American Hospital Association

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September 8, 2015

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-5516-P, Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule (Vol. 80, No. 134), July 14, 2015.

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) Comprehensive Care for Joint Replacement (CCJR) Payment Model proposed rule published July 14.

Our members support the health care system moving toward the provision of more accountable, coordinated care. As such, they are in the process of redesigning delivery systems to increase value and better serve patients. **The AHA supports the CCJR payment model as a program that could help further these efforts to transform care delivery through improved care coordination and financial accountability. As such, we also support CMS's proposal that hospitals serve as episode initiators in the CCJR program.**

At the same time, CMS's proposal raises important questions as to how to appropriately design a program that would be required for hospitals of many different sizes and types, and at very different points in the transformation process. 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 the CCJR program. This is no small task; it will require significant investments of time, effort and finances. For example, hospitals and health systems will need to build upon their current infrastructure for health information technology, patient and family education, care management and discharge planning.

They also will need to align with other providers, both physicians and post-acute facilities, to achieve efficiencies under the model. This will entail forming new and different contractual relationships that build valuable partnerships and incentivize successful strategies. While some hospitals have already taken significant steps toward achieving such alignment, others are not as far down this path.

With these considerations in mind, we believe that joint replacements are appropriate procedures upon which to launch Medicare's first mandatory bundled payment program. They are prevalent in the Medicare population and have high episode payments, low variance in payments, and clear, evidence-based practice guidelines. It will take time for providers to be able to standardize care patterns and identify opportunities for care redesign, but if adequate opportunity for testing and evaluation is afforded, we will reap valuable lessons from hospitals' experience under this model. As such, while we are supportive and mindful of the Department of Health and Human Services Secretary's goal of tying 30 percent of fee-for-service Medicare payments to quality or value through alternative payment models by the end of 2016 and tying 50 percent of payments to these models by the end of 2018, **we caution the agency against expanding a mandatory bundled payment model to other geographic areas or conditions before there has been enough time spent under the CCJR model to assess the lessons learned.**

To optimize the effectiveness of the CCJR model 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 will help accomplish these goals.

First and foremost, 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 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 CCJR 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 CCJR that comply with the requirements in the proposed rule. As CMS recognized in the preamble to the calendar year 2016 Physician Fee Schedule proposed rule that was issued within one day of this rule, the self-referral law was designed for a different world of care delivery and payment. At its core, the self-referral law is about separating hospitals and referring physicians, while the evolving Medicare and Medicaid models "are premised on the close integration of a variety of different health care providers." The Anti-kickback Statute is similarly no longer compatible with the new models.

As proposed, any financial arrangement or agreement under the CCJR model that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor. That is an unacceptable risk for hospitals, whose participation in this program would be mandatory. They should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient work-arounds to try to ensure that their efforts meet the demands of this new program and do not run afoul of such laws and regulations. **Hospitals are supportive of the mandate,**

but it should not take effect unless and until the needed, explicit protections are in place and adequate time is given to form the necessary financial arrangements – as the administration is aware, the program cannot be successful for Medicare and its beneficiaries without them.

We also are concerned that the scope of the proposed payment waivers is too limited, particularly the failure to propose waivers to hospital discharge planning requirements that prohibit hospitals from specifying or otherwise limiting the providers who may provide post-hospital services. **We urge CMS to provide participating hospitals with 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 SNF 'three-day rule,' and the IRF '60% 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.

Second, the AHA urges CMS to delay the start date of the CCJR program until July 1, 2016, and to delay implementation of downside risk until the third year of the program. Specifically, we are concerned that the proposed Jan. 1, 2016 start date does not provide adequate time for hospitals to put in place the care processes and procedures necessary to achieve success in the program. They very well may be heading into performance year 2 and an immediate acceptance of downside risk having been able to complete only limited work toward restructuring care. However, hospitals want and need time to adequately prepare so that they can be successful throughout the program by, for example, obtaining and analyzing CMS data to identify areas for performance improvement, to establish systems to track patients across the continuum of care, and to, as discussed above, form necessary financial arrangements. Hospitals also want and need to be afforded the opportunity to take full advantage of the transition to accepting downside risk, especially given that many have very limited experience doing so.

In addition, we urge CMS to restrict the program to elective hip and knee replacement episodes only. The clinical and resource-use differences between this patient population and the non-elective hip/knee fracture patient population included in the major joint replacement Medicare-Severity Diagnosis-Related Groups (MS-DRGs) are pronounced. Non-elective fracture patients follow a very different clinical pathway. Their surgeries are unplanned and they are more medically complex and functionally impaired – they have serious renal, cardiovascular and liver disease, as well as multiple comorbidities. In addition, including only elective hip and knee replacement episodes would more closely align the various components of the CCJR program. For example, CMS's proposed readmissions and complications quality measures include only elective joint replacement procedures.

Similarly, we urge CMS to incorporate a risk-adjustment methodology into the CCJR program. As proposed, CMS would not make risk adjustments in the program beyond setting separate target prices for MS-DRGs 469 and 470. However, the increasing use of a regional spending component will 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. Relying on the MS-DRG as the program's only risk adjustment does not

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.

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 balance is misaligned. **The proposed rule places too much risk and burden 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:

- Adopt a more balanced approach to quality measurement by excluding the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure from the CCJR program, and make hospitals ineligible for reconciliation payments only if their performance on both the hip/knee readmission and hip/knee complications measures is statistically worse than the national average;
- Provide hospitals with protection against having to make repayments resulting from adverse events beyond their control by setting a repayment target price equal to historical payments *plus* 2 percent (instead of *minus* 2 percent) in years three through five of the program;
- Both phase in the stop-loss limit more gradually and adopt a maximum limit of 10 percent in year five; and
- Provide additional protections in the form of lower stop-loss limits for hospitals that have a low volume of episodes.

These changes would help facilitate hospitals' success under the program with regard to providing quality care to Medicare beneficiaries, achieving savings for the Medicare program, and also having an opportunity for reward that is commensurate with the risk they are assuming. We appreciate your consideration of these issues and look forward to continuing to work with CMS on matters of great importance to hospitals, beneficiaries and the Medicare program.

Our detailed comments are attached. If you have any questions, please feel free to contact me or 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

PARTICIPATION IN THE COMPREHENSIVE CARE FOR JOINT REPLACEMENT (CCJR) MODEL

The Centers for Medicare & Medicaid Services (CMS) proposes to require inpatient prospective payment system (PPS) hospitals in certain geographic regions to participate in the CCJR model as episode initiators. Specifically, it proposes that inpatient PPS hospitals physically located in one of 75 specific metropolitan statistical areas (MSAs) be included in the CCJR model. However, the agency would exclude Model 1 Bundled Payments for Care Initiative (BPCI) participant hospitals as well as episode initiators for lower extremity joint replacement (LEJR) episodes in the risk-bearing phase of Model 2 or 4 of BPCI, as of July 1, 2015. In selecting participating MSAs, CMS excluded those that had a very low volume of LEJR episodes and those with a large amount of BPCI participation.

The AHA supports CMS's proposal that hospitals serve as episode initiators. We also support the proposal that an LEJR episode be included in the CCJR model if the surgery takes place at a participating hospital. We agree with the agency that utilizing the hospital as the episode initiator is a straightforward approach because the hospital furnishes the LEJR procedure. In addition, CMS notes that about 55 percent of episode spending 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 LEJR episodes that begin at a participant hospital be included in the model, except for certain exclusions, such as for beneficiaries who are enrolled in Medicare Advantage.

While we support this type of consistent approach to handling Medicare LEJR episodes within a hospital, we are concerned about inconsistencies with the proposed approach to handling Medicare LEJR episodes *across* hospitals. Specifically, several of our system members have multiple hospitals in selected MSAs, some of which are participating in BPCI. They have expressed concerns that participating in two different Center for Medicare and Medicaid Innovation (CMMI) bundling programs in the same market would be confusing because, for example, the programs may:

- have different episode lengths;
- have different services and providers included in the episode;
- have different target prices;
- distribute data on different timelines;
- distribute data in different formats; and/or
- apply Medicare waivers differently.

It would be difficult and burdensome for hospitals to track these differences and how they apply to patients. As a specific example, under BPCI, CMMI waives the skilled nursing facility (SNF) three-day rule if a *majority* of the hospital's BPCI patients go to a SNF with at least three stars on the *Nursing Home Compare* website. However, under CCJR, CMMI proposes to waive the rule only for *individual patients* going to a SNF with at least three stars. Hospitals would be challenged to track which type of waiver applies to which patients. Doing so correctly is critical, as a mistake could result in non-coverage of a beneficiary's SNF stay. **Therefore, we urge the agency to allow hospitals to elect to include their otherwise-CCJR-eligible hospitals instead in BPCI, or to include their BPCI hospitals instead in CCJR. We also urge CMS to allow CCJR hospitals already participating in BPCI, but not for LEJRs, to expand their current participation in BPCI to include LEJRs.** Doing so would ensure that hospitals participate only in one bundling program in a given market.

In addition, under CMS's proposal, eligible BPCI hospitals would be excluded from CCJR for only their BPCI performance period – they would be required to enter CCJR once the BPCI performance period concludes. We are concerned that, under this proposal, some BPCI participants would be required to enter CCJR in the middle of the program, which would be confusing and difficult to operationalize for many reasons, including the differences between the programs outlined above. **We urge CMS to allow BPCI participants the option of extending their participation in BPCI, rather than transitioning to CCJR.**

Lastly, 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, has created a considerable amount of confusion about which individual hospitals would actually be required to participate. **Therefore, in addition to stating its criteria for inclusion, we urge CMS to publish a list of the actual hospitals that it believes would be required to participate in the CCJR 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 CCJR model for five years, beginning Jan. 1, 2016 and ending Dec. 31, 2020. An episode of care in the CCJR model would begin upon admission to an inpatient PPS hospital for a stay paid under either Medicare-severity diagnosis-related group (MS-DRG) 469 or 470. Episodes would end 90 days after discharge from the hospital.

CCJR Start Date and Introduction of Downside Risk. **We are concerned that the proposed program start date of Jan. 1, 2016, and the proposed downside risk implementation date of Jan. 1, 2017, provide a very short amount of 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, a Jan. 1 start date means that hospitals would be using this first year to operationalize their participation in the program, rather than as a transition to accepting downside risk. It is akin to building the airplane while it is flying. For example, among many other tasks, hospitals will need to:

- Educate staff and physicians on the CCJR program;
- Analyze claims data to understand episode spending;
- Build relationships with physicians and post-acute care providers;
- Negotiate and execute CCJR 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 CCJR patients upon admission;
- Create protocols to determine if potential CCJR 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 CCJR 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.

In addition, under the proposed rule, hospitals would not receive the data necessary to succeed under a risk-bearing model until at least 60 days after the start of the program. Hospitals participating in BCPI, Pioneer accountable care organization (ACO) and other CMMI demonstrations have repeatedly expressed concern that the clinical and financial data they receive from the agency is neither timely nor complete. Moreover, 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 will 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.

Thus, hospitals may very well may be heading into performance year 2 and an immediate acceptance of downside risk having been able to complete only limited work toward restructuring care. 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 the start date of the CCJR program until July 1, 2016, and to delay downside risk until year three of the program.**

Episode-initiating Procedures. **We urge CMS to limit the CCJR to elective hip and knee replacements only, which account for about 82 percent of MS-DRG 469 and 470 episodes.** Specifically, MS-DRGs 469 and 470 do not encompass a homogenous patient population; in fact, they contain four distinct patient groups:

1) Elective Hip/Knee Replacement;
2) Emergent Hip Fracture Treated with Partial Replacement;
3) Pathologic Hip Fractures; and
4) Non-union Hip/Knee Fracture Treated with Replacement

Our members have stated that the clinical and resource-use differences among these four patient populations are clear during the acute care hospitalization and become even more pronounced once the patients enter post-acute care: it does not make sense to group them into the same 90-day bundles. Specifically, non-elective fracture patients are a unique population within MS-DRGs 469 and 470, and they follow a very different clinical pathway. Their surgeries are obviously unplanned and they are more medically complex and functionally impaired – they have serious renal, cardiovascular and liver disease, as well as multiple comorbidities. These patients typically require care in an inpatient rehabilitation facility (IRF). In fact, hip fractures are one of the 13 clinical conditions on which Congress and CMS has directed IRFs to concentrate their services. Further, the number of non-elective hip fractures treated by individual hospitals varies widely on an annual basis, putting participating hospitals at risk of not achieving their target prices simply because they had an anomalous number of hip fracture patients in a given year.

CMS itself excludes non-elective procedures when measuring joint replacement quality, acknowledging that the elective and non-elective patient populations are significantly different and that these differences cannot yet be accounted for with risk adjustment. For example, the agency's 30-day LEJR readmission measure excludes non-elective patients, because they "have a higher mortality, complication, and readmission rates," and "are typically performed on patients who are older, frailer, and who have more comorbid conditions."[1] The agency's hip and knee complications measure excludes non-elective patients for the same reasons.[2] Lastly, CMS's recently finalized measure of hip and knee episode spending also excludes non-elective patients.[3]

In addition, the agency's proposed approach to measure CCJR episode spending is incongruent with its proposals to measure quality of care and define related services. Specifically, although CMS proposes to include non-elective LEJR procedures when measuring episode spending, it would use the above readmissions and complications measures, which exclude non-elective

[1] 2015 Procedure-Specific Readmission Measures Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) – Version 4.0 and Isolated Coronary Artery Bypass Graft (CABG) Surgery – Version 2.0.

[2] 2015 Procedure-Specific Complication Measure Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure – Version 4.0.

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

procedures, when measuring CCJR episode quality. Also, CMS would exclude services linked with oncology diagnoses from CCJR episode spending, yet would include oncology-driven pathologic hip fractures in episode spending. **Including only elective hip and knee replacement in the CCJR program would more closely align the various components of the agency's proposal.**

Included and Excluded Services. CMS proposes that episodes would include the surgical procedure and inpatient stay, as well as all related care covered under Medicare Parts A and B within 90 days of discharge, including inpatient and outpatient, readmission, physician, inpatient rehabilitation, skilled-nursing and home health (HH) services. Unrelated services would be excluded, in a manner that is consistent with the LEJR episode definition currently being used in BPCI Model 2. Specifically, CMS would exclude:

- Unrelated hospital readmissions, as identified by MS-DRG;
- Unrelated Part B services based on ICD-9-CM/ICD-10-CM code;
- Drugs paid outside of the MS-DRG (hemophilia clotting factors); and
- Inpatient PPS new technology payments.

We generally support these proposals, but further exclusions are warranted. CMS has intermittently reviewed and modified the list of exclusions under BPCI, but we recommend that it continue its research to expand 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 CCJR is to test how to optimize quality and costs for LEJR episodes – including the costs of caring for ongoing chronic conditions will muddy the waters.

In addition, all post-acute care services are included in the episode cost without exclusion. In the circumstance when a readmission for an excluded MS-DRG occurs during the episode, then 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. Once an episode begins, CMS proposes that it continue to the end unless the beneficiary no longer meets the inclusion criteria, in which case the episode would be cancelled. The agency proposes to cancel an episode for several reasons, including when the beneficiary dies during the anchor hospitalization. **However, we urge CMS to cancel all episodes in which the beneficiary dies – either during the anchor hospitalization or during the 90 days post discharge.** We found that a very small number of patients die during the 90 days after discharge (0.3 percent), but their episode spending is very high. Specifically, episode spending for patients who died during the 90 days post-discharge was 33 percent and 76 percent higher than the

average for MS-DRG 460 and 470, respectively. We believe this trend is due to these patients receiving extensive end-of-life care and clearly demonstrates that these episodes are atypical.

RETROSPECTIVE PAYMENT METHODOLOGY

During a performance year, CMS proposes to use a retrospective payment methodology, under which it would pay all providers and suppliers involved in CCJR episodes 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 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. No hospital would be penalized in year one of the program.

The AHA supports the 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 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. Such prospective payment also would sever the direct and valued tie that such facilities have to the Medicare program.

However, 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 problematic under the CCJR program is the plentiful barriers to care coordination that exist under FFS – we comment on that troublesome issue later in this letter. 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 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 the CCJR, 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. **Therefore, we 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 CCJR patients with shorter-than-average stays, with payment capped at the full IRF PPS amount.

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 appreciate 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 and benchmarks for any providers without putting quality of care at risk.

To that point, in selecting the 75 MSAs, CMS "oversampled" from the MSAs with higher payments and "undersampled" from the MSAs with lower payments because it believed that MSAs with the lowest expenditures are already performing relatively efficiently. However, while this methodology lessens a low-spending MSA's chances of being chosen for the CCJR program, it does nothing to alleviate that area's disadvantage in terms of attempting to further reduce episode spending. **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 CCJR participants in both high- and low-spending areas.

In addition, CMS proposes to make certain technical adjustments to historical data when calculating target prices (as well as when calculating actual episode payments). For example, CMS proposes to exclude special payment provisions that are intended to improve quality and efficiency in service delivery, such as under the hospital value-based purchasing (VBP) program, the various quality reporting programs and indirect medical education payments. However, CMS does not specify whether it would include or exclude capital payments made under the inpatient PPS. **We urge the agency to exclude capital payments, as it does in the Medicare spending per beneficiary pricing standardization approach that it proposes to follow for this program.**

We also 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.

Lastly, 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 CCJR 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 incorporate a risk-adjustment methodology into the CCJR program.** As proposed, CMS would not make risk adjustments in the program beyond the fact that it is setting separate target prices for MS-DRGs 469 and 470. However, the increasing use of a regional spending component will 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 in the CCJR program would penalize hospitals treating the sickest, most complicated and most vulnerable patients.**

CMS states that it did not propose to risk adjust CCJR episodes beyond MS-DRG-specific pricing because it does not believe that a sufficiently reliable approach exists, and that there is no current standard on the best approach. This statement is extremely perplexing to us given that the agency just recently finalized a risk-adjustment methodology as part of its measure of "Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)," which will be included in the inpatient quality reporting program. This measure's risk adjustment methodology accounts for many factors that are both beyond hospitals' control and also affect their performance on the measure, including type of procedure, age, obesity and the presence or absence of many different chronic conditions, such as chronic heart failure and diabetes. We note, however, that it is only adequate in risk adjusting for the *elective* patient population. While we urge CMS to narrow the CCCJR program to elective LEJR patients only, in the event that it includes patients beyond that population, it would need to re-evaluate this methodology to include additional risk adjustment factors.

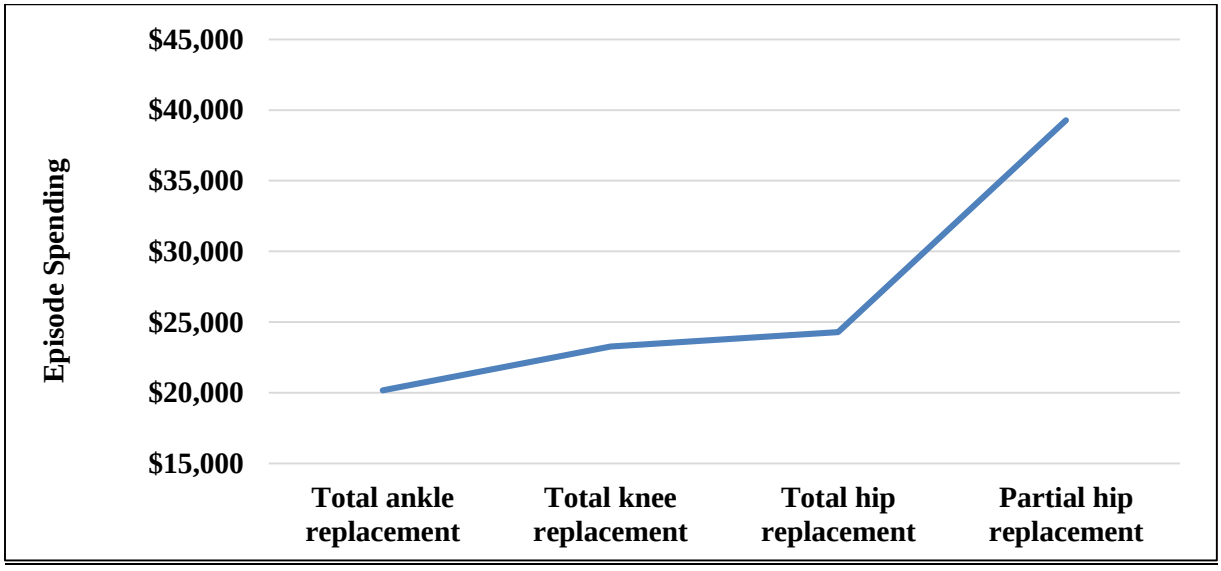
Table 1 below demonstrates that relying on the MS-DRG as the program's only risk adjustment does not fully account for numerous factors that affect spending and that are beyond hospitals' control. Specifically, our analysis found that hospitals with higher episode spending have a very different risk profile. In conducting this analysis, we divided CCJR hospitals into quintiles based on the difference between their regional target price and their payments per episode. We then looked at their cases by different risk factors. We found that hospitals in the highest quintiles had a lower number of episodes and a higher percentage of emergency or trauma episodes, patients at least 85 years old, patients with at least three complications and comorbidities/major complications and comorbidities (CCs/MCCs), and patients that were dually-eligible for Medicare and Medicaid. In fact, each of these factors increased/decreased linearly by quintile.

Table 1: Distribution of Risk Factors for CCJR 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 with 3+ CC/MCC	Percent Patients Dually Eligible	Average Payment per Episode	Average Target per Episode	Percent Difference between Target and Payment
Highest Spending Quintile	151	89	29.7%	20.7%	13.1%	36.2%	$38,399	$28,816	-33.3%
2nd Quintile	151	232	18.0	16.3	10.8	19.7	31,032	26,503	-15.8
3rd Quintile	151	416	15.5	14.2	8.6	13.3	28,264	26,504	-6.6
4th Quintile	151	579	9.5	11.7	7.3	10.8	25,253	25,340	0.3
Lowest Spending Quintile	153	588	6.0	9.6	6.2	8.4	23,725	26,466	10.4
Total	757	381	11.7	12.6	7.9	12.9	26,746	26.284	-1.8

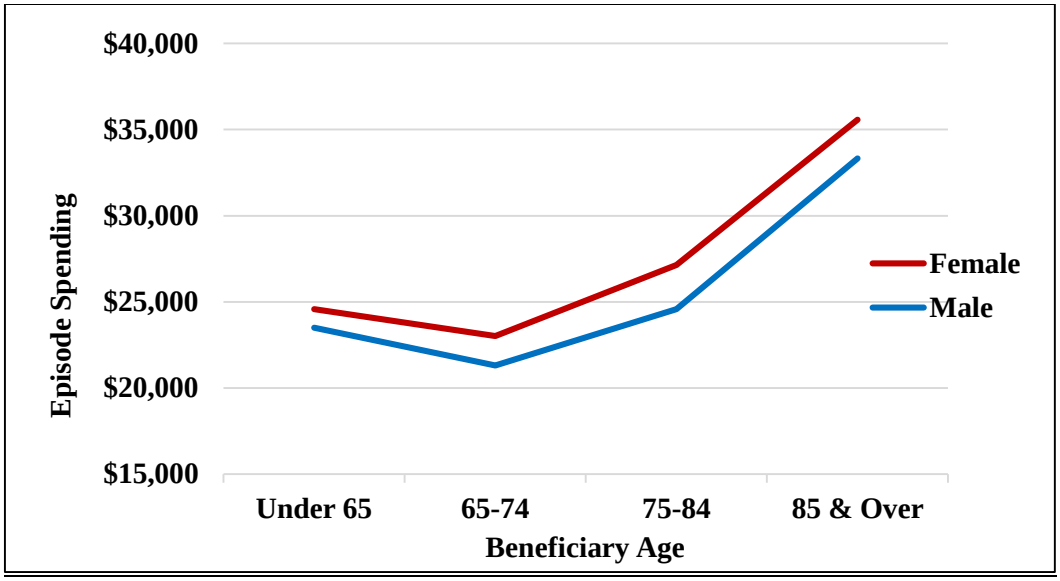
We conducted more detailed analyses of certain patient factors and their effect on episode spending – they further support the need for a risk-adjustment methodology in the CCJR program. Specifically, our findings confirm that substantial variation in episode payments exist within each MS-DRG, not just between the two MS-DRGs. First, as shown in Figure 1, we found that episode spending for MS-DRG 470 differs substantially by the type of procedure performed. Specifically, spending for partial hip replacement episodes was between 62 and 95 percent higher than for other episodes. The same trend occurs with MS-DRG 469 episodes.

Figure 1: CCJR MS-DRG 470 Episode Spending, by Type of Procedure



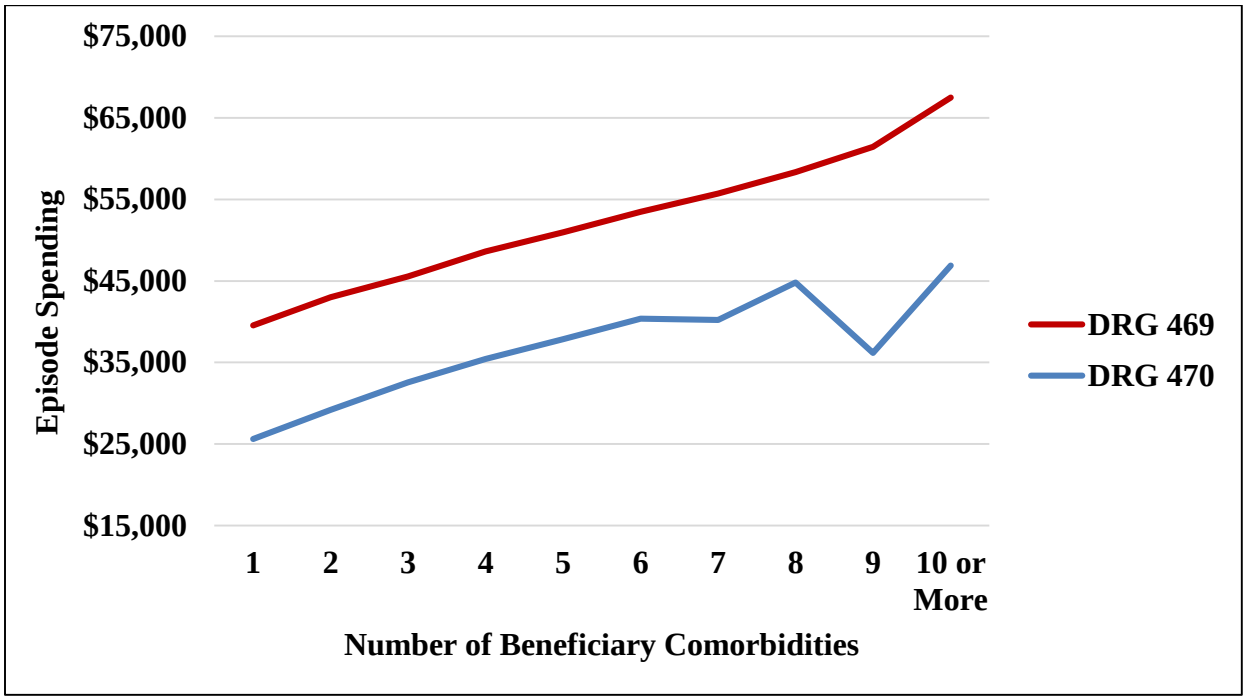
We also found that spending per episode increases almost linearly by beneficiary age. As shown in Figure 2, MS-DRG 470 episode spending for female beneficiaries age 85 and older is about 55 percent higher than for beneficiaries age 65 to 74. MS-DRG 470 episode spending for male beneficiaries age 85 and older is about 56 percent higher than for beneficiaries age 65 to 74. The same trend occurs with MS-DRG 469 episodes.

Figure 2: CCJR MS-DRG 470 Episode Spending, by Age and Sex



In addition, as shown in Figure 3, we found that spending for MS-DRG 470 episodes increases almost linearly by the number of beneficiary comorbidities. Episode spending for beneficiaries with 10 or more comorbidities is 83 percent higher than spending for beneficiaries with only one comorbidity. The same trend occurs with MS-DRG 469 episodes.

Figure 3: CCJR MS-DRG 470 Episode Spending, by Number of Beneficiary Comorbidities



We also analyzed individual comorbidities to identify those that may affect episode spending the most. We found that comorbidities including, but certainly not limited to, congestive heart failure, dementia, malnutrition, Parkinson's/Huntington's disease and stroke substantially affected episode spending. For example, MS-DRG 470 episode spending for patients with congestive heart failure was 30 percent higher than the average MS-DRG 470 episode spending of $25,352. Episode spending for patients with dementia was 56 percent higher and for patients with stroke was 41 percent higher. The same trend occurs with MS-DRG 469 episodes.

Table 2: CCJR MS-DRG 470 Episode Spending, for Certain Comorbidities

Comorbidity	Adjusted Spending per Episode	Percent Above Average MS-DRG Spending per Episode
Congestive Heart Failure (428.0x)	$33,021	30%
Dementia (290.xx)	39,593	56
Malnutrition (261.xx-263.xx)	35,545	40
Parkinson/Huntington (332.xx, 333.4x)	34,616	37
Stroke (430.xx, 431.xx 432.xx, 433.x1, 434.x1, 436.xx, 438.xx)	35,799	41

Discount Factor. In order to determine reconciliation payments, CMS proposes to set a target price equal to a hospital's hospital-specific and regional-blended historical payments minus a 2 percent discount. In order to determine repayments to Medicare, CMS would set a target price

equal to a hospital's hospital-specific and regional blended historical payments minus 1 percent in year two and minus 2 percent in years three through five. The agency would not require any repayments to Medicare in year one of the program.

We are concerned that this proposal essentially shifts all of Medicare's risk to the participating hospital. That is, when downside risk is fully phased in, Medicare guarantees itself a savings of 2 percent; notwithstanding the (rather large) proposed stop-loss limit, hospitals are completely responsible for making up the difference to Medicare if that is not achieved. Viewed through another lens, the 2 percent discount helps ensure that Medicare makes reconciliation payments for savings achieved through improved performance, not simply through random chance. However, there is no equivalent provision that helps ensure that hospitals do not have to make repayments that result from adverse events beyond their control.

At this stage, the CCJR program is experimental. It will take time, investment and hard work for a hospital to be poised to achieve savings. Therefore, the design of the CCJR program should provide ample time for the less-experienced participants to fully organize themselves into an effective risk-bearing structure. Though we understand CMS's eagerness to test alternative payment models, it is already testing down-side risk bundling models through BPCI and should proceed with caution in this new, mandatory CCJR program. **As such, we encourage the agency to provide hospitals with protection against having to make repayments that result from adverse events beyond their control, similar to the protections it offers under the Medicare Shared Savings Program.** Specifically, in years three through five of the program, instead of setting a repayment target price equal to historical payments *minus* 2 percent, we urge CMS to set a repayment target price equal to historical payments *plus* 2 percent. Hospitals with historical payments falling between 98 percent and 102 percent of historical payments would neither receive reconciliation payments nor be held responsible for repaying Medicare. Our suggested adjustment factors to be applied to historical payments are shown in Table 3 below.

Table 3: AHA's Suggested Reconciliation and Repayment Adjustment Factors by Performance Year

Performance Year	Adjustment to Historical Payments for Purposes of Calculating Reconciliation Payments	Adjustment to Historical Payments for Purposes of Calculating Repayments to Medicare
1	- 2%	No repayments required
2	- 2%	No repayments required
3	- 2%	+ 2%
4	- 2%	+ 2%
5	- 2%	+ 2%

"Unpooling" Target Prices. Because CMS had pooled together MS-DRG 469 and 470 episodes to obtain a higher historical episode volume, as a last step in calculating target prices, it must

"unpool" the target prices so that it has separate target prices for MS-DRG 469 and 470. We agree with the agency that, as noted in its Aug. 19 CCJR Correction Notice, the correct methodology for determining the MS-DRG 469 unpooled target price is to multiply the MS-DRG 470 target price by the national "anchor factor," not by the "hospital weight."

Proposed Stop-loss Limits on Payment Amounts. Beginning in year two of the program, CMS would require hospitals to repay Medicare for episode expenditures that are greater than the applicable target price. However, to limit a hospital's overall repayment responsibility, CMS proposes a stop-loss limit of 10 percent of a hospital's target price multiplied by its number of episodes in performance year two, and 20 percent of a hospital's target price in performance years three through five.

The AHA supports limitations on the repayment responsibility for participant hospitals. However, we are concerned that the agency's approach does not provide an adequate glide path for hospitals participating in the program. Although CMS would limit losses to 20 percent of the *target price* in years three through five, the reality is that this is a much higher percentage limit when considering *hospitals' actual payments*. Specifically, CMS states that, on average, hospital payments account for 55 percent of total episode payments. Therefore, if hospitals are at risk for repayments equal to 20 percent of the target price, they are actually at risk for repayments equal to 36 percent of their MS-DRG payments. For example, if the target price were $100 and hospital payments accounted for $55 (55 percent) of that, a stop loss of $20 (20 percent) would represent 36 percent ($20/$55) of the hospital's payment.

In addition, although CMS would make adjustments for high-payment episodes when calculating target prices and actual spending by capping spending for a given episode at two standard deviations above the regional mean, a significant number of very high-cost episodes remain. Specifically, our analysis shows that almost 3 percent of MS-DRG 469 episodes have costs that are more than double the average cost per episode. For MS-DRG 470, this number is even higher, with almost 6 percent of episodes having costs that are more than double the average cost per episode.

Given the realities of this program and the limited experience hospitals and CMS have with bundled payments, we urge CMS to phase in the stop-loss limit more gradually and adopt a maximum limit of 10 percent in year five. For Track 2 accountable care organizations participating in the Medicare Shared Savings Program, CMS has adopted a policy consistent with this recommendation, limiting the amount owed to 5 percent of the benchmark in the first year, 7.5 percent in the second year and 10 percent in the third year. Given the mandatory nature of the CCJR (and in light of our recommendation to delay downside risk until year three of the program), we would urge slightly lower limits of, for example, 3 percent in year three, 6 percent in year four, and 10 percent in year .

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 five percent for years three through five for these hospitals. **The AHA appreciates these additional protections. However, given the realities of this program and the limited experience hospitals and CMS have with bundled payments, we again urge CMS to phase in the stop-loss limit more gradually.** For example, limits of 1 percent in year three, 3 percent in year four, and 5 percent in year five would be appropriate for these groups of hospitals.

In addition, we urge CMS to extend the same additional protections to hospitals that perform a low volume of LEJR episodes, less than 35, 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 4.

Table 4: Gain/Loss Values Per CCJR Episode for Hospitals, Before Application of Proposed Stop-loss and Stop-gain Limits, Jan. 2011-Sept. 2013

					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	76	11	1	21	-$6,521	-$33,440	$9,649	$43,090
2	75	40	22	60	-$7,608	-$24,677	$5,104	$29,781
3	76	80	61	103	-$5,651	-$17,754	$6,291	$24,045
4	76	128	104	154	-$4,471	-$16,099	$3,245	$19,344
5	76	196	155	237	-$2,594	-$11,016	$4,039	$15,055
6	75	284	237	338	-$2,767	-$11,454	$6,160	$17,613
7	76	391	339	453	-$893	-$8,440	$5,015	$13,455
8	76	526	453	618	-$296	-$7,234	$6,612	$13,845
9	75	768	627	907	$64	-$4,701	$4,638	$9,339
10	76	1,391	907	3,215	$979	-$3,312	$7,017	$10,330

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 show in Table 4 above, as well as Table 5 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 100 LEJR episodes over an 11 quarter period (January 2011 – September 2013), which would equate to 35 episodes per year.

Table 5: Gain/Loss Values Per Episode for Hospitals, After Application of Proposed Stop-loss and Stop-gain Limits, Jan. 2011 – Sept. 2013

					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	76	11	1	21	-$2,464	-$10,006	$7,436	$17,442
2	75	40	22	60	-$3,903	-$8,100	$5,104	$13,204
3	76	80	61	103	-$3,774	-$7,546	$6,291	$13,836
4	76	128	104	154	-$3,254	-$7,550	$3,245	$10,795
5	76	196	155	237	-$2,304	-$7,295	$4,039	$11,335
6	75	284	237	338	-$2,291	-$7,371	$5,933	$13,304
7	76	391	339	453	-$793	-$5,142	$5,015	$10,157
8	76	526	453	618	-$272	-$5,806	$6,612	$12,417
9	75	768	627	907	$67	-$4,701	$4,638	$9,339
10	76	1,391	907	3,215	$913	-$3,312	$6,845	$10,157

USE OF QUALITY MEASURES IN PAYMENT DETERMINATION

CMS proposes to make hospitals' eligibility for reconciliation payments contingent on meeting or exceeding certain performance thresholds on quality measures. Specifically, the agency would require that CCJR hospitals meet or exceed the 30th percentile (performance years (PYs) one through three) or 40th percentile (PYs four and five) of national performance on three measures currently used in the hospital inpatient quality reporting (IQR) program:

- Elective hip and knee replacement readmissions;
- Elective hip and knee replacement complication rates; and
- Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey results.

CMS states that it believes this "pay-for-performance" approach would ensure continued attention to quality of care throughout the duration of the CCJR program and promote collaboration among all parties involved in beneficiaries' care. **However, the AHA is deeply concerned that this approach fails to reflect the quality of care delivered in the context of**

the model. Instead, it arbitrarily draws distinctions in performance among hospitals that are not borne out by the data or even by CMS's own method of rating performance on the *Hospital Compare* website. We also are concerned that, assuming a similar level of hospital performance next year, CMS's misguided approach would result in more than half of CCJR hospitals (52 percent according to our analysis) being deemed ineligible to receive reconciliation payments essentially even before the program begins, regardless of their achievements in care coordination and reduced episode spending.[4]

The AHA strongly recommends that CMS adopt a more balanced approach. Specifically, CMS should exclude the HCAHPS measure from the CCJR program, and make hospitals ineligible for reconciliation payments only if their performance on both the hip/knee readmission and hip/knee complications measures is statistically worse than the national average.

The Limitations of Pay-for-Performance in a Bundled Payment Context. The AHA strongly agrees that maintaining or improving the quality of care for joint replacement patients must be a foundational goal for the CCJR model. **However, we do not believe that the best, or even only, way to achieve this goal is simply to tie 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 to payment. In spite of this lack of experience with pay-for-performance in a bundled payment context, CMS proposed to use three IQR program measures in the CCJR program, and to establish performance thresholds for each of those measures based on percentiles. We are concerned that the agency has done so without an understanding of what level of performance should be expected from providers in bundled payment contexts.

The AHA believes the "pay-for-performance" approach conceived in this rule is inappropriate for this demonstration and urges CMS to reassess its use of quality measurement in the program. America's hospitals are clearly committed to quality and patient safety, and firmly believe that it is appropriate to measure quality within the context of this kind of experiment. However, the proposed link between payment and performance on two hip/knee performance measures, and on an unrelated measure of patient experience as proposed in this rule, is misguided for the reasons provided in the following sections.

CMS 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, to reduce costs with no adverse impact on 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:

- Changes in critical aspects of quality for hip and knee replacement patients;
- Performance versus the national average of all providers of care along the continuum;

[4] Based on AHA analysis of July 2015 *Hospital Compare* data on the three proposed measures.

- Potential changes in the types of patients undergoing joint replacements;
- Potential changes in the nature or types of services provided to these patients; and
- Changes in patient outcomes.

None of these critically important issues can be answered under the current proposals. Further, this analysis should be about the program as a whole, and not about the individual performance of any given hospital in 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 are inadequate to that task for a variety of reasons, as described in more detail below.

Limitations of the Proposed Measures. 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 the CCJR model, the measures have four significant drawbacks, detailed below, that limit their utility in assessing the quality of care delivered under the model and that make them poorly suited for use as pay-for-performance measures in the CCJR model.

Misalignment with CCJR Patient Population. **The AHA is concerned that the patient populations for all three proposed measures are poorly aligned with the proposed cohort and episode length of patients included in the two MS-DRGs defining the CCJR's applicable patient population.** For example, as mentioned above, the CCJR bundle would apply to both elective and non-elective hip and knee replacements. Yet the proposed readmission and complication measures apply *only* to elective procedures. CMS suggests the complications and readmission measures still are appropriate for the CCJR since elective procedures constitute the vast majority of hip and knee replacements. Nevertheless, as proposed, the measures would fail to provide insight on quality for a significant portion of the patient population included in the model. If CMS adopts our recommendation above to limit the CCJR program to elective patients only, however, we believe these two measures would be appropriate for the program.

The AHA is especially troubled by the mismatch of the HCAHPS measure with the CCJR patient population and episode length and urges the agency to exclude this measure from the CCJR model. To fulfill IQR requirements, hospitals are required to collect HCAHPS data on a sample of *all* of their adult inpatients, regardless of clinical service line. As a result, the HCAHPS measure results reflect the patient experience of all adult hospital inpatients, not just joint replacement patients and not even just Medicare patients. Unfortunately, if CMS were to limit the HCAHPS patient population to just joint replacement patients, the measure's reliability would fall to an unacceptably low level. Furthermore, the HCAHPS survey is focused only on in-hospital experience, despite the fact that the CCJR episode of care encompasses a 90-day period after the initial inpatient admission. As a result, we fail to see how HCAHPS results would be a meaningful performance measure for the providers in the CCJR model.

We certainly agree with CMS that it would be helpful to understand whether patients cared for under the CCJR model had a positive experience. **Thus, rather than using HCAHPS results, CMS should explore the feasibility of funding the administration of the Surgical CAHPS**

survey to a sample of the patients cared for under the CCJR model.[5] In contrast to HCAHPS, the Surgical CAHPS survey is intended to assess the patient experience along the continuum of surgical care – from pre-operative care, to the hospitalization, to post-discharge outpatient care. The Surgical CAHPS has not yet been tested for nationwide implementation in CMS's public reporting programs for hospitals, so we believe it would be inappropriate to use the Surgical CAHPS survey as a pay-for-reporting or pay-for-performance tool at this time. However, the use of the survey by CMS for CCJR model evaluation purposes may provide the agency with a better understanding of the patient experience in the context of the CCJR's bundled payment approach.

Time Lag. **The AHA is concerned by the significant time lag between the proposed data reporting periods and the actual performance years. Specifically, it will be difficult to draw meaningful conclusions about the quality of care delivered under the CCJR 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 5, the reporting periods for the complications and readmissions measures in PYs one through three would include a significant amount of data that pre-date the start of the model, currently proposed as Jan. 1, 2016.

Table 6: Proposed CCJR Measure Performance Periods

Measure	PY 1 (CY 2016)	PY 2 (CY 2017)	PY 3 (CY 2018)	PY 4 (CY 2019)	PY 5 (CY 2020)
THA/TKA Complications	Apr. 1, 2013 – Mar. 31, 2016	Apr. 1, 2014 – Mar. 31, 2017	Apr. 1, 2015 – Mar. 31, 2018	Apr. 1, 2016 – Mar. 31, 2019	Apr. 1, 2017 – Mar. 31, 2020
THA/TKA Readmissions	Jul. 1, 2013 – Jun. 30, 2016	Jul. 1, 2014 – Jun. 30, 2017	Jul. 1, 2015 – Jun. 30, 2018	Jul. 1, 2016 – Jun. 30, 2019	Jul. 1, 2017 – Jun. 30, 2020
HCAHPS	Jul. 1, 2015 – Jun. 30, 2016	Jul. 1, 2016 – Jun. 30, 2017	Jul. 1, 2017 – Jun. 30, 2018	Jul. 1, 2018 – Jun. 30, 2019	Jul. 1, 2019 – Jun. 30, 2020

Lack of Sociodemographic Adjustment. **The AHA remains deeply concerned by the lack of sociodemographic adjustment in both the complications and readmissions measures. We once again urge CMS to consider incorporating such adjustment into the measures for all of the reporting or pay-for-performance programs in which these measures are used.**

The CCJR program will involve a bundled payment arrangement over a 90-day episode of care. Therefore, we expect community factors beyond providers' control – such as the availability of post-hospitalization care, the ability for patients to afford medications, easy access to appropriate food and so forth – to significantly influence the likelihood of a patient's health improving after discharge from the hospital. A sociodemographic adjustment using a well-established proxy for

[5] For additional information on the survey, see https://cahps.ahrq.gov/surveys-guidance/surgical/about/index.html

community factors – such as income – would help to level the playing field among providers caring for large numbers of disadvantaged patients, and those who do not.

Furthermore, a failure to adjust measures for sociodemographic factors when necessary and appropriate can harm patients and worsen health care disparities by diverting resources away from hospitals and other providers treating large proportions of disadvantaged patients. It also can mislead patients, payers and policymakers by blinding them to important community factors that contribute to poor outcomes. Hospitals and other providers clearly have an important role in improving patient outcomes and are working hard to identify and implement effective improvement strategies. However, as a growing body of research demonstrates, there are other factors that contribute to poor outcomes. If quality measures are implemented without identifying those other factors and helping all interested stakeholders understand their role in poor outcomes, then the nation's ability to improve care and eliminate disparities will be diminished.

Limited Performance Variation. **The AHA is very concerned that the limited performance variation in both the readmissions and complications measures would result in hospitals losing reconciliation payments based on insignificant differences in performance.** As CMS itself has acknowledged in its other quality measurement programs, it is problematic to pay providers based on very small differences in performance that may not be clinically significant. Yet, an AHA analysis of the readmissions and complications measures based on July 2015 *Hospital Compare* data (Table 7 below) shows that, nationally, there is only a *1.6 percentage point* difference between the 10th and 90th percentile of performance for both the complications and readmissions measures. And the difference in complications performance between the 20th percentile, which would be ineligible for reconciliation payments, and the 30th percentile, which would qualify for reconciliation payments, is 0.2 percentage points.

Table 7: National Hip/Knee Readmission and Complication Measure Performance by Percentile, based on July 2015 *Hospital Compare* Data

Percentile	Hip/Knee Complications	Hip/Knee Readmissions
10th	4.0 %	5.7 %
20th	3.6 %	5.4 %
30th	3.4 %	5.1 %
40th	3.2 %	5.0 %
50th	3.1 %	4.8 %
60th	3.0 %	4.7 %
70th	2.8 %	4.6 %
80th	2.7 %	4.4 %
90th	2.4 %	4.1 %
National Average	3.1 %	4.8 %

In fact, the level of performance on the readmissions measure appears to be very close to the level CMS would deem to be "topped out" in the hospital VBP program. In the context of the hospital VBP program, CMS applies another set of tests to determine whether a measure has reached "topped out" levels of performance. CMS deems that measures have topped out when national measure data meet the following criteria:

- The difference in performance between the 75th and 90th percentile is statistically insignificant. In general, this means that the difference between the 75th and 90th percentile differs by less than two standard deviations.
- The truncated coefficient of variation (TCV) is less than 0.10. TCV is a statistic with a score ranging from 0 to 1 reflecting the variation of scores across a sample. The larger the TCV, the greater the variation in performance.

An AHA analysis of July 2015 *Hospital Compare* data shows that the TCV for the readmissions measure is 0.096, and that the 75th and 90th percentiles are less than 2 standard deviations different in performance.[6]

Alternative Scoring Approach. **Given the significant misalignment of the measures with the patient population, the time lag between the measure reporting periods and the performance year, and the limited performance variation in the measures, the AHA believes it is misguided and arbitrary to use a percentile achievement approach for determining hospital quality performance. The AHA recommends that CMS instead make hospitals ineligible for reconciliation payments if their performance on both the hip/knee readmission and hip/knee complications measures is statistically worse than the national average.**

We believe a test of statistical significant is a far more appropriate way to evaluate performance on a measure with limited performance variation than using a forced percentile ranking where the difference between being eligible for incentives or not is tenths of a point. Furthermore, CMS already publicly reports information on which hospitals are statistically worse than average on *Hospital Compare*, so it would be a highly feasible approach that would not require significant reworking of the measure. This approach also would serve to reduce confusion among the public who might be interested in understanding how hospitals have performed on the CCJR model.

We acknowledge that such an approach is imperfect given the limitations of the measures. However, we believe it would strike an appropriate balance of ensuring that hospitals remain focused on quality performance while given them a fairer opportunity to earn reconciliation payments. Indeed, the AHA's analysis suggests that there are 22 hospitals that have performance on either measure that is statistically worse than average, and only one hospital that is worse than average on both measures.

Voluntary Reporting of Patient-reported Outcome (PRO) Measure. CMS proposes that participating hospitals have the opportunity to report voluntarily a PRO measure to help the

[6] The standard deviation for the July 2015 data is 0.6. The 75th percentile score is 4.5 percent, while the 90th percentile is 4.1 percent.

agency with the development of such a measure for future public reporting programs. CMS proposes to provide a financial incentive for hospitals that report the specified PRO measure successfully by reducing their discount factor from 2.0 to 1.7 percent. Thus, hospitals that report the PRO measure would have a higher target price, meaning it is easier to meet and would result in them keeping more of the savings they achieve. To qualify for a reduced discount factor, CMS proposes that hospitals submit PRO measure data on 80 percent or more of their eligible elective total hip or knee replacement patients.

The AHA supports a reduction of the CCJR target price tied to the voluntary reporting of the PRO measure. However, we urge CMS to consider reducing the amount of information it intends to require to report the measure. The measure involves the collection of extremely detailed information on elective THA and TKA patients in both the pre-and-post operative time period. Some of the individual items listed in the proposed rule encompass lengthy survey questionnaires. Indeed, the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire alone is 42 items. The amount of data required to collect the PRO measure may deter hospitals from engaging in even a voluntary reporting effort.

Furthermore, **we believe CMS should wait to establish a threshold for successful measure reporting until it gains additional experience with the measure.** Indeed, the CCJR program would be the first opportunity hospitals and others have had to gather information to collect the measure. The ability of a hospital to report such detailed information on 80 percent of its patients is simply unknown at this point. Indeed, several AHA members that report similar data into joint replacement registries have had far lower response rates.

Future CCJR Program Measurement. The proposed rule seeks comment on how health IT can be used and encouraged in coordinating care across care settings and, specifically, whether successfully meeting the requirements of the Medicare Electronic Health Record (EHR) Incentive Program should be required for providers to receive reconciliation payments. The AHA encourages CMS to focus on the desired outcomes of the CCJR, rather than the use of specific inputs such as EHRs.

Hospitals have been working diligently to implement health IT to improve the quality and coordination of care for patients. According to the most recent AHA survey data, hospitals experienced a five-fold increase in EHR use between 2010 and 2014 – an unprecedented growth that was spurred, in great part, by the meaningful use program. However, experience in the meaningful use program has shown that prescriptive, process-focused requirements are burdensome and can actually force providers to shift their focus from achieving good outcomes to meeting the regulatory requirements.

Hospitals have experienced challenges in using their EHRs to connect with post-acute care providers because those entities, including SNFs, long-term care hospitals (LTCHs), IRFs and HH agencies, cannot participate in the meaningful use program and have not yet, in most cases, adopted EHRs that are compatible with those adopted by hospitals. That said, hospitals are working within their own markets to establish connectivity with their post-acute care providers to improve care coordination, reduce readmissions and meet meaningful use requirements. The approaches taken vary and may include use of health information exchanges, allowing

authorized access to a shared data set, or sending specific summary of care documents when a patient is transferred.

Hospitals that participate in a bundling program will have even greater incentive to find ways to share information, given that success in the program will require close coordination. **Given that many different approaches can be taken to share needed information, we recommend that the bundling program refrain from introducing specific requirements regarding the use of health IT and allow hospitals and their partners the flexibility to determine the best approaches to achieve better coordinated care.**

FINANCIAL ARRANGEMENTS AND BENEFICIARY INCENTIVES

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 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 CCJR 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 CCJR that comply with the requirements in the proposed rule. As CMS recognized in the preamble to the calendar year 2016 Physician Fee Schedule proposed rule issued within one day of this proposed rule, the self-referral law was designed for a different world of care delivery and payment than the new models. At its core, the self-referral law is about separating hospitals and referring physicians, while the evolving Medicare and Medicaid models "are premised on the close integration of a variety of different health care providers." The Anti-kickback Statute is similarly no longer compatible with the new models.

As proposed, any financial arrangement or agreement under the CCJR model that implicates fraud and abuse laws would not be protected unless it falls under an existing exception or safe harbor. That is an unacceptable risk for hospitals, whose participation in this program would be mandatory. They should not have to spend hundreds of hours or thousands of dollars in hopes of stringing together components from the existing exceptions and safe harbors or developing inefficient work-arounds to try to ensure that their efforts meet the demands of this new program and do not run afoul of such laws and regulations. **The mandate to participate should not take effect unless and until hospitals have the needed, explicit protections in place and adequate time to form the necessary financial arrangements. Although hospitals are supportive of the CCJR initiative, as the administration is aware, such programs cannot be successful for Medicare and its beneficiaries without these protections, e.g., the Accountable Care Organization program.**

CMS's mandate that certain hospitals in the targeted MSAs participate in the CCJR model is, at its core, a mandate that those hospitals bear responsibility for the financial and quality outcomes of other providers who provide care to Medicare beneficiaries during qualifying episodes. In the proposed rule, CMS notes that participating hospitals may rely on financial arrangements with those providers – which CMS refers to as "CCJR collaborators" – to share the program's potential risks and rewards. Indeed, our members report that such financial arrangements are not

just a desirable but essential component of successful participation in the CCJR model. CMS itself acknowledges in the proposed rule that the financial relationships between hospitals and CCJR collaborators may implicate fraud and abuse laws. Despite this recognition, the proposed rule does not include waivers of any of the potentially applicable fraud and abuse laws. Nor does the proposed rule indicate that such waivers are forthcoming. Given that these waivers are essential to hospitals' ability to form financial arrangements with CCJR collaborators, what CMS proposes would effectively hold hospitals accountable, in part, for other providers' performance, yet tie their hands by substantially limiting their ability to guarantee that those providers have a real stake in the program's outcomes.

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

Additionally, CMS has proposed a very detailed regulatory structure that would govern any financial arrangements formed subject to the CCJR and would also serve as a built-in safeguard against fraud and abuse concerns. Hospitals, for example, would be required to set forth a written participation agreement that includes the terms of any sharing arrangements, such as sharing of program savings or internal cost savings, or of repayments to Medicare. The written agreement detailing the sharing arrangements would be subject to extensive requirements, including descriptions of the methodologies used to calculate any payments to and from hospitals and CCJR collaborators (known as gainsharing and alignment payments); plans regarding care redesign, changes in care coordination or delivery, and a description of how success would be measured; and information on management and staffing personnel. Further, any gainsharing and alignment payments would be subject to specific requirements.

As CMS itself states in the proposed rule, "[w]e believe these proposed requirements and responsibilities are essential to ensuring that all CCJR Sharing Arrangements are for the *sole purpose of aligning the financial incentives of collaborating providers and suppliers with those of the participant hospital toward the CCJR model goals of improved LEJR episode care quality and efficiency*" (emphasis added). We agree, and believe that satisfaction of these requirements and responsibilities should provide participant hospitals protection under fraud and abuse laws.

In addition, the AHA urges the Secretary either to waive the beneficiary inducement civil monetary penalty (CMP) for beneficiary incentives that comply with the requirements in the proposed rule, or state explicitly that any incentive program established under the CCJR that complies with the proposed requirements meets a statutory exception to the CMP law. In the proposed rule, CMS states that CCJR participant hospitals may want to provide in-kind patient engagement incentives to beneficiaries in CCJR episodes. The agency proposes to

allow participant hospitals to provide in-kind patient engagement incentives to beneficiaries in CCJR 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, nor to declare that compliance with the terms and conditions satisfies a statutory carve-out to the prohibition. Therefore CMS's proposal, as drafted, provides hospitals with a false sense of security that the beneficiary enhancements offered by CMS as a programmatic element of the CCJR do not run afoul of the law.

WAIVERS 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. **Participating hospitals should have maximum flexibility to identify and place beneficiaries in the clinical setting that best serves their short- and long-term recovery goals.** The specific waivers that we request below would do just that, providing our members with valuable tools to increase quality and reduce unnecessary costs. They 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.

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.

SNF 'Three-day Rule'. CMS proposes to waive the SNF three-day rule for performance years two through five only, and only for discharges to SNFs with at least a three-star rating in the Five-Star Quality Rating System for SNFs on the *Nursing Home Compare* website. **We urge CMS to waive the SNF three-day rule in all years of the CCJR program.** The agency stated that it did not propose its waiver in year one because there is no downside risk in that year and, therefore, hospitals do not have an incentive to closely manage care and may not be mindful of any increasing episode spending resulting from increased SNF stays. We strongly disagree. Hospitals want to be successful under this program and will be actively managing care in all years of the program, including in year one, with an eye toward the approach of downside risk. Further, hospitals will be spending this first year of the program putting in place the care processes and procedures necessary to achieve success, including reviewing and likely modifying discharge planning protocols. It is burdensome and unwarranted to ask hospitals to again revise these protocols in year two of the program.

In addition, we are concerned about CMS's proposal to limit the waiver to SNFs with at least a three-star rating, given their limited availability in certain markets. In speaking with our clinicians, we estimate that approximately 20 percent of elective joint replacement patients would need to be discharged to a SNF and would be able to do so safely after fewer than three days. Yet, we found that, in almost one quarter of the CCJR MSAs, more than half the SNFs would be ineligible for this waiver because they have fewer than three stars. In almost one tenth of the CCJR MSAs, more than 60 percent of the SNFs would be ineligible for this waiver, and in 3 percent of the MSAs, more than 70 percent would be ineligible. In addition, six of the MSAs have only one, two or three SNFs with at least three stars. Yet, hundreds of elective joint replacement patient in some of these areas would need to be discharged to a SNF and would be able to do so safely after fewer than three days. We are concerned the structure of CMS's proposed waiver would lead to two separate and unequal tiers of care: a more flexible, patient-centered level for patients in markets with an adequate supply of three-star SNFs, and a more restrictive, regulation-driven level of care for patients in markets with an inadequate supply of three-star SNFs.

We also have concerns about the star rating methodology itself. For example, the biggest part of a SNF's star rating is the facility inspections conducted by CMS or, most likely, state surveyors. While surveys are an important activity for assuring compliance with regulations, there is significant state-to-state, and surveyor-to-surveyor, variation in how survey standards and guidance are applied. As a result, the findings from surveys can be highly subjective. Although CMS has attempted to account for the variation in survey practices by creating a distribution of star ratings on inspection data based on the relative performance of facilities within a state, we have concerns about the extent to which this adequately addresses the problem. Since CMS proposes to hold participating hospitals financially accountable for the quality and costs of the entire episode of care, the decision to admit a patient to a setting of care should be at the discretion of the patient's physician, working together with the beneficiary and the participating hospital.

Post-discharge Home Visits. **The AHA supports CMS's proposal to waive the "incident to" rule, which would allow a CCJR 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 CCJR episode.

Home Health 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, CCJR participants 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 CMS's proposed telehealth waivers.** 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 CCJR 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, CCJR 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 CCJR 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 one-on-one. **We urge CMS to waive the "preponderance" requirement under the CCJR 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 CCJR 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.

MONITORING AND BENEFICIARY PROTECTION

CMS proposes to require participating hospitals to, as part of discharge planning, provide beneficiaries with a complete list of all available post-acute care options in the service area consistent with medical need. This list would include beneficiary cost-sharing and quality information. These requirements would supplement the existing discharge planning requirements. However, as noted above, 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. In addition, we note that hospitals do not have access to beneficiaries' post-acute care cost-sharing details. **As such, we urge CMS not to finalize this requirement.**

DATA SHARING

Beneficiary Claims Data. CMS proposes to provide participants with beneficiary-level claims data for the historical period used to calculate a participant's target price as well as ongoing quarterly beneficiary-identifiable claims data in response to a participant's request for such data. **The AHA urges CMS to routinely make these data available on a monthly basis as it does for BPCI.** Providing data only quarterly does not give providers sufficient time to identify and intervene in episodes as they are occurring. Furthermore, these data should be provided to hospitals that sign a data use agreement (DUA) on a routine basis without the necessity of a lengthy data request process that is burdensome to both hospitals and CMS. Instead, CMS could create a streamlined process to ensure hospitals certify that they will meet the requirements of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule.

We support CMS's proposal to make the data available in two formats (summary beneficiary-level reports as well as line-level claims data), though we believe that all participants should routinely receive both sets of data. Specifically, the summary-level data would be highly beneficial to all participants, in allowing them to quickly ascertain performance and potentially intervene in episodes as they are occurring. In addition, we support CMS's proposal to provide data for a period that would cover the past 18 months.

We urge CMS to provide the data in the form in which it has provided data to BPCI participants, which has facilitated its use. Specifically, CMS should provide fully adjudicated claims with the episodes already constructed. In this format, only relatively minor manipulations have been necessary to place the data into a usable form.

Finally, CMS proposes not to provide data related to substance use diagnoses and services in the files. However, this information is key for bundlers to understand the full risk associated with the patient and identify appropriate care management. While we understand the sensitivity of such services and CMS's well-intentioned exclusion of them in the files, we think there are options that would provide bundlers with more information, while not risking beneficiary privacy by suppressing identifiable elements. **We, therefore, urge CMS to provide de-identified cost and claims data for these services. If this is not possible, at a minimum, CMS should provide the aggregate payment amount for these services in the monthly CCJR files.**

Aggregate Regional Data. CMS also proposes to provide CCJR hospitals with aggregate data on the average total expenditures for relevant episodes in their census division. These data would not include beneficiary-identifiable claims data. We believe this data will be critical to hospitals in tracking their performance relative to benchmarks over time and urge CMS to provide it on a monthly basis for a rolling 18 month period as well.

Timing and Period of Baseline Data. CMS proposes to begin making historical data for the period used to set the hospital's target price available to CCJR hospitals within 60 days of CMS's receipt of the request for such data, but requests will not be accepted until Jan. 1, 2016, the effective date of the model. **The AHA strongly urges CMS to provide all participating hospitals with these data at least six months prior to the start of the program without any process to request such data.** As noted above, such a timeframe is warranted to give hospitals the time they need to identify opportunities for care redesign, assess the performance of potential partners, and begin to establish the relationships necessary to better manage care across the continuum.

Legal Permission to Share Beneficiary-identifiable Data. **We strongly oppose CMS's proposal to provide beneficiaries with the opportunity to opt out of claims data sharing.** Without data on all beneficiaries, hospitals will be unable to assess their performance relative to their target price, intervene in episodes as they are occurring, and evaluate the performance of other providers across the care continuum.

APPEALS PROCEDURES

CMS proposes to institute an appeals process under this model that would allow participant hospitals to appeal matters related to reconciliation and payment, as well as non-payment related issues, such as enforcement matters. CMS also proposes a dispute resolution process for claims where judicial review is not precluded. **The AHA supports this proposal. We request that CMS monitor this process to ensure the agency is complying with all necessary time frames and hospitals are afforded due process in the review of these claims.**