodic payment models. Our members believe the stop-loss provision for each episode needs to be calculated on an episode specific basis for each provider as the degree of outcome variability will differ significantly based on the provider's volume and starting price position relative to the region. If CMS chooses to ignore the recommendation above limiting SCH, MDH, RRCs, and low-volume hospitals to upside-only, adopting this method will not only protect low-volume providers, but better protect SCHs, MDHs, and RRCs than simply randomly decreasing the threshold to a lower amount.

Second, CMS proposes to eliminate stop-loss protection for spending in the 30-day post-episode period, making hospitals in the CJR model and proposed EPMs responsible for repaying CMS for any spending that exceeds the three-standard deviation threshold. HFMA agrees with CMS's analysis that, given the threshold, these cases will be rare. **However, we believe that this is the exact purpose of a stop-loss provision as these cases will be extremely expensive outliers that have the potential to cause significant financial harm to the hospitals that incur them. We strongly encourage CMS to maintain its current policy and not adopt this new proposal.** We believe CMS is significantly overstating the risk that providers will try to delay care beyond the episode time period. CMS's proposal is offensive in that it suggests that hospitals are willing to sacrifice patient outcomes for financial outcomes, which we do not believe to be true.

Finally, CMS also proposes to exclude situations in which the CJR or EPM discount percentage from prior periods is paid to an ACO as shared savings from stop-loss or gain limits. **HFMA strongly encourages CMS not to finalize this proposal as well.** Again, the purpose of the stop-loss is to protect hospitals from catastrophic losses, regardless of the source of this loss. It is not inconceivable that a hospital participating in the EPM or CJR could both meet their stop-loss threshold based on performance against target prices and then have to repay additional funds related to the ACO discount.

Episode Pricing:

HFMA appreciates CMS's thoughtful discussion of the various provisions in the proposed rule that affect both EPM and CJR pricing. **HFMA strongly supports CMS's statement in the proposed rule that it will provide EPM participants target prices in advance.** Our members encourage CMS to make target prices and the data used to calculate them available to participants at least 90 days in advance of an episode start date. **We also believe that CMS needs to make all of the components necessary to calculate the target price for both the CJR model and proposed EPMs available to participants so they can verify that CMS accurately calculated the target price.** We continue to hear from our members that have been compelled to participate in CJR that they are unable to replicate the target price calculation due to CMS's use of "black box" inputs for certain national factors.

HFMA’s members strongly support CMS’s proposal to adjust target prices so that they include NPRA amounts (both positive and negative). There is a theoretical threshold below which the cost of care cannot fall. Although this does not fully ameliorate the issue of providers competing against their prior success (or a region’s success) to achieve diminishing returns, it does create a more equitable benchmark in the short term.

Beyond the recommendations discussed above, HFMA’s members would like to make the following suggestions to improve pricing in both the EPM and CJR models (where applicable).

- 1) HFMA believes that payments for Chronic Care Management (CCM), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) services need to be excluded from CJR model and EPM pricing (both benchmark and actual) due to low historical utilization.** First, CCM services were not paid by CMS until January 1, 2015, so CCM was not a payable service during two of the years used to set the target price for the first two performance years. This is illustrated below in the table outlining the various years used to set target prices for each performance year.

Performance Year	Historical Data Period
PYs 1 and 2	January 1, 2013 through December 31, 2015
PYs 3 and 4	January 1, 2015 through December 31, 2017
PY 5	January 1, 2017 through December 31, 2019

Further, anecdotal evidence suggests that many physicians currently are not billing for CCM services.¹⁵ However, HFMA expects the volume of CCM codes billed will increase. Improvements to simplify billing for CCM, which HFMA strongly supports, have been proposed by CMS in the 2017 Physician Fee Schedule. Our members anticipate that these administrative simplifications coupled with programs like the EPM will drive a significant increase in volume of CCM services. While the amount of revenue at the margin isn’t significant, if CPT code 99490 is billed for the three months of an episode but not captured in the target price it will add approximately \$140 to \$150 of episode expense that is not likely captured in the baseline. If CCM services are not excluded from the target and actual price calculations, we are concerned that providers who bill for these services will be negatively impacted at reconciliation.

Similarly, CMS states that both CR and ICR services have historically been underused for cardiac patients – hence the proposed incentives to increase utilization. HFMA strongly supports CMS’s proposed incentives (see comments below) to encourage select providers to increase patient referrals into these programs and remove barriers to participation. However, our members are concerned that unless payments for CR and ICR services aren’t removed from historical target and actual price calculation hospitals that successfully expand access to these programs could be have their NPRA negatively impacted as a result of low historical underutilization. HFMA estimates that if the utilization of CR or ICR increases to levels that have led to demonstrated quality improvements it could add \$300 to \$600 per episode¹⁶ to the cost, which is currently not

¹⁵ <http://www.medpagetoday.com/publichealthpolicy/medicare/52145>

¹⁶ HFMA estimate, assumes a patient that received no CR or ICR services in the baseline period would receive 13 to 24 sessions of CPT code 99490.

reflected in the baseline period. We are concerned that providers who increase utilization of what has been shown to be a highly effective intervention for decreasing AMI patients' long-term mortality will be significantly penalized for doing so unless this episode pricing correction is made.

- 2) In calculating the target price, similar to CJR, CMS proposes to blend together hospital-specific and regional historical episode payments, transitioning from primarily hospital-specific to completely regional pricing over the course of the five performance years. **As discussed above, HFMA appreciates that this policy would help ensure that a hospital does not have to compete against its own improving performance.** Hospitals that generate savings should not be penalized in subsequent performance years by having their success make future savings more difficult to achieve. However, to be clear, no matter the adjustments CMS makes, programs that are designed to achieve savings for the Medicare program year after year will see diminishing returns over time as there is a minimum boundary below which the cost to provide quality care cannot fall. Providers in low-spending areas will first begin to encounter such limited opportunities for additional gains in efficiency, but eventually, the agency will no longer be able to continue decreasing target prices and benchmarks for any providers without putting quality of care at risk. **Therefore, we urge the agency to instead use the higher of national or regional historical episode payments in calculating the target price for both the CJR model and proposed EPMs.** Doing so would help ensure that appropriate incentives are provided to participants in both high- and low-spending areas.
- 3) CMS states in the proposed rule that it “wants to ensure that any savings achieved by EPM participants are not due to random variation...” As such, CMS will take up to a three percent discount (adjusted for quality) off of the final episode target price to ensure that any savings generated by the provider are not the result of random variation. **HFMA strongly believes that if CMS is going to protect the program from paying providers for gains as a result of random variation, it also should protect hospitals from losses due to random variation.**

At this stage, the CJR model and proposed EPMs are experimental. It will take time, investment, and hard work for a hospital to be poised to achieve savings. Therefore, the design of the CJR model and EPM programs should provide ample time for the less-experienced participants to fully organize themselves into an effective risk-bearing structure. Though we understand CMS's eagerness to test alternative payment models, it is already testing downside risk bundling models through BPCI and should proceed with caution in the mandatory programs. As such, we encourage the agency to provide hospitals with protection against having to make repayments that result from adverse events beyond their control, similar to the protections it offers under the Medicare Shared Savings Program. **Specifically, during risk-bearing periods of the program, instead of setting a repayment target price equal to historical payments *minus* x percent, we urge CMS to set a symmetric target price equal to historical payments *plus or minus* x percent.** For example, in performance years four and five hospitals with historical payments falling between 97 percent and 103 percent of historical payments would neither receive reconciliation payments nor be held responsible for repaying Medicare. We believe that this is an appropriate mechanism to protect hospitals from random variation given the small caseloads most providers will have.

- 4) HFMA's members believe CMS's proposed pricing methodology for cardiac transfer cases is deeply flawed. In the rule, CMS proposes to "set a chain-adjusted AMI model-episode benchmark price or 'price MS-DRG' based on the AMI, PCI, or CABG MS-DRG in the chained anchor admission with the highest IPPS weight," for cases where a patient is initially admitted to one hospital and then is transferred to another hospital because the patient requires a higher level of care than can be provided at the facility to which the patient was initially admitted.

Mathematically, this policy means transfer cases would be averaged into the episode pricing for each individual MS-DRG based episode. As a result, assuming all other resource utilization is held constant, an episode of care with a discharge MS-DRG of 251 that does not involve a transfer will more likely come in below the episode price, while the same episode that involves a transfer will exceed the episode price due to the two MS-DRG payments (or transfer adjusted MS-DRG payment in the case of the sending facility) made – one to the facility that initially admitted the patient and one to the facility that received the transfer.

This policy will drive a number of unintended consequences. Most obviously, our members believe that this pricing structure provides a natural advantage to hospitals that can manage more complex cardiac cases such as those hospitals with cardiac catheterization labs and the surgical expertise to perform coronary artery bypass surgeries. Conversely, it will disadvantage those that do not have these capabilities. Given this tilt, one of two undesired outcomes is likely. First, it could lead to an increased volume of cases, which could be managed in a community hospital setting, being transferred from the emergency department to facilities with more sophisticated capabilities. Not only will this complicate post-discharge care coordination (as in some areas – particularly rural areas – the receiving hospital may not have an established relationship with post-acute providers in the community) but could lead to increased Medicare spending as the receiving hospital will be more likely to have higher Medicare "add-on" payments for Disproportionate Share (DSH) and Indirect Medical Education (IME) which are (appropriately) not accounted for in the episode price. The other alternative is that hospitals could attempt to manage more complex cases in-house, leading to lower quality outcomes or duplication of resources within a community as hospitals invest in the capabilities required to do so. **HFMA's members strongly suggest that CMS create separate transfer prices for each cardiac MS-DRG so episode prices more accurately reflect the resources necessary to provide medically necessary care in the most clinically appropriate setting.**

- 5) HFMA's members are also concerned with CMS's pricing proposal for episodes that involve an initial discharge for an AMI or PCI MS-DRG with a subsequent readmission during the episode for a CABG procedure. CMS proposes that "if a CABG readmission occurs during an AMI model episode with a price MS-DRG of 280-282 or 246-251, CMS proposes to calculate a CABG-readmission AMI model-episode benchmark price equal to the sum of the standard AMI model-episode benchmark price corresponding to the price MS-DRG (AMI MS-DRGs 280-282 or PCI MS-DRGs 246-251) and the CABG anchor hospitalization benchmark price corresponding to the MS-DRG of the CABG readmission."

Similar to the comments above, HFMA's members are concerned that simply adding a MS-DRG payment to the existing episode pricing will not accurately capture all of the costs inherent in these episodes of care. HFMA's members believe that for instances where a patient is

readmitted for a subsequent planned CABG procedure, the initial episode should be canceled and a new CABG episode should be triggered. Further, similar to CABG episodes that include an AMI diagnosis on the claim, HFMA's members believe that a subsequent CABG episode following a canceled AMI episode should be priced separately due to the likely increased cost.

Episode Assignment:

In the rule CMS proposes to assign responsibility for episodes to the hospital that initially admits a patient who is discharged with a qualifying cardiac MS-DRG. CMS's rationale is the hospital that initially admitted the patient is more likely to be in the community where the patient lives and will have connections both with the patient's primary care provider and the PAC provider(s) who will provide post-discharge care. HFMA's members believe the accuracy of CMS's assertion varies significantly based on the type and size of the market in question. Further, while the "community" hospital may have deeper relationships with PCPs and PAC providers that will ultimately provide care post-discharge, it is the discharging hospital that will develop the discharge plan, make recommendations on both the type of PAC necessary and make arrangements with a specific provider, secure a follow-up appointment, and be responsible for providing the patient (and his or her caregivers) with condition specific education, and communicate post-discharge instructions. As CMS suggests, a "community" hospital could develop a gainsharing relationship with a hospital it transfers a significant volume of EPM cases to. Developing gainsharing arrangements (discussed below) is administratively complex and burdensome. HFMA recommends that in, in instances of transfer cases, in addition to allowing for hospitals to develop gainsharing arrangements, CMS factor the clinical quality outcome into the receiving hospital's discount calculation instead of the episode initiating hospital's discount. Our members believe this is an appropriate way to align incentives between the two institutions. Further, the discharging hospital will have the greatest ability to impact HCAHPs scores and the quality of discharge planning and coordination with both community providers and the transferring hospital which impact mortality and "excess days" measures.

Quality Measurement:

HFMA's members strongly support tying payment to quality measures. Our members believe providers who can demonstrate superior quality should receive higher levels of payment. Beyond the specific issues with the quality measures proposed in the SHFFT episode (discussed above), HFMA's members believe CMS needs to address the following issues in its approach to using quality measures to adjust payment in the proposed EPMs:

- 1) **There is insufficient risk adjustment for the clinical outcome measures for CJR, AMI, and CABG episodes.** HFMA continues to be concerned by the dearth of patient socioeconomic variables included in the risk-adjustment mechanism of CMS's clinical outcomes measures, given the role that these factors play in a patient's likelihood of mortality, readmissions, emergency room admissions, and observation stays.

HFMA recommends CMS include SSI and other similar economic indicators (e.g., presence of Medicaid as a secondary payer) to improve risk adjustment for its various outcome measures until the NQF develops a mechanism that fully accounts for economic drivers.

HFMA believes refining the risk-adjustment mechanism is necessary to ensure a level playing field for all hospitals participating in the CJR model and proposed EPMs, while protecting safety

net hospitals and their communities from the unintended and counterproductive consequences of an incomplete risk-adjustment mechanism. For these facilities, inpatient Medicare payments are a larger than average component of their revenue. Any reduction in Medicare payment related to an incomplete risk adjustment will have both direct and indirect consequences. As a direct consequence, it will limit hospitals' ability to invest in programs to reduce unnecessary readmissions and the socioeconomic factors that cause them, further harming Medicare beneficiaries.

- 2) **Correct the mismatch of the HCAHPS measure with the CJR model and proposed EPM patient populations or exclude this measure from the CJR model and proposed EPMs.** To fulfill inpatient quality review requirements, hospitals are required to collect HCAHPS data on a sample of all of their adult inpatients, regardless of clinical service line. As a result, the HCAHPS measure results reflect the patient experience of all adult hospital inpatients, not just patients admitted for joint replacement, surgical fracture repair, or acute exacerbations of coronary artery disease. The sample includes all patients, not just Medicare patients. Furthermore, the HCAHPS survey is focused only on in-hospital experience, despite the fact that an episode of care as proposed encompasses a 90-day period after the initial inpatient admission. As a result, we fail to see how HCAHPS results would be a meaningful performance measure for the providers in either the CJR model or proposed EPMs.

However, HFMA agrees with CMS that it would be helpful to understand whether patients cared for under the CJR model or surgical EPMs had a positive experience. **Thus, rather than using HCAHPS results, CMS should explore the feasibility of funding the administration of the Surgical CAHPS survey to a sample of the patients cared for under the CJR, SHFFT, and CABG models.** In contrast to HCAHPS, the Surgical CAHPS survey is intended to assess the patient experience along the continuum of surgical care – from preoperative care, through hospitalization, to post-discharge outpatient care. The Surgical CAHPS has not yet been tested for nationwide implementation in CMS's public reporting programs for hospitals, so we believe it would be inappropriate to use the Surgical CAHPS survey as a pay-for-reporting or pay-for-performance tool at this time. However, the use of the survey by CMS for CJR, SHFFT, and CABG model evaluation purposes may provide the agency with a better understanding of the patient experience in the context of the CJR or proposed surgical EPMs.

- 3) The proposed AMI measure Excess Days in Acute Care after Hospitalization is not NQF endorsed. HFMA did not support this measure being included in the Hospital Inpatient Quality Reporting Program (HIQR) in the proposed FY 2016 IPPS rule due to concerns about the measure's validity.¹⁷ **HFMA continues to believe it is inappropriate to include a measure that has not been thoroughly vetted by the NQF in an outcomes based payment program and therefore believes it should not be finalized.**
- 4) The quality measurement periods for outcomes measures do not align with the performance year period.

¹⁷ <http://www.hfma.org/Content.aspx?id=32061>

TABLE 30: SUMMARY OF PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY YEAR OF THE AMI MODEL

Measure Title	Model Performance Year				
	1 st	2 nd	3 rd	4 th	5 th
	July 1, 2017 – Dec 31, 2017	Jan 1, 2018 – Dec 31, 2018	Jan 1, 2019 – Dec 31, 2019	Jan 1, 2020 – Dec 31, 2020	Jan 1, 2021 – Dec 31, 2021
MORT-30-AMI	July 1, 2014 – June 30, 2017.	July 1, 2015 – June 30, 2018.	July 1, 2016 – June 30, 2019.	July 1, 2017 – June 30, 2020.	July 1, 2018 – June 30, 2021.
AMI Excess Days	July 1, 2014 – June 30, 2017.	July 1, 2015 – June 30, 2018.	July 1, 2016 – June 30, 2019.	July 1, 2017 – June 30, 2020.	July 1, 2018 – June 30, 2021.

As illustrated above using the AMI outcome measures (Table 30 from the proposed rule) the first year performance period does not overlap with the quality measurement period. In subsequent years, there is only a six-month overlap. Given that the quality performance period has very little overlap with the payment performance period, hospitals and their physician collaborators are not truly assessed on performance within the EPM model. With performance largely “baked-in” due to both the lack of overlap and the difficulty of changing a three-year rolling average with significant improvement in one year, HFMA’s members are concerned that it will be difficult to engage physicians and post-acute providers in gainsharing arrangements if, as a result of quality being predetermined, there will be no savings to share.

Recognizing the difficulty in demonstrating improvement and the fact that hospitals are being judged on performance preceding the EPM financial performance period, **we believe hospitals must be given more time to implement quality improvement strategies before they are held accountable.** Accordingly, we suggest all hospitals that achieve savings beyond the discounted target price should receive a reconciliation payment so that they can reinvest in quality improvement. Rather than exclude hospitals who perform “worse than the national rate” from savings pools, CMS should ensure they are improving by allowing them to achieve savings and simultaneously requiring a corrective action plan. Hospitals who undertake a corrective action plan should be provided with technical assistance and should be monitored for improvement. Savings could be linked to investment in the tools necessary to achieve greater improvements in subsequent performance years.

Finally, HFMA¹⁸ strongly supports the move to patient reported outcomes measures (PROMs) as does HHS’s LAN CEP Work Group.¹⁹ We would encourage CMS to use the proposed EPMs and other innovative payment models as an opportunity to experiment with PROMs. We understand that there are several PROMs currently used in existing cardiology disease registries and strongly encourage CMS

¹⁸ <http://www.hfma.org/ValueProject/Phase2/>

¹⁹ <https://hcp-lan.org/groups/cep/clinical-episode-payment/>

to explore the feasibility of incorporating them into the EPMs when they are implemented in 24 to 36 months.

Data to Support Care Redesign:

HFMA fully supports CMS's decision to provide both claims level and aggregate data to participants in the CJR model and EPM. We ask that CMS and its contractors work to improve the quality of the data it provides EPM participants (and BPCI and CJR participants). We continue to hear from our members the multiple Public Use Files (PUFs) they receive are unwieldy to work with, frequently riddled with errors, and not delivered in a timely manner. These files frequently are received later than promised and include significant errors, further delaying analysis and results calculation.

CMS needs to institute and enforce service level agreements (SLA) with its contractors that dictate acceptable time frames in which to provide episodic payment model participants with accurate, complete data files. If the contractor fails to meet the terms specified in the SLA, it should be materially penalized. Further, CMS needs to create an episodic payment model ombudsman who will serve as the conduit for complaints from providers regarding data. The ombudsman will be responsible for determining whether the contractor is in violation of the SLA and subject to penalty.

Beyond improving the timeliness and accuracy of the data, CMS needs to improve the quality of reports it provides hospitals. Many hospitals do not have the capability to manipulate claims level data or can afford to purchase it. And for providers that have the ability to manipulate claims level data, we hear that this capability is expensive to acquire and maintain. CMS has clearly indicated it is moving toward longitudinal payment models (both 12 month – MSSP or 90 day – EMP). **As part of this move, HFMA's members believe CMS and its contractors need to develop standardized reporting capabilities (and reports) that will fully support providers. An electronic platform that provides summary data with the capability to drill down into individual patient episodes would provide the information necessary to support episodic payments. This should be made available to providers before CMS expands its portfolio of mandatory episodic payment models further.**

Finally, CMS again proposes to exclude individually identifiable data related to substance abuse from claims files as it currently does in other programs. This information is key for hospitals to understand the full risk associated with patients and identify appropriate care management. While we understand the sensitivity of such services and CMS's exclusion of them in the files, we think there are options that would provide risk-bearing entities with more information, while not risking beneficiary privacy. **Given that hospitals are now forced to bear risk for these patients, HFMA believes that CMS at a minimum must provide cost and claim data for these services. If CMS is unwilling to do this, we believe hospitals should not be forced to bear risk for these cases. Additionally, we strongly encourage the Center for Medicare and Medicaid Innovation (CMMI) to use its waiver authority to make beneficiary specific claims level substance abuse information available to hospitals. If CMS does not believe it has sufficient authority, it must work with Congress to create an exception to 42 CFR part 2 to provide claims level, identifiable data.**

Gainsharing Models:

The EPM proposed rule makes hospitals the primary risk-bearing entity for AMI, CABG, and SHFFT episodes for qualifying Medicare beneficiaries. However, hospitals would be permitted to enter into

gain/risk sharing arrangements with physician groups, other hospitals, ACOs, and post-acute providers referred to hereafter as “collaborators.”

HFMA appreciates CMS encouraging hospitals to enter into gain/risk sharing agreements with episode collaborators in their markets. While in theory, gain/risk sharing arrangements should align financial incentives across the care continuum, a surprisingly small percentage of HFMA’s members who participate in the either BPCI or CJR programs currently use these agreements with their collaborators beyond orthopedic surgeons. Based on feedback from our BPCI and CJR participating members, HFMA attributes the underutilization of gainsharing to three things:

- 1) The complexity of CMS’s framework and the related administrative burden imposed on BPCI and CJR participants if they initiate a gainsharing arrangement.
- 2) A lack of clearly articulated safe harbors from the myriad of fraud and abuse regulations implicated by gainsharing arrangements.
- 3) Outside of large orthopedic (for LEJR episodes) and cardiology (for AMI and CABG cases) groups, few collaborators have a sufficient volume of cases for the gainsharing to be a financially meaningful incentive.

HFMA urges CMS to make the following improvements to the provisions related to financial arrangements in its episodic payment models (CJR, SHFFT, AMI, and CABG).

- 1) Reduce the administrative reporting requirements currently imposed on organizations using gainsharing arrangements. HFMA’s members believe it is unnecessary to require the gainsharing arrangements to document the “management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out EPM activities.” Our members believe it is sufficient to spell out each party’s obligation under the arrangement and then leave them latitude to determine how those obligations will be met.
- 2) Work with the Office of Inspector General (OIG) to provide the waivers from related fraud and abuse regulations.
- 3) Allow for gainsharing on commercial and Medicaid episodic payment arrangements that are similar to CJR model or proposed EPMs to increase the volume of cases on which hospitals can share gains with collaborators.
- 4) Increase the amount of savings that can be shared with physicians and advanced practice nurses (APN) who are providing primary care for patients in CJR model and EPM episodes. The proposed rule limits total gainsharing payments for any individual physician, individual APN, or physician group practice to 50 percent (or less) of total approved MPFS payments for services furnished to EPM beneficiaries. Given the importance of primary care management in preventing readmissions, we believe that it is likely that the potential value of care management services provided during the discharge period is significantly greater than total approved MPFS payments a physician will receive for these services. However, under the CJR model and proposed EPMs, these providers are not allowed to realize the full value they create by aligning with hospitals to improve outcomes given the 50 percent cap on gainsharing.

Further, HFMA's members ask CMS to clarify the following:

- 1) CMS proposes to hold hospitals fully responsible for the actions of downstream collaboration partners (e.g., EPM collaborator, collaboration agent, or downstream collaboration agent). In doing so, the proposed rule outlines a number of remedial actions it will take in the event that a collaborator, collaboration agent, or downstream collaboration agent fails to comply with either EPM rules or general CMS regulations. **While this appears to be a stepwise process, HFMA's members ask CMS to confirm this. Otherwise, they are concerned that they could incur a significant penalty or administrative action as a result of actions that the participant was unaware of, taken by a downstream collaboration agent.** If the remedial actions outlined in the proposed rule are not stepwise, HFMA is concerned it will limit use of gainsharing as participating hospitals will be reticent to expose themselves to significant regulatory risk as a result of actions taken by a downstream collaborator or rogue collaboration agent.
- 2) In the proposed rule, CMS states an EPM or CJR participant could be found to be noncompliant because it "takes any action that CMS determines for program integrity reasons is not in the best interest of the applicable episode payment model, or fails to take any action that CMS determines for reasons of program integrity should have been taken to further the best interests of the EPM." **HFMA's members ask CMS in the final rule to provide examples of actions that are not clear violations of existing fraud and abuse statutes that would fall into this category of noncompliance. Further, we ask CMS to discuss in the final rule how the patient's clinical outcome might be considered when determining noncompliance with this provision.** We believe there may be scenarios where something that is not "in the best interest of an EPM" may be clinically in the best interest of the patient.
- 3) The proposed rule makes semantic changes to several of the terms CMS uses to refer to entities involved in gainsharing agreements. **HFMA's members who are participating in the CJR model ask CMS if they must modify existing gainsharing arrangements to reflect these semantic changes.**

Beneficiary Notification:

HFMA's members have several concerns about CMS's proposed beneficiary notification policies. We believe that they are administratively burdensome, in some cases duplicative, and impractical from an operational standpoint. These concerns are heightened given that CMS is proposing to penalize participating hospitals for their noncompliance (or noncompliance of their collaboration partners) by nullifying any positive NPRA payments the participating facility may be entitled to through its efforts to improve patient outcomes and reduce the total cost of care.

- 1) The proposed rule requires each participating hospital to notify the beneficiary at admission or immediately following the decision to schedule a procedure or service resulting in a patient being included in the episode. The notice must be provided to all beneficiaries in the EPM and if it is not feasible to provide the notice on admission or immediately following a decision to schedule a procedure that would begin an episode, then such notice would be required to be provided to the beneficiary or his or her representative as soon as is reasonably practicable but no later than discharge. Given that most of the cases covered under the new EPM models will be emergent cases, HFMA's members are concerned that it may not be practical to provide a notice to every patient before they are discharged. In instances where patients are admitted and then subsequently transferred to another facility for a higher level of care, there may not be time to

provide the notice. And as a result, HFMA's members are concerned that they may be penalized due to a clinical situation that is beyond their control. **HFMA believes CMS needs to work with the provider community to identify these types of exceptions where delivering a notification is not possible prior to discharge and create an exception in its beneficiary notification protocol.**

- 2) The proposed rule requires participating hospitals, as part of their notifications, to provide beneficiaries in a proposed EPM or CJR model with a list of the providers and suppliers with whom the hospital has a sharing arrangement. The rule also requires each collaborating physician, advance practice nurse, physician group practice, post-acute care provider, hospital, and ACO that has an agreement with a participating hospital to provide the beneficiary notice. **First, HFMA's members believe requiring collaboration partners to provide notice is administratively unnecessary.** The beneficiary will have already received a notice from the participating hospital. That notice will include a list of all collaborators. **Second, HFMA's members believe that in some cases this is impractical unless the hospital administers the notice on behalf of the physician or practice.** Examples include but are not limited to an independent hospitalist who has a collaboration agreement and only sees patients while they are admitted to the participating facility or an anesthesiologist who has an internal gainsharing agreement based on improving operating room efficiency. In both instances, it is unlikely that these providers will practically be able to collect administrative documentation from a patient in the course of patient care, particularly in the time frame envisioned by CMS. The proposed rule states, "The notice would have to be provided no later than the time at which the beneficiary first receives services from the CJR collaborator or their collaboration agent during the CJR episode." **Therefore, HFMA's members believe that CMS needs to eliminate this requirement from the final rule.**
- 3) If CMS does not eliminate the collaboration notification requirement from the final rule, HFMA's members ask CMS to provide specific examples of when various collaborators would need to provide notice. The following scenario illustrates an example of a case where additional clarity is needed.

An ACO has a collaboration agreement with a participating hospital. The ACO includes an independent group of cardiothoracic surgeons and an independent group of primary physicians who both have collaboration agreements with the same participating hospital. If a patient who undergoes a CABG episode that includes physician services from each group, would the ACO and both physician groups need to provide the beneficiary with notification?

Expansion of Waivers from Outdated Fraud and Abuse Regulations:

Prior to issuance of a final rule, HFMA urges the Secretary to use the full scope of the combined authority granted by Congress under the Affordable Care Act to issue waivers of the applicable fraud and abuse laws that inhibit care coordination to enable participating hospitals to form the financial relationships necessary to succeed in the CJR and EPM models. Specifically, the Secretary should waive the Physician Self-Referral Law and the Anti-Kickback Statute with respect to financial arrangements formed by hospitals participating in the CJR model and EPMs that comply with the requirements in the proposed rule. As CMS recognized in the preamble to the calendar year 2016 Physician Fee Schedule proposed rule, the self-referral law was designed for a different world of care

delivery and payment than the new models. At its core, the self-referral law is about separating hospitals and referring physicians, while the evolving Medicare and Medicaid models “are premised on the close integration of a variety of different health care providers.” The Anti-Kickback Statute is similarly no longer compatible with the new models.

As currently exists under the CJR model, and is proposed for the EPM models, any financial arrangement or agreement under these models that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor. That is an unacceptable risk for hospitals, whose participation in this program is mandatory. Hospitals should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient workarounds to try to ensure that their efforts meet the demands of this new program and do not run afoul of such laws and regulations. **The mandate to participate should not take effect unless and until hospitals have the needed, explicit protections in place and adequate time to form the necessary financial arrangements. Although hospitals are generally supportive of the episodic payment models as currently conceived by CMS, such programs cannot be successful for Medicare and its beneficiaries without these protections.**

CMS’s mandate that certain hospitals in the targeted Metropolitan Statistical Areas (MSAs) participate in these models is, at its core, a mandate that those hospitals bear responsibility for the financial and quality outcomes of other providers who provide care to Medicare beneficiaries during qualifying episodes. Under CJR and in the proposed EPM rule, CMS notes that participating hospitals may rely on financial arrangements with those providers to share the program’s potential risks and rewards. Indeed, our members report that such financial arrangements are not just a desirable but an essential component of successful participation in a retrospective episodic payment model. CMS itself acknowledges in the proposed rule that the financial relationships between hospitals and collaborators may implicate fraud and abuse laws. Despite this recognition, neither the CJR final rule, nor the EPM proposed rule include waivers of any of the potentially applicable fraud and abuse laws. Nor does the proposed rule indicate that such waivers are forthcoming. Given that these waivers are essential to hospitals’ ability to form financial arrangements with collaborators, what CMS proposes would effectively hold hospitals accountable, in part, for other providers’ performance, yet tie their hands by substantially limiting their ability to guarantee that those providers have a real stake in the program’s outcomes.

The absence of waivers of the relevant fraud and abuse laws as part of this proposed mandatory program is both disappointing and perplexing given that the Secretary has used that authority to test such waivers in multiple voluntary payment and delivery system reform models to date. Those programs, which include the Pioneer Accountable Care Organization program, the Medicare Shared Savings Program and the BPCI, provide a good template for the waivers needed in CJR and the proposed EPMs. Further, the mandatory nature of this program supports the Secretary’s need to exercise waiver authority to protect financial relationships formed subject to these episodic payment models that may otherwise implicate fraud and abuse laws. Hospitals that form financial arrangements subject to these programs would be doing so in order to comply successfully with a CMS mandate.

Additionally, CMS has developed a very detailed regulatory structure that would govern any financial arrangements formed subject to episodic payment models and would also serve as a built-in safeguard against fraud and abuse concerns. Hospitals, for example, would be required to set forth a written

participation agreement that includes the terms of any sharing arrangements, such as sharing of program savings or internal cost savings, or of repayments to Medicare. The written agreement detailing the sharing arrangements would be subject to extensive requirements, including descriptions of the methodologies used to calculate any payments to and from hospitals and collaborators, and a description of how success would be measured. Further, any gainsharing and alignment payments would be subject to specific requirements.

Beyond the broad safe harbors discussed above, HFMA's members believe that CMS should grant providers who are compelled to participate in the CJR model or the proposed EPMs the following waivers:

- 1) Provide beneficiaries with reduced cost sharing for use of preferred PAC settings. Hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services should be relaxed. If hospitals are held responsible financially for overall episode costs, they must be able to select, based on quality data, their preferred post-acute partners and develop steerable relationships with them. HFMA believes that beneficiaries should still retain full choice. However, CMS should use a tiered network model similar to benefit designs that are widely used in commercial health plans. If a beneficiary chooses to remain in the CJR model or EPM participant's network, CMS will reduce out of pocket cost sharing for that individual for the related post-acute stay. **HFMA believes the ability to increase (or decrease) referrals to a post-acute care provider is a more effective and administratively simple mechanism for aligning incentives across the care continuum than sharing savings (or less likely, sharing losses, as discussed below).**

Concerns about "stinting" on care can be addressed under the current regime of Civil Monetary Penalties. Given that CMS proposes to collect and monitor both quality measures and post-acute episode spending, it has the data necessary to identify and pursue bad actors.

- 2) Provide incentives related to prevention or adherence. HFMA appreciates CMS's efforts to waive the *Beneficiary Inducements Civil Monetary Penalty* and the *Federal Anti-Kickback Statute* related to the provision of items and services provided to CJR model and proposed EPM episode beneficiaries for free or less than fair market value goods or services, as part of care received under the models and as part of a treatment goal such as prevention or adherence to a treatment regimen. However, the administrative burden imposed on hospitals that opt to provide free or reduced cost items or services related to models is considerable.

The proposed rule requires hospitals to:

- Document the provision of any item or service in excess of \$25. **HFMA strongly recommends increasing the threshold to \$50.**
- Retrieve any technology item provided worth more than \$100 from the beneficiary. It will cost hospitals more to pick up the technology item than the item is worth. **HFMA strongly recommends increasing the threshold to \$500.**
- Limit technology given to beneficiaries to \$1,000. **HFMA's members strongly recommend removing the cap given that CMS is requiring providers to pick up items valued in excess of \$100 (as proposed).**

Further, HFMA's members request examples of what would be permissible under this waiver. While it appears that providing socioeconomically challenged patients with transportation to follow-up appointments would be permissible, HFMA's members ask CMS to clarify whether or not the following are acceptable:

- Paying for a beneficiary's medications for management of coronary artery disease (either copayment or entire prescription in the instance of a patient who lacks Part D).
- Paying for a beneficiary's medications for management of an exacerbating chronic disease (e.g., diabetes) (either copayment or entire prescription in the instance of a patient who lacks Part D).
- Providing food assistance to indigent patients who have trouble accessing whole foods.
- Providing housing assistance for homeless patients.

In each of these examples, HFMA asks CMS to provide guidance on specific circumstances where these or other social support services would be permissible (e.g., applicable patient screening protocols, expenditure caps, etc.). Evidence has shown that providing these types of social supports to indigent patients has the potential to significantly reduce readmissions and improve outcomes. Readmissions, beyond being detrimental to patients, are a significant cost driver for CJR model and EPM episodes. **HFMA strongly encourages CMS to allow hospitals, who have been mandated to take risk on these cardiac and orthopedic episodes of care, a full suite of tools to provide economically challenged patients the social supports necessary to minimize the risk of readmissions.** HFMA believes this is particularly important given the lack of SES risk adjustment in the current episode pricing.

- 3) Provide direct patient financial incentives. In addition to CMS reducing a CJR model or EMP beneficiary's post-acute cost sharing (as discussed above), HFMA believes the waivers addressing patient incentives promulgated as part of the MSSP should apply to CJR and EPM participants as well. This waiver would waive primary care copays. Doing so would encourage beneficiaries within an episode to seek the appropriate follow-up care that would not only help reduce readmissions, but also allow patients to be discharged to a lower level of post-discharge care.
- 4) Facilitate transition planning. Additionally, HFMA believes the federal Anti-Kickback Statute should be waived to allow CJR model and EPM participants, including, without limitation, home health providers, to assist with discharge planning for beneficiaries and coordinate care transitions. For instance, better transition planning, in particular the assessment of readiness for in-home care services or other lower cost settings, is critical to the success of this population, since patients prefer to recover in their communities, and to model participants, who are best positioned, along with discharge planners and patient's families, to help identify the most clinically appropriate and cost-effective post-hospital setting for the patient. Current restrictions that prevent active coordination in transition planning obstruct the models' goals of ensuring that patients are discharged to the setting that best suits their needs.

Dispute Resolution Process:

CMS proposes that hospitals provide a written notice of any error in a calculation within 45 days of receiving a reconciliation report. HFMA finds this time frame problematic. We continue to hear from CJR

and BPCI participants that they continue to experience issues with the data files and reconciliation reports they receive from the contractors administering the program. The monthly data feeds from CMMI regularly omit data elements that are used by the contractor to identify and reconcile episodes to target prices. Without these data elements, it is impossible to replicate the reconciliation results calculated by CMMI. Participants are left to hope the contractor did not make an error in reconciling the data. This practice would not be acceptable in a commercial episodic payment contractual arrangement.

Given these data issues and the amount of time it will take hospitals to replicate CMS's results, HFMA believes CMS should allow hospitals an initial 180 days to file an appeal for both the CRJ model and the proposed EPMs. This time frame is similar to the time frame afforded hospitals to appeal adjustments in the Medicare Cost Report, a document that in many respects is far less complicated than replicating CMS's reconciliation for the CJR model or EPM programs.

Additionally, CMS needs to provide CJR model and EPM participants with all data, methods, and underlying calculations necessary to replicate the reconciliation results. This check is necessary to ensure that inadvertent errors did not occur (as will happen from time to time) when the contractor reconciled actual episode prices to targets. The ability to replicate the reconciliation results also helps maintain a transparent and open relationship among the episodic payment model participants, CMS, and CMS's contractor.

Alignment with Ongoing State Efforts:

Currently at least two states (Arkansas and Tennessee) have implemented (or are implementing) bundled payment programs that include CABG episodes. These efforts to implement bundled payments include the state Medicaid plan and commercial health plans. In at least one state that HFMA is aware of (Arkansas), the episode definition is consistent (duration, responsible entity, included services/conditions) across all participating payers.

Unfortunately, the episodes described in the EPM proposed rule are not consistent with these state level efforts. **If MSAs in Arkansas and Tennessee are included in the EPM final rule, HFMA believes CMS should align its CABG episode definition with that of the state Medicaid plan.** Doing this would reduce the number of episode definitions for the same procedure, decreasing both the complexity and cost providers would encounter as they attempt to manage CABG episodic payment. It would also reduce overlapping, independent efforts at care redesign that both hospitals and orthopedic groups would be simultaneously undertaking (potentially independently). Further, it would allow CMS to experiment with episode definitions outside of those it developed as part of either EPM or BPCI.

Proposed Cardiac Rehabilitation Incentive Payment Model:

HFMA's members strongly support the incentives included in the proposed rule to help expand the utilization of cardiac rehabilitation services given the potential for them to improve long-term patient outcomes. However, our members do not believe the proposed incentives go far enough and make the following recommendations:

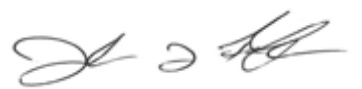
- 1) **Expand the Cardiac Rehabilitation Incentive Payment Model to all 98 MSAs selected for the cardiac EPMS.** Given that the model is mandatory, HFMA believes it is unfair that CMS proposes to provide one set of hospitals specific tools that will help improve both their patient outcomes and financial results while denying these same tools to other hospitals who are also being held at risk. While we appreciate that CMS is attempting to isolate the impact of the CR incentive from the incentives in the EPM, our members believe it is inappropriate to use both randomly selected Medicare beneficiaries and hospitals as test subjects when the studies cited in the proposed rule demonstrate the dramatic positive impact that results from increased utilization of cardiac rehabilitation services.

- 2) **Allow both EPM and FFS Cardiac Rehabilitation Payment Model participants to either waive copayments upfront for Medicare beneficiaries or rebate copayments to beneficiaries once they have completed at least 12 sessions.** In the proposed rule, CMS cites the financial burden on beneficiaries as one of the barriers to increasing utilization of cardiac rehabilitation services. The median income for households headed by persons 65 or older in 2013 was \$51,486.²⁰ HFMA estimates that cost sharing for 24 sessions (the number of sessions that produced lower relative mortality over a four-year follow-up period) of cardiac rehab services (HCPCS code 93798) in 2016 is approximately \$122.²¹ This is a significant amount of money for someone who is living on a fixed income, is likely paying copayments for multiple medications to manage a host of chronic conditions, and is now facing both an inpatient deductible of \$1,288 and the related copayments for physician services while in the hospital and for care immediately following discharge. It is disappointing the proposed rule gives participants tools to overcome the transportation barrier to increasing utilization, but it does not give hospitals – particularly those serving economically challenged Medicare beneficiaries – the flexibility to overcome cost barriers.

HFMA looks forward to any opportunity to provide assistance or comments to support CMS's efforts to refine and improve outcomes based payment models. As an organization, we take pride in our long history of providing balanced, objective financial technical expertise to Congress, CMS, and advisory groups.

We are at your service to help CMS gain a balanced perspective on this complex issue. If you have additional questions, you may reach me or Richard Gundling, Senior Vice President of HFMA's Washington, DC, office, at (202) 296-2920. The Association and I look forward to working with you.

Sincerely,



Joseph J. Fifer, FHFMA, CPA

²⁰ http://www.aoa.acl.gov/aging_statistics/profile/2014/docs/2014-profile.pdf

²¹ <https://www.cms.gov/apps/physician-fee-schedule/search/search-results.aspx?Y=0&T=0&HT=0&CT=0&H1=93798&M=5>, HFMA analysis



President and Chief Executive Officer
Healthcare Financial Management Association

About HFMA

HFMA is the nation's leading membership organization for more than 40,000 healthcare financial management professionals. Our members are widely diverse, employed by hospitals, integrated delivery systems, managed care organizations, ambulatory and long-term care facilities, physician practices, accounting and consulting firms, and insurance companies. Members' positions include chief executive officer, chief financial officer, controller, patient accounts manager, accountant, and consultant.

HFMA is a nonpartisan professional practice organization. As part of its education, information, and professional development services, HFMA develops and promotes ethical, high-quality healthcare finance practices. HFMA works with a broad cross-section of stakeholders to improve the healthcare industry by identifying and bridging gaps in knowledge, best practices, and standards.

Links to Prior Comment Letters Related to BPCI and CJR:

<http://www.hfma.org/Content.aspx?id=32061>

<http://www.hfma.org/Content.aspx?id=31072>

<http://www.hfma.org/Content.aspx?id=1279>

<http://www.hfma.org/Content.aspx?id=41399>