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June 16, 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-1632-P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, including Changes Related to Electronic Health Record Incentive Program (Vol. 80, No. 83), April 30, 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) hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2016. We will submit comments separately on CMS's proposed changes to the long-term care hospital (LTCH) PPS.

While we support a number of the inpatient PPS proposed rule's provisions, we have concerns about cuts to disproportionate share hospital (DSH) payments, lack of data transparency and certain proposed changes to the Inpatient Quality Reporting (IQR) Program and Hospital Readmissions Reductions Program (HRRP). In addition, as CMS requested, we provide our views on the Bundled Payments for Care Improvement (BPCI) Initiative. We also are concerned that the agency did not propose or discuss any changes to the two-midnight policy in this rule.

TRANSPARENCY OF DATA

The AHA has serious concerns about the lack of transparency around the Office of the Actuary (OACT) calculations that were used to support proposals in this and other recent inpatient PPS rules. Specifically, the agency has used OACT estimates to calculate proposed DSH payments, as well as its previously finalized 0.2 percent payment reduction related to the two-midnight policy. Yet, sufficient detail around these calculations, including the specific figures used, what they



encompass and the assumptions behind them, have never been disclosed. **Not having access to this information severely hampers our ability to replicate the analysis and provide meaningful comment on these issues of great importance to the hospital field. We ask the agency to improve its transparency with regard to OACT's estimates.**

TWO-MIDNIGHT POLICY

In light of the fact that CMS will be addressing issues related to the two-midnight policy in the outpatient PPS rule, with any changes likely to take effect Jan. 1, 2016, we urge the agency to extend the partial enforcement delay of the two-midnight policy until March 30, 2016. This will not only provide additional time for CMS to issue guidance related to any new policies or admission criteria for hospitals and review contractors; it will allow hospitals time to implement changes put forth by the agency. Additionally, we ask the agency to repeal the unlawful 0.2 percent reduction to the standardized amount that was implemented in FY 2014.

IQR PROGRAM CHANGES

CMS proposes several significant changes to the IQR program. Most notably, for FY 2018, CMS proposes to require hospitals to submit 16 of 28 available electronic clinical quality measures (eCQMs). **While we strongly support the long-term goal of using electronic health records (EHRs) to streamline and reduce the burden of quality reporting, setting a date certain to require eCQM reporting for the IQR is premature given the serious questions about eCQM feasibility and accuracy.** CMS also proposes eight new measures for FY 2018. Yet all eight measures lack endorsement by the National Quality Forum (NQF), giving the field limited insight on whether the measures are reliable, accurate and feasible enough for public reporting programs. The measures also do not seem to be focused on any concrete national priority area or goal for improving care. **For this reason, we strongly urge CMS to consider adopting the recommendations for streamlining and focusing national quality measurement efforts outlined in the Institute of Medicine's recent *Vital Signs* report.** If adopted, the report's recommendations would facilitate the better use of quality measures by all stakeholders to advance care.

HRRP CHANGES

CMS proposes to substantially expand the patient population included in its pneumonia readmissions measure, which would result in more than 630,000 (or 65 percent) more patients being included in the measure. Every hospital's readmission rate would be affected. **The AHA urges CMS not to finalize this proposed change unless and until the measure has been reviewed and endorsed by the NQF.**

In addition, we once again urge CMS to incorporate sociodemographic adjustment into the HRRP's measures. The existing readmissions measures fail to account for community factors beyond hospitals' control that affect the likelihood of readmission, such as poverty and access to support services. The AHA remains very concerned that, without sociodemographic adjustment, readmissions penalties will continue to accrue disproportionately to hospitals treating our nation's poorest and most vulnerable patients.

Mr. Andrew M. Slavitt

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BPCI INITIATIVE

The AHA urges CMS to continue to expand the BPCI Initiative with additional rounds of voluntary participation. More testing and evaluation is necessary, with additional participants and episode types. Also, we urge CMS to carefully monitor the financial arrangements entered into by providers and third parties to ensure that they support the care transformation goals of BPCI. Finally, CMS should evaluate carefully the precedence rules governing which entity “owns” the bundle because it is a risk to high-quality and efficient patient care to have different awardee types vying for management of the same episode.

Our detailed comments on the proposed rule are attached. If you have any questions, please feel free to contact me or Priya Bathija, senior associate director of policy, at (202) 626-2678 or pbathija@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

**American Hospital Association (AHA)
Detailed Comments on the Inpatient Prospective Payment System
(PPS) Proposed Rule for Fiscal Year (FY) 2016**

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MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP (MS-DRG) DOCUMENTATION AND CODING ADJUSTMENT

The Centers for Medicare & Medicaid Services (CMS) proposes a cut of 0.8 percentage points in FY 2016 to fulfill part of the American Taxpayer Relief Act of 2012 (ATRA) requirement that CMS *recoup* what the agency claims is the effect of documentation and coding changes from FYs 2010, 2011 and 2012 that CMS says do not reflect real changes in case mix. This is in addition to the two cuts of 0.8 percentage points that were finalized by CMS for FYs 2014 and 2015. **While we continue to believe these congressionally mandated adjustments are not warranted, the agency's implementation of the ATRA requirement through cuts of the same magnitude each year helps mitigate extreme annual fluctuations in payment rates and provides hospitals with additional time to manage these sizeable cuts.**

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

FY 2015 DSH PAYMENT CALCULATION

The Affordable Care Act (ACA) requires that, beginning in FY 2014, hospitals initially receive 25 percent of the Medicare DSH funds they would have received under the DSH formula in place prior to FY 2014 – “empirically justified DSH payments” – with the remaining 75 percent flowing into a separate funding pool for DSH hospitals – “additional DSH payments.” This pool will be reduced as the percentage of uninsured individuals declines and distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides relative to the national total.

TRANSPARENCY-RELATED TO DSH CALCULATION

The AHA has concerns about the agency's lack of transparency with regard to how CMS and the Office of the Actuary (OACT) are calculating DSH payments. This is particularly troubling because Congress has generally foreclosed subsequent review, making the adequacy and completeness of notice and comment rule-making that much more important from a constitutional due process perspective. The AHA highlights some examples below of where we recommend the agency improve transparency related to the DSH calculation; however, this list is not inclusive, and we urge CMS to provide any additional information possible related to this complex calculation.

Our biggest concern relates to calculation of Factor One, which is discussed on page 24485 of the rule. There, CMS includes a table explaining the factors applied for FYs 2013 through 2016 to estimate Medicare DSH expenditures. The text below in that table states:

The figures for FYs 2013 and 2014 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2015 is based on preliminary data for 2015. The discharge figure for FY 2016 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare FFS and also Medicare Advantage (MA) plans.

However, the agency provides neither OACT's "completion factor" used to adjust the claims data for FYs 2013 and 2014 nor an explanation of how OACT calculated this "completion factor." CMS also fails to provide an explanation of the "preliminary data for 2015" that OACT used in the FY 2015 figure, such as what the data are and what they cover, and the "assumptions" used for the FY 2016 figure. **Not having access to this information severely limits the AHA's ability to sufficiently comment on this issue. We request that this information be provided to the hospital field in advance of publication of the final rule and in the inpatient PPS proposed rule each year going forward. This will enable the field to have the data necessary to replicate CMS's DSH calculation and comment sufficiently in future years.**

In addition, in comparing the "other" values for the Medicare DSH projections for FY 2014, between the *FY 2015 IPPS Final Rule Medicare DSH Estimates-September 2014* and *FY 2016 IPPS NPRM Medicare DSH Estimates* files, we notice that the value posted in the FY 2016 file (0.9993 in cell E14) is less than 1, whereas the corresponding value in the FY 2015 file (1.0355 in cell E15) is greater than 1. These numbers are dramatically different, and the considerably lower value in the FY 2016 file has a significant impact on the FY 2016 Medicare DSH estimate. In contrast, the "discharge" and "case mix" values across FYs 2014, 2015 and 2016 are relatively similar, leading to additional concerns regarding the accuracy of the 0.9993 value in the FY 2016 file. If, for example, we were to substitute the seemingly incorrect value of 0.9993 with 1.0355, the FY 2016 Medicare DSH estimate would be \$13.821 billion instead of the CMS-estimated value of \$13.338 billion, a difference of \$483 million.

The AHA has requested clarification from CMS regarding this significant discrepancy, but CMS has failed to provide any explanation. **We request that CMS include a detailed explanation, including calculations, of how this factor and the "other" values for all years have been calculated by OACT. In addition, the AHA would like to see detailed calculations of the discharge and case mix values for all years as well. We remain concerned regarding OACT's calculations and these inconsistencies, and request that CMS address these concerns in the FY 2016 inpatient PPS final rule.**

PERCENTAGE OF UNINSURED INDIVIDUALS

The *King v. Burwell* Supreme Court decision, expected in late June of this year, has the potential to drastically impact the DSH calculation and could result in a reduction in the total uncompensated care pool paid to hospitals of nearly \$2 billion. **The AHA urges CMS to account for the increase in the uninsured population that would result if the Supreme Court issues a decision in favor of King.**

Specifically, in Factor Two, CMS measures the difference between the percentage of individuals under the age of 65:

- (I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education

Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

- (II) who are uninsured in the most recent period for which data is available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.¹

CMS has already determined the first part of the calculation, or the percentage of those who were uninsured in 2013. For the second part of the calculation, or the percentage of uninsured in the most recent period, CMS has used “the most recent available [Congressional Budget Office (CBO)] estimates to calculate this percent of individuals without insurance.”² More importantly, CMS has indicated that it may update its proposed Factor Two if a new CBO estimate becomes available *after* the proposed rule is published: “Our proposal for Factor Two is subject to change if more recent CBO estimates of the insurance rate become available at the time of the preparation of the final rule.”³

We strongly support CMS’s policy to use new CBO estimates that become available after the publication of the proposed rule – especially where there is a significant difference between: (1) the estimate of the percentage of uninsured used to calculate Factor Two in the proposed rule, and (2) an estimate of the percentage of uninsured issued by CBO after publication of the proposed rule, but before publication of the final rule. That is precisely the situation that is expected to occur if the Supreme Court rules for the Petitioners in the *King* case: A large increase in the number of uninsured individuals is anticipated⁴ and CBO would almost certainly issue an updated estimate of the percentage of individuals under 65 who will be uninsured in subsequent years. **As a result, if the Supreme Court rules for the Petitioners, we urge CMS to adhere to its articulated policy and use an updated insurance rate to calculate Factor Two in promulgating the final rule.**

Even if the increase in the uninsured rate did not occur until CY 2016, it would still significantly alter the FY 2016 Factor Two value, as shown in Table 1 below. Table 1 walks through the Factor Two analysis, comparing the Factor Two calculation using CBO’s March 2015

¹ 42 U.S.C. § 1395ww(r)(1)(B).

² 80 Fed. Reg. 24,324, 24,486 (Apr. 30 2015). *See also* 79 Fed. Reg. 49,854, 50,013 (Aug. 22, 2014).

³ *Id.*

⁴ The Robert Wood Johnson Foundation (“RWJF”), in conjunction with the Urban Institute, issued a study in January 2015, Linda J. Blumberg, Matthew Buettgens, and John Holahan, *The Implications of a Supreme Court Finding for the Plaintiff in King v. Burwell: 8.2 Million More Uninsured and 35% Higher Premiums*, Exhibit 1 hereto, that estimates that if the Supreme Court sets aside the subsidies in states without state-operated exchanges, approximately 8.2 million more Americans would be uninsured in CY 2016, resulting in a national uninsured rate of 15.1 percent. A more recent May 2015 study by the same authors, *The Combined Effect of Not Expanding Medicaid and Losing Marketplace Assistance*, Exhibit 2 hereto, calculates the impact of such a decision on the 20 states that did not expand Medicaid under ACA, estimating an increase in the uninsured population of 9.8 million people in those 20 states in CY 2016. Of this 9.8 million uninsured increase, 4.3 million come from Texas and Florida alone. The uninsured rate would increase to 18.3 percent in those states in CY 2016. The actual increase in the uninsured population could be larger than this estimate when it includes the impact of such a Supreme Court decision on states that did expand Medicaid, but do not have state-operated exchanges.

projections with the Factor Two calculation using RWJF’s more modest uninsured projection for CY 2016. It demonstrates that, should the petitioners prevail, the total uncompensated pool for FY 2016 should be nearly \$2 billion higher. Indeed, America’s hospitals will desperately need these uncompensated care payments to offset the significant increase in uncompensated care provided to the many uninsured patients walking through their doors.

Table 1: Comparison of Factor Two Calculated Using CBO’s March 2015 Projections and RWJF’s Petitioner-Prevailing Projections

	FY 2016 Proposed Rule Factor 2	FY 2016 Factor 2 Projection if <i>King</i> Decided in Favor of Petitioner
CY 2015 rate of insurance coverage (March 2015 CBO estimate)	87 percent	87 percent
CY 2016 rate of insurance coverage (March 2015 CBO / RWJF estimate)	89 percent	85 percent
FY 2016 rate of insurance coverage	88.5 percent [(87 percent x .25) + (89 percent x .75)]	85.5 percent [(87 percent x .25) + (85 percent x .75)]
FY 2016 rate of uninsurance	11.5 percent (1 – 88.5 percent)	14.5 percent (1 – 85.5 percent)
2013 rate of uninsurance (March 2010 CBO estimate)	18 percent	18 percent
Factor 2	63.69 percent [(1 + ((0.115 - 0.18)/0.18)) - .002]	80.36 percent [(1 + ((0.145 - 0.18)/0.18)) - .002]
FY 2016 Uncompensated Care Amount	\$6,371,181,591.01 (\$10,003,425,327.39 x 0.636)	\$8,038,752,593.09 (\$10,003,425,327.39 x 0.8036)

In light of the impending decision in *King v. Burwell*, the AHA requests that CMS take one of two courses of action if there is a decision in favor of *King*.

First, if there is no CBO estimate issued after the case is decided, but before the final rule is published, CMS could use the latest CBO estimate that does not take into account a *King* decision and calculate from that estimate the percentage of uninsured as a consequence of the *King* decision. After all, the statute requires only that CMS make its calculation based on the most recent CBO estimates available. CMS has discretion regarding how to use those estimates and can, therefore, factor the consequences of an adverse *King* decision into its calculation.

Alternatively, if CMS believes a longer period of time is necessary to calculate the uninsured percentage after an adverse Supreme Court decision or if the agency wishes to see if CBO will

issue a new estimate of the percentage of uninsured individuals⁵ and then use that estimate in the calculation, CMS could, for example, issue that portion of the rule concerning the uncompensated care payment calculation in interim final form, and finalize the calculation before October 1 of this year, the effective date of the rule. Either approach would help ensure an accurate payment that reflects the actual uninsured population.

The timely consideration of the Supreme Court’s decision by CMS in the context of this part of the rule will be of great assistance to hospitals that will struggle under such a decision.

WORKSHEET S-10

In the FYs 2014 and 2015 inpatient PPS final rule, CMS discussed the alternative of using Worksheet S-10 of the Medicare cost report to determine the amount of uncompensated care each hospital provides. However, CMS did not propose to use these data to determine the uncompensated care costs at that time because of concerns regarding variations in and completeness of these data. In this proposed rule, CMS indicates that it believes it is still premature to use the Worksheet S-10 for purposes of determining uncompensated care payments in FY 2016. The agency states that it still intends to propose use of the Worksheet S-10 sometime in the future.

The AHA agrees that the S-10 uncompensated care data are not appropriate for use in FY 2016. However, we continue to note that, if reported in an accurate and consistent manner, these data have the potential to serve as a more exact measure of the treatment costs of uninsured patients. We have communicated our major concerns and suggestions regarding the S-10 to CMS on multiple previous occasions, including in a stakeholder discussion group lead by Dobson DaVanzo & Associates, LLC in January 2014 and in our [comments](#) to the FY 2015 inpatient PPS proposed rule. **We urge the agency to take action to revise and improve both the Worksheet S-10 and the instructions and, once stakeholders have had an opportunity to weigh in on the proposed changes, educate both the field and CMS’s contractors about the Worksheet S-10 so that these data could potentially be used as soon as possible. CMS also should consider taking additional steps to verify the accuracy of these data given the concerns about their current validity and completeness.**

ELIMINATION OF THE SIMPLIFIED COST ALLOCATION METHODOLOGY

In the FY 1997 inpatient PPS final rule, CMS implemented the simplified cost allocation methodology for hospitals as an alternative to the standard cost-finding methodology.⁶ The simplified cost allocation methodology reduces the number of “statistical bases” that a hospital must use for purposes of allocating overhead cost centers. For example, a hospital using the simplified cost allocation methodology must use square footage for allocating costs associated

⁵ We note that CBO quickly responded to the Supreme Court’s decision on Medicaid expansion (i.e., CBO released new estimates on July 24, 2012, to account for the Supreme Court’s June 28, 2012 decision in *National Federation of Independent Business v. Sebelius*).

⁶ 42 CFR 412.302(d)(4).

with buildings, fixtures and moveable equipment, and salaries for allocating costs associated with employee benefits.

According to CMS, the simplified cost allocation methodology was devised in response to concerns expressed by the hospital field regarding the high costs of the recordkeeping required under the cost reporting rules. CMS now proposes to eliminate simplified cost allocation methods for hospitals for three reasons:

1. Based on FY 2013 data, only nine of 1,269 critical access hospitals (CAHs) and 23 of 4,389 hospitals other than CAHs used the simplified cost allocation methodology;
2. There have been “advances in technology and recordkeeping for hospitals, resulting in less arduous and costly recordkeeping and a diminished need for hospitals to use the simplified cost allocation methodology;” and
3. The failure to use dollar value as the allocation basis for CT and MRI are distorting cost to charge ratios for those new cost centers.

The AHA believes these reasons are inaccurate and inadequate to support this proposed change. We urge the agency to withdraw this proposal.

First, we believe CMS has incorrectly interpreted the cost reporting forms when asserting that only 32 CAHs and other hospitals use the simplified cost allocation methodology.

When a hospital first elects this method of cost allocation it must check a “yes” to question 149, “*Was there a change to the simplified cost allocation method?*” on Worksheet S-2, and thereafter it is committed under CMS rules to use the simplified method for at least three years.⁷ Once a hospital checks “yes” on question 149 of Worksheet S-2, it does not need to check that box in subsequent years. Therefore, if CMS’s source for the “32” figure was the number of hospitals that selected “yes” to this question in FY 2013, the agency has incorrectly calculated the number of hospitals using the simplified allocation method in that year.

The AHA attempted to estimate the number of hospitals using the simplified cost allocation method in FY 2013. Using FY 2013 cost report data from the first quarter 2015 HCRIS file, we looked at worksheet B-1, line 30 (Adults and Pediatrics – General Routine Care). Capital-related costs for buildings and fixtures (square feet) are included in column 1 and those for movable equipment (dollar value) are in column 2. It is AHA’s general understanding that hospitals using the simplified cost allocation method will likely report square footage in both columns 1 and 2. On the other hand, hospitals not using the simplified method are likely to report a dollar value in the movable equipment column. Assuming that any hospital with identical values in both columns used the simplified method, we estimate that 1,928 of the 3,363 hospitals (57 percent) used the simplified cost allocation method in FY 2013. While this analysis is not perfect, and some hospitals not using the simplified cost allocation method may report square footage in both columns 1 and 2, the large discrepancy between our number and CMS’s number makes it clear that CMS’s statistic is flawed. **Indeed, far more than 32 CAHs and other hospitals use the simplified cost allocation method and would be negatively impacted by the proposal.**

⁷ CMS Pub. 15-02 Section 3604 (line 45.03) and Section 3617.

In addition, despite advances in technology and recordkeeping for hospitals, our members tells us that elimination of the simplified cost allocation method would create a significant administrative burden for hospitals. Although CMS has indicated that making this change will result in more precise cost to charge ratios, it has not provided any data supporting this assertion or evidence that any additional value would outweigh the additional reporting burden to hospitals.

TWO-MIDNIGHT POLICY – SHORT-STAY PAYMENT METHODOLOGY

TWO-MIDNIGHT POLICY

CMS finalized its “two-midnight” policy in the FY 2014 inpatient PPS final rule. Under this policy, CMS will generally consider hospital admissions spanning two midnights as appropriate for payment under the inpatient PPS. We support the decision to pay these cases under Part A. In contrast, hospital stays of less than two midnights will generally be considered outpatient cases, regardless of clinical severity.

CMS does not propose any changes to the two-midnight policy in the proposed rule. However, the agency acknowledges that the hospital field has expressed a variety of concerns related to the two-midnight policy. CMS indicates that it will consider this feedback from the hospital field, as well as recent Medicare Payment Advisory Commission (MedPAC) recommendations, and expects to include a further discussion of the broader set of issues related to short inpatient hospital stays, long outpatient stays with observation services and the related 0.2 percent inpatient PPS adjustment in the calendar year (CY) 2016 hospital outpatient PPS proposed rule that will be published in the summer.

As we have stated previously, we appreciate CMS’s attempt to clarify what is required for payment of inpatient hospital services under Medicare Part A. However, the two-midnight policy is an arbitrary time-based benchmark that clouds the role of physician judgment. CMS itself professes to hold physician judgment paramount, but this arbitrary standard seems to override that longstanding policy. In addition, while the two-midnight policy may address some problems, it has generated many others. For example, the two-midnight policy fails to provide adequate reimbursement for beneficiaries who require an inpatient level of care, but who do not meet the two-midnight benchmark for admission. Specifically, CMS reimburses for this care under the outpatient PPS, which does not cover the cost of the standard of care that is provided and typically results in a higher cost-sharing burden for the beneficiary. The AHA believes CMS must pay hospitals fairly and adequately for the care they provide to Medicare patients, including short-stay cases.

Below, we provide our thoughts on MedPAC’s recommendations and other two-midnight policy related issues. **We look forward to continuing to work with CMS to further consider these issues of great importance to both hospitals and the Medicare program.**

COMMENTS ON MEDPAC RECOMMENDATIONS ON HOSPITAL SHORT-STAY ISSUES

At its April meeting, MedPAC finalized several recommendations regarding hospital short inpatient stay issues. The commission did not make a recommendation related to a short-stay payment methodology; however, it recommended that CMS withdraw its two-midnight policy. Currently, the AHA is gathering feedback from our members related to this and other recommendations made by MedPAC. If the two-midnight policy is withdrawn, hospitals would no longer be required to follow this arbitrary time-based benchmark. Hospitals also would lose the certainty of an inpatient payment for a stay spanning at least two midnights, and be subject to the overzealous audits of the recovery audit contractors (RACs).

The commission also recommended modifications to the RAC program, including:

- Targeting RAC reviews to hospitals with the highest number of short inpatient stays;
- Tying a RAC's contingency fee to its denial overturn rate;
- Shortening the RAC look-back period for patient status reviews; and
- Evaluating a formula-based payment penalty for hospitals with "excess" levels of short inpatient stays.

The AHA supports some of MedPAC's RAC recommendations; for example, the recommendation for CMS to base each RAC's contingency fee, in part, on its denial overturn rate. RACs should be held financially accountable for their overzealous audit behavior. And with some modifications, this change could help address the misaligned financial incentives that drive inappropriate RAC denials. Our additional concerns regarding the current RAC's contingency structure follow elsewhere in this section.

On the other hand, however, we are concerned that MedPAC's recommendations do not fully address the RAC program's systemic problems. For example, MedPAC's recommendation that CMS focus reviews of short inpatient stays on hospitals with the highest rates of short stays would neither reduce RAC scrutiny nor administrative burden for hospitals that are not targets of the short-stay audits, nor decrease the overall number of claims audited and denied by RACs. This is because RACs are not limited to auditing short inpatient stays; they may receive approval from CMS to audit any number of Medicare payment rules. Further, CMS allows RACs to audit a certain number of claims per hospital, based on the hospital's Medicare volume (e.g., for large hospitals, RACs can request 600 records every 45 days). The contingency fee structure encourages RACs to demand the maximum number of records every time period. Unless CMS also reduces the audit limits, RACs simply will shift their focus to other audit issues for those hospitals that do not have high rates of short stays.

Similarly, the recommendation that CMS evaluate a formulaic penalty on "excess" short stays to substitute for RAC reviews of short inpatient stays would not curb RAC review for those hospitals unless corresponding reductions are made to RAC audit limits. These hospitals simply would be subjected to the penalty *in addition to* routine RAC audits. We are deeply concerned about the concept of applying penalties based on an arbitrary threshold of what constitutes an "excess" number of short stays. It is unclear how an "excess" number of short stays would be determined. Setting an arbitrary threshold clouds the role of physician judgment, challenges Medicare program's longstanding policy that medical necessity drives coverage decisions, and

ignores legitimate variation in practice. It is imperative to establish any and all policies in a way that recognizes medical necessity and the critical role of physician judgment.

It is clear that any attempt to address the issues of the two-midnight policy or short inpatient hospital stays will continue to fail if it is not combined with meaningful reform and management of the RAC program. Therefore, we continue to urge the following additional changes that would address the systemic problems with the RAC program:

1. **Prohibit any payment structure that encourages RACs to deny claims.** The current contingency fee structure is one-sided in that RACs can deny claims with impunity. Instead, RACs should be paid similarly to other Medicare contractors, such as through a cost-based contract.
2. **Impose a financial penalty on RACs when a denial is overturned on appeal.** A penalty assessed in such instances would curb overzealous RACs and create a level playing field for both RACs and providers in addressing incorrect payments.
3. **Require RACs to consider only the medical documentation available at the time the admission decision was made in determining whether an inpatient stay was medically necessary.** Currently, RACs can review claims three years after the date of service and are able to utilize information that may not have been available to the physician at the time of the admission decision in order to deny claims. This requirement would restrain RACs' current practice of second-guessing physicians' judgment based on the outcome rather than the facts the physician had at the time.
4. **Eliminate application of the one-year filing limit to rebilled Part B claims.** When a Part A claim for a hospital inpatient admission is re-opened and denied by a Medicare review contractor because the inpatient admission was determined not to be reasonable and necessary, the hospital should be able to submit a subsequent Part B claim for services provided within 180 days of a revised or final determination. This would allow hospitals to either rebill immediately after the claim is denied or pursue their appeals rights and receive a final determination on the Part A claim before rebilling under Part B.
5. **Limit RAC auditing of approved issues to a defined time period, instead of approving them indefinitely, as is now the practice.** After the issue's audit time period has expired, RACs should be prohibited from auditing that issue. CMS should then analyze the audit results and offer education to providers in that jurisdiction if warranted. A RAC would need to seek new approval from CMS to audit for that same issue again, but must wait a certain defined time period to allow providers to incorporate education before requesting new approval. Additionally, a senior CMS official should be held accountable for approval of audit issues.

MedPAC also made recommendations related to beneficiary payment obligations, including:

- Expanding the three-day hospital stay requirement for skilled nursing facility (SNF) coverage to allow up to two outpatient observation days to count toward meeting the criterion;
- Requiring beneficiary notification of outpatient observation status; and
- Packaging payment for self-administered drugs provided during outpatient observation stays into the hospital outpatient PPS.

The AHA believes that changes must be made to alleviate the problems regarding beneficiary cost-sharing created by the two-midnight policy. Our members believe that beneficiaries requiring short inpatient hospital stays should be considered inpatients and cost-sharing obligations should be calculated under Medicare Part A. We appreciate MedPAC's consideration of these issues, as well as additional beneficiary considerations related to observation and SNF coverage and self-administered drugs. We support CMS's further examination of policies to address these concerns.

OBSERVATION SERVICES

We continue to encourage CMS to evaluate the adequacy of the outpatient PPS rates Medicare pays for observation care, which is the type of care hospitals often provide while making a determination of whether inpatient admission is appropriate. We do not believe the observation care rates cover hospitals' costs. Because outpatient PPS payment rates are based on the specific procedures a hospital provides to a patient, observation care payment rates historically have been quite low. Specifically, the CY 2015 payment rate for eight or more hours of observation services (furnished in conjunction with a hospital clinic visit and certain high-level emergency department visits) is \$1,234.70. Further, this payment rate is the same whether a patient requires eight hours of observation care, or 48 hours of observation care. Therefore, hospitals receive the same reimbursement, regardless of the length, level or intensity of observation services (e.g., nursing and monitoring services) they actually provide to a patient. In many cases, the payment rates are far less than the costs incurred by the hospital for providing these services. As a solution, CMS could, for example, consider allowing hospitals to record a room and board charge associated with these services, thereby more accurately reflecting their costs.

PAYMENT REDUCTION

As part of the FY 2014 inpatient PPS final rule, CMS unlawfully imposed a *permanent* prospective 0.2 percent reduction to the operating PPS standardized amount, the Puerto Rico-specific standardized amount, the hospital-specific payment rates and the capital Federal rate to offset what the agency claimed would be an increase of \$220 million in inpatient PPS expenditures resulting from implementation of the two-midnight policy. This reduction was based, CMS claimed without further explanation and analysis, on OACT's estimate of an anticipated net increase in hospital inpatient encounters that would result from the implementation of the two-midnight policy.

Specifically, without setting forth its actuaries' reasoning or calculations, CMS asserted that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net *increase* of 40,000 inpatient encounters. The agency stated that this shift would increase inpatient PPS expenditures

by approximately \$220 million, and necessitated the reduction by 0.2 percent of the standardized amount, the hospital-specific rates, the Puerto Rico-specific standardized amount and the capital Federal rate.

The agency's failure to provide any explanation of the data, methods and assumptions behind the above calculations renders it impossible for hospitals to critique the actuaries' estimates. Additionally, the agency's imposition of the 0.2 percent reductions is not in compliance with the notice and comment procedures required by the Administrative Procedures Act or the Medicare Act statutory mandate to promulgate them as a regulation. **Nonetheless, analyses we conducted of CMS's own data clearly demonstrate that, in its first full year of implementation, the two-midnight policy *did not* result in a net increase in inpatient encounters, as OACT estimated.** First, a straightforward comparison of FY 2014 and FY 2013 shows a decrease, not an increase, in the number of inpatient encounters (see Table 2). Specifically, total inpatient encounters declined by four percent and total inpatient encounters of less than two-midnights declined by 11 percent.

Table 2: Percent Change in Inpatient Encounters, FY 2013 to FY 2014

Type of Case	FY 2013	FY 2014	% Change
Less than 2 midnights	1,179,469	1,053,668	-11%
More than 2 midnights	8,361,749	8,103,355	-3%
All cases	9,541,218	9,157,023	-4%

Source: FY 2013 and 2014 MedPAR (December updates).

In addition, the analysis we conducted took into account and recognizes that even prior to implementation of the two-midnight policy, inpatient encounters were decreasing. Specifically, our analysis examined case counts for those stays that were less than two midnights and those that were greater than two midnights from FY 2009 through FY 2013, using final rule Medicare Provider Analysis and Review (MedPAR) data sets for each year. We looked at different compound annual growth rates (CAGRs) and created one for each of the following time periods:

1. FY 2009-2013;
2. FY 2009-2011 (the time period used by OACT in the FY 2014 final rule); and
3. FY 2011-2013 (a more recent time period for comparison purposes).

We then used these numbers to calculate projected inpatient encounters for FY 2014 absent the two-midnight policy, and compared these to the actual inpatient encounters for FY 2014, which, include the effect of the two-midnight policy.⁸ The difference in encounters can be deemed as the two-midnight effect. **Under no scenario did the numbers support OACT's estimation that the two-midnight policy would cause a net increase of 40,000 inpatient encounters. In fact, as shown in Table 3, using the longer term FY 2009-2013 CAGR, the two-midnight policy caused a net decrease of almost 200,000 inpatient encounters.**

⁸ Note that the CAGRs were calculated using the final rule FY 2009 - 2013 MedPAR data since these are complete data. However, since we only have access to the proposed rule FY 2014 MedPAR data at this time, we applied the CAGRs to the FY 2013 proposed rule MedPAR data to maintain consistency between the FY 2013 and 2014 comparison data sets.

Table 3: Inpatient Encounters by Length of Stay and Difference between Actual and Expected Cases Using 2009-2013 CAGR

Length of Stay	Actual FY 2013 Case Counts	Actual FY 2014 Case Counts (With 2 MN Policy in Effect)	2009-2013 CAGR	Projected FY 2014 Case Counts Absent 2 Midnight Policy Using 2009-2013 CAGR	Difference between Actual and Projected FY 2014
Less than 2 midnights	1,179,469	1,053,668	-4.2%	1,130,279	-76,611
More than 2 midnights	8,361,749	8,103,355	-1.7%	8,222,870	-119,515
All Cases	9,541,218	9,157,023	-2.0%	9,353,149	-196,126

Source: FY 2013 and 2014 MedPAR (December updates); FY 2009 – 2013 MedPAR (March updates).

While we recognize that there are many factors that influence the number of admissions in a given year, these data clearly do not support OACT’s estimation that there would be a net increase in inpatient encounters. In fact, they directly contradict OACT’s estimates. As a result, we believe strongly that the agency should fully reverse its 0.2 percent reduction and urge that the payment rates (the standardized amount, hospital-specific rate, Puerto Rico-specific standardized amount and capital Federal rate) for FY 2014 and subsequent years be revised accordingly and the hospitals reimbursed for the shortfall in Medicare payments they received for hospital discharges on or after Oct. 1, 2013 that have resulted from CMS’s unlawful imposition of the 0.2 percent payment reductions.

ENFORCEMENT DELAY

There is a partial enforcement delay of the two-midnight policy in effect thru Sept. 30, 2015. Under this partial enforcement delay, CMS prohibits the RACs from conducting post-payment patient status reviews for claims with dates of admission from Oct. 1, 2013 through Sept. 30, 2015. **In light of the fact that CMS will be addressing issues related to the two-midnight policy in the outpatient PPS rule, and any changes will likely take effect Jan. 1, 2016, we urge CMS to extend the partial enforcement delay of the two-midnight policy until March 30, 2016.** This will not only provide additional time for CMS to issue guidance related to any new policies or admission criteria for hospitals and review contractors; it will allow hospitals time to implement any new policies created put forth by the agency.

PROBE AND EDUCATE AUDITS

During the partial enforcement delay, Medicare Administrative Contractors (MACs) have been performing prepayment patient status probe reviews on a sample of 10 claims for most hospitals, 25 claims for large hospitals, with dates of admission on or after Oct. 1, 2013. These “probe and educate” reviews are being conducted to assess provider understanding and compliance with the two-midnight policy. CMS released results of the initial reviews on Feb. 24, 2014, but has not shared any data or findings related to the probe and educate process since that time. **The AHA urges CMS to release a status update related to these audits that includes, at a minimum, a summary of: the audits conducted (including number of medical records requested,**

received and MAC reviews completed); the results of these audits (including common denials made); and the education efforts conducted by the MACs upon completion of the audits. Doing so will further educate the hospital field on compliance with this complex policy and provide transparency related to the audits conducted and the MACs' ability to interpret the two-midnight policy.

HOSPITALS EXCLUDED FROM AREA WAGE INDEX (AWI) PUBLIC USE FILE (PUF)

It has come to the AHA's attention that a number of our member hospitals have been excluded from the FY 2016 AWI PUF released in February and May 2015. Exclusions to the PUF can have significant impact on the AWI in a core-based statistical area. In our conversations with the agency, CMS staff indicated that the agency has increased its scrutiny of the wage data submitted by hospitals in an effort to ensure that the AWI is as accurate as possible. **The AHA appreciates CMS's efforts to ensure accuracy in the AWI process.**

We are, however, concerned that hospitals have not been fully informed about the exclusion process or provided with a notice from the MAC that they were excluded from the PUF. In fact, in some cases, hospitals have reported being notified by their MAC that they will be included, only to find that CMS made an independent and separate decision to exclude them for aberrant data. **As a result, the AHA requests that CMS provide additional transparency and education to the hospital field related to this process – in addition to the existing AWI Timetable – including the criteria used to determine whether a hospital is included or excluded from the PUF and the specific procedures and mechanisms for a hospital to ask for reconsideration. In addition, the AHA urges CMS to create a mechanism whereby CMS or its MACs provide hospitals with timely notification, in writing, if they are excluded from the PUF.**

We know that many hospitals have been working cooperatively with CMS as it reviews these hospitals' data and supporting documentation to determine whether they will be in the FY 2016 AWI. **We urge CMS to continue working with these hospitals to reach a timely resolution of this issue.**

HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

The HAC Reduction Program imposes a 1 percent reduction on all Medicare inpatient payments for hospitals in the top (worst performing) quartile of certain risk-adjusted national HAC rates. CMS adopted the basic framework for the HAC Reduction Program in the FY 2014 inpatient PPS final rule and implemented the program in FY 2015.

America's hospitals remain deeply committed to eliminating avoidable harm, and we are succeeding in reducing harm. According to a recent interim report from the Agency for Healthcare Research and Quality, a composite measure of 28 different HACs fell nationwide by

17 percent between 2010 and 2013, from 145 to 121 per 1,000 discharges.⁹ Though more work remains, hospitals are making progress and their efforts are proving successful.

The AHA continues to support quality measurement and pay-for-performance programs that effectively promote improvement, especially value-based approaches that measure both a hospital's actual performance, as well as how much it has improved over a baseline period. However, we are concerned that the design and implementation of the HAC Reduction Program unfairly places some hospitals at greater risk of a penalty and imposes penalties on hospitals as a result of bad measurement, not bad performance. CMS's own data show that teaching hospitals, which handle more complex cases, and hospitals that care for the poor are more likely to be penalized under the program. We also remain concerned that smaller hospitals lacking sufficient data to be scored on Domain 2 measures are unfairly penalized. The HAC Reduction Program performance of these hospitals is assessed solely based on the Domain 1 PSI 90 composite measure, which is widely viewed as containing serious flaws. In particular, studies have shown that some of the individual components of PSI 90 have low levels of reliability.

Although the statutory language establishing the HAC Reduction Program limits CMS's ability to address the program's shortcomings, **we again urge the agency to make changes within its authority to improve how the program is implemented. As the AHA has previously recommended, CMS should eliminate the measure overlap between the HAC and value-based purchasing (VBP) programs.** The VBP program uses all three of the current HAC measures but employs a different methodology to delineate good and bad performance. The measure overlap has created "double penalties" for some hospitals, while assessing disparate scores on the same measures for other hospitals.

In addition, CMS should phase out the PSI 90 composite measure altogether. PSI 90 should be replaced with alternative measures that address a variety of quality and safety issues. Until PSI 90 is phased out and replaced, hospitals without enough data to report at least one of the infection measures in Domain 2 should be excluded from the HAC Reduction Program altogether. **We urge CMS to amend the program to include only hospitals with enough data to report at least one of the infection measures in Domain 2. In addition, hospitals eliminated for lack of Domain 2 data also should be excluded from the pool of hospitals from which CMS determines the penalty quartile.**

PROPOSALS FOR FY 2016 AND BEYOND

We support CMS's proposal to adjust the weighting of Domains 1 and 2 so that the weight of Domain 1 would be 15 percent and the weight of Domain 2 would be 85 percent. CMS made this proposal in part because MedPAC and other stakeholders believe that the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) chart-abstracted measures in Domain 2 are more reliable and actionable than the claims-based PSI 90 composite measure in Domain 1. The AHA agrees that the PSI 90 measure comprising Domain 1 is unreliable and should be phased out completely, as noted above.

⁹ Source: U.S. Department of Health and Human Services. Interim Update on 2013 Annual Hospital-acquired Condition Rate and Estimates of Cost Savings and Deaths Averted from 2010 to 2013. Available at: <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.pdf>.

We support CMS’s proposal to amend how the Domain 2 score is calculated for the FY 2017 program and onward. Currently, a score is assigned for each measure within the domain, and the measure scores are averaged to provide a Domain 2 Score. For the FY 2016 program, if a hospital reported data for at least one of the Domain 2 measures, its Domain 2 Score will be based only on the measure(s) the hospital reported. For FY 2017 and onward, CMS proposes that each Domain 2 measure be reviewed independently, unless the hospital has a waiver for non-reporting. If data are not submitted by a hospital for a measure and there is no valid waiver, CMS proposes to apply the worst possible score of 10 to that measure. **In addition to exempting those with waivers, CMS must continue its practice of not calculating a score for a hospital for which data have been submitted, but there are not enough data to calculate the standard infection ratio. We ask CMS to clarify in the final rule that it will continue this practice.**

We support CMS’s proposal to expand the central line-associated blood stream infection (CLABSI) and catheter-associated urinary tract infection (CAUTI) measure data used to calculate HAC penalties so they include locations beyond the intensive care unit (ICU). The current CLABSI and CAUTI measures in the HAC Reduction Program reflect hospital performance only in pediatric and adult ICUs. However, hospitals already have begun to collect CAUTI and CLABSI data on non-ICU locations (including pediatric and adult medical wards, surgical wards and medical/surgical wards) for the Inpatient Quality Reporting (IQR) Program. CMS proposes to include data from both the ICU and non-ICU locations to calculate hospital performance on CAUTI and CLABSI beginning with the FY 2018 HAC Reduction Program, using CYs 2015 and 2016 as the performance years. We agree with CMS’s proposal to delay incorporation of the non-ICU data until FY 2018 to allow all hospitals, including those without ICUs, to contribute two years of data.

At the same time, we recognize that the FY 2018 program results also will likely be impacted by the fact that the CDC is updating its standard population (or “national baseline”) data, which is used to calculate the predicted number of infections included in the CDC’s healthcare-associated infection (HAI) measures. The HAI measures are calculated as a “standardized infection ratio” (SIR), where a hospital’s observed number of infections is compared to a predicted number infections. The predicted number of infections is based on data collected on a “standard population” during a specified time period, and effectively serves as a national baseline for performance on each HAI measure. Because the national baseline data for some HAI measures dates back to 2006, CDC intends to update the standard population using data collected during CY 2015.

We agree with the need to update the baselines used to calculate HAI performance. However, **we have concerns about how CMS will incorporate the updated baseline into the HAC Reduction Program.** If we understand correctly, CMS anticipates that the applicable reporting period for the FY 2018 HAC Reduction Program will likely be CYs 2015 and 2016, *but that only the measure results using infections reported in CY 2016 will use the new standard population data.* Thus, the FY 2018 penalty determinations would be based upon data from different standard populations for the two reporting years.

For reliability purposes, using two years of performance data calculated under the same methodology makes sense. Therefore, we believe there is merit in exploring other options for how and when to implement the standard population data changes. For example, CMS could calculate the CY 2016 measure results using the current standard population data, meaning that the FY 2018 program penalties would be based on a single benchmark for both reporting years. The FY 2019 program penalties could also be based upon a single benchmark, but they could use the updated standard population data for both reporting years (CY 2016 and CY 2017).

We ask CMS to engage in further conversations with the CDC and hospital stakeholders to evaluate these different approaches before the agency makes a final decision. At the very least, the incorporation of the updated standard population data should be accomplished in a way that allows hospitals ample time to be able to review, understand, and explain the changes in performance that may occur due to a new baseline before the changes affect payment. For example, if CMS implements the program as proposed, the preview period for data using the new standard population would occur extremely close to the payment impact date. If CMS chooses the alternate option, the agency could provide that data to hospitals far in advance of the payment impact.

We support CMS's proposal to establish an Extraordinary Circumstance Exception (ECE) policy for the HAC Reduction Program for FY 2016 and Onward. CMS proposes an exceptions policy "to provide relief for a hospital whose ability to accurately collect quality measure data and/or to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital." Under the proposed policy, hospitals would submit an ECE request form within 90 calendar days of a natural disaster or other extraordinary circumstance. CMS would review each request on a case-by-case basis. We appreciate that CMS has already implemented ECE policies for other quality-reporting programs and agree that the substance of such policies should be consistent across the board. To that end, we recommend that CMS develop a single request form, encompassing all quality reporting programs from which a hospital might request an exception. For example, the request form could list all of the various quality-reporting programs and require a hospital to "check off" the programs for which it has encountered difficulty collecting data. In this way, a hospital that has experienced an extraordinary circumstance will not need to submit multiple forms.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP assesses penalties on hospitals for having "excess" readmissions rates for specific clinical conditions when compared to expected rates. CMS does not propose to add any additional readmission measures beyond the six measures already finalized for the program. However, for the FY 2017 HRRP, CMS proposes to expand significantly the patient population included in the pneumonia (PN) readmission measure. CMS also proposes a new ECE process that would begin with the FY 2016 HRRP.

America's hospitals are committed to reducing unnecessary readmissions, and recent CMS data show that national hospital readmission rates are declining.¹⁰ Nevertheless, the HRRP continues to have significant flaws that result in unfair penalties to hospitals. **We again strongly urge CMS to adjust the measures in the program for sociodemographic factors, and to exclude readmissions unrelated to the initial reason for admission. We also recommend the agency consider how to update the measures in the HRRP to address emerging evidence that reductions in hospital admissions may not lead to lower HRRP penalties.**

We first comment on the agency's specific proposals in the rule, then discuss additional policy considerations we urge the agency to address in future rulemaking.

FY 2017 PN READMISSION MEASURE CHANGES

The AHA urges CMS not to finalize its proposed expansion of the PN readmission measure population unless and until the measure change has been reviewed and endorsed by the NQF. For FY 2017, the HRRP would include two additional groups of hospitalized patients in the PN readmission measure:

- Patients with a principal discharge diagnosis of aspiration pneumonia; and
- Patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that is coded as present on admission.

CMS indicates the proposed changes would result in a more accurate measure that assesses performance on the "complete population" of patients receiving treatment for pneumonia. CMS also suggests that the expanded measure population would reduce potential biases in performance resulting from variation in coding practices across hospitals. Specifically, the agency states that hospitals increasingly are using sepsis and respiratory failure as the principal diagnosis codes for pneumonia patients, and that this practice results in better performance on the readmission measure by excluding patients who might be more severely ill. We appreciate that CMS wishes to improve the PN measure's accuracy, and that the agency intends to submit the revised measure for NQF review "when the appropriate project has its call for measures in 2015."

Nevertheless, we strongly urge the agency to await the outcome of the NQF review before finalizing the measure for the HRRP because the proposed changes effectively create a new measure. Indeed, CMS estimates the proposed changes would result in the inclusion of more than 630,000 (or 65 percent) more patients in the PN measure population, thereby increasing the national average PN readmissions rate by 0.9 percentage point. Given that the national readmission rate is used to calculate hospital-specific performance, we expect that nearly every hospital's performance would be affected. Before implementing such a major change, it is critical that multiple stakeholders have an opportunity to conduct in-depth review of the quality of the evidence to support the change, and analyze testing data that would demonstrate the extent to which the measure's accuracy actually improves. This is especially important since the two studies on which CMS bases its proposal examine coding differences for in-hospital mortality

¹⁰Department of Health and Human Services. (7 May 2014). New HHS Data Shows Major Strides Made in Patient Safety, Leading to Improved Care and Savings. <http://innovation.cms.gov/Files/reports/patient-safety-results.pdf>.

rates, and not 30-day readmission rates. Those same studies also do not reach any conclusions about the *causes* of the coding differences, which would be important to understand more fully before including new diagnoses in the measure population. Indeed, several clinical leaders from the AHA's membership have expressed concern that the inclusion of the three new groups may inadvertently conflate pneumonia as a discrete medical event with other underlying disease conditions. For example, aspiration PN has symptoms similar to the community acquired pneumonia included in the current measure. However, the causal mechanism – foreign particles entering the airway, often due to swallowing difficulties – is different. Similarly, respiratory failure can be caused by a number of factors, and pneumonia is often an associated morbidity of the diseases, rather than the underlying cause.

EXTRAORDINARY CIRCUMSTANCE EXCEPTION

The AHA supports CMS's proposal to adopt an ECE process for the HRRP beginning in FY 2016, and applauds the agency for recognizing the impact of issues such as natural disasters on measure collection and performance. CMS proposes that, beginning with the FY 2016 HRRP, those hospitals affected by natural disasters and other extenuating issues can request that CMS not use data from the time period affected by the circumstance to calculate HRRP performance. Hospitals would be required to submit, within 90 days of the occurrence of the extraordinary circumstance, an exception request that identifies the affected measures and time periods, and explains the impact of the circumstance on measure performance.

We also appreciate that CMS has already implemented ECEs policies for other quality reporting programs and agree that the substance of such policies should be consistent across the board. To that end, we recommend that CMS develop a single request form, encompassing all quality reporting programs from which a hospital might request an exception. For example, the request form could list all of the various quality reporting programs and require a hospital to “check off” the programs for which it has encountered difficulty collecting data. In this way, a hospital that has experienced an extraordinary circumstance will not need to submit multiple forms.

THE NEED FOR SOCIODEMOGRAPHIC ADJUSTMENT

The AHA remains concerned about the lack of a sociodemographic adjustment in the HRRP, and again we strongly urge the agency to incorporate such an adjustment as soon as possible. Since the HRRP's beginning, hospitals caring for the poorest patients have been significantly more likely to receive penalties. The AHA estimates that, in FY 2015, nearly 85 percent of hospitals in the highest quartile of disproportionate patient percentage (DPP) received a penalty, compared to 61 percent in the lowest DPP quartile (higher DPP quartiles indicate a poorer patient population). This is because the current HRRP fails to recognize that community factors outside of a hospital's control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other rehabilitative services – significantly influence the likelihood of a patient's health improving after discharge from the hospital or whether a readmission may be necessary.

Failing 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.

For these reasons, a growing number of stakeholders and policymakers also have urged that the HRRP include sociodemographic adjustment. MedPAC recommended a specific adjustment approach in 2013, and the recommendations of the NQF's 2014 expert panel on sociodemographic adjustment received widespread support. Bipartisan and bicameral legislation that mandates sociodemographic adjustment in HRRP has been introduced in the past two Congresses. And the NQF is in the early stages of launching a "trial period" in which measures can be submitted for NQF endorsement with sociodemographic adjustment. Yet, CMS has repeatedly resisted calls for such adjustment and, to our knowledge, has yet to even submit any of its measures for NQF's pilot project.

At a minimum, we urge CMS to submit immediately the six readmission measures in the HRRP for consideration in the NQF trial period for sociodemographic adjustment. We also strongly urge the agency to assess how it would implement sociodemographic adjustment based on a combination of Census-derived data on income and education level, and claims-derived data on the proportion of patients dually eligible for Medicare and Medicaid. We believe using these data is the most realistic way to implement sociodemographic adjustment in the short term. They also have consistent data definitions, are readily available to the agency and are part of the recently introduced legislation.

ACCOUNTING FOR DECLINING HOSPITAL ADMISSIONS

The AHA recommends CMS examine the effect of declining hospital admissions on readmission penalties, and consider whether future revisions to its readmission measures are needed. Recent research has raised concerns that efforts to reduce unnecessary hospitalizations may inadvertently serve to increase readmissions penalties. The Altarum Institute studied readmission rates in San Diego County after area hospitals began participating in the Center for Medicare & Medicaid Innovation's (CMMI) Community-Based Care Transitions Program in 2010. Altarum found that readmissions and hospitalizations *per 1,000 Medicare fee-for-service (FFS) beneficiaries* in the county fell 15 percent and 11 percent, respectively, in 2013 compared to 2010.¹¹

However, the HRRP calculates readmissions on a *per hospital discharge* basis. As a result, because hospitals' readmissions and discharges declined at about the same rate, it appears that their readmission rates did not improve significantly. On a per discharge basis, San Diego County hospitals ultimately only had a 4 percent decline in their readmission rate, with 10 of 14 hospitals incurring a FY 2015 HRRP penalty. In essence, decreases in discharges masked

¹¹ Altarum Institute. (16 December 2014). Medicare's Measure for Readmissions Fails to Identify Excellence and Improvement. <http://altarum.org/about/news-and-events/medicare%E2%80%99s-measure-for-readmissions-fails-to-identify-excellence-and-improvement>.

reductions in total readmissions. Worse yet, if discharges fall at a faster rate than readmissions, then hospital readmission rates would increase, despite a decline in the total number of readmissions.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

As required by the ACA, CMS proposes to fund the FY 2016 VBP program by reducing base operating DRG payment amounts to participating hospitals by 1.75 percent. The VBP program is budget neutral; all funds withheld must be paid out to hospitals. For FY 2018, CMS proposes the removal of two measures, while adding a care coordination measure for FY 2018, and a chronic obstructive pulmonary disease mortality measure for FY 2021. CMS also proposes to eliminate the VBP clinical process of care measure sub-domain after FY 2017.

The AHA continues to support several aspects of the VBP program. In general, the AHA favors pay-for-performance programs, such as VBP, that assess multiple aspects of care, and that recognize providers for both achievement versus national benchmarks and improvement versus baseline performance. We believe this incentive structure can provide greater inducement for providers to work collaboratively to improve performance.

However, as noted in our comments on the HAC Reduction Program, we remain concerned about the overlap of measures between the VBP and HAC programs given the different constructions and goals of each program. We again urge CMS to ensure the programs do not provide hospitals with conflicting signals or double payment penalties by using measures in either the VBP or the HAC program, and not both. Moreover, we are concerned the agency has not yet articulated a plan for calculating VBP scores affected by the transition from ICD-9 to ICD-10. We urge the agency to work with all stakeholders to address this critically important issue.

Our comments on CMS's specific proposals are outlined below.

FY 2018 PROPOSED MEASURE REMOVALS

The AHA supports CMS's proposals to remove IMM-2 (patient influenza vaccination) and AMI-7a (Fibrinolytic therapy received within 30 minutes of hospital arrival) from the VBP program. CMS suggests it is appropriate to remove IMM-2 because its performance has "topped out," and AMI-7a because many hospitals no longer have a sufficient minimum volume to collect it. We agree that both measures are no longer well-suited for the VBP program.

FY 2018 PROPOSED MEASURE ADDITION

The AHA supports CMS's proposal to add the three-item Care Transition Measure (CTM-3) to the VBP program beginning in FY 2018. The CTM-3 would be added to the patient experience of care/care coordination measure domain. CTM-3 is calculated from the responses to three questions on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey that are designed to solicit patient feedback on hospital care transition planning. The AHA agrees that transitions in care are an important quality issue, and that FY 2018 is an appropriate time to move it into the VBP program. Indeed, the CTM-3 has been

collected and reported by hospitals since the beginning of CY 2014, and will have been publicly reported by the time it is tied to VBP performance in FY 2018.

FY 2021 PROPOSED MEASURE ADDITION

The AHA urges CMS to improve the reliability of the chronic obstructive pulmonary disease (COPD) mortality measure it proposes for the FY 2021 before finalizing it for the program. While it is reasonable to include mortality measures in VBP, the AHA has long been concerned that the level of reliability of the mortality measures used in the program is insufficient. Reliability reflects the extent to which a measure's results are the same if you take repeated samples of a hospital's data. The evidence to date suggests the measures in the program do not meaningfully reflect hospital performance. A 2012 CMS-commissioned analysis of claims-based measures demonstrated the acute myocardial infarction (AMI), heart failure (HF) and PN mortality measures in the VBP program achieved only the "lower limit" of moderate reliability.¹² When the COPD measure was reviewed for NQF endorsement in 2012, its testing results also showed only moderate reliability.¹³ **The public, CMS and hospitals deserve measures that have more than "moderate" reliability, especially in the context of a program where up to 2 percent of a hospital's payment is at risk for performance.** We again urge CMS to develop a plan to improve or replace the claims-based mortality measures used in the VBP and other programs.

FY 2018 VBP DOMAIN WEIGHT CHANGES

The AHA supports CMS's proposal to remove the Clinical Care Process measure domain beginning with the FY 2018 VBP program, and to re-weight the four remaining measure domains so that each one comprises 25 percent of a hospital's VBP score. We believe this approach is reasonable in light of the agency's proposal to remove all but one process of care measure from the VBP program. Last year, the AHA engaged hospital leaders in an exercise to identify quality measurement priority areas. Hospital leaders expressed support for measurement programs that prioritize the use of outcome rather than process measures.

However, CMS must pay careful attention to whether the measures comprising particular measure domains reliably assess hospital performance and, therefore, are appropriate for determining payment incentives. Measures and measure domains with highly reliable and accurate measures should receive greater emphasis in determining hospital performance. Hospital leaders are eager to transition to a VBP program comprised of mostly outcome measures. However, they believe that such measures should be carefully crafted to ensure they accurately reflect hospital performance, and are appropriately risk-adjusted for issues outside of the control of the organization being measured (e.g., acuity of illness, sociodemographic factors). When measures do not meet these standards, using them to assess hospital performance can have negative unintended consequences.

¹² See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf

¹³ See <http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=69927>

As noted above, the AHA remains concerned about the reliability of the mortality measures in the Clinical Care measurement domain. Absent a plan to improve or replace the mortality measures, the agency may wish to consider temporarily reducing the weight assigned to the domain. The agency could then consider increasing the weight of the Safety domain, which is largely comprised of the much more reliable HAI measures. These temporary changes would ensure that hospitals are scored on measures that are an accurate reflection of their performance while CMS transitions to using more reliable outcome measures.

The AHA also cautions that it may be appropriate to use a limited number of process measure in future VBP programs. Hospitals are on a continuum of quality improvement. Depending on what is being measured, it may be appropriate to use a mix of both process and outcome measures. In the initial phases of improving an aspect of care, hospitals may need both process measures and outcomes measures so that process impediments to improving outcomes are identified. The concurrent use of an outcomes measure enables hospitals to assess the effectiveness of the interventions in improving care. As the field improves and it becomes clearer which process changes lead to real improvements in care, then a focus on outcome measures is likely sufficient. We believe the four overarching VBP domains of Clinical Care, Safety, Patient Experience and Efficiency can accommodate process of care measures in the future, if needed.

FY 2019 HAI MEASURE CHANGES

The AHA supports CMS's proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures beginning with the FY 2019 VBP program. The AHA supported CMS's decision to broaden the reporting of CLABSI and CAUTI to non-ICU locations beginning in January 2015, and believes it is important for the agency to include this new data in its pay-for-performance programs.

The AHA also supports CMS's proposal to use updated "standard population data" for calculating VBP baseline and performance data beginning with the FY 2019 VBP program. The HAI measures are calculated as an SIR, where a hospital's observed number of infections is compared to a predicted number of infections. The predicted number of infections is based on data collected on a "standard population" during a specified time period, and effectively serves as a national baseline for performance on each HAI measure. Because the national baseline data for some HAI measures dates back to 2006, CDC intends to update the standard population using data collected during CY 2015. The agency would then apply the new standard to calculating VBP baseline period data for CY 2015, and performance period data for CY 2017. We appreciate that, in contrast to the agency's proposals for the HAC program, CMS does not propose to mix two different standard populations in comparing baseline and performance period data.

BASELINE AND PERFORMANCE PERIODS AND THE ICD-9 TO ICD-10 TRANSITION

Hospitals are required to transition to the use of ICD-10 beginning on Oct. 1, 2015. The AHA is concerned that CMS has both finalized and proposed VBP baseline and performance periods that mix performance data collected using both ICD-9 and ICD-10 codes (Figures 1 and 2 below). We strongly urge the agency to work with hospitals, measure developers and all other stakeholders to develop a plan to address the potential

unintended consequences of combining measure data collected under ICD-9 and ICD-10 as soon as possible.

ICD codes are integral to collecting and calculating quality measures in CMS's programs. For chart-abstracted measures, ICD codes allow hospitals to identify the patient population (i.e., the denominator) that is included or excluded from data collection. ICD codes are used to generate the initial patient population, to determine performance, and for risk adjustment. There are significant differences between ICD-9 and ICD-10 codes, and as a result, the agency must re-specify measures previously collected in ICD-9 so the specifications work in an ICD-10 environment. CMS has updated the specifications for its chart-abstracted measures, but we see little evidence such re-specification has occurred for the claims-based measures such as PSI-90, the Medicare spending per beneficiary (MSPB) measure and the mortality measures. **Given CMS's intent to use claims-based measures in future VBP and other quality measurement programs, we ask the agency to use the final rule to elaborate on whether and how it has begun to re-specify claims-based measures in ICD-10.**

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

Figure 1: Finalized FY 2017 VBP Baseline and Performance Periods

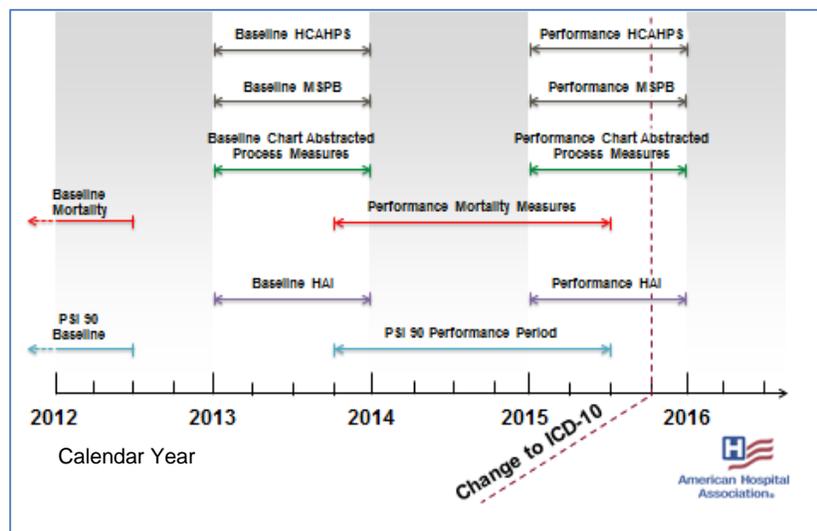
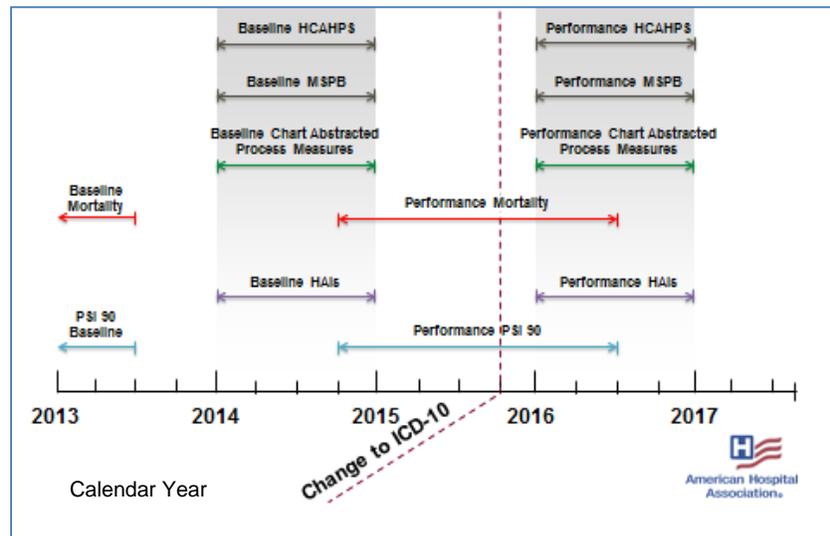


Figure 2: Finalized and Proposed FY 2018 VBP Baseline and Performance Periods



HOSPITAL IQR PROGRAM

Hospitals are required to report measures and meet the administrative requirements of the IQR program to avoid having their annual market basket reduced by one quarter. While the IQR program is “pay-for-reporting” only, the measures used in the IQR are foundational to CMS’s pay-for-performance programs, including VBP, HRRP and the HAC Reduction Program.

CMS proposes several significant changes to the IQR program. Most notably, for FY 2018, CMS proposes to require hospitals to submit 16 of 28 available electronic clinical quality measures (eQMs). The agency suggests it wishes to foster greater alignment between the Medicare Electronic Health Record (EHR) Incentive Program and the IQR, as well as promote the use of EHRs to report quality data. CMS also proposes to add eight new measures to the IQR program focused on the use of patient safety culture surveys, Medicare spending during episodes of care for five conditions, and excess acute care days within 30 days of hospital discharge.

THE NEED TO RE-FOCUS THE IQR PROGRAM

America’s hospitals remain committed to the foundational goals of the IQR program – to provide the public and hospitals with *accurate* and *comparable* information for transparency and for improving quality on *important* areas. However, the AHA is concerned that CMS’s proposals for the IQR do not achieve these goals. Specifically, the proposal to require eCQM reporting seems focused on advancing a particular way to collect and report data, rather than meeting a specific national goal or objective for quality improvement. While we strongly support the long-term goal of using EHRs to streamline and reduce the burden of quality reporting, there remain far too many questions about eCQM feasibility and accuracy for CMS to mandate their use in the IQR at this time. Having important, reliable and accurate performance data is a higher priority than advancing a particular

measure submission approach.

Furthermore, the eight proposed new IQR measures lack NQF endorsement, giving the field limited insight on whether the measures are reliable, accurate and feasible enough for public reporting programs. The measures also do not seem to be focused on any concrete national priority area or goal for improving care. For example, while there is broad agreement of the importance of improving the efficiency of care, CMS provides little explanation for why the five conditions (i.e., total hip and total knee arthroplasties, lumbar spine fusion/refusion, cellulitis, kidney/urinary tract infection, gastrointestinal hemorrhage) covered by its Medicare spending measures are more important to address with measures in the IQR program than other conditions.

The AHA has repeatedly and consistently urged CMS to identify concrete, actionable national goals for quality improvement, and to use those goals to select a small number of reliable, accurate and care-setting appropriate measures to ensure each relevant part of the health care system contributes to the overall goals. For this reason, we strongly urge CMS to consider adopting the recommendations outlined in the Institute of Medicine’s (IOM) *Vital Signs* report for streamlining and focusing national quality measurement efforts.¹⁴ If adopted, the report’s recommendations would facilitate the better use of quality measures by all stakeholders to advance health care.

The *Vital Signs* report notes that progress in improving the quality of health care has been stymied by discordant, uncoordinated measurement requirements from CMS and others. Hospitals and others spend significant resources documenting, interpreting and training staff on reporting requirements, thereby missing important opportunities to improve care.¹⁵ To ensure that all parts of the health care system – hospitals, physicians, the federal government, private payers and others – are working in concert to address priority issues, the *Vital Signs* report recommends 15 “Core Measure” areas with 39 associated priority measures. Each stakeholder would be measured on the areas most relevant to their role in achieving common goals and objectives. The recommended core measure areas that appear to be most salient to hospitals, and where CMS may wish to focus future IQR measurement efforts, include patient safety, evidence-based care, preventive services, population spending, care matched to patient goals and addictive behavior.

The AHA is eager to work with the agency to help it implement the *Vital Signs* recommendations. The recent collaboration of America’s hospitals and CMS in the Hospital Engagement Network (HEN) shows the great potential for a focused, deliberate approach to quality measurement and improvement. Indeed, the HEN program prevented an estimated 92,000 instances of harm and saved an estimated \$988 million. We also believe an IQR program focused on publicly reporting hospital progress on the core areas most relevant to achieving national priorities would provide the patients and communities we serve with far more meaningful and accurate information than the IQR program provides today.

¹⁴ Institute of Medicine, 2015. *Vital Signs: Core Metrics for Health and Health Care Progress*. Available for download at www.iom.edu/vitalsigns.

¹⁵ Institute of Medicine, 2015. *Vital Signs: Core Metrics for Health and Health Care Progress*. Available for download at www.iom.edu/vitalsigns.

PROPOSED MEASURE REMOVAL FOR FY 2018

The AHA supports CMS’s proposal to remove the chart-abstracted versions of nine measures from the IQR. We agree that several of the stroke and venous thromboembolism (VTE) measures CMS proposes for removal are now topped out and unlikely to show further improvement. We also agree it is appropriate to stop collecting AMI-7a (Fibrinolytic therapy received within 30 minutes of hospital arrival) since most hospitals no longer have sufficient volume to report it. And we appreciate that the agency recognizes that collecting SCIP-Inf-4 (Cardiac surgery patients with controlled postoperative blood glucose) and IMM-2 (Pneumococcal vaccination) is no longer feasible for hospitals.

While we do not object to the agency’s proposal to retain the eCQM versions of six measures, we urge the agency to maintain eCQM reporting as a *voluntary* rather than *mandatory* requirement for the FY 2018 IQR program. We describe our concerns about the eCQM reporting option elsewhere in this section.

PROPOSED NEW MEASURES FOR FY 2018

CMS proposes eight new measures for the FY 2018 IQR program. **The AHA is very disappointed that none of the proposed measures are endorsed by the NQF. Indeed, the Measure Applications Partnership (MAP) only conditionally supported seven of the measures, and urged that they receive NQF endorsement before being placed into the IQR.** Our comments on the specific measures are provided below.

Hospital Survey on Patient Safety Culture. **The AHA does not object to the agency’s proposal to add a measure on the use of safety culture surveys. However, we are not confident this measure adds much value to a public reporting program.** America’s hospitals agree with the importance of fostering organizational cultures that promote the reporting of safety issues by frontline staff and the robust use of safety event information to improve care. Patient safety culture surveys are useful tools for helping hospitals to identify opportunities to improve their cultures. However, this measure does not actually assess the safety cultures of hospitals. Rather, it simply asks hospitals to report whether, how frequently and with what survey tool they conduct safety culture surveys. As the proposed rule suggests, the field has not yet achieved consensus on a best-in-class survey tool, or on how frequently such surveys are necessary. Therefore, it is unclear how patients would be expected to judge “good” versus “bad” performance on this measure.

CMS suggests the use of this measure would “help inform [the agency] whether a measure targeting the culture of patient safety using a specific survey is feasible.” We appreciate the agency’s interest in identifying a class-leading patient safety culture survey tool and encourage CMS to support research and other activities to support this goal. However, for the purposes of the IQR program, we believe a measure assessing the use and scores from a specific survey tool would be far less useful to patients and hospitals than good, reliable measures of patient safety outcomes like infections, medication safety and other serious preventable safety events. We encourage the agency to enhance its measure development efforts for patient safety outcome measures, rather than focus its resources on a measure based on a particular safety culture survey.

***Clinical Episode-based Payment Measures.* The AHA does not support CMS’s proposal to add four measures reflecting Medicare “resource use” during episodes of care for kidney/urinary tract infection, cellulitis, gastrointestinal hemorrhage and lumbar spine fusion/refusion. However, given that hospitals are beginning to engage in new payment and care delivery models, we encourage the agency to consider providing data and information about the episodes of care to hospitals using a mechanism other than the IQR program.**

The measures capture risk-adjusted Medicare FFS payments during episodes of care that span the three days before an initial (or “trigger”) hospital admission to 30 days after hospital discharge. An episode is attributed to the hospital from which the patient was discharged for his/her trigger stay, and the measure excludes episodes that involve transfers between hospitals. The measures use “grouping rules” intended to ensure the measures include those payments that are “clinically related” to the given condition or procedure.

The AHA agrees that well-designed measures of cost and resource use that assist with assessing the value of care are urgently needed. However, we oppose the adoption of these particular measures in the IQR program for a number of reasons. As noted previously, the measures lack NQF endorsement, which would provide insight on whether they are reliable, accurate and feasible. We also are concerned the measures would be used in the IQR program without corresponding measures of quality. We believe the “value” of care is most appropriately measured when information on cost and resource use is combined with information on quality. This ensures that cost and resource use measures are not used to blindly push toward the lowest possible cost. The measures also lack adjustment for sociodemographic factors. Yet, the NQF recently acknowledged the importance of considering the impact of such factors on cost and efficiency measures by asking that several condition-specific measures be considered in its upcoming “trial period” for sociodemographic adjustment.¹⁶

Lastly, we are concerned that the measures are being proposed for a hospital quality reporting program despite the fact that they reflect the actions of a multitude of health care entities, some of which are beyond hospitals’ control. In general, a performance measure should assess processes and outcomes over which the measured entity (e.g., hospital, physician group) can exercise a reasonable level of control. Some hospitals are at the center of highly integrated delivery systems, or participating in bundled payment arrangements that include a range of services across the care continuum. In reality, however, there is considerable national variation in the mix of services and degree of integration in health care markets.

The AHA recognizes that hospitals are beginning to explore new payment and delivery models in which information on cost and resource in the post-hospitalization period use may be beneficial. Given that the models remain in flux, and the measures are not endorsed by the NQF, using the data for a reporting program like the IQR would be premature. Nevertheless, the data may be of interest to hospitals exploring models such as bundled payments. Thus, the agency should determine whether it can provide the resource use data to hospitals using a mechanism other than the IQR. For example, the agency could conduct a “dry run” of the measure in which

¹⁶ See National Quality Forum, Cost and Resource Use - Phase 3 Final Report. February 2015. Available at: http://www.qualityforum.org/Publications/2015/02/Cost_and_Resource_Use_-_Phase_3_Final_Report.aspx.

it provides hospitals with confidential reports, and solicits feedback on the usefulness of the information. The agency also could consider the suitability of the measures for use in the BPCI initiative in the future.

Elective Total Hip Arthroplasty / Total Knee Arthroplasty (THA/TKA) 90-day Episode of Care Payment Measure. **The AHA does not support the adoption of the THA/TKA episode of care payment measure for the IQR program.** We appreciate that in contrast to the other four proposed episode of care measures, this measure has a corresponding quality measure (THA/TKA complications) in the current IQR program. This may mitigate the possibility that driving toward lower cost would be prioritized over quality. However, similar to the other measures, the measure is intended to reflect payments over an episode of care (in this case, 90 days) that spans the post-hospitalization period, which includes services and entities that hospitals may not control. Moreover, the measure lacks NQF endorsement and sociodemographic adjustment. If the agency is intent on adopting this measure, then we encourage it not to finalize the measure unless and until it receives NQF endorsement. Additionally, we would support the agency providing the resource use data to hospitals using a mechanism other than the IQR, as described in the previous section.

Excess Acute Care Days after AMI and HF Hospitalization. **The AHA urges CMS not to adopt its two proposed Excess Acute Care Days measures for AMI and HF.** The measures are intended to assess excess “all-cause acute care utilization” in the 30-days after discharge for AMI and HF. In contrast to the existing all-cause readmissions measures, the proposed measures would include both emergency department (ED) visits and observation stays, in addition to hospital readmissions. The measure would calculate a rate of excess acute care days per 100 discharges, and employ a risk-adjustment approach similar to that of the existing readmission measures. CMS suggests this measure improves upon the existing hospital readmissions measures because “there exists concern that the high use of observation stays could in some cases replace readmissions, and hospitals with high rates of observation stays may therefore have low readmission rates that do not accurately reflect the quality of care.”

The AHA has long been supportive of efforts to assess measures for potential unintended consequences. However, we do not believe there is clear or consistent evidence to suggest hospitals are substituting observation stays and ED visits in place of readmissions. In fact, a 2014 article published in CMS’s own peer-reviewed journal, *Medicare and Medicaid Research Review*, suggested that the drop in national readmission rates in 2012 “was not primarily the result of increases in either post-index ED visits or post-index observation stays.”¹⁷ Furthermore, this measure is being proposed in the context of a Medicare payment policy in which any hospital admission spanning less than two midnights is generally considered to be an outpatient visit. At a minimum, the agency should seek to better understand the interaction of this policy with the measure before moving forward.

¹⁷ Gerhardt, G., Yemane, A., Apostle, K., et al, 2014. Evaluating Whether Changes in Utilization of Hospital Outpatient Services Contributed to Lower Medicare Readmission Rate. *Medicare and Medicaid Research Review*. Vol. 7. No. 4. pp. E1 – E13.

In the short term, we believe the best way to improve upon the readmission measures used in CMS programs is to incorporate sociodemographic adjustment. As noted in greater detail in the HRRP section of this letter, such adjustment would ensure hospitals do not score worse on the measures simply because they care for large numbers of poor, vulnerable patients.

PROPOSED EXPANSION PN MORTALITY AND READMISSION MEASURES

The AHA urges CMS not to finalize its proposal to expand the patient population for the PN mortality and readmission measures unless and until the measure change has been reviewed and endorsed by the NQF. We refer the agency to our discussion of this issue in the HRRP section of this letter.

CDC MEASURE STANDARD POPULATION UPDATE

The AHA asks CMS to provide in the final rule a detailed chart describing exactly when the updated standard population data for its HAI measures will be reflected in data reported on *Hospital Compare*. In addition, we urge CMS to work with CDC and hospitals on how best to communicate the standard population data update to the public to help patients interpret the changes accurately. Further, for pay-for-performance programs, CMS should include in that chart the date that the data changes will affect hospital payments. For additional information, we refer the agency to our discussion of the standard population changes in the HAC and VBP sections of this letter.

VALIDATION

The AHA supports CMS's proposed changes to its IQR measure validation process. In light of the agency's proposal to remove the influenza vaccination measure (IMM-2) from the hospital VBP program, CMS suggests it is no longer necessary to include a separate validation sample for the measure. As a result, the agency proposes to include IMM-2 in its general process of care validation sample, and to revise the validation score weights so that general process of care measures count toward 33.3 percent of a hospital's validation score, with the remaining 66.7 percent of the score attributable to HAI measures.

MANDATORY eCQM MEASURE REPORTING FOR FY 2018 IQR PROGRAM

The AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting while increasing access to real-time information to improve care. Hospital experience with the use of EHRs for eCQM reporting indicates significant work will be required before eCQMs are feasible, reliable and valid for use in hospital quality reporting programs. **The AHA urges CMS not to require electronic reporting of eCQMs for the IQR program before there is evidence of the readiness of eCQMs to support quality reporting.**

Utilize the eCQM data submitted in the EHR Incentive Program. The AHA is concerned that CMS's proposal to use two quarters of data for the IQR program would set a troubling precedent. The goals and requirement of the IQR program are focused on continuous hospital quality improvement. We believe the EHR Incentive Program is the appropriate program for hospitals to submit eCQMs in support of the proposal. **The AHA recommends that CMS use the data submitted electronically by eligible hospitals in the EHR Incentive Program to provide insight on the feasibility, reliability and validity of eCQMs for future use in quality reporting programs.** The electronic submission option available for eCQMs in the EHR

Incentive Program is intended to provide insight on the ability of certified EHRs to capture, calculate, report and submit quality measure data.

Public Reporting of eCQMs Should Not Precede Validation of eCQMs for Clinical Fidelity. The AHA is encouraged by the 2015 launch of the eCQM validation pilot. We believe that information from the pilot should inform the next steps in the ongoing work to improve eCQMs. Participation in the pilot is available to hospitals that are in Stage 2 of meaningful use. In 2014, fewer than half of eligible hospitals in the EHR Incentive Programs had attested for Stage 2. **The AHA recommends that CMS continue the eCQM validation pilot in 2016 to ensure that a diverse group of hospitals and certified EHRs are represented and to inform an assessment of the work required to make eCQM feasible, reliable and valid.** We also urge CMS to make the findings of the eCQM validation pilot publically available for the benefit of all stakeholders who are working to validate the eCQMs.

Ensure that EHR Vendors Support any Proposed Requirement that Hospitals Electronically Submit Updated Versions of eCQM Specifications. CMS proposes to require hospitals to use the May 2015 specification for eCQMs and the 2014 edition certified EHR in order to report the 16 eCQMs. Currently, certified EHRs are not required to be updated to eCQM specifications annually. Because the annual update is outside of the scope of the certification requirement, additional costs are incurred by providers in order to support implementation of the measure update, and updates to other systems that support the eCQM data capture. Additionally, the timeframe for implementing an update to the measure specifications is up to 19 months. Until the infrastructure for eCQM development and testing in certified EHRs is improved, CMS's proposal to require the annual use update specifications is premature. **The AHA urges CMS not to require the use of updated specifications for eCQM reporting until EHR vendors are required to support the annual specification updates as part of the certification process for EHRs. We recommend that CMS and the Office of the National Coordinator (ONC) continue to work with stakeholders to improve the process for annual updates to eCQMs, including the testing infrastructure for eCQMs.** The AHA is engaged in this work and is committed to continued participation.

DATA SUBMISSION FOR HYBRID ECQMS

CMS solicits comment on whether it should ask hospitals to submit "core clinical data elements" that the agency could use in conjunction with claims data to calculate certain outcome measures such as readmissions and mortality. The core data elements include information patient characteristics (e.g., age), vital signs from the first two hours of hospital admission (e.g., heart rate, oxygenation) and laboratory results during the first 24 hours of admission (e.g., hemoglobin and creatinine levels). The agency suggests that the use of data from the EHR could enhance the accuracy of risk-adjustment for claims-based measures by using actual clinical data.

The AHA appreciates CMS's interest in improving its existing measures. However, the process to standardize the definitions used to express the electronic core clinical data elements continues. Likewise, there are instances where the value sets that support the core clinical data elements do not use a consistent naming convention. As a result, the data collected will vary based on the interpretation of the terminology by the EHR vendor. **We urge CMS to continue the collaboration with ONC, the National Library of Medicine, providers, measure**

stewards and electronic measure developers to improve the standardization of the terminology used to support electronic capture of core clinical data elements. This work is foundational to the successful development of hybrid measures.

OUTLIER PAYMENTS

In order to estimate the proposed FY 2016 outlier fixed loss threshold, CMS inflated the charges in the FY 2014 MedPAR file by two years, from FY 2014 through FY 2016. To estimate the one-year average annualized rate-of-change in charges per case for FY 2016, CMS proposes to compare charges from Jan. 1 – Dec. 31, 2013 to charges from Jan. 1 – Dec. 31, 2014. CMS finds a rate-of-change of 4.8 percent (1.048116) or 9.8 percent (1.098547) over two years.

However, the publicly available FY 2014 MedPAR dataset contains claims only through Sept. 30, 2014. Therefore, we do not have access to claims in the first quarter of FY 2015 (Oct. 1 – Dec. 31, 2014) and, hence, cannot replicate the rate-of-change computed by CMS. **The AHA urges CMS to add the claims data for the first quarter of FY 2015 (and any other quarters that it may use in the future for such calculations) to its list of limited data set (LDS) files that can be ordered through the usual LDS data request process. This will enable the field going forward to obtain the data necessary to replicate CMS’s calculation of the charge inflation factor. Not having access to these data severely limits our ability to sufficiently comment on this issue.**

CHANGES TO MS-DRG CLASSIFICATIONS

In general, the AHA has no objections to CMS’s proposed changes to the MS-DRG classifications and the Medicare Code Editor, which seem reasonable given the data and information provided.

CODE FREEZE

The AHA continues to support CMS’s recommendations to continue limited code updates to ICD-10-CM/PCS to capture new technologies and diseases through FY 2016. However, we are extremely disappointed that CMS has finalized the introduction of a new section of ICD-10-PCS codes—section X codes. The adoption of these codes was finalized prior to the end of the public comment period for codes discussed during the March 2015 Coordination and Maintenance Committee meeting.

ICD-10 COVERAGE DETERMINATION POLICIES

The Coverage and Analysis Group at CMS is the Federal entity that oversees National Coverage Determination (NCD) and Local Coverage Determination (LCD) policies. NCDs and LCDs constitute Medicare coverage decisions made by CMS and are applied both nationally and locally across all health insurance payers. In light of the Health Insurance Portability and Accountability Act (HIPAA) as it relates to ICD-10, CMS is responsible for converting the ICD-9 codes to ICD-10 codes in NCDs and LCDs as the agency finds appropriate. There are approximately 330 NCDs spanning a range of time. While CMS has noted that not all NCDs are appropriate for translation, it is unclear how many more NCDs/LCDs remain to be translated. Per

information on the CMS website, CMS is still in the process of determining which NCDs/LCDs should be translated and completing the associated systems changes. To date, it appears that fewer than 50 NCDs have been posted. **We strongly urge CMS to expeditiously finish translating and posting all policies and edits related to systems referencing diagnosis and procedure codes, including NCDs and LCDs. If CMS is finished with the process and does not intend to translate any more NCDs or LCDs prior to the go-live date, an announcement to that effect should be made. Providers need this information in order to allow for testing, hands-on training, financial analysis and financial modeling.**

ICD-10 MS-DRGs

In response to CMS’s inquiry as to how well the most recent version of the ICD-10 MS-DRGs, Version 32, replicates the logic of the MS-DRGs Version 32 based on the ICD-9-CM code set, we respectfully submit the comments below. We have listed the ICD-10 codes and descriptions and the ICD-10 MS-DRGs along with the corresponding ICD-9-CM codes and descriptions and the ICD-9-CM based MS-DRGs.

Chronic Skin Ulcer of Ankle/Heel with Excisional Debridement of Tendon. Regardless of the ICD-10-CM code used for the depth of the ulcer, the ICD-10 MS-DRG returns as DRG 983 Extensive OR procedure unrelated to the principal diagnosis. In contrast, the ICD-9 MS-DRG groups to 581, Other skin, subcutaneous tissue and breast procedures. CMS should consider adding code 0LBTOZZ to MS-DRG 581 when performed for deep ulcers of the ankle.

ICD-10-CM/PCS Code	ICD-10-PCS Description	ICD-10 MS-DRG	ICD-9-CM Code	ICD-9-CM Description	ICD-9-CM MS-DRG
0LBTOZZ	Excision of left ankle tendon, open approach	983 Extensive operating room procedure unrelated to principal diagnosis w/o CC/MCC	83.39	Excision of lesion of other soft tissue	581 Other skin, subcutaneous tissue and breast procedure without CC/MCC

Post-Delivery Procedures. While Medicare may not cover a significant number of pregnancies, it is important for the MS-DRG Grouper to be an accurate and complete classification of all possible clinical scenarios since other payers, including Medicaid, utilize the MS-DRG Grouper. Several procedures performed following delivery are currently calculating outside of Major Diagnostic Category (MDC) 14 Pregnancy, Childbirth and the Puerperium. We recommend that the ICD-10-PCS codes listed below be grouped to MS-DRGs 774-775 when assigned in conjunction with codes from ICD-10-CM Chapter 15 Pregnancy, Childbirth and the Puerperium.

ICD-10-PCS Code	ICD-10-PCS Description	ICD-10 MS-DRG	ICD-9-CM Code	ICD-9-CM Description	ICD-9-CM MS-DRG
0HBJXZZ	Excision of left upper leg skin, external approach	983 Extensive operating room procedure unrelated to principal diagnosis w/o CC/MCC	86.3	Local excision/destruction of lesion/tissue of skin and subcutaneous tissues	775 Vaginal delivery without complicating diagnosis
0DQR0ZZ	Repair Anal Sphincter, open approach (3 rd degree obstetrical laceration repair)	989 Non-Extensive operating room procedure unrelated to principal diagnosis w/o CC/MCC	75.62	Repair of current obstetric laceration of rectum and sphincter ani	775 Vaginal delivery without complicating diagnosis
OUQJXZZ	Repair clitoris, external approach	989 Non-extensive operating room procedure unrelated to principal diagnosis w/o CC/MCC	75.69	Repair of current obstetric laceration	775 Vaginal delivery without complicating diagnosis
0UBMXZZ	Excision of vulva, external approach	983 Extensive operating room procedure unrelated to principal diagnosis	71.3	Other local excision or destruction of vulva and perineum	775 Vaginal delivery without complicating diagnosis

Third Degree Obstetric Laceration. In addition to the problem listed above for code 0DQR0ZZ, it appears that when code ICD-10-CM O70.2, Third degree perineal laceration during delivery, is assigned with code Z37.0 (single live birth) and a procedure code for the repair of the anal sphincter (0DQR0ZZ), code Z37.0 incorrectly triggers DRG 989, Nonextensive OR procedure unrelated to Prin Dx without CC/MCC. If code Z37.0 is deleted, the case is grouped to DRG 769 postpartum & abortion DX without OR px. Instead, the case should group to MS-DRG DRG 775 Vaginal delivery without complicating diagnoses.

Manual Removal of Retained Placenta. Manual extraction of a retained placenta (ICD-9-CM procedure code 75.4) is a non-operating room procedure in ICD-9-CM. The General Equivalence Maps (GEMS) map ICD-9-CM code 75.4 to ICD-10-PCS codes 10D17ZZ or 10D18ZZ, either of which results in the surgical DRG. Because ICD-10-PCS does not differentiate a surgical from a manual extraction of retained products of conception, manual removal of the placenta is classified incorrectly as a surgical D&C as noted in the examples below.

ICD-10-PCS Code	ICD-10-PCS Description	ICD-10 MS-DRG	ICD-9-CM Code	ICD-9-CM Description	ICD-9-CM MS-DRG
10D17ZZ	Extraction of products of conception, retained, via natural or artificial opening	767 Vaginal delivery with sterilization and/or dilatation and curettage	75.4	Manual removal of retained placenta	774 Vaginal delivery with complicating diagnosis
10D17ZZ	Extraction of products of conception, retained, via natural or artificial opening	767 Vaginal delivery with sterilization and/or dilatation and curettage	69.02	Dilation and Curettage following delivery/abortion	767 Vaginal delivery with sterilization and/or dilatation and curettage

MS-DRG 945 & 946 Rehabilitation. Several member hospitals identified problems with MS-DRGs 945 and 946 Rehabilitation (with CC/MCC and without CC/MCC). Many common diagnoses for rehabilitation are not sequencing to the correct MS-DRG for Rehabilitation, even with the addition of PCS rehabilitation codes that are listed in the ICD-10-CM/PCS MS-DRGv32 Definitions Manual. For example, all diagnosis codes from category I69, Sequelae of cerebrovascular disease, group to MS-DRG 056-057 Degenerative Nervous System disorders. ICD-10-CM has significantly changed the guidelines for coding of admissions/encounters for rehabilitation. Under ICD-9-CM, Section I.B.15. of the *Official Guidelines for Coding and Reporting*, indicates that “when the purpose for the admission/encounter is rehabilitation, sequence the appropriate V code from category V57, Care involving use of rehabilitation procedures, as the principal/first listed diagnosis.” The concept of the ICD-9-CM category V57

codes is no longer valid in ICD-10-CM and the guidelines have been revised to provide greater specificity. Instead, the ICD-10-CM guidelines state in Section II.K., “When the purpose for the admission/encounter is rehabilitation, sequence first the code for the condition for which the service is being performed. For example, for an admission/encounter for rehabilitation for right-sided dominant hemiplegia following a cerebrovascular infarction, report code I69.351, Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side, as the first-listed or principal diagnosis.” **Therefore, we recommend that CMS review ICD-10-CM codes for conditions requiring rehabilitation (such as codes from category I69) and add them to MS-DRGs 945 and 946 when rehabilitation services are provided in order to replicate the logic found in the ICD-9-CM MS-DRG Grouper.**

PROCESS TO IMPLEMENT PENALTY FOR FAILING TO MEET MEANINGFUL USE

The AHA remains concerned that CMS has not yet established a transparent and reliable process to identify and notify hospitals that are subject to the significant payment penalties for failure to meet meaningful use. **Given the magnitude of the penalties, and the newness of the program, the AHA believes it is crucial for the agency to be transparent and fair in its process for applying the penalties, as it has done for several quality reporting programs.**

FY 2015 was the first year that CMS implemented the meaningful use penalties. CMS provided little advance notice that a hospital was subject to the penalty and was not sufficiently clear about the steps the hospital should take if it believed the penalty was applied in error. We urge CMS to develop a more structured approach for implementing penalties in FY 2016 and to widely disseminate information on:

- The data and methods CMS will use to identify hospitals subject to the penalty;
- The process CMS will use to notify hospitals subject to the penalty, including who the notification will be sent to and how it will be sent;
- The specific procedures and mechanisms for a hospital to ask for reconsideration of the penalty based on its own documentation (such as proof of attestation or hardship exception), within at least 30 days after receiving notification; and
- The specific mechanisms for a hospital to appeal the agency’s determination after reconsideration, within at least 30 days after receiving the determination.

PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM (PCHQR)

The ACA mandated a quality reporting program for PPS-exempt cancer hospitals (PCHs). For FY 2018, CMS proposes to remove six measures and add three new measures. CMS also proposes to report publicly several additional PCHQR measures.

MEASURE REMOVAL FOR FY 2018

The AHA applauds CMS’s proposal to remove the six Surgical Care Improvement Project (SCIP) measures from the PCHQR program. However, we recommend the agency remove the measures from the program immediately, rather than wait for the FY 2018 program.

CMS states that it is no longer operationally feasible to collect the measures, and suggests their removal would reduce the data collection burden on PCHs. Yet, PCHs would still be required to submit SCIP data for discharges from the first three quarters of CY 2015 to meet PCHQR requirements for FYs 2016 and 2017. Given that the agency intends to sunset the measures from the program, we believe there is little added value – and a considerable burden – to PCHs in retaining them in the program.

PROPOSED NEW MEASURES FOR FY 2018

The AHA supports CMS’s proposal to add three new HAI measures to FY 2018 PCHQR program, but cautions that the agency must exercise considerable care in reporting measure data publicly. CMS proposes to add measures assessing the rates of *MRSA* bacteremia and *C Difficile* in PCHs. The agency also proposes the same measure of influenza vaccination coverage among health care providers that it uses in other programs.

While we agree that HAIs are an important topic for all hospitals – including PCHs – the patient population of PCHs is very different from other acute care facilities. Cancer diagnoses and treatments often leave patients far more immunocompromised and, therefore, more likely to contract HAIs. We believe benchmarking the *MRSA* and *C Difficile* rates of PCHs against other hospitals may lead to unfair performance comparisons. We encourage CMS to work with CDC and PCHs to determine the most appropriate way of capturing and publicly reporting measure results.

PUBLIC REPORTING

The AHA supports CMS’s proposal to report six additional PCHQR measures during 2016, including three oncology measures, two prostate cancer measures and HCAHPS. However, we encourage the agency to work closely with PCHs to clarify the patient populations and sampling requirements for several measures before publicly reporting them. Our PCH members have expressed some confusion about whether the radiation dosing measure (NQF #382) applies to lung and pancreas patients only, or whether it also should be applied to patients with breast and rectal cancer.

We also urge CMS to clarify the sampling requirements of NQF measures #0383 (Plan of Care for Pain) and #0384 (Pain Intensity Quantified). The existing sampling protocol requires PCHs to include a minimum of 25 patients in the numerator for both measures. However, since the numerator population of #0384 then becomes the denominator population of #0383, PCHs may have to “oversample” NQF # 0384 in order to meet the minimum requirement of 25 patients for NQF #383.

Finally, the AHA encourages CMS to delay the public display of CLABSI and CAUTI measure data that it finalized in last year’s rule. As noted above, we absolutely agree HAIs are an important issue for all hospitals. However, we have several concerns about the appropriateness of the benchmarks that would be used to report PCH performance. For example, the exclusions

in the CLABSI and CAUTI measure may not be complete enough for the PCH population. We encourage CMS to continue to work with CDC and PCHs to determine the most appropriate way to publicly report these data.

EXPANDING BUNDLED PAYMENTS FOR CARE IMPROVEMENT (BPCI) INITIATIVE

Since 2011, CMS has been working to develop and test four models of bundling under the BPCI initiative. Under this initiative, organizations take responsibility for quality and financial performance for episodes of care. The initiative is designed to test whether bundled payment can reduce Medicare's costs while maintaining or improving quality. In this proposed rule, CMS solicits comments on a potential expansion of the program and a number of other issues related to operation and administration of the BPCI initiative.

BREADTH AND SCOPE OF AN EXPANSION

The AHA urges CMS to continue voluntary participation in all four models to allow the program to grow and mature. In the meantime, the agency should complete a comprehensive evaluation of program results to date. In February 2015, the Lewin Group released evaluation results for participants during the first year of the program. However, because of the short window of time for evaluation and analysis and the relatively small number of participants in the program and few types of episodes tested at the time, the Lewin Group report was unable to determine whether or not the goals of improving the quality of care and patient experience for beneficiaries while reducing cost are being met. Lewin determined that additional testing and evaluation is needed, examining a longer time period and more participants and episode types.

To support ongoing testing and evaluation of the BPCI models, we encourage CMS to facilitate additional rounds of voluntary participation. Rounds 1 and 2 of BPCI served as a "testing ground" for participants and allowed providers to explore their various options for redesigning care under a bundled payment. Additional rounds would:

- give providers greater confidence about being able to make sound decisions for care redesign, in part because there would be more available research on which protocols work and which do not;
- afford an incremental approach to improving and expanding BPCI in that new participants would benefit from "lessons learned" from Round 1 and 2 participants;
- give Round 1 and 2 providers an opportunity to reflect on their performance during the initial years and explore options for effectively moving forward; and
- allow CMS to further hone its administration of the program.

In addition, we urge CMS to allow continued voluntary selection of clinical conditions by participating providers. Providers need to be able to evaluate whether: 1) relevant evidence-

based care redesign protocols have been established; 2) they have the capacity to implement appropriate care redesign; and 3) they have sufficient patient volume in the clinical conditions to be effective. Furthermore, allowing providers to select the clinical conditions in which they choose to participate will ensure they can select conditions for which they have sufficient patient volume. Over time, as more research is compiled concerning the care redesign models that have been most successful, providers should be given the opportunity to expand their selection of clinical conditions under the BPCI.

EPISODE DEFINITIONS

The following section provides comments on potential refinements to the BPCI episode definitions as part of an expansion of the program, including exclusions, episode classification, and episode duration.

Exclusions. **We recommend that CMS continue its research to expand the list of services that are excluded from the bundles.** Specifically, certain acute care hospital readmissions, physician services and hospital outpatient services that are unrelated to the “anchor” acute care hospitalization are excluded from the BPCI episode cost. The current 48 anchor MS-DRG families are grouped into 13 categories for exclusions purposes. For each of the 13 major condition groups, BPCI specifies the MS-DRGs (for hospital readmissions) and principal diagnosis codes (for physician and hospital outpatient services) that are considered unrelated to the anchor MS-DRG. CMS has intermittently reviewed and modified the list of excluded MS-DRGs and diagnosis codes, but further exclusions are warranted. 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 HRRP).

In addition, under both Models 2 and 3, all post-acute care service costs (i.e., SNF, home health, inpatient rehabilitation and long-term care) are included in the episode cost without exclusion. In the circumstance when an acute hospital readmission occurs during the episode with an excluded MS-DRG (and the readmitting hospital is not a BPCI participant) 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 an awardee 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.

Episode Classification for Model 2. Currently, 181 MS-DRGs are grouped into 48 clinical conditions that consist of “families” of MS-DRGs. For example the AMI clinical condition category includes three MS-DRGs: 280 AMI with MCC; 281 AMI with CC; and 282 AMI without MCC or CC. BPCI awardees cannot select individual MS-DRGs, but must take risk on all MS-DRGs in the group.

While in most cases, we agree with this method for Model 2 episodes, we urge CMS to evaluate ways to deal with cases that do not fit well into this group definition. For example, a hip joint replacement is most commonly done to treat osteoarthritis. This is a fairly standard

high volume procedure. Less commonly, a joint replacement is done to replace a broken hip. The course of treatment and costs vary considerably. Therefore it would be appropriate to treat them as different types of episodes even though they fall under the same MS-DRG.

Episode Classification for Model 3. Using MS-DRGs as the basis of episode assignment may be appropriate for Model 2 episodes that begin with an acute care hospitalization. However, there are issues with using MS-DRGs as the basis for defining episodes for Model 3, which begins with a stay in a post-acute care setting. First, Model 3 episode initiators have found it difficult to obtain the anchor MS-DRG in a timely manner from the acute care hospital from which the patient was discharged prior to the post-acute stay. Second, unlike Model 2 episode initiators who can reasonably determine the patient's MS-DRG for the stay, the reason for post-acute care admission may be very different from the reason for the acute care stay (e.g., a patient requiring post-discharge recovery for simple pneumonia or requiring ventilator support following an inpatient stay for cardiac surgery). Finally, MS-DRGs do not take into account the patient's functional status, which is an important indicator for determining patients' post-acute care needs.

In other words, while MS-DRGs do a good job of explaining differences in patient resource use for acute care services, they often do not help explain post-acute level of care. Indeed, studies have found that MS-DRGs by themselves are an inadequate unit of payment for post-acute care payment bundles.¹⁸ Also, MedPAC found that only 8 percent of the variation in charges for 30-day post-acute care-only episodes could be explained by the MS-DRG from the prior acute care hospital stay.¹⁹

We encourage CMS to study other ways to define episodes for Model 3. For example, some long-term care hospitals (LTCHs) would consider participating in a ventilator support bundle, but ventilator support does not map specifically to any particular MS-DRGs, nor is it often the primary reason the patient was first admitted to the acute care hospital. Although it may be difficult initially to use different episode classification systems across post-acute care provider types, the Improving Medicare Post-Acute Care Transformation Act of 2014 requires development and implementation of a uniform clinical assessment tool across post-acute settings, which will allow for a standardization of episode classification across post-acute care providers in the future.

Episode Duration. **We recommend that BPCI participants continue to be able to choose the episode length.** BPCI Model 2 participants have the option of selecting episode lengths that begin with the admission to the hospital and end 30, 60 or 90 days following discharge. Similarly, BPCI Model 3 participants have the option of selecting episode lengths that begin with the admission to the post-acute provider and end 30, 60 or 90 days following the admission. In addition, Model 2 and 3 episode initiators may select different episode lengths for their different clinical conditions.

¹⁸ James C. Vertrees, Richard F. Averill, Jon Eisenhandler, Anthony Quain, James Switalski, "Bundling Post-Acute Care Services into MS-DRG Payments", Medicare & Medicaid Research Review 2013: Volume 3, Number 3.

¹⁹ MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System", June 2013.

Prior research has shown that the difference in average Medicare payments across episode lengths varies by MS-DRG. Analysis has found that among certain MS-DRGs, such as MS-DRG 247 (percutaneous cardiovascular procedure with drug-eluting stent w/ MCC), the vast majority (over two-thirds) of Model 2 episode payment occurs within seven days following the anchor hospitalization. In other MS-DRGs, such as MS-DRG 291 (heart failure and shock w/ MCC), only a minority (less than half) of Medicare episode payment occurs within seven days in a 90 day episode.²⁰ Given this and given that there has been little research performed to date on optimal episode lengths, we continue to support allowing participants the option of selecting episode lengths that they deem appropriate for managing patients through the course of the episode.

However, we urge CMS to consider allowing for longer episode periods for certain episodes, where optimal outcomes may not be realized for six to 12 months. Chronic conditions such as COPD, diabetes and renal failure might be good candidates for longer episode duration. Also, should CMS develop a ventilator support bundle, a longer episode length might be optimal.

MODELS FOR EXPANSION

As noted above, we urge CMS to complete a comprehensive evaluation of the program. Determining which BPCI models to consider for expansion should take into account the results of this evaluation. In the first two rounds of the BPCI demonstration, there has been a considerable amount of interest in Models 2 and 3, whereas few organizations are participating in Models 1 and 4.

However, the primary difficulty with expanding Models 2 and 3 is that both models cannot co-exist for the same clinical condition groups in the same health care markets. Both Model 2 and 3 episodes are triggered by an acute care hospitalization. The Model 2 episode begins with the acute care hospital admission, and the Model 3 episode begins with admission to a post-acute provider following the acute care hospital stay. Since beneficiaries cannot be in two episodes at the same time, one episode must take precedence over the other. The current BPCI precedence rules for determining which provider is awarded the episode are complex and may not be applicable under an expansion. For example, if a Model 3 awardee's participation date, the date they joined the program, for a clinical condition precedes the participation date of a Model 2 awardee, the Model 3 awardee would receive precedence regardless of which organization originally treated the patient. However, if a Model 2 awardee and Model 3 awardee have the same participation date for a clinical condition, the Model 2 awardee would receive precedence. Because Model 2 covers similar post-acute care services as Model 3, simultaneous expansion of both models has the potential to make Model 3 obsolete. Thus, it will not be effective for BPCI to expand multiple models for the same clinical conditions in the same markets.

A potential option to address the precedence concern is to separate models by clinical condition. Model 2 may be more effective when treating some conditions while Model 3 may be more effective for others. For example, Model 3 may be best for handling more complex patients with multiple chronic conditions while Model 2 may be a more appropriate option for procedural

²⁰ Dobson | DaVanzo, "Medicare Payment Bundling: Insights from Claims Data and Policy Implications: Analyses of Episode-based Payment", May, 2013

episodes that have established care pathways in which patients do not always require care in the four PAC settings. Therefore, it is important that the BPCI evaluation examines the effectiveness of the different models across clinical conditions on quality of care and patient experience, as well as provider financial impact.

Another difficulty in expanding BPCI Models 2 and 3 is that episode costs vary dramatically depending on the post-acute care placement of the patient following the acute hospital stay. These differences in costs may be due more to the “siloes” nature of Medicare’s post-acute care payment systems and conditions of participation requirements than the efficiency of the providers. BPCI expansion should ensure that there are no barriers to the clinically appropriate and cost effective placement of patients into post-acute care settings and allow post-acute care providers to fairly compete with one another on the basis of costs and quality.

In order to help facilitate this, CMS should consider making additional waivers of post-acute regulations to untie the hands of organizations that want to try new treatment approaches that truly reflect a patient-centered – rather than regulation – focused approach. Specifically, existing Medicare regulations prevent BPCI participants from fully testing bundled payment for patients receiving post-acute services. For these patients, efforts to re-engineer and improve services are hampered by numerous regulations that make sense in the FFS environment, but do not align with the BPCI goals or structure. For example, the efforts of Model 2 and Model 3 organizations to develop and test more efficient clinical pathways are highly restrained by FFS regulations that direct patients to particular post-acute settings and levels of care. In recognition of this significant restriction, BPCI rules already waive the SNF “3-day stay” and home health “homebound” requirements. However, several other regulations continue to tie the hands of Model 2 and Model 3 participants that want to optimize the BPCI opportunity to test new post-acute methodologies – but cannot due to regulations such as:

- The inpatient rehabilitation facility (IRF) “3-hour rule,” which requires that IRF patients require and receive at least three hours of therapy at least five days per week;
- The IRF “60% Rule,” which requires that at least 60 percent of an IRF’s patients have one of 13 qualifying conditions;
- The LTCH requirement for an average length of stay of greater than 25 days; and
- The LTCH “25% Rule,” which reduces payment for certain patients based on the volume of patients transferred to an LTCH from a particular general acute-care hospital.

In addition, such regulatory waivers would allow hospital-level post-acute providers to more fully participate in BPCI, as their competencies related to specialized clinical programs, higher-level clinical staff, and more advanced physical plant could bring unique value in the treatment of higher-acuity post-acute patients.

ROLES OF ORGANIZATIONS AND RELATIONSHIPS NECESSARY OR BENEFICIAL TO CARE TRANSFORMATION

Bundling under BPCI represents a potential transformation in the way health care services are provided, organized and delivered. However, our members’ experience is that the possibilities

for savings, while real, are narrow – particularly given the large investment hospitals must make to plan for and implement care transformation.

We urge CMS to closely examine the contributions to its goals of improving quality of care, patient experience and reducing costs relative to the share of savings by third parties that do not participate in care management or delivery. These third parties act as conveners, helping organizations with data analytics and other tasks. In some cases, rather than charging a fee for their services, they share in the risk that program participants take on. If third parties take risk and draw down on provider savings, these arrangements must allow for providers to accumulate adequate capital to effectuate and sustain changes in the delivery system. It is clearly in CMS's interest to monitor evolving organizational and financial relationships to ensure that providers retain adequate financial reserves to support sustained change under any type of expansion. If only a few episodes are bundled, threats to providers' financial strength are minimal. If expansion is extensive across episode initiators and episode types, however, the role of third parties becomes more apparent and needs to be carefully considered such that value is received.

Unintended financial consequences could play out such that CMS takes 2 to 3 percent as savings and third parties take 2 percent for administrative and operational support and also share in savings. Yet, under the best of circumstances, CMS evaluations show that efficiency savings are in the 5 percent range. Therefore, it is possible for there to be very little shared savings left for the provider to pay for the operational costs required to pay for care transformation.

We urge CMS to carefully monitor the financial arrangements entered into by providers and third parties to ensure that they are aligned with BPCI program success, high-quality patient care and sustainability.

SETTING THE BUNDLED PAYMENT AMOUNTS

The methodology that CMS uses to set bundled payment amounts must balance savings to the Medicare program with provider financial stability and patient access to care, and has important implications for the future sustainability of bundled payments. Currently, CMS sets target prices using provider-specific historical spending data from 2009 through 2012 with adjustments for low-volume clinical conditions and reductions for specific discounts to Medicare. All providers rendering services to a beneficiary in a BPCI episode, including episode initiators, continue to be paid on a FFS basis for actual care delivered. These FFS expenditures are later reconciled against target prices on a quarterly basis. **Under an expansion of BPCI, CMS should consider refinements to its methodology for determining target prices.**

First, targets currently change quarterly based on national trends in episode costs from the 2012 base period to the quarter of performance. Reconciliation is performed at least five months after episodes are completed and awardees do not know what the actual target price will be until reconciliation. It is not appropriate policy to hold BPCI participants at risk for prices that are unknown until after the episodes are complete.

We urge CMS to set target prices annually and make them available prior to the beginning of the year, which is consistent with all other Medicare payment systems. Without more

information on the degree to which these target prices change quarter to quarter, participants do not know how volatile prices will be at the awardee-convenor level. Setting and updating target prices on an annual basis, such as the annual baseline spending targets for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP), would allow for participants to better implement efficient care redesigns linked explicitly to established payment rates for each type of episode. CMS also would be able to reduce its administrative burden of recalculating and reconciling target prices on a quarterly basis if it transitioned to an annual payment setting methodology comparable to the other Medicare prospective payment systems.

Second, low-cost providers do not have a strong incentive to participate in the BPCI initiative nor do providers who achieve significantly lower costs in their first three years of participation in BPCI have an incentive to continue in the program. These providers have only a limited opportunity to make additional gains in efficiency that could produce savings. However, CMS should allow more time for providers to operate under bundled payments, and for analysis of spending trends, patient outcomes and access to care, before considering a transition from facility-specific to nationally set target prices or target price adjustments weighted toward national rather than historical or regional updates.

In order to encourage continued participation, we urge CMS to consider the following options for adjusting target prices for these providers:

- Reducing the required discounts for low-cost providers.
- Setting the target rate at the higher of the facility-specific rate or a specific percentile of the national average.
- Providing an additional incentive in the payment-setting methodology for these types of providers. For example, a series of quality measures could be incorporated into the payment system such that the discount off of the target price is reduced for providers delivering high-quality, low-cost care or a bonus payment could be provided.

MITIGATING THE RISK OF HIGH-COST CASES

We support the maintenance of risk tracks as the method for mitigating the risk of high-cost episodes pending further evaluation. Risk track outlier policies assist in narrowing the boundary of financial uncertainty and mitigating provider risk. Because high-cost cases normally occur at random, the events of a preceding quarter may not be reflective of a future quarter. Risk tracks are based on percentiles of the national cost of episodes. The three risk tracks are as follows:

- Risk Track A: Higher Outlier Limit= 99th percentile/ Lower Outlier Limit= 1st percentile
- Risk Track B: Higher Outlier Limit= 95th percentile/ Lower Outlier Limit= 5th percentile
- Risk Track C: Higher Outlier Limit= 75th percentile/ Lower Outlier Limit= 5th percentile

Participants appreciate the freedom of choice this method gives them, as diversity of provider organization environments and strategies affect risk track considerations and preferences.

Organizations that plan to reduce Medicare costs through care management activities will generally select a higher risk track (risk track A or B). Organizations focused on internal cost savings will often select risk track C to obtain maximum insulation from high-cost cases. There are a number of strategic considerations when addressing high-cost cases, and the option to select from three distinct risk tracks allows the participant to choose the level of risk that they are most comfortable with.

In addition, BPCI participants appreciate the option to select different risk tracks across different episode groups. The variation in Medicare spending per episode as measured by coefficient of variation (CV) can range from 0.33 (bilateral or multiple major joint procedures of lower extremity) to 0.80 (heart failure and shock). Higher CV values mean greater variability in episode payments. Surgical procedures generally have a lower CV than medical conditions, but for many conditions there is a wide variation in costs. These wide variations in cost offer opportunity for savings but present the risk of high-cost cases.²¹ Different participants have a different tolerance for risk and, thus, appreciate the option to choose the level of risk that they are most comfortable with.

Although high-cost cases cannot be accurately predicted, it is important for BPCI participants to continue to receive historical claims data to help understand the risk track option that would best fit with their unique circumstances. Long-term historical data will assist in comparing individual results against the national risk track calculations to help determine the percentage of patients that are expected to exceed outlier limits in the participant's population.

ADMINISTRATING BUNDLED PAYMENTS

We recommend that CMS continue with retrospective payment. The retrospective bundling model allows providers to experiment with bundling without altering existing revenue cycle practices, which is critical to helping encourage participation for a number of reasons. Additionally, many awardee conveners are not Medicare providers and even those that are may not have the infrastructure that would allow them to accept and distribute the bundled payment to the various providers involved in the care. Also, prospective payment would require participants in the bundle to change their billing practices for a subset of their cases. For example, physicians would need to bill the BPCI participant rather than CMS for episodes that fall within the program, but continue billing CMS for those that do not. As one of the current problems with the bundling program is identifying episodes that fall into the specific bundles, it would be difficult for organizations to determine who to bill.

Additionally, FFS payments maintain a predictable cash flow to all providers participating in the BPCI initiative. They also hold downstream providers harmless from the episode initiator for spending in excess of the target price, which is necessary while issues relating to the administration of bundled payments from CMS to awardee conveners to downstream providers are resolved over time.

²¹ Dobson | DaVanzo, "Medicare Payment Bundling: Insights from Claims Data and Policy Implications: Analyses of Episode-based Payment", May 2013.

Finally, by paying providers on a FFS basis, CMS will continue to generate claims data that will allow for the analysis of trends in utilization and spending within episodes over time. Medicare FFS claims data are widely recognized as a complete and accurate longitudinal source of information on health care spending and utilization; this lies in contrast to encounter-type data collected under other forms of bundled payment, such as global or capitation-type payments, which lack information on service-level spending and are often incomplete and/or of unknown quality.

DATA NEEDS

In order to understand and manage costs under a bundled payment system, BPCI participants need access to data on patient utilization and spending for all services provided across the entire episode of care. In addition, BPCI participants need real-time data on patients to actively manage their care throughout the episode. Currently, CMS provides detailed Medicare claims data to individual awardees and awardee conveners for each participating episode initiator and each clinical episode group selected. These data have provided valuable insight into patients' utilization of services, Medicare spending and patient care pathways over the course of an episode. **We urge CMS to continue to provide these data to BPCI participants since it is the only complete source of utilization and spending data for all services provided during an episode.**

Although the claims data provided by CMS has been very useful to providers, there are limitations to the data and areas that can be improved. We urge CMS to consider the following enhancements to the monthly data feeds:

- The format of the detailed claims data are complex (i.e., 19 separate data files per month). In order for the data to be useful, providers must group it into episodes and calculate payments within various periods during the episode, which requires complex programming based on dozens of pages of specifications. In many cases, providers do not have the experience or expertise to do this. Often they must use an outside vendor to manage and compile the data provided, which is an added expense of BPCI participation. CMS could make these data more “user friendly” by adding calculated payment amounts and utilization by provider type to the “episode summary” file as well as continue to provide the detailed claims data.
- Claims data are only provided for patients who are in clinical groups that were selected by the episode initiator, but not for other conditions that are eligible for BPCI but were not selected. We urge CMS to make data available to awardees for all BPCI clinical episode groups.
- We urge CMS to make available completion factors to allow providers to better estimate the value of outstanding claims within its episodes.
- Currently, participants only know when a patient qualifies for a bundle from their monthly data feeds. We encourage CMS to evaluate ways that providers can get faster notification of when a patient qualifies for a bundle.

- Currently, CMS calculates the Hierarchical Condition Categories (HCC) scores for each patient involved in a bundled payment episode. These scores are used for quality measurement. We urge CMS to make the HCC scores of patients available to BCPI participants so they can better understand the acuity of their patient population.
- Claims data include only claims for the episode initiator's patients. Although this data is useful for examining utilization and costs for a provider's own episodes, it does not allow for benchmarking their performance against other providers. We encourage CMS to consider providing summary cost and utilization data at the state or regional level across different provider types and by clinical condition or MS-DRG. These data would allow providers to determine their performance relative to peer benchmarks.
- We urge CMS to improve the timeliness and accuracy of data. CMS occasionally makes mistakes in the data that are disseminated to BCPI participants. Although we understand the potential for mistakes when working with this volume of information, some of these errors were material. However, CMS provided only a very short window of time for providers to reassess their decisions using the corrected data. In these situations, we urge CMS to provide participants with ample time to reassess decisions when corrected data is issued.

Because BCPI waivers and incentives are linked to patients in BCPI episodes, providers need to know as soon as possible if patients are in a BCPI episode and, if so, under which MS-DRG designation. In addition, providers need to know MS-DRG assignments immediately upon patient discharge to a post-acute care setting in order to improve the link between hospitals and the patient stay in a post-acute care setting.

Participants also need real-time information on patients as they move across the continuum of care. Data should flow seamlessly and allow visibility into all care provided as it occurs. Each provider should know almost everything about their patients at each care transition. Organizations will need to develop data sharing mechanisms to be successful. The additional costs to providers of trying to develop such data sharing mechanisms may discourage participating in the program. We encourage CMS to consider ways of creating financial support for the development of such systems.

USE OF HEALTH INFORMATION TECHNOLOGY (IT)

The proposed rule seeks comment on how health IT can be used and encouraged in coordinating care across care settings, including post-acute care. **The AHA encourages CMS to focus its rules on the desired outcomes of the bundling initiatives, rather than the use of specific inputs such as EHRs.**

Hospitals have been working diligently to implement new health IT to improve the quality and coordination of care for patients. According to the most recent AHA survey data, hospitals have 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, LTCHs, IRFs and home health 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 the outcomes of better coordinated care.

QUALITY MEASUREMENT AND PAYMENT FOR VALUE

The AHA encourages CMS to continue exploring ways of measuring the quality of care provided to beneficiaries in the BPCI initiative. However, we believe it is premature to tie the discount percentage to performance on quality measures. CMS and BPCI participants are still learning which measures are most relevant to evaluating care in a bundled payment context. Some of the high-level outcome measures (e.g., all-cause readmissions, emergency department visits, mortality) used in CMS's February 2015 evaluation report may be useful for evaluating the overall impact of the program in the aggregate. However, we caution that CMS's ability to use such measures in a value-based payment approach for individual BPCI providers would be severely limited by issues of sample size and measure reliability and validity. Furthermore, to truly understand whether the use of bundled payments increases quality, CMS may need measures more directly tied to the specific conditions or procedures included in particular bundles.

PRECEDENCE RULES FOR MODEL TWO

It is a risk to high-quality and efficient patient care to have potential awardees such as hospitals, post-acute care providers, physician groups and physician group practices (PGPs) vying for management of the same episode type. The current precedence rules are very concerning and should not be carried over to a permanent, national program. At present, Model 2 bundles automatically attribute to a physician group bundler even if the physician of a hospital bundler is also involved in the care. This puts hospitals at a distinct disadvantage and encourages physician groups to enter the program without the hospitals, causing further fragmentation. **We believe a more equitable process to attribute the patients to a bundler would be to consider the role of the physicians who are part of the hospital group compared to that of the physician group, or developing a plurality of services model more closely aligned with the MSSP.** Regardless of the method, hospital groups should be allowed as conveners and put on an equal

playing field with physicians. Hospital systems have much to offer in terms of capital, post-acute care coordination (e.g., nurse navigators, care managers), EHRs, outpatient rehabilitation therapies, diagnostic testing facilities, long-standing quality reporting and improvement initiatives, data analysis capabilities and comprehensive financial metrics. A central tenant of the program is to bring providers together by removing the payment silos associated with standard FFS payments. Hospitals have accepted the challenge and are forging relationships across the continuum to provide better care under the Triple Aim,TM CMS should ensure there is an avenue for them to participate.

ADDITIONAL WAIVERS

In addition to the waivers of post-acute regulations cited earlier, the AHA urges the following refinements to the waivers for the BPCI program:

- *Patient Incentives.* Waivers to the *Beneficiary Inducements Civil Monetary Penalty*²² and the *Federal Anti-Kickback Statute* would permit BPCI participants to provide items and services to beneficiaries for free or less than fair market value, as part of care received under the BPCI and as part of a treatment goal such as prevention or adherence to a treatment regimen. For example, under such a waiver, a beneficiary being treated under the BPCI could receive an electronic device to access a BPCI organization's electronic platform to conduct activities including scheduling follow-up appointments, medication compliance, and submitting questions or concerns. Many of such items and services will serve to better engage beneficiaries compared to FFS Medicare and improve the likelihood of patient satisfaction and quality outcomes. A waiver addressing patient incentives also has been promulgated as part of the MSSP.²³

Additionally, as is being considered within MSSP and the Next Generation ACO Model, and was part of the president's FY 2016 proposed budget, we recommend the waiver of primary care copays. This would encourage beneficiaries within a bundle to seek the appropriate follow-up care that would not only help reduce readmissions, but also allow patients to be discharged to a lower level of post-discharge care.

- *Gainsharing.* Non-physician practitioners should be added to the list of suppliers with whom a bundler can gainshare. Physician assistants, nurse practitioners and others are key team members in the care transformation that bundlers are undertaking.
- *Pre-admission Home Evaluation Services.* Home health agencies are prohibited from performing free pre-operative home safety assessments for patients scheduled to undergo surgery.²⁴ A waiver of this policy would result in more informed post-acute care plans, a decreased likelihood of falls and readmissions, and a more patient-centered care

²² See SSA § 1128A(a)(5).

²³ 76 Fed. Reg. 67992.

²⁴ See U.S. Dept. Health and Human Services-Office of Inspector General ("HHS-OIG") Advisory Opinion No. 06-01, March 27, 2006; concluding that performing these assessments potentially generates prohibited remuneration under the *Anti-Kickback Statute*.

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plan. Home health agencies are especially adept at working with clinicians to assess the patient's care needs, including his or her ambulatory limits or other functional impairments, and should not be prevented under the BPCI from working collaboratively to generate a care plan at the pre-admission stage that helps transition the beneficiary to the more patient preferred, lower-cost community-based setting.