American Hospital Association

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September 30, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
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); Proposed Rule (Vol. 81, No. 48), August 2, 2016.***

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Cardiac and Comprehensive Care for Joint Replacement (CJR) Bundled Payment Model proposed rule.

Our members support the health care system moving toward the provision of more accountable, coordinated care and are in the process of redesigning delivery systems to increase value and better serve patients. **As such, the AHA agrees with the principles underlying the proposed cardiac bundled payment model and believes it could help further these efforts to transform care delivery through improved care coordination and financial accountability.** However, while we are mindful of the Department of Health and Human Services (HHS) Secretary's goals for moving to alternative payment models, **this proposed rule raises serious concerns about the agency's pace of change, as well as its ability to accurately track and process the outcomes of its myriad increasingly complex alternative payment models. As such, we urge CMS, in the strongest possible terms, to refrain from expanding mandatory bundled payment models to other geographic areas or conditions before there has been enough time to assess the lessons learned under the existing models.**

Of great concern is that CMS's proposal to implement a cardiac bundled payment model came less than four months after the CJR program began. This aggressive timeline is reflected in the fact that the programmatic details of this new model are almost exactly the same as CJR. Because the programs come so closely on the heels of one another other, CMS has been unable to garner, let alone apply, any lessons learned. **In failing to take the time to learn from CJR, the agency has missed a critical opportunity to move bundled payment models forward in a meaningful way.**

Also of concern is the significant complexity of the proposed cardiac model. For example, CMS would set no fewer than 75 different target prices for different combinations of cardiac diagnoses and procedures, making it difficult for even trained clinicians to know whether the agency's proposals are directionally correct. Because hospitals' data and resources are limited, they will have little, if any, ability to independently verify any of CMS's calculations. **We urge the agency to proceed at a more deliberate pace and simplify the rule.** For example, we urge the agency to consider including only coronary artery bypass grafts (CABGs) in the cardiac model to start. As hospitals work through implementation and gain experience, the agency could then phase in the inclusion of the much more complicated acute myocardial infarction (AMI) episodes.

**In addition, we do not support CMS's proposal to expand the CJR program to include surgical hip and femur fracture treatment (SHFFT) episodes, or to require certain CJR hospitals to also implement the cardiac bundled payment model.** As noted above, we are generally supportive of bundled payment and of hospitals serving as episode initiators, but these new proposals go too far too fast. Hospitals do not have an unlimited capacity to implement bundled payment models. Indeed, the proposal to expand CJR also was put forth less than four months after the program began. Neither CMS nor hospital participants have had the time or the data to be able to analyze any lessons learned, successes or failures. **In fact, CJR hospitals do not yet even have any complete episode data. We have supported CMS's reform efforts many times, but cannot support efforts such as these that prioritize speed over learning and evaluation.** Over the next several years, as CMS and hospital participants continue their work under CJR, we all will begin to gather important lessons on how to achieve success. **We urge CMS to reconsider expanding the model only when a solid foundation of evidence, analyses and evaluations is present.**

**Further, we urge CMS not to implement the cardiac bundles in the same geographic areas as the CJR model.** To ask hospitals in locations already grappling with CJR to both expand the conditions in that model and implement cardiac bundles at the same time is inappropriate and may compromise both the success of the models and patient care. While we recognize the importance of reforming the payment system, doing so will be a hollow victory if CMS accomplishes it in such a way as to overload providers to the point that they have so many competing priorities that they are unable to do well on any of them. As we have stated in the past, hospitals and health systems have built care processes and policies around the current regulatory payment structures, and these systems will have to be changed if they are to achieve success in bundled payment programs. This is no small task. **Hospitals strongly support CMS's push for adoption of alternative payment models and are working to help ensure these complex models work for patients. However, if the agency does not, in turn, support hospitals by recognizing the significant investments of time, effort and finances that these models require, neither we nor the agency will find success.** The agency must instead allow time for providers to standardize care patterns and identify opportunities for care redesign, as well as adequate opportunity for testing and evaluation of bundled payment models – if all these factors are afforded, we will reap valuable lessons from hospitals' experiences.

To optimize the effectiveness of the bundled payment models in terms of efficiently testing how to best transform care delivery through improved care coordination and financial accountability, CMS must both provide hospitals with the necessary tools to be successful under the program and appropriately balance the risk versus reward equation. We have several recommendations for program improvements that would help accomplish these goals.

**First and foremost, we urge CMS to incorporate a risk-adjustment methodology into the cardiac model, the existing CJR model and the SHFFT model if, and when, it is reconsidered for implementation.** As proposed, CMS would not include a comprehensive risk adjustment in any of these programs. However, the use of a regional spending component would increasingly hold all hospitals in a region to the same target price, despite the fact that they treat patient populations with differing levels of severity and, therefore, differing episode costs. **This lack of a risk-adjustment methodology fails to fully account for numerous factors that affect spending and are beyond hospitals' control, and would inappropriately penalize hospitals treating the sickest, most complicated and most vulnerable patients.**

**Second, the AHA urges CMS to incorporate a more robust transfer-adjustment methodology for cardiac episodes.** Generally, the highest weighted cardiac Medicare Severity-Diagnosis Related Group (MS-DRG) from either participant hospital would determine the episode type. However, we are concerned that this policy does not go far enough to provide a level playing field for episodes involving a transfer. Specifically, the use of a regional spending component would increasingly hold all hospitals in a region to the same target price, despite the fact that they have differing levels of clinical capability, and, therefore, differing rates of more costly transfer episodes. **Therefore, CMS's policy would penalize smaller hospitals that do not have the most sophisticated cardiac care available. To avoid doing so, we recommend that CMS exclude the amount paid to the initially admitting hospital when calculating target prices and actual episode spending.** We believe that doing so would help put these hospitals on a more level playing field and encourage the best provision of care.

**In addition, we urge CMS to implement smaller discount factors in the cardiac model than proposed.** Specifically, to determine a hospital's bonus payments, CMS would set a target amount equal to their historical spending minus a percent discount. The discount factors proposed for the cardiac model are the same as those CMS uses in the CJR program. However, the opportunity to achieve savings under the cardiac model is *not* the same as in the CJR program – it is much less. This is especially true over time, as target prices decline further. To avoid turning this cardiac model into a straight payment cut, CMS must provide hospitals with a fair opportunity to achieve enough savings to garner a reconciliation payment.

**We also urge the Secretary, prior to issuance of a final rule, 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 these 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 model that comply with the requirements in the proposed rule.** The Secretary, ultimately, recognized the necessity of these waivers to the success of the CJR, issuing them in conjunction with the rule finalizing that program. We urge that the same occur for this proposed model. These waivers are essential to enable hospitals to form financial arrangements with other providers collaborating in the model, without which hospitals would have no real ability to make sure those providers – for whose outcomes hospitals will be held accountable – have a stake in achieving the model's goals.

We also are concerned that the scope of the proposed payment waivers is too limited. **We urge CMS to give providers maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.** The waiver of certain Medicare

program regulations in all years of the program, including discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services, the inpatient rehabilitation facility (IRF) "60% Rule," and the home health homebound rule is essential so that hospitals and health systems may coordinate care and ensure that it is provided in the right place at the right time. CMS also must begin to consider innovative approaches for overcoming the challenges that are created by building a bundled payment system on a fee-for-service foundation, including the waiver of payment rules to allow flexibility in how providers such as IRFs are paid. **Doing so would allow for efficiencies that are gained in these settings to be reflected in their payments, which would help not only achieve savings, but also ensure beneficiary access to these critical services.**

Finally, the AHA recognizes that, in crafting the proposed regulation, CMS attempted to achieve a balance between offering incentives for providers who achieve success and fulfilling CMS's obligation to protect taxpayers and the Medicare Trust Fund. **However, as proposed, the rule places too much risk on providers with little opportunity for reward in the form of shared savings, especially in light of the significant upfront investments required.** A more appropriate balance is needed. For example, CMS should:

- Delay downside risk implementation until 15 months after the models begin;
- Provide additional protections in the form of lower stop-loss limits for hospitals that have a low volume of episodes;
- Remove the proposed excess days in acute care measure from the AMI model measure set and adopt a flexible reporting approach to the proposed voluntary AMI mortality measure; and
- Assess all measures for the impact of socioeconomic factors and incorporate adjustments if needed.

The changes we recommend above would help facilitate hospitals' success in providing quality care to Medicare beneficiaries, achieving savings for the Medicare program and having an opportunity for reward that is commensurate with the risk they are assuming.

Our detailed comments are attached – thank for your consideration. Please contact me if you have questions or feel free to have a member of your team contact Joanna Hiatt Kim, vice president of payment policy, at (202) 626-2340 or jkim@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

cc: Sylvia Mathews Burwell, Secretary, Department of Health and Human Services
Daniel R. Levinson, Inspector General, Department of Health and Human Services

**AMERICAN HOSPITAL ASSOCIATION (AHA)**

**DETAILED COMMENTS**

## EXPANSION OF THE COMPREHENSIVE CARE FOR JOINT REPLACEMENT (CJR) MODEL

The Centers for Medicare & Medicaid Services (CMS) proposes to expand the current CJR model to include surgical hip/femur fracture treatment (SHFFT) other than joint replacement.[1] Specifically, CMS would implement a SHFFT bundle in the same 67 geographic areas already participating in the CJR model. However, inpatient prospective payment system (PPS) hospitals in these areas that are participating in Bundled Payments for Care Improvement (BCPI) Model 2 and 4 episodes for SHFFT would be excluded from this expansion. **The AHA does not support this proposal. Although we have been and continue to be generally supportive of CMS's mandatory bundled payment programs, the proposal to expand CJR is too much, too soon. It prioritizes speed over learning and evaluation.**

Hospitals strongly support serving as episode initiators, but do not have an unlimited capacity to implement bundling models. While we understand that CMS may be looking to BPCI participants that are working on multiple bundling models in this regard, we note that the situation is very different with a mandatory program. Such programs affect hospitals of many different sizes and types, and at very different points in the transformation process. While some had already taken significant steps toward building their infrastructure and achieving alignment with physicians and post-acute facilities, many are not as far down this path. They need time to "get their arms around" the CJR model before it is expanded. Indeed, CMS itself has acknowledged that bundling implementation takes a substantial amount of time and resources – it is one of the reasons the agency has provided a delayed introduction of downside risk in these models. Yet, its proposal to add SHFFT episodes to CJR was put forth less than four months after the CJR program began. Neither CMS nor hospital participants have had the time or the data to be able to analyze any lessons learned, successes or failures. In fact, CJR hospitals do not yet even have any complete episode data. The only data they have is partial data for episodes that began in April, which does not in any way allow them to gauge their performance to date, what strategies are working, what strategies are not working, and changes they should consider. **This is not an appropriate environment in which to expand the program.**

Further, the quality measures CMS has proposed for the SHFFT population are poorly aligned with the SHFFT population. For example, the SHFFT model applies to *hip fracture* patients; yet, the proposed complications measure applies only to *elective hip and knee replacement* patients. These two populations do not overlap at all. **Without appropriate quality measures, we are concerned that CMS is sending a signal that it is focused only on reducing cost, and not on**

[1] CMS proposes to include MS-DRG 480 (Hip and femur procedures except major joint with major complication or comorbidity (MCC)), MS-DRG 481 (Hip and femur procedures except major joint with complication or comorbidity (CC)) and MS-DRG 482 (Hip and femur procedures except major joint without CC or MCC.)

**improving quality for the SHFFT population.** Indeed, the statute requires Center for Medicare and Medicaid Innovation (CMMI) models to reduce program expenditures while simultaneously preserving or enhancing the quality of care for those individuals who receive Medicare benefits. In fact, the statute explicitly instructs CMMI to give preference to testing models that "also improve the coordination, quality, and efficiency of health care services" furnished to Medicare beneficiaries. Absent the inclusion of quality measures that include the SHFFT population in a meaningful way, we are concerned that this model does not satisfy these requirements.

Over the next several years, as CMS and hospital participants continue their work under CJR, we all will begin to gather important lessons on how to achieve success. **Only when a solid foundation of evidence, analyses and evaluations are present should CMS reconsider expanding the model.** Below, we outline several recommendations that we believe the agency should consider at that time.

Introduction of Downside Risk. **We urge CMS to provide hospitals with additional time before downside risk is implemented in all bundled payment programs.** Under both the CJR and proposed SHFFT models, downside risk would begin after nine months. However, because of the way that episodes are defined, hospitals actually have only six months before episodes that will incur downside risk begin. Specifically, CMS proposes to start the SHFFT model July 1, 2017; downside risk would begin for episodes *ending* April 1, 2018 and later. However, episodes that end April 1, 2018 would have begun over 90 days earlier, or prior to Jan. 1, 2018. Therefore, hospitals actually only have from July 1, 2017 until about Jan. 1, 2018 before episodes that will incur downside begin.

Six months is not an adequate timeframe in which to begin managing episodes that will be subject to downside risk. First, hospitals do not receive the data necessary to succeed under a risk-bearing model until at least 60 days into this six-month period. In addition, as noted previously, these initial data sets do not include full episodes, since an episode is 90 days long. Further, once hospitals have these data, it can take an additional two to four months to complete the necessary analysis to understand where there is systematic, unwarranted variability in care pathways and identify key physician groups and post-acute organizations to partner with in order to coordinate care. It would then likely take an additional two to three months for a hospital to develop sharing arrangements with these other providers, given the complexity of the program. Even after care pathways are redefined and targeted interventions installed, it can still take many months for them to yield significant improvements in quality and reductions in the overall cost of care delivery. **We cannot emphasize enough that hospitals want and need time to adequately prepare because they want be successful throughout the duration of the program.** They also want and need to be afforded the opportunity to take full advantage of the transition to downside risk, especially given that many have very limited experience doing so. **Therefore, we urge CMS to delay downside risk implementation until 15 months after the SHFFT model begins, which would provide hospitals with a full year before episodes that will incur downside begin.**

Included and Excluded Services. **We continue to urge CMS to conduct additional research on the list of services to be excluded from the bundles.** For example, we urge CMS to consider excluding hospital readmissions or outpatient procedures that were planned for the patient prior

to the start of the episode. Doing so would be consistent with other CMS policies (e.g., CMS currently excludes planned readmissions from the Hospital Readmissions Reduction Program). We also urge CMS to consider excluding ongoing care for patients' chronic conditions. One goal of these bundled payment models is to test how to optimize quality and costs for certain episodes – including the costs of caring for ongoing chronic conditions would muddy the waters.

In addition, under both the CJR and proposed SHFFT models, all post-acute care services have been included in episode costs without exclusion. In the circumstance when a readmission for an excluded Medicare Severity-Diagnosis Related Group (MS-DRG) occurs during the episode, the cost of the readmission is not counted toward the episode cost. However, 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 post-acute care providers. **We urge CMS to study potential exclusions for post-acute care following an excluded readmission.** Holding participating hospitals accountable for all patient pathways is unreasonable given how little is known about the causal relationship between the hospital readmission and subsequent post-acute care services.

Cancelled Episodes. As with CJR, CMS proposes that, once an episode begins, it would continue to the end unless the beneficiary no longer meets the inclusion criteria, in which case the episode would be cancelled. However, whereas one reason that CMS would cancel a CJR episode is if the beneficiary dies at any time *during the episode*, it proposes to cancel a SHFFT episode only if the beneficiary dies *during the anchor hospitalization*. Yet, episodes during which a beneficiary dies usually include atypical courses of care, which may include extensive end-of-life care. Hospitals should not be penalized for providing this care. **Therefore, as a rule, the AHA urges CMS to cancel all episodes in which the beneficiary dies – either during the anchor hospitalization or during the 90 days post discharge.**

In addition, we are concerned that this proposal effectuates a lack of consistency between hip fracture beneficiaries included in the CJR program. That is, hip fracture beneficiaries treated with a SHFFT would be subject to one set of rules, while those treated with a hip replacement would be subject to another set. Indeed, in its rationale for this proposal, CMS seems to disregard the fact that a substantial portion of the hip fracture population is already in the CJR program. For example, it cites a 2009 study that, in analyzing data from 1985 through 2005, shows a 30-day hip fracture mortality rate for Medicare beneficiaries of approximately 5 percent.[2] CMS concludes that this rate is significantly higher than the mortality rate following lower-extremity joint replacement (LEJR) procedures. The age of these data is certainly cause to question the agency's conclusion, but also we are concerned that it is ignoring the fact that a substantial portion of the hip fracture population is treated with an LEJR. This overlap confounds the comparison the agency is trying to make, and we therefore question its validity.

Retrospective Payment Methodology. For both the CJR and proposed SHFFT models, CMS has used a retrospective payment methodology under which it pays all providers and suppliers involved in an episode their usual fee-for-service (FFS) payment. After the completion of a performance year, payments for services furnished to beneficiaries in that year's episodes would

[2] 81 *Federal Register* 50841 citing Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and Mortality of Hip Fractures in the United States. JAMA. 2009;302(14):1573– 1579.

be grouped into episodes and aggregated. CMS would compare a participating hospital's actual episode payments to its "target price." If actual episode payments were below the target price, Medicare would pay the hospital the difference in the form of a "reconciliation payment," so long as it achieved the appropriate quality outcomes. If spending was in excess of the target price, the hospital would repay Medicare the difference, but only in years two through five of the program. No hospital would be penalized in year one.

**The AHA supports CMS's continued use of a retrospective payment methodology.** We believe that this is the most administratively feasible and straightforward payment option since it uses the existing payment system infrastructure and processes. Further, we agree with CMS's statement that a prospective payment methodology that makes one lump sum payment to the hospital for the episode would be challenging to implement given the infrastructure changes it would entail for both hospitals and Medicare. Moreover, such a prospective methodology would require extensive infrastructure and administrative changes, not only for hospitals and Medicare, but also for our post-acute care members, including inpatient rehabilitation facilities (IRFs). It would necessitate these providers entering into contracts with acute care hospitals and changing their own systems to put in place the processes and procedures for both billing and collecting payment from hospitals.

**However, as we have previously articulated to CMS, building a bundled payment system on a FFS foundation necessitates changing provider systems to address challenges that either did not exist or were not as problematic when they rested more clearly in their individual silos.** For example, one problem that becomes even more apparent is the plentiful barriers to care coordination that exist under FFS. In addition, a new challenge arises as a result of the varying design of the different FFS prospective payment systems. Specifically, many of them, such as the IRF PPS, are designed exactly how one would envision by virtue of their name – they make predetermined per-discharge payments based primarily on the patient's condition. However, others, such as the skilled nursing facility (SNF) PPS, are not so all-encompassing and make, for example, per-diem or per-service payments. If these post-acute care payment systems are brought closer together under a bundled payment program, it creates an unequal playing field – efficiencies achieved in the per-discharge payment system settings are not reflected in their payments. The only opportunity for hospitals to achieve payment efficiencies in such settings is to avoid them, which is, needless to say, not an ideal strategy for any party involved. **As such, we again urge CMS to consider ways to allow for efficiencies that are achieved in the IRF setting to actually be reflected in their payments.** This could be accomplished in different ways, including by implementing a policy similar to the current IRF PPS post-acute care transfer policy for short-stay IRF patients. Such a policy would allow IRFs to voluntarily elect to receive a per-diem payment based on a reduced case rate/weights for patients with shorter-than-average stays, with payment capped at the full IRF PPS amount.

We note that when we made this recommendation for the CJR program, CMS specifically stated in response that it would "review the information provided by the commenters and our early model experience and may consider waiving additional requirements during the course of the model test."[3] **We are disappointed that, in the agency's rush to push out new bundled**

[3] 80 *Federal Register* 73439.

**payment models, it has failed to allow itself time to consider innovative payment policies, such as IRF pricing flexibility, that have been suggested to improve the bundled payment models. Doing so shortchanges not only providers, but also program beneficiaries.** We urge CMS to make serious consideration of this issue when it reconsiders proposing this program in the future. In the meantime, we also strongly urge the agency to specifically discuss the pricing flexibility proposal in the final rule so that we can begin to have a thoughtful conversation about the policy.

Risk Adjustment. **We urge CMS to apply a full risk-adjustment methodology to SHFFT episodes. We also renew our request to apply such a methodology to CJR episodes, at the very least before downside risk begins for the existing program on Jan. 1, 2017.** For SHFFT episodes, CMS does not propose to make any risk adjustments beyond the fact that it would set separate target prices for MS-DRGs 480, 481 and 482. For CJR episodes, CMS does not risk adjust beyond the fact that it sets separate target prices for MS-DRGs 469 and 470, and hip fracture and non-hip fracture episodes. However, the use of a regional spending component would increasingly hold all hospitals in a region to the same target price, despite the fact that they treat patient populations with differing levels of severity and, therefore, differing episode costs. **This lack of a robust risk-adjustment methodology penalizes hospitals treating the sickest, most complicated and most vulnerable patients.** Indeed, researchers recently confirmed this fact, finding that CJR may penalize hospitals that treat medically complex patients.[4] Specifically, they determined that the use of region-based target pricing led to reduced reconciliation payments for these hospitals. However, after risk adjusting with CMS Hierarchical Condition Categories (HCC) risk scores, they found that reconciliation payments were substantially increased for hospitals that treat patients with high complexity and reduced for hospitals that treat patients with low complexity.

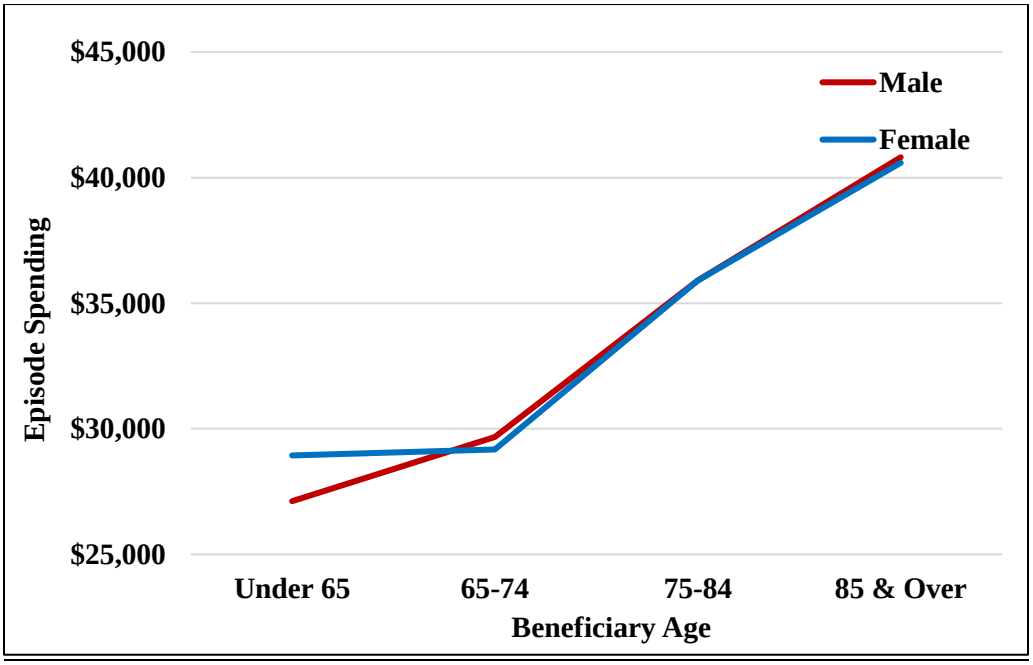
CMS states that it does not risk adjust existing CJR episodes or new SHFFT episodes because it does not believe that a sufficiently reliable approach exists, and that there is no current standard on the best approach. It specifically comments on the use of HCCs, stating that it does not believe their use is appropriate because they are used to predict total Medicare expenditures in an upcoming year for Medicare Advantage (MA) plans and may not be appropriate for use in predicting expenditures over a shorter period of time. However, this statement is very perplexing to us given that HCCs also are used to perform risk adjustment in a variety of CMS applications that are very similar to CJR. Specifically, HCCs are applied to quality measures such as Medicare Spending per Beneficiary (MSPB), 30-day mortality and readmission, all of which are used in CMS pay-for-performance programs. In addition, HCCs include a number of factors that, as shown below, affect episode spending, such as age and number of comorbidities. Certainly, they could serve as a basis for CMS to begin to construct an appropriate risk adjustment for CJR episodes, as well as for SHFFT episodes if it re-proposes their implementation in the future.

We conducted analyses of certain patient factors and their effect on episode spending – they demonstrate that relying on the MS-DRG as the program's only risk adjustment does not fully

[4] Ellimoottil C, Ryan AM, Hou H, Dupree J, Hallstrom B, Miller DC. Medicare's New Bundled Payment for Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. Health Aff (Millwood). 2016; 35(9):1651–7.

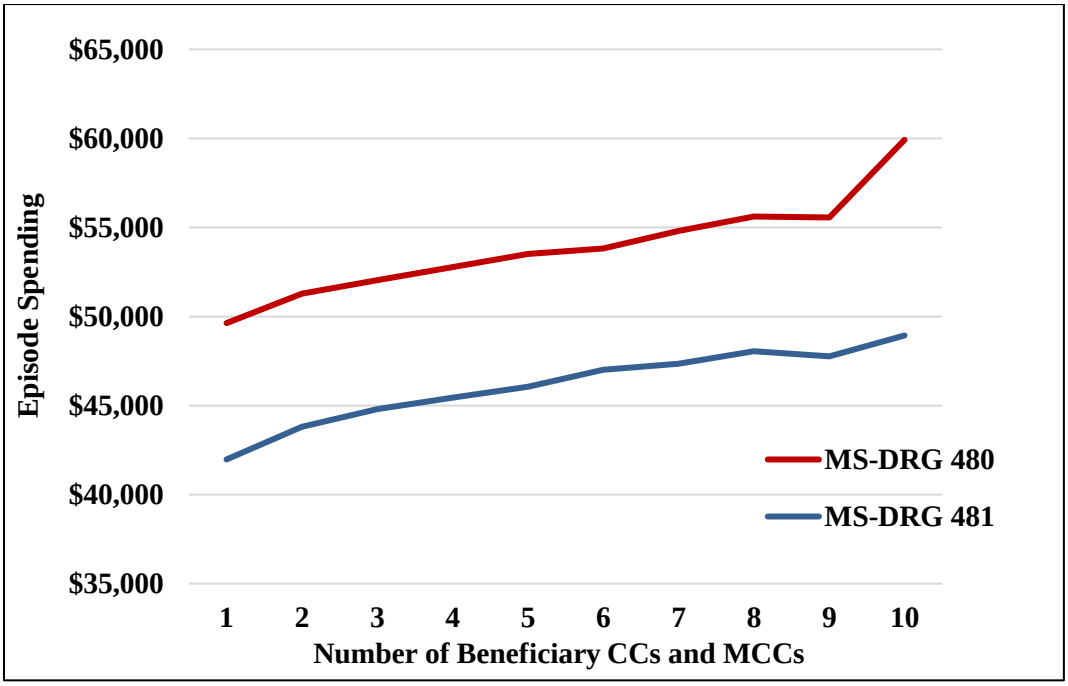
account for numerous factors that affect spending and that are beyond hospitals' control. Our analysis related to the CJR program can be found in our comment letter to the agency on that proposed rule. Our analysis related to SHFFT episodes is below. Specifically, our findings confirm that substantial variation in episode payments exist within each MS-DRG, not just between the CJR and SHFFT MS-DRGs. First, we found that spending per episode increases almost linearly by beneficiary age. As shown in Figure 1, MS-DRG 482 episode spending for male beneficiaries age 85 and older is about 51 percent higher than for beneficiaries under 65 years of age. MS-DRG 482 episode spending for female beneficiaries age 85 and older is about 40 percent higher than for beneficiaries under 65 years of age. The same trend occurs with MS-DRG 480 and 481 episodes.

**Figure 1: SHFFT MS-DRG 482 Episode Spending, by Age and Sex**




In addition, as shown in Figure 2, we found that spending for MS-DRG 480 and 481 episodes increases almost linearly by the number of beneficiary CCs and MCCs (beneficiaries in MS-DRG 482 do not have any CCs or MCCs, by definition). Episode spending for MS-DRG 480 beneficiaries with 10 or more comorbidities is 21 percent higher than spending for beneficiaries with only one comorbidity. Episode spending for MS-DRG 481 beneficiaries with 10 or more comorbidities is 17 percent higher than spending for beneficiaries with only one comorbidity.

**Figure 2: SHFFT MS-DRG 480 and 481 Episode Spending, by Number of Beneficiary CCs and MCCs**




Additional Proposals to Limit Repayment Responsibility for Certain Hospitals. CMS also proposes additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high-payment episodes. Specifically, for sole community hospitals, Medicare-dependent hospitals, rural referral centers and certain other rural hospitals, CMS proposes a stop-loss limit of 3 percent of episode payments in year two and a stop-loss limit of 5 percent for years three through five. **The AHA supports the application of these additional protections. However, we urge CMS to extend the same additional protections to hospitals that perform a low volume of SHFFT episodes, less than 27 each year, since they also would lack the infrastructure and support to achieve efficiencies.** Our regression analyses revealed that volume is an important determinant of per-episode spending. To determine how "low volume" should be defined, we analyzed the average loss per episode (i.e., spending in excess of the regional target price). We found that the average loss is largest for hospitals with the smallest number of episodes, as depicted in Table 1.

**Table 1: Gain/Loss Values Per SHFFT Episode for Hospitals, *Before* Application of Proposed Stop-loss and Stop-gain Limits, Oct. 2011-Sept. 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 75 | 5.7 | 1 | 14 | -$929 | -$30,485 | $23,598 | 54,083 |
| 2 | 76 | 24.7 | 14 | 37 | -3,925 | -19,047 | 18,444 | 37,491 |
| 3 | 75 | 45.5 | 38 | 55 | -3,121 | -15,476 | 7,362 | 22,838 |
| 4 | 76 | 69.2 | 56 | 81 | -3,209 | -13,297 | 4,987 | 18,284 |
| 5 | 76 | 94.9 | 82 | 107 | -2,838 | -11,823 | 6,183 | 18,006 |
| 6 | 75 | 119.6 | 108 | 133 | -2,421 | -11,711 | 4,012 | 15,723 |
| 7 | 76 | 147.5 | 133 | 167 | -2,202 | -8,839 | 7,883 | 16,723 |
| 8 | 75 | 188.9 | 168 | 215 | -1,858 | -10,153 | 8,253 | 18,406 |
| 9 | 76 | 245.7 | 216 | 283 | -1,780 | -8,798 | 3,804 | 12,602 |
| 10 | 76 | 401.4 | 288 | 1,042 | -1,354 | -8,403 | 6,626 | 15,029 |

In addition, we found that hospitals with the smallest number of episodes had the widest range of gain and loss values both before and even after applying the stop-loss and stop-gain limits proposed by CMS, as shown in Table 1 above, as well as Table 2 below. We also found that hospitals with the lowest episode volumes had the largest year-over-year variation in episode spending relative to target prices. High average losses coupled with high variation in annual episode spending tended to be found in hospitals with less than 81 SHFFT episodes over a 12-quarter period (Oct. 2011 – Sept. 2014), which would equate to 27 episodes per year.

**Table 2: Gain/Loss Values Per SHFFT Episode for Hospitals, *After* Application of Proposed Stop-loss and Stop-gain Limits, Oct. 2011 – Sept. 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 75 | 5.7 | 1 | 14 | -$641 | -$9,744 | $9,351 | $19,095 |
| 2 | 76 | 24.7 | 14 | 37 | -2,930 | -9,069 | 8,692 | 17,761 |
| 3 | 75 | 45.5 | 38 | 55 | -2,567 | -8,892 | 7,362 | 16,254 |
| 4 | 76 | 69.2 | 56 | 81 | -2,890 | -8,763 | 4,987 | 13,750 |
| 5 | 76 | 94.9 | 82 | 107 | -2,726 | -8,656 | 6,183 | 14,839 |
| 6 | 75 | 119.6 | 108 | 133 | -2,331 | -8,158 | 4,012 | 12,170 |
| 7 | 76 | 147.5 | 133 | 167 | -2,197 | -8,451 | 7,883 | 16,335 |
| 8 | 75 | 188.9 | 168 | 215 | -1,812 | -8,273 | 8,153 | 16,426 |
| 9 | 76 | 245.7 | 216 | 283 | -1,747 | -8,592 | 3,804 | 12,397 |
| 10 | 76 | 401.4 | 288 | 1,042 | -1,300 | -8,403 | 6,626 | 15,029 |

Use of Quality Measures in Payment Determination. CMS proposes to use a pay-for-performance approach for the SHFFT model that is nearly identical to the one it finalized for the CJR program. That is, CMS would tie each hospital's level of reconciliation payment or

repayment responsibility to a composite quality score. CMS proposes measures specific to each model, most of which already are reported in the Hospital Inpatient Quality Reporting (IQR) program. However, CMS also proposes a voluntary measure –a patient-reported outcome (PRO) measure – that would require hospitals to submit additional data to CMS.

**In general, the AHA agrees that the use of a quality composite score is a reasonable approach to pay-for-performance in the context of these models. However, we urge a number of changes to the proposed measures and scoring methodology to improve the fairness of CMS's approach.** Specifically, CMS should:

- Assess all measures in the measure set for the impact of socioeconomic factors and incorporate adjustments if needed; and
- Attempt to better align the patient populations for its measures with their proposed cohorts.

**In addition, we remain concerned by the limitations of the quality measures available to CMS for these bundled payment models, and urge CMS to ensure its assessment of quality of care goes beyond applying a pay-for-performance approach to hospitals.**

*Sociodemographic Adjustment.* **The AHA strongly urges CMS to assess all of the measures proposed for the SHFFT model for the impact of sociodemographic factors on hospital performance, and to incorporate adjustments where needed.** To perform this assessment, CMS could consider using the National Quality Forum's (NQF) sociodemographic adjustment "trial period." As part of the trial period, NQF is asking for measure developers to conduct a conceptual and empirical analysis of the impact of sociodemographic status on measure performance when measures are submitted for NQF review.

The evidence continues to mount that sociodemographic factors beyond providers' control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food and other supportive services – influence performance on outcome measures. For example, in January 2016, the National Academy of Medicine (NAM) released the first in a planned series of reports that identifies "social risk factors" affecting the health outcomes of Medicare beneficiaries and methods to account for these factors in Medicare payment programs. Through a comprehensive review of available literature, the NAM's expert panel found evidence that a wide variety of social risk factors may influence performance on certain health care outcome measures, such as readmissions, costs and patient experience of care. These community issues are reflected in readily available proxy data on sociodemographic status, such as U.S. Census-derived data on income and education level, and claims-derived data on the proportion of patients dually eligible for Medicare and Medicaid. The agency also recently adopted a proposal to provide an "interim" adjustment for sociodemographic factors for several measures in the MA Star Rating program. Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for hospitals and other providers.

We are concerned that, without sociodemographic adjustment, providers caring for poorer and sicker patients would appear to perform worse on some outcome measures than others treating a

different patient population. Indeed, measures that fail to adjust for sociodemographic factors when there is a conceptual and empirical relationship between those factors and the measure outcome lack credibility, unfairly portray the performance of providers caring for more complex and challenging patient populations, and may serve to exacerbate health care disparities.

*The Limitations of Pay-for-Performance in a Bundled Payment Context.* The AHA strongly agrees that maintaining or improving the quality of care for patients must be a foundational policy goal for any alternative payment model. **However, we believe that there are multiple ways to evaluate whether this goal has been achieved in addition to tying a provider's payment to performance on quality measures.** In fact, the field as a whole is still learning which measures and measurement approaches are the most appropriate for evaluating care in a bundled payment context. Indeed, this is part of the reason why CMS's own BPCI program includes requirements for quality reporting, but has yet to tie performance on the measure to payment.

In spite of this lack of experience with pay-for-performance in a bundled payment context, CMS proposes to use IQR program measures in these bundled payment models. The AHA appreciates that CMS has attempted to minimize provider data collection burden by proposing measures that already are part of the hospital IQR program. Nevertheless, when applied to these models, the measures have significant drawbacks, detailed below, that limit their utility in assessing the quality of care delivered under the model.

**First, the AHA is concerned that the patient populations for the measures are poorly aligned with their proposed cohorts. We urge the agency to strive for better alignment when it reconsiders this program in the future.** For example, CMS proposes to use the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) performance of a hospital's entire patient population, and not just those patients in the SHFFT model. While this approach is necessary for ensuring adequate measure reliability, it means that much of a hospital's HCAHPS performance will have little to do with the patients in the model.

The clinical outcome measures suffer from a similar misalignment. Specifically, the SHFFT applies to *hip fracture* patients. Yet, the proposed complication measure applies only to *elective hip and knee replacement* patients. Thus, the measures provide limited insight on the quality of care provided to the patients that are actually included in the SHFFT model. **Without appropriate quality measures, we are concerned that this model focuses only on reducing cost for the SHFFT population.** Indeed, the statute requires CMMI models to reduce program expenditures while simultaneously preserving or enhancing the quality of care for those individuals who receive Medicare benefits. Absent the inclusion of quality measures that include the SHFFT population in a meaningful way, we are concerned that this model does not satisfy these requirements.

**In addition, the AHA is concerned by the significant time lag between the proposed data reporting periods and the actual performance years (PYs). Specifically, it will be difficult to draw meaningful conclusions about the quality of care delivered under the models based on data that significantly pre-date the start of the program.** CMS has attempted to reduce confusion by proposing to use the same three-year rolling time periods for calculating

readmissions and complications performance that are used in the hospital IQR program. Similarly, for HCAHPS, CMS would align the performance periods for this program with the reporting used in the hospital IQR program. However, as shown in Table 3 below, the reporting periods for the complications measure in PYs 1 through 3 would include a significant amount of data that pre-date the start of the model.

**Table 3: Proposed Measure Performance Periods**

| Measure | Year 1 (Jul – Dec 2017) | Year 2 (CY 2018) | Year 3 (CY 2019) | Year 4 (CY 2020) | Year 5 (CY 2021) |
|---|---|---|---|---|---|
| THA/TKA Complications | Apr. 1, 2014 – Mar. 31, 2017 | Apr. 1, 2015 – Mar. 31, 2018 | Apr. 1, 2016 – Mar. 31, 2019 | Apr. 1, 2017 – Mar. 31, 2020 | Apr. 1, 2018 – Mar. 31, 2021 |
| HCAHPS | Jul. 1, 2016 – Jun. 30, 2017 | Jul. 1, 2017 – Jun. 30, 2018 | Jul. 1, 2018 – Jun. 30, 2019 | Jul. 1, 2019 – Jun. 30, 2020 | Jul. 1, 2020 – Jun. 30, 2021 |
| Voluntary PRO Measure | Sep. 1, 2016 – Jun. 30, 2017 | Jul. 1, 2017 – Jun. 30, 2018 | Jul. 1, 2018 – Jun. 30, 2019 | Jul. 1, 2019 – Jun. 30, 2020 | Jul. 1, 2020 – Jun. 30, 2021 |

**In addition, the AHA is concerned that the performance periods for the complications measures overlap with the ICD-9 to ICD-10 transition. The AHA again urges CMS to continue working with hospitals, measure developers and all other stakeholders to address the potential unintended consequences of combining measure data collected under ICD-9 and ICD-10.**

ICD codes are integral to collecting and calculating quality measures in CMS's programs. For chart-abstracted measures, ICD codes allow hospitals to identify the patient population (i.e., the denominator) that is included or excluded from data collection. For claims-based measures, ICD codes are used to generate the initial patient population, to determine performance, and for risk adjustment. There are significant differences between ICD-9 and ICD-10 codes, and as a result, the agency is now re-specifying measures previously collected in ICD-9 so the specifications work in an ICD-10 environment.

**We strongly urge the agency to undertake an analysis of any performance differences resulting from the transition to ICD-10 for all of the measures used in its bundled payment models, as well as CMS's other hospital pay-for-performance programs. The results of those analyses should be made available publicly.** Such data would help inform the field about any potential unintended biases and measure performance changes resulting from the use of the new codes. The data also would provide insight on whether it is actually appropriate to mix data collected using ICD-9 with data collected using ICD-10.

**Finally, the real analysis of quality needed to assess the impact of CMS's novel approach to bundling must examine the "big picture" of the project's impact on both cost and quality.** The desired goal is to reduce cost while improving quality, or at least having no decline in quality. This analysis must look at the whole care of patients across the entire episode to see if

CMS's design and execution of the program is successful in achieving these overarching goals. CMS should focus this analysis on questions such as:

- What were the changes in critical aspects of quality for hip fracture patients?
- Did the providers (not just the hospital, but all providers of care along the continuum) in this experimental program outperform other providers nationally?
- Were there changes in the types of patients undergoing SHFFT?
- Were these changes medically appropriate?
- Were there changes in the nature or types of services provided to these patients?
- Did these changes have an impact on patient outcomes?

None of these critically important questions can be answered under the current proposals. Further, this analysis is really about the program as a whole, and not about the individual performance of any given hospital with regard to its portion of the program. The performance of any set of providers in providing care across the entire episode is important to understand, but the measures that are currently available in the hospital IQR program provide an incomplete picture at best.

Financial Arrangements and Beneficiary Incentives. As it did with the CJR program, CMS proposes to mandate hospitals into a model that essentially requires them to form financial relationships with other providers to be successful, but does not provide the necessary protections under the federal fraud and abuse laws that would enable them to do so without fear of running afoul of those laws. Instead, the proposed rule says that any financial arrangement or agreement under the SHFFT model that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor.

**Prior to issuance of a final rule, the AHA urges the Secretary to use the full scope of the combined authority granted by Congress under the Affordable Care Act (ACA) 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 SHFFT model. 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 model that comply with the requirements in the proposed rule.** The Secretary ultimately recognized the necessity of these waivers to the success of the CJR, issuing them in conjunction with the rule finalizing that program. We urge the same to occur for this proposed model. These waivers are essential to enable hospitals to form financial arrangements with other providers collaborating in the model, without which hospitals have no real ability to make sure those providers – for whose outcomes hospitals would be held accountable – have a real stake in achieving the model's goals.

**In addition, the AHA urges the Secretary to waive the beneficiary inducement Civil Monetary Penalty (CMP) for beneficiary incentives that comply with the requirements in the proposed rule.** In the proposed rule, CMS states that participant hospitals may want to provide in-kind patient engagement incentives to beneficiaries in model episodes. The agency proposes to allow participant hospitals to provide in-kind patient engagement incentives to

beneficiaries in model episodes for free or below fair market value, subject to certain conditions that are laid out in the proposed rule. However, CMS has not proposed to waive the CMP that prohibits beneficiary inducement.

Waiver of Medicare Program Rules. The waiver of certain Medicare program regulations is essential so that hospitals and health systems may coordinate care and ensure that it is provided in the right place at the right time. **We urge CMS to provide hospital participants with maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.** As such, we recommend that the agency consider additional waivers, outlined below, that would provide our members with valuable tools to increase quality and reduce unnecessary costs. They are commensurate with the level of risk and accountability that CMS is asking hospitals to assume as it shifts the burden of risk further away from the Medicare program onto providers. We also urge CMS to waive audits of post-acute care and other collaborators participating in a SHFFT or CJR episode since the episode-managing entity is financially accountable for the provision of those services.

*Hospital Discharge Planning Requirements.* **The AHA strongly urges CMS to waive hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services.** Such regulations inhibit the efficient coordination of care. When a patient elects to receive a bundle of services from a provider, that patient also is electing to receive a carefully prescribed course of treatment, which can span multiple provider settings. CMS proposes to hold participating hospitals financially accountable for quality and costs for the entire episode of care. The agency also must provide them with the flexibility to direct patients to the most clinically appropriate, high-quality next setting of care.

*Post-discharge Home Visits.* **The AHA supports CMS's proposal to waive the "incident to" rule, which would allow a SHFFT beneficiary to receive post-discharge visits in his or her home or place of residence any time during the episode.** CMS proposes to allow up to nine post-discharge home visits to be billed and paid during each SHFFT episode.

*Home Health (HH) Homebound Rule.* **The AHA urges CMS to waive the requirement that a beneficiary is "home-bound" in order to receive HH services.** CMS states that this requirement provides a way to help differentiate between patients who require medical care at home versus patients who could more appropriately receive care in a less costly outpatient setting. However, hospitals would not have an incentive to direct patients to HH when a less costly option, such as outpatient therapy, also would be clinically appropriate. In contrast, they may find good clinical rationale for utilizing HH services for non-homebound patients. In fact, CMS itself acknowledges in the rule that waiving the homebound requirement could result in lower episode spending in some instances, such as helping a non-homebound beneficiary avoid a hospital readmission. Again, CMS should allow physicians, working together with participating hospitals, to determine the most clinically appropriate plan for a patient's post-acute care, unimpeded by regulatory barriers.

*Telehealth Services.* **The AHA supports waiver of telehealth regulations, as proposed.** Specifically, the agency would waive the geographic site requirements that limit telehealth

payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of Dec. 31, 2000. In addition, CMS would waive the originating site requirements that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system, but only when telehealth services are being furnished in the CJR beneficiary's home or place of residence during the episode.

*IRF "60% Rule."* **We urge CMS to waive the IRF 60% Rule that requires that at least 60 percent of an IRF's patients have one of 13 clinical conditions.** The rule itself is designed to control the types of cases being treated at IRFs; however, hospital participants would have no incentive to over-utilize or inappropriately direct patients to IRFs. In contrast, they may find good clinical rationale for IRF stays for some patients, such as allowing beneficiaries to return to their communities more quickly. Further, as a matter of principle, since CMS proposes to hold participating hospitals financially accountable for the quality and costs of the entire episode of care, the agency also must provide them with the flexibility to direct patients to the most clinically appropriate next setting of care. In combination with our above request to allow IRFs to voluntarily elect to receive per-diem payments for their SHFFT patients, waiver of the 60% Rule would serve as a valuable tool for participants to increase quality and reduce unnecessary costs.

*IRF "Three-hour Rule."* Medicare has a long-standing requirement that IRF patients require and receive at least three hours of therapy a day, the "preponderance" of which must be provided one-on-one. **We urge CMS to waive the "preponderance" requirement under the SHFFT program.** Medicare has stated that, for IRFs, the "standard of care is individualized (i.e., one-on-one) therapy." However, each mode of therapy is carefully selected by the therapist based on the individual needs of the patient, and hospital participants have every incentive to work with IRFs to obtain the best possible treatment for their patients. And for many patients, such as those for whom medical improvement, restoration of functional independence and the achievement of patient education goals are advanced through the social interaction and motivation gained through the group dynamic, concurrent or group therapy are often preferred treatment methods. Allowing more flexibility on the type of therapy an IRF provides would serve as a valuable tool for participants to increase quality and reduce unnecessary costs.

## CARDIAC BUNDLED PAYMENT MODEL

CMS proposes a new payment model that would bundle payment to acute care hospitals for heart attack and cardiac bypass surgery services. Under this new cardiac model, the hospital in which the initial services are provided would be held accountable for the quality and costs of care for the entire episode of care, from the date of admission through 90 days post-discharge. The cardiac model would be mandatory for hospitals in 98 geographic areas across the country, although selection of the specific areas will not be made until the final rule. **The AHA agrees with the principles underlying this proposed model and believe that it could help further efforts to transform care delivery through improved care coordination and financial accountability.**

**However, CMS's proposal raises serious concerns for hospitals about the agency's pace of change, as well as its ability to accurately track and process the outcomes of its myriad increasingly complex alternative payment models. As such, we urge the agency to refrain from expanding mandatory bundled payment models to other geographic areas or conditions before there has been enough time to assess the lessons learned under the existing models.** For example, as we stated previously, the proposed cardiac bundle is the third mandatory demonstration project that CMS has issued in a little over a year; it was proposed less than four months after the existing CJR program began. This aggressive timeline is reflected in the fact that the programmatic details of this new cardiac model are almost exactly the same as the CJR. Because the programs come so closely on the heels of one another, CMS has been unable to garner, let alone apply, any lessons learned.

In addition, the complexity of the proposed model is substantial. For example, CMS proposes to set no fewer than 75 different target prices for different combinations of cardiac diagnoses and procedures – 63 for acute myocardial infarction (AMI) episodes and 12 for coronary artery bypass graph (CABG) episodes. It also proposes to run concurrent bundles in certain circumstances so that a beneficiary could, for example, be in both an AMI and a CJR episode at the same time. And, its rules to reconcile shared savings payments for beneficiaries that are simultaneously in a bundled payment and a shared savings model, such as an accountable care organization (ACO), have become increasingly complex as more and more of these models emerge.

**Although we appreciate that the agency has been and continues to be transparent regarding the design of these programs, their complexity has effectively rendered this transparency useless.** In other words, because hospitals have limited data and resources, they have little, if any, ability to independently verify CMS's episode attributions, target price and actual episode spending calculations, or reconciliation of the overlap between models. **We strongly urge the agency to proceed at a more deliberate pace, simplify the rule, and take more time to learn from existing programs before implementing additional ones. For example, we urge the agency to consider including only CABGs in the cardiac model to start.** As hospitals work through implementation and gain experience, the agency could then phase in the inclusion of the much more complicated AMI episodes. Specifically, AMI patients have a much wider range of care pathways that often involve transfers and/or planned readmissions. This is, in large part, due to the fact that these are typically emergent cases, not planned admissions.

**PARTICIPATION IN THE MODEL**

CMS proposes to require inpatient PPS hospitals in certain geographic regions to participate in the cardiac model as episode initiators. Specifically, it proposes that inpatient PPS hospitals physically located in one of 98 specific metropolitan statistical areas (MSAs) be included in the model. However, the agency would exclude Model 2 and 4 BPCI participants from participating in the cardiac model for episodes anchored by MS-DRGs for which it is participating in BPCI.

**The AHA supports CMS's proposal that hospitals serve as episode initiators.** We agree with the agency that utilizing the hospital as the episode initiator is a straightforward approach because the hospital furnishes the cardiac care. In addition, CMS notes that most spending in the episode is attributable to hospital inpatient services. Therefore, we believe that, notwithstanding our recommendations in this letter, hospitals would have sufficient capacity to bear the amount of risk included in this program. We also agree that it is important that all Medicare episodes that begin at a participant hospital be included in the model, except for certain exclusions, such as for beneficiaries who are enrolled in MA.

**However, we oppose CMS's proposal to consider the 67 MSAs already participating in the CJR model as also eligible to participate in the cardiac model.** We again remind CMS that hospitals and health systems have built care processes and policies around the current regulatory payment structures, and these systems must be changed if they are to achieve success in the CJR program. This is no small task. While some hospitals have already taken significant steps toward achieving such alignment, others are not as far down this path. They simply cannot afford to now be required to implement another model. To do so would cause confusion, frustration and diversion of scarce resources, ultimately putting at risk the success that these hospitals – and CMS – will find in either program.

Finally, CMS's proposed use of MSAs, rather than the more commonly used core-based statistical areas (CBSAs), taken together with the fact that only certain BPCI hospitals would be excluded from the program, may create confusion about which individual hospitals would actually be required to participate. **Therefore, in addition to stating its criteria for inclusion as well as the chosen MSAs in the final rule, we urge CMS to publish a list of the actual hospitals that it believes would be required to participate in the program.** We request that hospitals be given 60 days following publication of said list to comment to CMS on its accuracy.

**EPISODE OF CARE**

CMS proposes to test the cardiac model for four-and-a-half years, beginning July 1, 2017 and ending Dec. 31, 2021. An episode would begin with a beneficiary's admission to an inpatient PPS hospital for either an AMI[5] or a CABG.[6] Episodes would end 90 days after discharge from the hospital.

Introduction of Downside Risk. **We are concerned that the proposed downside risk implementation date of April 1, 2018, does not provide enough time for hospitals to implement the processes and procedures necessary to achieve success in the program.** We appreciate that CMS does not require hospitals to take on downside risk in the first year of the program. However, as noted above, because of the way that episodes are defined, hospitals would actually have only six months before episodes that will incur downside begin.

[5] AMI episodes would be initiated for patients with admissions for MS-DRGs 280, 281, or 282 (Acute Myocardial Infarction, Discharged Alive), or MS-DRGs 246 - 251 (Percutaneous Cardiovascular Procedure) with an AMI International Classification of Diseases (ICD)-Clinical Modification (CM) diagnosis code in the principal or secondary diagnosis code position.
[6] CABG episodes would be initiated for patients with admissions for MS-DRGs 231 - 236.

Specifically, CMS proposes to start the cardiac model July 1, 2017; downside risk would begin for episodes *ending* April 1, 2018 and later. However, episodes that end April 1, 2018 would have begun over 90 days earlier, or prior to Jan. 1, 2018. Therefore, hospitals actually only have from July 1, 2017 until about Jan. 1, 2018 before episodes that will incur downside begin.

Six months is not an adequate timeframe in which to begin managing episodes that will be subject to downside risk. In addition to the concerns we have about the lack of data available in these first months (as described above in the SHFFT section above), hospitals would need to:

- Educate staff and physicians on the cardiac program;
- Analyze claims data to understand episode spending;
- Build relationships with physicians and post-acute care providers;
- Negotiate and execute cardiac sharing arrangements with physicians and post-acute care providers;
- Develop and implement use of documents to meet CMS's proposed beneficiary notification requirements;
- Create protocols to identify cardiac patients upon admission;
- Create protocols to determine if potential cardiac patients meet all of CMS's inclusion criteria (e.g., ensure they are not eligible for Medicare on the basis of end-stage renal disease);
- Create protocols to identify cancelled episodes (e.g., if a cardiac patient falls under a non-hospital BPCI initiator);
- Create protocols to ensure notification materials are shared with appropriate beneficiaries;
- Examine and modify discharge planning protocols;
- Create a system to meet the proposed requirement to provide beneficiaries with a complete list of all post-acute care options in the service area, including cost-sharing and quality information; and
- Create systems to track and monitor beneficiaries throughout the episode.

Hospitals want and need to be afforded the opportunity to take full advantage of the transition to downside risk, especially given that many have very limited experience doing so. **Therefore, we urge CMS to delay downside risk until Oct. 1, 2018, which would provide hospitals with a full year before episodes that will incur downside begin.**

Included and Excluded Services. **As noted above, we continue to urge CMS to conduct additional research on the list of services to be excluded from the bundles, including for post-acute care following an excluded readmission.** Holding participating hospitals accountable for all patient pathways is unreasonable given how little is known about the causal relationship between the hospital readmission and subsequent post-acute care services.

Transfers. Hospital-to-hospital transfers are common for beneficiaries being treated for cardiac conditions. As such, CMS proposes an overarching policy in which episodes involving a transfer, also called a "chained anchor stay," would be attributed to the first participant hospital to which the beneficiary is admitted. However, if the patient's discharge MS-DRG from the receiving

hospital is not one of the eligible cardiac model MS-DRGs, the episode would be cancelled. **The AHA supports this proposal to cancel episodes that include a chained anchor stay, but have a final discharge MS-DRG that is ineligible for the cardiac model.** We found that a minority of episodes fall into this category, but their spending is very high. For example, episode spending for patients discharged from the initial hospital for MS-DRG 231, but discharged from the receiving hospital for an ineligible MS-DRG, was 104 percent higher than for chained anchor stay patients ultimately assigned an MS-DRG 231 episode. The same trend also was found with the other 14 cardiac MS-DRGs – while the exact percentage varied, spending for chained episodes resulting in an ineligible final MS-DRG was between 27 percent and 138 percent higher than other chained episodes. We believe these data clearly demonstrate that these episodes are atypical.

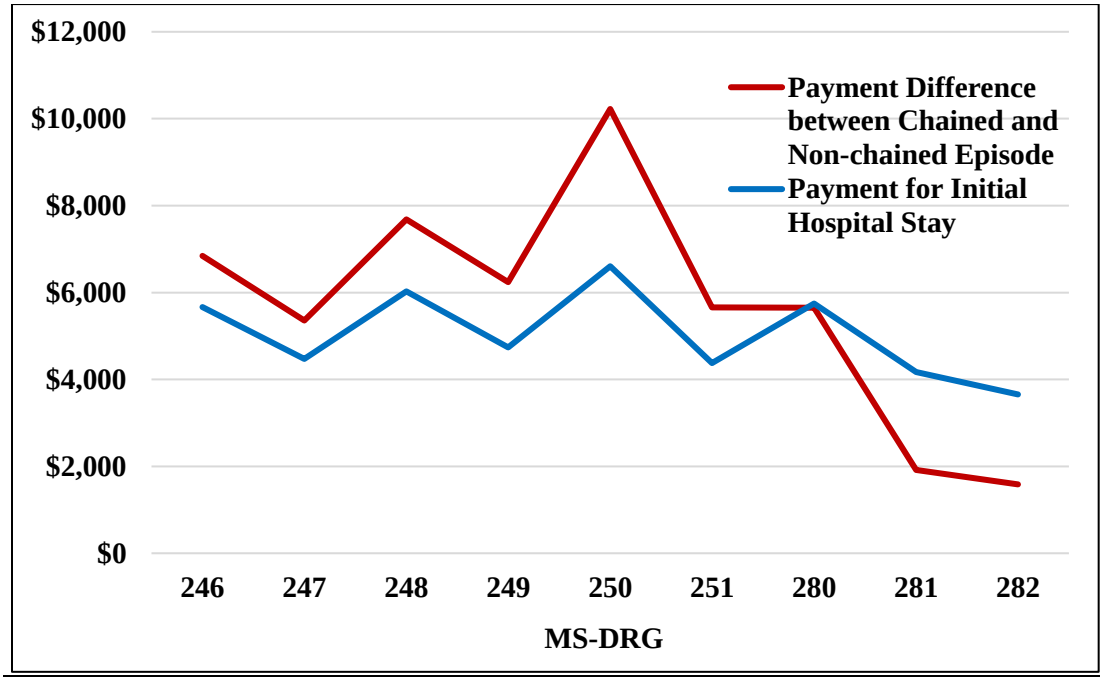
In addition to proposing to attribute chained anchor stay episodes to the first participant hospital to which the beneficiary is admitted, CMS also proposes a framework that would govern the type of episode assigned when a transfer is involved. Generally, the highest weighted AMI or CABG MS-DRG from either participant hospital would determine the episode type. **However, we are concerned that this policy does not go far enough to provide a level playing field for episodes involving a chained anchor stay.** Specifically, the use of a regional spending component will increasingly hold all hospitals in a region to the same target price, despite the fact that they have differing levels of clinical capability, and, therefore, differing rates of more costly transfer episodes. **As is shown in Table 4 below, the lack of a more robust transfer-adjustment methodology penalizes smaller community hospitals that do not have the most sophisticated cardiac care available.** Specifically, our analysis found that hospitals that transfer frequently are more likely to be smaller community hospitals. In conducting this analysis, we divided eligible hospitals in the 294 eligible MSAs into quintiles based on the percent of their episodes that included a transfer. We found that hospitals in the highest quintiles had a lower number of AMI episodes and were much more likely to have less than 100 beds and be a non-teaching hospitals. They also had much higher episode spending relative to their target price than other hospitals, which demonstrates the disadvantage they are put at by CMS's proposed transfer policy. The same trend was found for CABG episodes. These small community hospitals often have no choice but to transfer their most complicated patients to larger, tertiary hospitals so that they can receive the most appropriate cardiac care – they should not be penalized for doing so.

**Table 4: Distribution of Hospital Characteristics for AMI Episodes, by Quintile of Percent of Episodes Including a Transfer**

| | Hospitals | Episodes per Hospital | Percent of Episodes Including Transfer | Percent < 100 Beds | Percent Non-teaching | Average Spending per Episode | Average Regional Target Price | Percent Difference between Target and Spending |
|---|---|---|---|---|---|---|---|---|
| Highest Transfer Quintile | 394 | 63 | 32.2% | 46.2% | 73.4% | $27,911 | $25,095 | -11.2% |
| 2nd Quintile | 393 | 117 | 14.7 | 28.8 | 70.5 | 26,833 | 24,730 | -8.5 |
| 3rd Quintile | 393 | 219 | 3.2 | 7.6 | 56.5 | 25,007 | 23,868 | -4.8 |
| 4th Quintile | 393 | 411 | 0.4 | 2.5 | 40.2 | 23,671 | 23,460 | -0.9 |
| Lowest Transfer Quintile | 393 | 253 | 0.0 | 10.9 | 35.9 | 23,593 | 23,100 | -2.1 |
| Total | 1,966 | 213 | 4.4 | 19.2 | 55.3 | 24,529 | 23,695 | -3.5 |

As shown in Figure 3 below, we found that AMI model spending for episodes without a CABG readmission, but with a transfer, averaged almost $6,000 more than episodes of the same type without a transfer. We also found that this payment differential largely reflected the amount paid for the initial hospital stay. These trends also occurred with CABG episodes. **Therefore, in order to avoid inappropriately penalizing hospitals for transferring patients, we recommend that CMS exclude the amount paid to the initially admitting hospital when calculating target prices *and* actual episode spending.** We believe that doing so would help put all hospitals on a more level playing field and encourage the best provision of care.

**Figure 3: Difference in Payment between Chained and Non-chained AMI Episodes, and Payment for Initial Hospital Stay, by MS-DRG**




Lastly, we note that the framework CMS has proposed for chained anchor stays is quite complex, and as a result, there has been confusion in the field about some of its details. As such, it would be very useful for the agency to provide additional explanation in the final rule, perhaps through several illustrative examples, about how the methodology works.

Cancelled Episodes. CMS proposes to cancel a cardiac episode for several reasons, including when the beneficiary dies during the anchor hospitalization. **For the same reasons as articulated above regarding SHFFT episodes, we urge CMS to cancel all cardiac episodes in which the beneficiary dies – either during the anchor hospitalization or during the 90 days post discharge.** We found that a small number of patients die during the 90 days after discharge, but their episode spending is very high. Specifically, spending for the 2 percent of CABG episode patients who died during the 90 days post-discharge was between 12 and 32 percent higher than the average for each of the six CABG MS-DRGs. This same trend occurred for AMI episodes. We believe this is due to these patients receiving extensive care near the end-of-life and clearly demonstrates that these episodes are atypical. In addition, we note that CMS proposes to tie each hospital's level of reconciliation payment or repayment to a composite quality score, which includes measures of both AMI and CABG mortality. We believe that doing so is a more effective tool to incentivize hospitals to target beneficiary mortality "for

improvement through care redesign," as CMS states is the goal of this proposed cancellation policy.[7]

In addition, CMS proposes that if a beneficiary is in a SHFFT, AMI, CABG or CJR episode and has a hospital readmission that *is not* excluded from the episode definition and would otherwise initiate a SHFFT, AMI, CABG or CJR episode, that hospital readmission *would not* initiate another episode or cancel the ongoing episode. Instead, it would be included in the ongoing episode. We support this proposal.

However, if a beneficiary is in a SHFFT, AMI, CABG or CJR episode and has a hospital readmission that *is* excluded from the ongoing episode definition and could otherwise initiate a SHFFT, AMI, CABG or CJR episode, CMS proposes that the hospital readmission *would* initiate another episode, which would occur concurrently with the original episode. **The AHA opposes this proposal to allow concurrent episodes.** Although the agency provides several examples of how it would handle episodes when a readmission *is not* excluded (per the above paragraph), it does not provide any examples of how it would handle episodes when a readmission *is* excluded. We are concerned that concurrent episodes would be burdensome and overly complicated for hospitals to manage, especially given that there could be two different hospital episode initiators. In addition, CMS provided a paucity of details about how it would handle concurrent episodes. For example, the agency does not state whether or how it intends to attribute services provided during concurrent episodes to one episode or the other, or whether it intends to attribute all services to both episodes. **Instead, we recommend that the agency build upon the policy that it implemented for the CJR program.** Specifically, if a beneficiary is in a SHFFT, AMI, CABG or CJR episode and has a hospital readmission that *is* excluded from the ongoing episode definition and could otherwise initiate a SHFFT, AMI, CABG or CJR episode, the first episode should be cancelled and the readmission should initiate a new episode.

**RETROSPECTIVE PAYMENT METHODOLOGY**

As with the SHFFT and CJR models, CMS proposes to implement a retrospective payment methodology. **The AHA supports this proposal for the same reasons as articulated above regarding the proposed SHFFT model.**

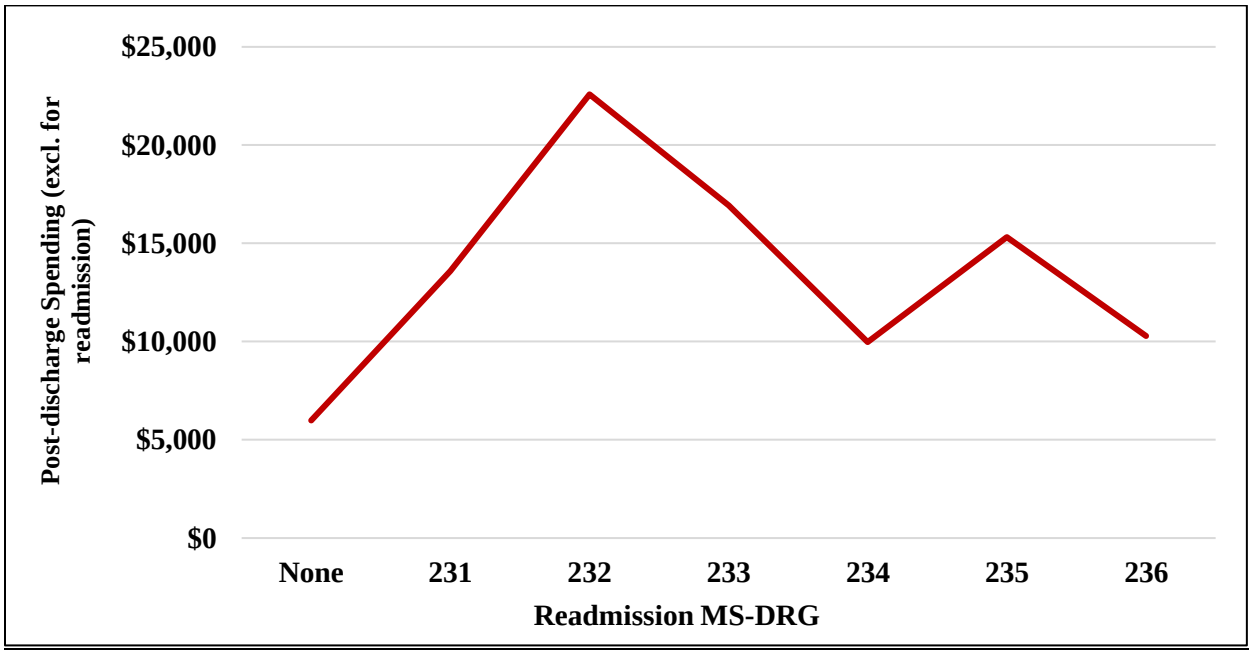
Calculating the Target Price. In calculating the target price, CMS proposes to blend together hospital-specific and regional historical episode payments, transitioning from primarily hospital-specific to completely regional pricing over the course of the five performance years. **The AHA appreciates that this policy would help ensure that a hospital does not have to compete against its own best 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. 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 for any providers without putting quality of care at risk.

[7] 81 *Federal Register* 50841

**Therefore, we urge the agency to instead use the higher of national or regional historical episode payments in calculating the target price.** Doing so would help ensure that appropriate incentives are provided to participants in both high- and low-spending areas.

In addition, as noted above, CMS proposes to set 75 separate target prices for cardiac model episodes, depending on the MS-DRG, other diagnoses and whether or not a beneficiary was readmitted for a CABG. This complexity has made it very difficult for us to evaluate the agency's proposals, but we have identified a concern specific to the agency's methodology for setting target prices for AMI model episodes with a CABG readmission. To set these prices, the agency would sum the target price for the applicable AMI MS-DRG episode without readmission for a CABG with the anchor hospitalization portion of the target price for the applicable CABG MS-DRG episode. **We are concerned that this methodology does not account for the increased post-acute care that a beneficiary typically receives after a CABG, but which they would not receive after only an AMI.** Therefore, we calculated the post-discharge spending (excluding spending for the CABG readmission itself) for AMI episodes by their CABG readmission DRG. As is shown in Figure 4 below, post-discharge spending for MS-DRG 247 episodes with a CABG readmission was substantially higher than for MS-DRG 247 episodes without a CABG readmission. For example, post-discharge spending for MS-DRG 247 episodes with a CABG readmission for MS-DRG 232 was 277 percent higher than for episodes without a CABG readmission. Post-discharge spending for MS-DRG 247 episodes with a CABG readmission for MS-DRG 234 was 67 percent higher than for episodes without a CABG readmission. This trend also applied to AMI episodes for other MS-DRGs.

**Figure 4: Post-discharge Spending (Excluding for Readmission) for MS-DRG 247 Episodes, by Readmission MS-DRG**



As a result, AMI episodes with a CABG readmission would look much more costly compared to their target price. For example, when we applied a 3 percent discount factor to calculate target prices, AMI episodes without a CABG readmission had actual spending that was about 3 percent higher than the target price. However, AMI episodes with a CABG readmission had actual spending that was much higher relative to the target price. For example, MS-DRG 247 episodes with a CABG readmission were between 8 and 20 percent higher than the target price, depending on the specific readmission MS-DRG. **We are concerned that this unfairly penalizes hospitals for episodes when a patient requires a readmission for a CABG. Therefore, we urge the agency to modify its methodology so that it accounts for the increased post-acute care that a beneficiary typically receives after a CABG, but which they would not receive after only an AMI.**

In addition, we recommend that CMS provide for exemptions for natural disasters and other emergency situations that might affect the utilization of health care resources or hospital operations in a region, as the agency does for other programs. Such exemptions also should include mechanisms to adjust target prices and quality measures to account for disaster-related health care needs.

Finally, CMS states that it intends to calculate and communicate target prices to hospitals prior to the time period to which they apply, although it does not state how far in advance it intends to do so. We fully support this proposal, as knowing the target price prior to the relevant performance period is essential for participants to be able to implement efficient care redesigns linked explicitly to established payment rates. **However, we urge the agency to convey this information at least 60 days prior to the start of the relevant performance period.** Moreover, a number of hospitals participating in the BPCI and Pioneer ACO models have indicated that the target prices for these programs have often changed during the performance period, sometimes significantly and inexplicably. **To further stabilize the target prices for model participants, we urge CMS only to update its underlying assumptions related to the target price annually, and to do so through notice-and-comment rulemaking.**

Risk Adjustment. **We urge CMS to apply a full risk-adjustment methodology to AMI and CABG episodes. We believe that such an approach would be not only at least as good as CMS's proposed approach, but also, importantly, much simpler and easier to understand.** Specifically, as noted above, CMS proposes to set no fewer than 75 different target prices for different combinations of cardiac diagnoses and procedures. It proposes to classify episodes according to their "price" MS-DRG, which may or may not be the same as the "anchor" MS-DRG. It proposes separate methodologies for calculating spending for AMI episodes with a CABG readmission, for any episode with a transfer, and for CABG episodes with an AMI diagnosis. **As a result of this astounding complexity, even the trained cardiologists with whom we have spoken have had difficulties commenting on whether CMS's proposals are clinically appropriate.** This is deeply concerning.

As we stated previously, the use of a regional spending component will hold all hospitals in a region to the same target price, despite the fact that they treat patient populations with differing levels of severity and, therefore, differing episode costs. **This lack of a robust risk-adjustment**

**methodology penalizes hospitals treating the sickest, most complicated and most vulnerable patients.**

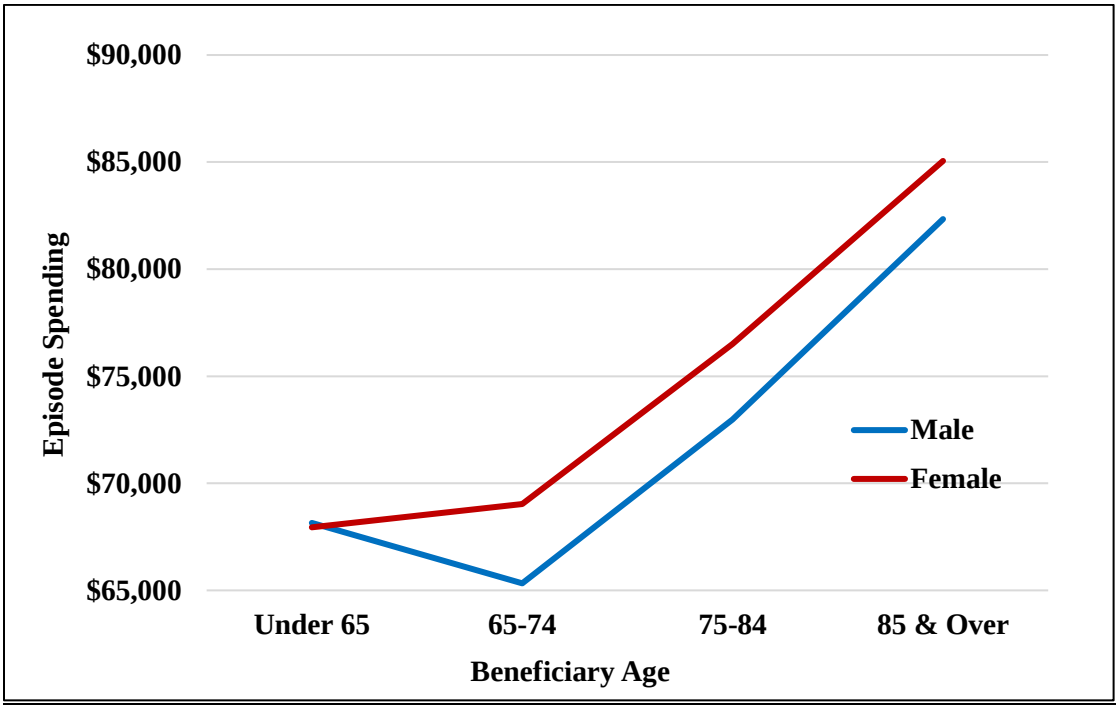
Table 5 below demonstrates that relying upon CMS's 63 AMI target price stratifications as the program's only risk adjustment does not fully account for numerous factors that affect spending and that are beyond hospitals' control. Specifically, our analysis found that hospitals with higher episode spending have a very different risk profile. In conducting this analysis, we divided eligible hospitals in the 294 eligible MSAs into quintiles based on the difference between their regional target price and their payments per episode for AMI. We then looked at their AMI episodes by different risk factors. We found that hospitals in the highest quintiles had a lower number of AMI episodes and a higher percentage of emergency or trauma AMI episodes, patients at least 85 years old, and patients that were dually-eligible for Medicare and Medicaid. In fact, all but one of these factors increased/decreased linearly by quintile. The same trend was found for CABG episodes

**Table 5: Distribution of Risk Factors for AMI Episodes, by Quintile of Percent by Which Hospital was Above or Below Regional Target Price**

| | Hospitals | Episodes per Hospital | Percent Emergency or Trauma Episodes | Percent Patients 85+ | Percent Patients Dually Eligible | Average Spending per Episode | Average Regional Target Price | Percent Difference between Target and Spending |
|---|---|---|---|---|---|---|---|---|
| Highest Spending Quintile | 393 | 91 | 84.0% | 32.1% | 33.4% | $29,460 | $24,407 | -20.7% |
| 2nd Quintile | 393 | 177 | 83.1 | 28.7 | 24.1 | 26,633 | 24,158 | -10.2 |
| 3rd Quintile | 393 | 247 | 76.5 | 27.0 | 20.4 | 24,724 | 23,563 | -4.9 |
| 4th Quintile | 393 | 302.5 | 74.2 | 24.2 | 20.1 | 23,591 | 23,525 | -0.3 |
| Lowest Spending Quintile | 394 | 245.8 | 64.7 | 23.3 | 19.3 | 22,153 | 23,442 | 5.5 |
| Total | 1,966 | 213 | 74.9 | 26.1 | 21.8 | 24,529 | 23,695 | -3.5 |

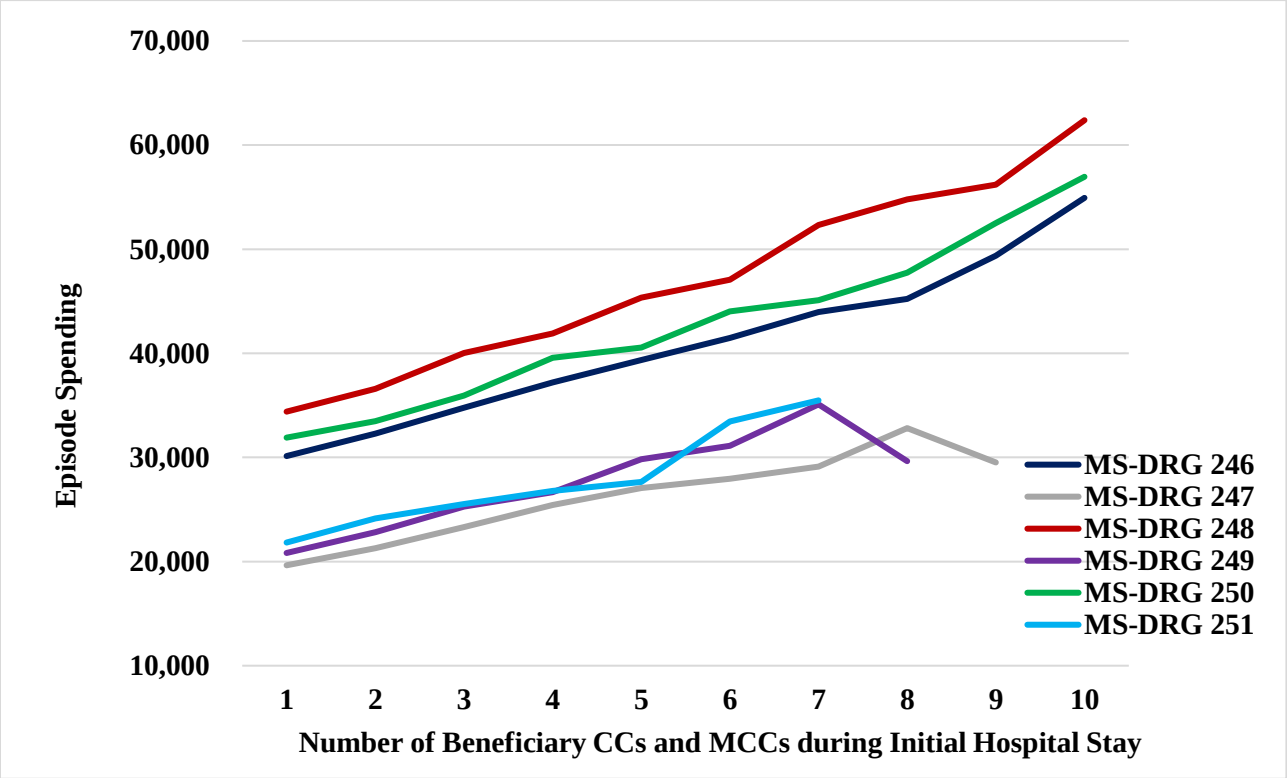
We conducted more detailed analyses of certain patient factors and their effect on episode spending – they further support the need for a risk-adjustment methodology in the cardiac model. Specifically, our findings confirm that substantial variation in episode payments exist within each target price category, not just between the target price categories. First, we found that spending per episode increases almost linearly by beneficiary age. As shown in Figure 5, CABG model spending for MS-DRG 231 episodes without an AMI diagnosis was 21 percent higher for male beneficiaries age 85 and older than for male beneficiaries under 65 years of age. CABG model spending for MS-DRG 231 episodes without an AMI diagnosis was 25 percent higher for female beneficiaries age 85 and older than for female beneficiaries under 65 years of age. The same trend occurs with the other CABG MS-DRGs.

**Figure 5: CABG Model Spending for MS-DRG 231 Episodes without AMI Diagnosis, by Age and Sex**




In addition, as shown in Figure 6, we found that AMI model spending for MS-DRG 246 – 251 episodes without a CABG readmission increases almost linearly by the number of beneficiary CCs and MCCs. For example, model spending for MS-DRG 246 episodes without a CABG readmission was 82 percent higher for beneficiaries with 10 comorbidities than for beneficiaries with only one comorbidity. In addition, model spending for MS-DRG 248 episodes without a CABG readmission was 81 percent higher for beneficiaries with 10 comorbidities than for beneficiaries with only one comorbidity. The same trend applies to the other AMI MS-DRGs as well.

**Figure 6: AMI Model Spending (Episodes Without CABG Readmission), by Number of Beneficiary CCs and MCCs**




Discount Factor. CMS proposes to vary hospitals' discount factors depending on their quality performance. Specifically, in order to determine reconciliation and repayments, CMS would set a target price equal to a hospital's hospital-specific and regional blended historical payments minus a percent discount that would vary depending on its quality score (see Table 6 below). Hospitals would not be subject to repayments in year one or the first quarter of year two of the program, but in the second through fourth quarters of year two and in years three through five, they would bear risk for spending above this percent discount.

**Table 6: Proposed Discount by Performance Year**

| | | Repayment Discount | | |
|---|---|---|---|---|
| **Quality Score** | **Reconciliation Discount** | **Year 1 and Q1 of Year 2** | **Q2-4 of Year 2 and Year 3** | **Years 4 & 5** |
| Below acceptable | N/a | N/a | 2.0% | 3.0% |
| Acceptable | 3.0% | N/a | 2.0% | 3.0% |
| Good | 2.0% | N/a | 1.0% | 2.0% |
| Excellent | 1.5% | N/a | 0.5% | 1.5% |

**We urge CMS to reduce its proposed discount by a percentage point.** The discount factors shown above for the cardiac model are the same as those CMS uses in the CJR program. However, the opportunity to achieve savings under the cardiac model is *not* the same as in the CJR program – it is much less. Specifically, about half of CJR episode spending is attributable to the initial hospitalization. However, CMS notes that about three-quarters of CABG episode spending is attributable to the initial hospitalization. This is problematic because there is virtually no opportunity to achieve efficiencies within the inpatient hospital payment amount – it is a predetermined per-discharge payment based primarily on the patient's condition, not on services provided. And, there is obviously no opportunity to achieve efficiencies by eliminating it because then no episode would be initiated.

In addition, for CABGs, of the 25 percent of episode spending that occurs outside the initial hospitalization, about 5 percentage points is attributable to readmissions. For AMIs, of the 50 percent of episode spending that occurs outside the initial hospitalization, about 17 percentage points is attributable to readmissions. We are similarly concerned that hospitals have a limited ability to achieve efficiencies in this area. Specifically, hospitals have done an enormous amount of work over the past decade to drive down cardiac readmissions. As a result, most that occur today are clinically appropriate and necessary – they are not readmissions that should be eliminated. The work hospitals have done has been spurred by, among other things, their public reporting of cardiac readmissions quality measures since 2009. In addition, AMI and congestive heart failure readmissions measures have been included in the Hospital Readmissions Reduction Program (HRRP) since its inception on Oct. 1, 2012, four years ago.

In fact, CMS itself recently touted the fact that, partly as a result of the HRRP, hospitals in 49 states and the District of Columbia have cut hospital readmission rates for Medicare enrollees since 2010, with hospitals in nearly a dozen states cutting readmission rates by more than 10 percent. Researchers recently published similar findings, determining that readmissions rates for AMI, heart failure and pneumonia were decreasing before the ACA created the HRRP, fell even more rapidly after passage of the ACA, and have continued since.[8] They also cite other CMS efforts that have aided hospitals in reducing readmissions, such as the Hospital Engagement Networks, established in 2011, that work to identify and disseminate best practices, including on reducing readmissions. In addition, the researchers note that at the passage of the ACA, readmission rates fell for conditions targeted by the law and as well as those not targeted by the law, which implies that changes in care in response to the HRRP may have had an effect beyond the targeted conditions.

As such, we are concerned that it would be difficult for hospitals to reasonably meet or exceed the proposed discount factors by achieving efficiencies in the very limited 20 and 33 percent of spending that occurs outside the initial hospitalization and readmissions for CABG and AMI episodes, respectively. This is especially true over time, as target prices decline further and further. To avoid turning this cardiac model into a thinly disguised payment cut, CMS must

[8] Zuckerman RB, Sheingold SH, Orav EJ, Ruhter J, Epstein AM. Readmissions, Observation, and the Hospital Readmissions Reduction Program. N Engl J Med 2016; 374: 1543-51.

provide hospitals with a fair opportunity to achieve enough savings to garner a reconciliation payment.

Additional Proposals to Limit Repayment Responsibility for Certain Hospitals. CMS proposes additional protections for certain groups of hospitals that may have a lower risk tolerance and less infrastructure and support to achieve efficiencies for high-payment episodes. Specifically, for sole community hospitals, Medicare-dependent hospitals, rural referral centers and certain other rural hospitals, CMS proposes a stop-loss limit of 3 percent of episode payments in year two and a stop-loss limit of five percent for years three through five for these hospitals.

**The AHA supports the application of these additional protections. However, similar to our comments on the SHFFT model above, we urge CMS to extend the same additional protections to hospitals that perform a low volume of episodes, less than 37 for AMI and less than 24 for CABG, each year, since they also would lack the infrastructure and support to achieve efficiencies.** Our regression analyses revealed that volume is an important determinant of per-episode spending. To determine how "low volume" should be defined, we analyzed the average loss per episode (i.e., spending in excess of the regional target price). We found that the average loss is largest for hospitals with the smallest number of episodes, as depicted in Table 7 and 8.

**Table 7: Gain/Loss Values Per AMI Episode for Hospitals, Before Application of Proposed Stop-loss and Stop-gain Limits, FY 2012 – 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 196 | 7.8 | 1 | 16 | -$3,436 | -$41,719 | $16,931 | $58,650 |
| 2 | 197 | 27.6 | 16 | 41 | -2,695 | -19.030 | 6,472 | 25,502 |
| 3 | 196 | 58 | 42 | 77 | -3,204 | -17,646 | 4,297 | 21,943 |
| 4 | 197 | 93.9 | 77 | 113 | -2,095 | -11,392 | 3,668 | 15,061 |
| 5 | 197 | 133 | 113 | 157 | -1,368 | -6,370 | 3,104 | 9,474 |
| 6 | 196 | 179.6 | 157 | 205 | -1,286 | -9,876 | 2,907 | 12,784 |
| 7 | 197 | 234.3 | 205 | 266 | -1,297 | -10,973 | 3,497 | 14,470 |
| 8 | 196 | 300.8 | 267 | 343 | -827 | -7,536 | 2,551 | 10,087 |
| 9 | 197 | 410.3 | 343 | 490 | -503 | -5,455 | 3,751 | 9,206 |
| 10 | 197 | 679 | 491 | 1,571 | -204 | -5,950 | 3,074 | 9,024 |

**Table 8: Gain/Loss Values Per CABG Episode for Hospitals, Before Application of Proposed Stop-loss and Stop-gain Limits, FY 2012 – 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 99 | 12.8 | 1 | 25 | -$3,886 | -$31,779 | $6,979 | $38,758 |
| 2 | 99 | 33.2 | 25 | 41 | -2,138 | -21,010 | 8,083 | 29,093 |
| 3 | 100 | 50 | 41 | 57 | -3,164 | -12,862 | 5,068 | 17,930 |
| 4 | 99 | 63.8 | 57 | 72 | -2,531 | -15,404 | 3,447 | 18,852 |
| 5 | 100 | 81.4 | 72 | 91 | -1,358 | -9,033 | 8,934 | 17,967 |
| 6 | 99 | 104.1 | 91 | 119 | -1,544 | -8,023 | 6,189 | 14,212 |
| 7 | 99 | 133.8 | 119 | 149 | -1,735 | -11,162 | 5,959 | 17,120 |
| 8 | 100 | 164.5 | 149 | 183 | -1,461 | -9,225 | 3,522 | 12,748 |
| 9 | 99 | 215 | 183 | 258 | -1,285 | -8,708 | 4,970 | 13,678 |
| 10 | 100 | 363.9 | 259 | 799 | -539 | -5,908 | 4,669 | 10,576 |

In addition, we found that hospitals with the smallest number of episodes had the widest range of gain and loss values both before and after applying the stop-loss and stop-gain limits proposed by CMS, as shown in Table 7 and 8 above, as well as Table 9 and 10 below. We also found that hospitals with the lowest episode volumes had the largest year-over-year variation in episode spending relative to target prices. High average losses coupled with high variation in annual episode spending tended to be found in hospitals with less than 113 AMI episodes over a 12-quarter period (Oct. 2011 – Sept. 2014), which would equate to 37 episodes per year. High average losses coupled with high variation in annual episode spending tended to be found in hospitals with less than 72 CABG episodes over a 12-quarter period (Oct. 2011 – Sept. 2014), which would equate to 24 episodes per year.

**Table 9: Gain/Loss Values Per AMI Episode for Hospitals, After Application of Proposed Stop-loss and Stop-gain Limits, FY 2012 – 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 196 | 7.8 | 1 | 16 | -$1,381 | -$14,478 | $6,846 | $21,325 |
| 2 | 197 | 27.6 | 16 | 41 | -1,891 | -5,488 | 5,234 | 10,722 |
| 3 | 196 | 58 | 42 | 77 | -2,382 | -5,757 | 4,297 | 10,054 |
| 4 | 197 | 93.9 | 77 | 113 | -1,881 | -5,517 | 3,668 | 9,186 |
| 5 | 197 | 133 | 113 | 157 | -1,343 | -5,158 | 3,104 | 8,262 |
| 6 | 196 | 179.6 | 157 | 205 | -1,189 | -5,307 | 2,907 | 8,214 |
| 7 | 197 | 234.3 | 205 | 266 | -1,219 | -5,079 | 3,497 | 8,576 |
| 8 | 196 | 300.8 | 267 | 343 | -786 | -4,977 | 2,551 | 7,528 |
| 9 | 197 | 410.3 | 343 | 490 | -485 | -5,455 | 3,751 | 9,206 |
| 10 | 197 | 679 | 491 | 1,571 | -189 | -4,759 | 3,074 | 7,833 |

**Table 10: Gain/Loss Values Per CABG Episode for Hospitals, After Application of Proposed Stop-loss and Stop-gain Limits, FY 2012 – 2014**

| | | | | | Gain/Loss Per Episode | | | |
|---|---|---|---|---|---|---|---|---|
| **Decile by Episode Volume** | **No. of Hospitals** | **Avg. No. Episodes** | **Min No. Episodes** | **Max. No. Episodes** | **Avg** | **Min** | **Max** | **Range** |
| 1 | 99 | 12.8 | 1 | 25 | -$3,034 | -$11,747 | $6,979 | $18,726 |
| 2 | 99 | 33.2 | 25 | 41 | -1,969 | -10,487 | 8,083 | 18,570 |
| 3 | 100 | 50 | 41 | 57 | -3,016 | -11,127 | 5,068 | 16,195 |
| 4 | 99 | 63.8 | 57 | 72 | -2,256 | -10,146 | 3,447 | 13,593 |
| 5 | 100 | 81.4 | 72 | 91 | -1,291 | -9,033 | 8,934 | 17,967 |
| 6 | 99 | 104.1 | 91 | 119 | -1,504 | -8,023 | 6,189 | 14,212 |
| 7 | 99 | 133.8 | 119 | 149 | -1,554 | -9,216 | 5,959 | 15,175 |
| 8 | 100 | 164.5 | 149 | 183 | -1,377 | -8,273 | 3,522 | 11,795 |
| 9 | 99 | 215 | 183 | 258 | -1,248 | -8,708 | 4,970 | 13,678 |
| 10 | 100 | 363.9 | 259 | 799 | -531 | -5,908 | 4,669 | 10,576 |

## USE OF QUALITY MEASURES IN PAYMENT DETERMINATION

CMS proposes to use a pay-for-performance approach for the cardiac model that is nearly identical to the one it finalized for the CJR program. That is, CMS would tie each hospital's level of reconciliation payment or repayment responsibility to a composite quality score. CMS proposes measures specific to both AMI and CABG, most of which already are reported in the hospital IQR program. However, CMS also proposes a voluntary measure – the hybrid AMI mortality measure – that would require hospitals to submit additional data to CMS.

**As with the SHFFT model, the AHA generally agrees that the use of a quality composite score is a reasonable approach to pay-for-performance in the context of these models. However, we urge a number of changes to the proposed measures and scoring methodology to improve the fairness of CMS's approach.** Specifically, CMS should:

- Remove its proposed excess days in acute care (EDAC) measure from the AMI model measure set;
- Adopt a flexible reporting approach to the proposed voluntary AMI mortality measure;
- Use the CJR model's approach to calculating improvement points; and
- Assess all measures for the impact of socioeconomic factors and incorporate adjustments if needed

**In addition, we remain concerned by the limitations of the quality measures available to CMS for these bundled payment models, as described further below.**

EDAC Measure Proposal. **The AHA urges CMS to remove its proposed EDAC measure from the AMI model measure set.** The proposed EDAC measure was adopted for the FY 2018 hospital IQR program, and is intended to capture "all-cause acute care utilization" in the 30 days after discharge for patients with a discharge diagnosis of AMI. In contrast to the existing all-cause hospital readmissions measures, the measure includes both emergency department (ED) visits and observation stays, in addition to hospital readmissions.

The purpose of the bundled payment is to create a financial incentive that aligns with the care goal of improving the patient's health to the point where a return to the hospital is unnecessary. Measuring EDAC might be important when the financial incentives push toward greater numbers of hospital encounters, as they do in a fee for service system. However, in a bundled payment, CMS needs to alter how it thinks about what to measure – and excess days in hospital care should not be the focus.

**Further, the AHA is concerned that this measure inappropriately overlaps with the HRRP, thereby creating inconsistent incentives to reduce readmissions.** Indeed, CMS itself asserts in the proposed rule that it did not propose any of the readmission measures used in the HRRP "due to the incentives, already in place by the HRRP, for hospitals to lower excess readmission rates." Yet, the EDAC measure is effectively a broadened 30-day readmission measure. Moreover, we note that the approach to determining hospital performance in the HRRP differs from that proposed for the AMI bundle's quality composite score. In the HRRP, performance is determined using a statutory formula that penalizes hospitals for the cost of excess readmissions. In contrast, the quality composite score awards points based on the decile of performance a hospital achieves versus all other hospitals nationally. As a result, it is entirely possible for hospitals to perform well in one program but poorly on the other. These mixed performance signals would hinder, and not help, the important work of reducing avoidable hospital readmissions.

**Furthermore, the AHA does not believe there is clear or consistent evidence to support CMS's assertion that the EDAC measure is necessary to address the rising use of observation stays.** CMS suggests "the rising use of observation stays among Medicare beneficiaries between 2001 and 2008 sparked concern among patients, providers and policymakers that [existing readmission measures] do not capture the full range of unplanned acute care events that occur in the post-discharge period." Yet, a 2014 article published in CMS's own peer-reviewed journal, *Medicare and Medicaid Research Review,* suggested that the drop in national readmission rates in 2012 "was not primarily the result of increases in either post-index ED visits or post-index observation stays."[9] This finding was further confirmed in an April 2016 study published in the *New England Journal of Medicine,* which found that the drop

[9] Gerhardt, G., Yemane, A., Apostle, K., et al, 2014. Evaluating Whether Changes in Utilization of Hospital Outpatient Services Contributed to Lower Medicare Readmission Rate. *Medicare and Medicaid Research Review*. Vol. 7. No. 4. pp. E1 – E13.

in national readmissions rates since the start of HRRP is not associated with a rise in observation stays.[10]

**The AHA also is concerned that the EDAC lacks endorsement by the NQF and has not yet been publicly reported on *Hospital Compare.*** As a result, the hospital field has limited insight on whether the measure is accurate and reliable. Moreover, the public reporting of measure data also affords an opportunity to ensure measures are actionable and that public reporting does not have any unintended consequences. Indeed, it is for this reason that Congress included a statutory requirement in the hospital value-based purchasing (VBP) program that measures be publicly reported for at least one year before they are moved into the VBP program.

**Lastly, the AHA is concerned that the EDAC measure lacks sociodemographic adjustment.** We offer additional information about the importance of assessing outcome measures for the impact of sociodemographic factors later in this section.

Voluntary Hybrid AMI Mortality Measure. **The AHA urges CMS to provide flexibility in reporting the voluntary hybrid AMI mortality measure.** This hybrid measure combines claims data with certain data abstracted from electronic health records (EHRs) to calculate performance. CMS has long been interested in moving toward the use of EHRs to collect and submit quality data, and views "hybrid" measures combining EHR-derived data with claims data as a way of improving the risk adjustment of outcome measures. This is because EHR data has the potential to include more precise clinical information than using claims alone.

The AHA agrees with the potential value of hybrid measures. Given the continued concerns about the extent to which electronic clinical quality measures (eCQMs) provide accurate and reliable data and the extent to which existing EHR products can support all measure reporting requirements, we also support CMS's decision not to mandate the collection of the hybrid measure or tie the level of performance on the measure to payment, at this time.

**However, we urge CMS not to finalize any data submission requirements for the hybrid eCQM beyond the first reporting period until the hospitals and the agency have gained experience with measure submission.** We believe the submission requirements for the first year of the program have an appropriate level of flexibility. That is, CMS would allow hospitals to submit measure data using either a spreadsheet, or its eCQM quality measure reporting standard – the quality reporting document architecture (QRDA). To allow maximum flexibility, as well as to assess which approach is most feasible for the measure, we believe CMS should allow hospitals to submit using either the QRDA-I (patient level) or QRDA-III (aggregate level) approach for the first performance period as well.

Furthermore, we believe CMS should wait to establish a threshold for successful measure reporting until it gains additional experience with the measure. The AMI bundled payment model is the first opportunity hospitals have had to gather information to collect the measure. The

[10] Zuckerman RB et al, 2016. Readmission, Observation and the Hospital Readmissions Reduction Program. *New England Journal of Medicine.* Vol. 374. pp. 1543 – 1551.

ability of hospitals to submit data on 50 percent of qualifying AMI hospitalizations is simply unknown at this point.

Improvement Point Calculation. **The AHA urges CMS to use the CJR approach to calculating improvement points.** For the AMI and CABG models, CMS proposes to award improvement points to those hospitals whose amount of improvement is in the top 10 percent of all hospitals nationally. Stated differently, CMS would calculate the difference in scores from the prior performance period on each measure. If the AMI or CABG participants have a level of improvement that falls into the top 10 percent of all hospitals nationally, CMS would award improvement points. In contrast, under the CJR model, CMS proposes to award improvement points to model participants whose performance on either the complications or HCAHPS measure improves by two or more deciles from the prior performance period.

We applaud CMS for proposing mechanisms for hospitals to be rewarded for improving their quality scores. However, we believe it would be confusing for hospitals participating in both the CJR and cardiac bundles to track two different approaches for calculating improvement points. Moreover, we believe the standard for improvement under the CJR model would provide a greater opportunity for hospitals to be recognized for improvement.

Sociodemographic Adjustment. **As urged above for the SHFFT model, the AHA believes CMS should assess all of the measures proposed for the cardiac model for the impact of sociodemographic factors on hospital performance, and to incorporate adjustments where needed.** Measures that fail to adjust for sociodemographic factors when there is a conceptual and empirical relationship between those factors and the measure outcome lack credibility, unfairly portray the performance of providers caring for more complex and challenging patient populations, and may serve to exacerbate health care disparities.

The Limitations of Pay-for-Performance in a Bundled Payment Context. As with the SHFFT model above, **we do not believe that the only way to evaluate whether quality of care has been maintained or improved for patients in a bundled payment model is to tie a provider's payment to performance on quality measures. We urge that CMS ensure its assessment of whether these bundled payment models are actually improving quality take a more comprehensive approach than a simple pay-for-performance system.**

*Misalignment with Patient Populations.* **The AHA is concerned that the patient populations for all of the measures are poorly aligned with the proposed cohorts in the bundled payments.** For example, CMS proposes to use the HCAHPS performance of a hospital's entire patient population, and not just those patients in the cardiac model. While this approach is necessary for ensuring adequate measure reliability, it means that much of a hospital's HCAHPS performance would have little to do with the patients in the bundle.

The clinical outcome measures also suffer from a similar misalignment. For example, the CABG mortality measure applies only to "isolated CABG" patients; that is, CABG procedures performed without concomitant valve or other major cardiac, vascular or thoracic procedures (e.g., valve procedures, procedures for atrial and/or ventricular septal defects, aortic bypass procedures, etc.). Yet the patients included in the bundle for CABG are much broader than that.

Thus, the measures provide limited insight on the quality of care provided to the entirety of the patient population.

*Time Lag.* **As with the SHFFT model, the AHA is concerned by the significant time lag between the proposed data reporting periods and the actual PYs. Specifically, it will be difficult to draw meaningful conclusions about the quality of care delivered under the model based on data that significantly pre-date the start of the program.** CMS has attempted to reduce confusion by proposing to use the same three-year rolling time periods for calculating readmissions and complications performance that are used in the hospital IQR program. Similarly, for HCAHPS, CMS would align the performance periods for this program with the reporting used in the hospital IQR program. However, as shown below in Table 11, the reporting periods for the mortality and EDAC measures in PYs 1 through 3 would include a significant amount of data that pre-date the start of the model.

**Table 11: Proposed Measure Performance Periods**

| Measure | Year 1 (July – Dec. 2017) | Year 2 (CY 2018) | Year 3 (CY 2019) | Year 4 (CY 2020) | Year 5 (CY 2021) |
|---|---|---|---|---|---|
| AMI Mortality | Jul. 1, 2014 – Jun. 30, 2017 | Jul. 1, 2015 – Jun. 30, 2018 | Jul. 1, 2016 – Jun. 30, 2019 | Jul. 1, 2017 – Jun. 30, 2020 | Jul. 1, 2018 – Jun. 30, 2021 |
| AMI EDAC | Jul. 1, 2014 – Jun. 30, 2017 | Jul. 1, 2015 – Jun. 30, 2018 | Jul. 1, 2016 – Jun. 30, 2019 | Jul. 1, 2017 – Jun. 30, 2020 | Jul. 1, 2018 – Jun. 30, 2021 |
| CABG Mortality | Jul. 1, 2014 – Jun. 30, 2017 | Jul. 1, 2015 – Jun. 30, 2018 | Jul. 1, 2016 – Jun. 30, 2019 | Jul. 1, 2017 – Jun. 30, 2020 | Jul. 1, 2018 – Jun. 30, 2021 |
| HCAHPS | Jul. 1, 2016 – Jun. 30, 2017 | Jul. 1, 2017 – Jun. 30, 2018 | Jul. 1, 2018 – Jun. 30, 2019 | Jul. 1, 2019 – Jun. 30, 2020 | Jul. 1, 2020 – Jun. 30, 2021 |
| Voluntary AMI Hybrid Measure | Jul. 1, 2017 – Aug. 31, 2017 | Sep. 1, 2017 – Jun. 30, 2018 | Jul. 1, 2018 – Jun. 30, 2019 | Jul. 1, 2019 – Jun. 30, 2020 | Jul. 1, 2020 – Jun. 30, 2021 |

*ICD-9 to ICD-10 Transition.* **The AHA is concerned that the first two performance periods for the EDAC and mortality measures overlap with the ICD-9 to ICD-10 transition.** The AHA again urges CMS to continue working with hospitals, measure developers and all other stakeholders to address the potential unintended consequences of combining measure data collected under ICD-9 and ICD-10. Additional suggestions on how to address the ICD-9 to ICD-10 transition are provided in the SHFFT section above.

*Looking Beyond Pay-for-Performance to Evaluate Appropriateness of Bundles.* **The real analysis of quality needed to assess the impact of CMS's novel approach to bundling must examine the "big picture" of the project's impact on both cost and quality.** Therefore, we urge CMS to look at the whole care of patients across the entire episode to see if its design and execution of the program is successful in achieving these overarching goals. The agency should focus this analysis on the questions outlined for the SHFFT model above.

### FINANCIAL ARRANGEMENTS AND BENEFICIARY INCENTIVES

**As with the SHFFT model, the AHA urges the Secretary to, prior to issuance of a final rule, use the full scope of the combined authority granted by Congress under the ACA 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 cardiac model. 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 model that comply with the requirements in the proposed rule.** These waivers are essential to enable hospitals to form financial arrangements with other providers collaborating in the model, without which hospitals have no real ability to make sure those providers – for whose outcomes hospitals will be held accountable – have a real stake in achieving the model's goals.

**In addition, the AHA urges the Secretary to waive the beneficiary inducement CMP for beneficiary incentives that comply with the requirements in the proposed rule.** In the proposed rule, CMS states that participant hospitals may want to provide in-kind patient engagement incentives to beneficiaries in model episodes. The agency proposes to allow participant hospitals to provide in-kind patient engagement incentives to beneficiaries in model episodes for free or below fair market value, subject to certain conditions that are laid out in the proposed rule. However, CMS has not proposed to waive the CMP that prohibits beneficiary inducement.

### WAIVERS OF MEDICARE PROGRAM RULES

Similar to our comments on the SHFFT model above, **we urge CMS to provide hospital participants with maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals**. We appreciate the agency's proposed waiver of the "incident to" rule, which would allow a cardiac model beneficiary to receive post-discharge visits in his or her home or place of residence any time during the episode. We also support the waiver of Medicare telehealth regulations, as proposed. However, we recommend that the agency consider also waiving hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the information provided on post-hospital services. In addition, we urge CMS to waive the requirement that a beneficiary is "home-bound" in order to receive HH services. This would provide our members with valuable tools to increase quality and reduce unnecessary costs. Such waivers also are commensurate with the level of risk and accountability that CMS is asking hospitals to assume as it shifts the burden of risk further away from the Medicare program onto providers. We also urge CMS to waive audits of post-acute care and other collaborators participating in a cardiac episode since the episode-managing entity is financially accountable for the provision of those services.

## ADVANCED ALTERNATIVE PAYMENT MODEL (APM) CONSIDERATIONS

Beginning April 1, 2018 (when downside risk begins), CMS proposes to offer two tracks for the SHFFT, cardiac and CJR models – one that would qualify as an APM under proposed Medicare

Access and CHIP Reauthorization Act (MACRA) regulations, and one that would not. To participate in the advanced APM track (Track 1), hospitals would need to meet and attest to use of certified EHR technology. A hospital selecting Track 1 also would need to submit to CMS a list of the clinicians with whom it has financial arrangements, which the agency would use when determining whether a clinician has qualified for MACRA incentives for advanced APM participation.

**We support CMS's proposal to create a track that would allow physicians to receive credit toward MACRA incentives for partnering with hospitals to provide high-quality, cost-effective care and advance the goals of this model. We urge the agency to go a bit further to align this model with the upcoming Quality Performance Program (QPP) and configure Track 2, the non-advanced APM track, so that it could qualify as a Merit-based Incentive Payment System (MIPS) APM, as defined under the QPP proposed rule.** In that rule, CMS proposed that the entity participating in an APM must include eligible clinicians on a participants list in order to qualify as a MIPS APM. Since, as proposed, Track 2 hospitals would not submit to CMS a list of clinicians with whom they have formed financial relationships, Track 2 would not qualify as a MIPS APM. CMS should allow interested Track 2 hospitals to submit lists of its participating clinicians, so that those clinicians may receive the benefits of streamlined performance reporting and MIPS APM scoring proposed in the QPP rule.

## CARDIAC REHABILITATION INCENTIVE PAYMENTS

CMS proposes to test a payment methodology designed to encourage the use of cardiac rehabilitation services. Specifically, CMS would make incentive payments to hospitals caring for beneficiaries with a heart attack or bypass surgery based on their utilization of cardiac rehabilitation and intensive cardiac rehabilitation services in the 90-day care period following hospital discharge. These payments would be available to hospital participants in 45 of the 98 geographic areas selected for the cardiac bundled payment model; they also would be available in 45 of the geographic areas eligible, but not selected for the cardiac model. This test would cover the same five-year period as the cardiac care bundled payment models. **The AHA supports this proposal, including the exclusion of these incentive payments from hospitals' target prices and actual episode spending.**