American Hospital Association

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June 17, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–1655–P, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Proposed Rule (Vol. 81, No. 81), April 27, 2016.

Dear Mr. Slavitt:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital inpatient prospective payment system (PPS) proposed rule for fiscal year (FY) 2017. We have submitted separate comments on the agency's proposed changes to the long-term care hospital (LTCH) PPS.

We support a number of the inpatient PPS proposed rule's provisions and appreciate that CMS has decided to reverse the 0.2 percent payment reduction the agency implemented in conjunction with the original "two-midnight" policy. However, we have concerns about the documentation and coding reduction, changes to disproportionate share hospital (DSH) payments, and the implementation of many of CMS's quality programs. Below is a summary of our key recommendations.

TWO-MIDNIGHT POLICY

In the proposed rule, CMS proposes two-adjustments that would reverse the effects of the 0.2 percent reduction in inpatient PPS rates the agency implemented in conjunction with its two-midnight policy. **The AHA appreciates that CMS has decided to reverse this payment reduction and supports the agency's proposals to restore the resources that hospitals are lawfully due.**

DOCUMENTATION AND CODING ADJUSTMENT

The American Taxpayer Relief Act of 2012 (ATRA) requires CMS make adjustments to the standardized amount to recoup $11 billion that the agency claims is the effect of documentation and coding changes from FYs 2010 – 2012 that CMS says do not reflect real changes in case mix. Regrettably, for FY 2017, CMS proposes a coding cut of 1.5 percentage points to inpatient PPS payments to allegedly fulfill this requirement within the statutory four-year timeline. **The AHA is extremely troubled by this proposal and believes it is inconsistent with Congress' intent in ATRA, as well as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) where Congress reiterated its belief that the reduction should be 0.8 percentage points. We urge CMS to ensure that the amount it originally estimated – 0.8 percentage points – is removed in FY 2017, rather than the proposed cut of 1.5 percentage points. If CMS removes more than this amount, we strongly urge CMS to ensure that any amount over 0.8 percentage points is returned to the standardized amount in FY 2018.**

DSH PAYMENT PROPOSALS

Starting in FY 2018, CMS proposes to begin a three-year phase-in of incorporating hospitals' Worksheet S-10 data into the methodology for determining uncompensated care payments. Generally speaking, we continue to believe that, if reported in an accurate and consistent manner, the Worksheet S-10 data have the potential to serve as a more exact measure of the treatment costs of uninsured patients. **The AHA remains concerned, however, about Worksheet S-10 data and urges CMS to take additional steps to ensure the accuracy, consistency and completeness of these data prior to their use, as specifically described in our detailed comments. Once CMS ensures the accuracy and consistency of the Worksheet S-10 data, we believe that transitioning to its use, either through a potentially longer phase-in approach and/or a stop-loss policy, is appropriate.**

HOSPITAL-ACQUIRED CONDITIONS (HAC) REDUCTION PROGRAM CHANGES

The proposed rule includes several policies intended to improve the fairness of the HAC Reduction Program, including a new scoring methodology. **The AHA commends CMS's willingness to consider program changes within its statutory authority. However, we do not believe the proposed policy changes are sufficient to remedy the fundamental flaws with the program.** Teaching hospitals, large hospitals, and hospitals caring for large numbers of poor patients still would be disproportionately more likely to receive penalties. The AHA welcomes the opportunity to work with CMS and Congress to improve the design for the program so that it scores hospitals more fairly and accelerates improvements in patient safety.

HOSPITAL READMISSION REDUCTION PROGRAM (HRRP) CHANGES

The AHA once again urges 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, readmission penalties will continue to accrue disproportionately to hospitals treating our nation's poorest and most vulnerable patients.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM CHANGES

CMS proposes a significant expansion of reporting for certain electronic clinical quality measures (eCQMs). While proposing to remove 13 eCQMs, the agency would require hospitals to report a full year of data on *all* of the remaining 15 eCQMs in the IQR program. **While the AHA strongly supports the long-term goal of using electronic health records to streamline and reduce the burden of quality reporting, there remain far too many questions about eCQM feasibility and accuracy for CMS to mandate an expanded reporting requirement in the IQR.** Furthermore, the AHA continues to urge CMS to take steps to streamline and focus the measures in the IQR program around high-priority quality and safety issues.

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/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

American Hospital Association (AHA)
Detailed Comments on the Inpatient Prospective Payment System (PPS) Proposed Rule for Fiscal Year (FY) 2017

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The American Taxpayer Relief Act of 2012 (ATRA) requires the Centers for Medicare & Medicaid Services (CMS) to make adjustments to the standardized amount to recoup $11 billion that the agency claims is the effect of documentation and coding changes from FYs 2010 – 2012 that CMS says do not reflect real changes in case mix. Regrettably, for FY 2017, CMS proposes a coding cut of 1.5 percentage points to inpatient PPS payments; CMS claims that this would allow the agency to fulfill the $11 billion ATRA recoupment requirement within the statutory four-year timeline when combined with the effects of the previous cuts of 0.8 percentage points in FYs 2014 – 2016. **The AHA is extremely troubled by this proposal. We believe this cut, which is almost double the cut anticipated by hospitals, should be reduced to what the agency originally estimated and planned – 0.8 percentage points for FY 2017.**

ATRA does not require CMS to update or reconcile its initial estimate with actual discharges. Instead, the ATRA required that CMS *project* and implement an $11 billion documentation and coding reduction to hospital inpatient payments based on *estimated* discharges. In the FY 2014 hospital inpatient PPS final rule, CMS laid out a plan, based on its actuaries' analyses, to impose a series of cuts in order to fulfill this requirement. Specifically, the agency projected that, if it made cuts of 0.8 percentage points in each of FYs 2014 – 2017 based on its *estimated* discharges in those years, it would recoup the full amount required by the law.

CMS acted in accordance with this policy in FYs 2014 – 2016; however, now the agency proposes to deviate in FY 2017 by implementing a cut of 1.5 percentage points. CMS claims that this larger cut is necessary because inpatient PPS discharges have been less than its actuaries had anticipated, and an additional cut is necessary to fully account for the $11 billion. **To be clear, ATRA allows CMS to continue using the analysis its actuaries prepared for the FY 2014 inpatient PPS final rule that was based on estimated discharges and projected a cut of 0.8 percentage points in FY 2017. Accordingly, we urge CMS to reduce this documentation and coding cut to what it originally estimated and planned – 0.8 percentage points for FY 2017.**

If CMS insists on updating its adjustments, we encourage CMS to consider a broad interpretation of inpatient PPS discharges that accounts for the shift of patients from Medicare Part A to Part C. The impact of the documentation and coding cuts imposed by ATRA do not affect Part A payments alone. Instead, they also affect Part C Medicare Advantage payments through the Medicare Advantage rate determination process. Consequently, Part C discharges also should be included in the agency's discharge estimates. From our modeling, if CMS includes Part C discharges in its estimates, it would recoup the full $11 billion ATRA requirement by taking a 0.8 percentage point cut for FY 2017.

In addition, the AHA urges CMS to act in accordance with Congress' intent in both the ATRA and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to ensure that the appropriate amount is restored to hospitals going forward. The ATRA cuts were recoupment cuts; as such, Congress intended that the cumulative 3.2 percentage point cut

(0.8 percentage points for each of FYs 2014-2016, plus 0.8 percentage points in FY 2017) be restored in FY 2018 through a one-time increase in inpatient PPS payments. Congress altered the timing for recoupment of these funds when it passed MACRA. Specifically, relying on CMS's actuaries' estimate that the final ATRA cut would be 0.8 percentage points in FY 2017, Congress used the anticipated 3.2 percentage point restoration in FY 2018 to help generate savings to pay for a permanent fix to the sustainable growth rate for physician payments under Medicare. MACRA spread the restorative adjustments over six years – hospitals will receive an increase of 0.5 percentage points for discharges occurring during each of FYs 2018 – 2023. In total, these adjustments would restore 3.0 percentage points of the 3.2 percentage point cut from hospitals for ATRA.

If CMS implements a cut of 1.5 percentage points in FY 2017, the agency will, in total, remove 3.9 percentage points from the standardized amount. Yet, MACRA allows for only 3.0 percentage points to be returned to hospitals by FY 2023. Consequently, CMS's proposed cut would leave hospitals with a permanent cut of 0.9 percentage points after the MACRA adjustments have been made, instead of the 0.2 percentage point cut that Congress intended. This additional 0.7 percentage point cut is inconsistent with Congress's intent in the ATRA and MACRA, which, together, required restoration of the documentation and coding cuts.

Lastly, Congress did not intend for the recoupments to exceed $11 billion and any additional recoupment will unfairly penalize hospitals. ATRA limits CMS's total documentation and coding recoupment to $11 billion. If CMS does not restore the 0.7 percentage points to the standardized amount, it will continue to recoup funds from hospitals each year going forward; resulting in recoupments that far exceed the $11 billion authorized by the ATRA. The AHA has long argued that these documentation and coding cuts are unwarranted. For America's already financially strained hospitals, this additional reduction could result in a loss of health services and programs that are essential for Medicare beneficiaries, as well as other patients. Further, it penalizes hospitals for successfully doing what CMS and Congress have asked them to do – decrease admissions and reduce unnecessary admissions. To allow their ongoing effects to continue indefinitely will significantly impact hospitals in a manner that was never intended by Congress. **Therefore, as stated above, CMS should act in accordance with Congress' intent in the ATRA and MACRA to ensure that the appropriate amount – 0.8 percentage points – is removed in FY 2017. If CMS removes more than this amount, we strongly urge CMS to ensure that any amount over 0.8 percentage points is returned to the standardized amount in FY 2018.**

DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

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 pre-FY 2014 formula, known as "empirically justified DSH payments." The remaining 75 percent flows into a separate funding pool for DSH hospitals, known as "uncompensated care DSH payments." This pool is 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.

For FY 2017, CMS estimates that the total amount of Medicare DSH payments that would have been made under the pre-FY 2014 formula is $14.227 billion. Therefore, the agency estimates that the empirically justified DSH payments, or 25 percent of the Medicare DSH payments hospitals would initially receive is $3.556 billion. The remaining $10.670 billion flows into the 75-percent pool. To calculate what portion of the 75-percent pool is retained, CMS determines that the percentage of uninsured for FY 2017 would be 10.25 percent. After inputting that rate into the statutory formula, CMS proposes to retain 56.74 percent – or $6.054 billion – of the 75-percent pool in FY 2017. This amounts to a reduction of about $134 million in Medicare DSH payments in FY 2017 compared to FY 2016.

The AHA reconvened our Medicare DSH Advisory Committee to discuss the agency's specific proposals. Our comments below reflect the work of this committee, as well as our members at large. While AHA agrees with certain proposals, we are very concerned about others. **Specifically, we are concerned about the accuracy and consistency of the Worksheet S-10 data. The AHA urges CMS to take additional steps to ensure the accuracy, consistency and completeness of these data prior to their use. This entails auditing the S-10 data, as well as making other modifications to the S-10 worksheet, including, but not limited to, adopting a broad definition of uncompensated care costs to include all unreimbursed and uncompensated care costs, such as Medicaid shortfalls and discounts for the uninsured.**

CMS'S PROPOSED CHANGES FOR FY 2017 DSH PAYMENT CALCULATION

Transparency Related to DSH Calculation. **The AHA is concerned 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 rulemaking that much more important from a constitutional due process perspective. The AHA highlights some examples below of improvements that could be made to promote 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.

We are concerned primarily about the calculation of Factor One (the total amount of Medicare DSH payments that would have been made under the pre-FY 2014 formula), which is discussed on page 25085 of the rule. There, CMS includes a table explaining the factors applied for FYs 2014 – 2017 to estimate Medicare DSH expenditures. CMS states:

> The figures for FYs 2014 and 2015 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2016 is based on preliminary data for 2016. The discharge figure for FY 2017 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 Advantage (MA) plans.

However, the agency provides neither OACT's "completion factor" used to adjust the claims data for FYs 2014 and 2015, nor an explanation of how OACT calculated this "completion factor." CMS also fails to provide an explanation of the "preliminary data for 2016" that OACT

used in the FY 2016 figure, such as what the data are and what they cover, and the "assumptions" used for the FY 2017 figure. **Not having access to this information severely limits the AHA's ability to comment sufficiently 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, as OACT labels them, for the Medicare DSH projections for FY 2016, between the *FY 2016 FR Medicare DSH Estimates* file and the *Estimates for Factor 1* tab in the *FY 2017 Proposed DSH Supplemental Data File*, we notice that the value posted in the FY 2016 file (1.045 in cell E11) is greater than 1, whereas the corresponding value in the FY 2017 file (0.9993 in cell E10) is less than 1. These numbers are dramatically different, and the considerably lower value in the FY 2017 file has a significant impact on the FY 2017 Medicare DSH estimate. For example, if we were to substitute the seemingly incorrect value of 0.9993 with 1.045, the FY 2017 Medicare DSH estimate would be $14.878 billion instead of the CMS-estimated value of $14.227 billion, a difference of approximately $651 million.

We request clarification from CMS regarding this significant discrepancy. **We also 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. We remain concerned regarding OACT's calculations and these inconsistences, and request that CMS address these concerns in the FY 2017 inpatient PPS final rule.**

Changes to DSH Payment Methodology Beginning in FY 2017. CMS proposes one additional change to its DSH payment methodology. Specifically, the agency proposes to expand the time period for the data used to calculate hospitals' Medicaid and Medicare Supplemental Security Income (SSI) inpatient days from one year to three years. CMS believes this change will address the concern from the hospital field that using only one year of data to determine a hospital's share of uncompensated care may result in unpredictable swings and anomalies. **The AHA supports this proposal.**

CMS'S PROPOSED CHANGES FOR FY 2018 DSH PAYMENT CALCULATION

For several years, CMS has discussed the alternative of using Worksheet S-10 of the Medicare cost report to determine the amount of uncompensated care each hospital provides. This worksheet contains data on hospitals' charity care and bad debt and would be used in place of their Medicaid and Medicare SSI days when distributing the 75-percent pool. However, because of concerns regarding variations in the data reported on Worksheet S-10 and the completeness of these data, CMS had indicated it was premature to propose the use of Worksheet S-10 for purposes of determining uncompensated care payments in each of those years.

CMS reiterates that assessment for FY 2017; but, for a variety of reasons, proposes to, starting in FY 2018, begin a three-year phase-in of incorporating hospitals' Worksheet S-10 data into the

methodology for determining uncompensated care payments. Therefore, for FY 2018, CMS proposes to use FY 2014 Worksheet S-10 data in combination with FYs 2012 and 2013 Medicaid days and FYs 2014 and 2015 Medicare SSI days to determine the distribution of uncompensated care payments.

Generally speaking, we continue to believe that, if reported in an accurate and consistent manner, the Worksheet S-10 data have the potential to serve as a more exact measure of the treatment costs of uninsured patients. However, the AHA remains concerned about Worksheet S-10 data and urges CMS to take additional steps to ensure the accuracy, consistency and completeness of these data prior to their use, as specifically described below. In addition, we have communicated our major concerns and suggestions regarding the Worksheet 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 FYs 2015 and 2016 inpatient PPS proposed rules. To that end, the AHA supports CMS's proposal to allow hospitals that have either not submitted a Worksheet S-10 with their FY 2014 cost report or find errors on a submitted Worksheet S-10 to work with MACs to complete and revise their FY 2014 Worksheet S-10.

Auditing of Worksheet S-10. While CMS's proposals would account for some anomalies in the cost-to-charge ratio (CCR), they do not improve the accuracy or ensure consistency of the S-10 charity care and bad debt data itself. In our analysis of the Worksheet S-10 data, we were able to easily identify examples of what we believe is incorrect data. For example, we found a limited number of hospitals that had uncompensated care costs on line 30 of the Worksheet S-10 that totaled more than 50 percent of their total expenses for the facility as a whole. One of these hospitals had uncompensated care costs that were over 800 percent of its total expenses. Because the 75-percent pool is a fixed amount, inaccurately reported data by one hospital will affect the DSH payments of all other hospitals. **Simply tying the S-10 to payment and requiring its regular use will not improve its accuracy. Therefore, we strongly urge CMS to audit the S-10 data prior to their use to verify that they are correct and complete.** The agency may wish to consider a side audit to expedite the process, similar to audits for the occupational mix survey data.

In addition, once CMS ensures the accuracy and consistency of the Worksheet S-10 data, we believe that transitioning to its use, either through a phase-in approach and/or a stop-loss policy, is appropriate. We also believe that if a phase-in approach is used, a longer time period than proposed may be warranted, such as CMS has implemented in the past with, for example, the capital PPS. These types of policies would help mitigate large payment fluctuations and promote stability in DSH payments to hospitals.

Uncompensated Care Costs. CMS proposes that, beginning in FY 2018, uncompensated care costs would be defined to include line 30 of the Worksheet S-10, which includes the cost of all charity care and non-Medicare bad debt; we support uncompensated care costs including these costs. However, the agency also proposes that Medicaid shortfalls (i.e., the unreimbursed costs of Medicaid, State Children's Health Insurance Program, and other state and local government indigent care programs) reported on line 19 of Worksheet S-10 would not be included in the definition of uncompensated care. **The AHA continues to recommend that the definition of**

uncompensated care be broad based and include all unreimbursed and uncompensated care costs, including the unreimbursed costs of Medicaid, State Children's Health Insurance Program (SCHIP), and other state and local government indigent care programs) reported on line 19 of Worksheet S-10. This broad definition of uncompensated care costs will be important in accurately measuring a hospital's unreimbursed costs, and it will ensure the most appropriate basis for calculating future uncompensated care payments.

In addition, the ACA directed this pool to account for the uncompensated costs of the "uninsured." Yet, Worksheet S-10 does not comprehensively account for the costs incurred by hospitals in treating the uninsured. Specifically, while line 30 includes charity care and non-Medicare bad debt, as CMS itself indicates in the rule, there is variation in how different States, provider organizations and federal programs define uncompensated care. Our members have indicated that they incur costs of treating uninsured patients that are not categorized as either charity care or non-Medicare bad debt and, therefore, are not appropriately captured on the S-10. For example, some, as a matter of course, provide discounts to uninsured individuals who are unable or unwilling to provide income information to the hospital. **Consistent with the AHA's recommendation that CMS adopt a broad definition of uncompensated care costs, we also recommend that these discounts (regardless of whether they are called "discounts" or some other term) for uninsured individuals be included in the definition of uncompensated care in the Worksheet S-10.** They are clearly costs that hospitals incur in providing treatment to the uninsured – not including them would inappropriately penalize these hospitals and runs contrary to the underlying intent of uncompensated care payments under the ACA.

Timing of Reporting Charity Care and Bad Debt. Historically, CMS required that the amounts claimed on line 20 and lines 26-29 of the Worksheet S-10 relate to services rendered in the cost reporting year. For a variety of reasons, including the fact that the AHA does not believe that hospitals would have identified and resolved all of the charity and bad debt accounts related to services provided in the current cost-reporting year by the time the cost report is due five months after the close of the hospital's fiscal year, we recommended that line 20 capture only charity care and lines 26-29 capture only bad debt that was written off in the particular cost-reporting year. CMS now proposes to revise the Worksheet S-10 cost report instructions concerning the timing of reporting charity care, such that charity care will be reported based on the date of write-off, and not based on the date of service. **The AHA supports this proposal.**

Revisions to the CCR for Worksheet S-10. The ratio of cost to charges calculation on line 1 of Worksheet S-10 flows from Worksheet C, column 3 (costs) and column 8 (charges). Column 3 costs do not include the cost of training residents (direct graduate medical education (GME) costs), but Column 8 charges do inherently include the cost of training residents. Therefore, the numerator and denominator of the CCR are not consistent. The AHA has recommended that GME costs be included in the formula calculating the CCR for Worksheet S-10 because they are a significant part of the overhead for teaching hospitals. In the proposed rule, however, CMS states that it does not believe that it is appropriate to modify the calculation of the CCR on line 1 of Worksheet S-10 to include GME costs. **The AHA continues to recommend that the formula calculating the CCR for Worksheet S-10 be modified to include GME costs. This could be accomplished easily by using costs from Worksheet B, column 24, line 118.**

Trims to Apply to CCRs on Line 1 of Worksheet S-10. CMS proposes one potential way it could trim the data to control for data anomalies. Specifically, the agency proposes a policy whereby all hospitals with a Worksheet S-10 CCR that is above a CCR "ceiling" or that is greater than 3.0 standard deviations above the geometric mean would receive the statewide average CCR.[1] **The AHA is concerned that CMS's methodology is trimming hospitals that have CCRs that appear to be anomalous, but which are actually the result of their use of alternative methods of cost accounting.**

Using the FY 2014 Worksheet S-10 data from the March 31, 2016 release of the Healthcare Cost Report Information System (HCRIS), we estimate that 23 hospitals would have their CCRs trimmed to the statewide average CCR. Of the 23 hospitals that we identified, 9 reported zero or negative uncompensated care costs on line 30 of Worksheet S-10. Nine of the remaining 14 hospitals are all-inclusive providers that, according to the Worksheet S-10 instructions, must enter their CCRs as calculated in accordance with CMS Pub. 15-1, chapter 22, §2208. **In other words, these are providers that are using methods of cost apportionment and CCRs that have been approved by the Medicare audit contractor (MAC) and, indeed, 12 of these 14 providers have CCRs that are close to 1.0 which is not unusual for an all-inclusive provider.**

Trimming these CCRs raises doubts about the soundness of CMS's trimming methodology, since none of the uncompensated care costs calculated using the original line 1 CCRs for these 12 providers appear erroneous. Yet, because their CCRs were trimmed, their uncompensated care costs were also trimmed substantially. **Accordingly, we urge CMS to revise its trim methodology so it does not penalize providers that use alternative methods of cost apportionment.**

Medicaid Reporting. The AHA has made three recommendations related to the reporting of Medicaid DSH data on lines 2-6 of the Worksheet S-10. Specifically, we have indicated that hospitals should be required to report Medicaid DSH on a separate line, rather than having the options of including DSH in total Medicaid revenues (Line 2) without breaking it out separately. In addition, non-DSH supplemental payments (e.g., upper payment limit) should be reported on a separate line from Medicaid revenue and Medicaid DSH and the instructions for Medicaid lines should be revised to indicate that stand-alone S-CHIP should not be included in Medicaid line items. SCHIP is difficult to interpret from a DSH perspective given the various forms of implementation across states. **CMS has taken no action related to these recommendations; therefore, the AHA renews its request for CMS to address these issues related to Medicaid reporting on Worksheet S-10.**

Private Grants, Donations, Endowments and Government Grants, Appropriations and Transfers. The AHA has requested, on numerous occasions, that CMS clarify the purpose of Lines 17 and 18 on the Worksheet S-10, both in the near term and for the future. Line 17 requires the reporting of grants, gifts and investment income that are related to uncompensated care. Line 18 requires reporting of a very broad scope of data related to the general operation of the hospital, whether or

[1] The CCR "ceiling" is the one that was published in the final rule of the fiscal year that is contemporaneous to the particular worksheet S-10 data being used.

not they relate to uncompensated care. Both lines appear to be informational only, since they are not included in any of the totals elsewhere on Worksheet S-10. **The AHA requests, again, that CMS offer clarification related to Lines 17 and 18 and, in the absence of such clarification, recommends that these lines be deleted.**

We look forward to working with CMS to improve the Worksheet S-10 and the associated methods for calculating uncompensated care payments to hospitals.

TWO-MIDNIGHT POLICY

In the proposed rule, CMS includes its "final notice" in response to the federal court order in the consolidated federal challenge to the 0.2 percent reduction in inpatient PPS rates the agency implemented in conjunction with the original "two-midnight" policy.[2] Specifically, CMS proposes two adjustments that would reverse the effects of the 0.2 percent cut – a permanent adjustment of approximately 0.2 percent to remove the cut prospectively for FYs 2017 and onward; as well as a temporary, one-time adjustment of 0.6 percent to address the retroactive impacts of this cut for FYs 2014 – 2016. **The AHA appreciates that CMS has decided to reverse the 0.2 percent payment reduction and supports the agency's proposals to restore the resources that hospitals are lawfully due. We eagerly await finalization of these adjustments with publication of the final rule and a formal resolution by the Court.**

PROPOSED NOTIFICATION PROCEDURES FOR OUTPATIENTS RECEIVING OBSERVATION SERVICES

CMS proposes to implement the provisions of the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act, which requires hospitals and critical access hospitals (CAHs) to provide Medicare beneficiaries receiving observation services for more than 24 hours a written notice – the Medicare Outpatient Observation Notice (MOON) – and an oral explanation that the beneficiary is an outpatient receiving observation services and the implications of that status.

IMPLEMENTATION TIMELINE

The AHA believes that hospitals and practitioners should communicate clearly with Medicare beneficiaries and their families about their status in the hospital. CMS will not issue a final rule with its inpatient policies until around Aug. 1. However, while we understand that the law requires the notice procedures to be effective starting on Aug. 6, we are concerned that it will be challenging for hospitals and CAHs to fully implement these policies within a few days after the final rule is issued, particularly if there are changes made to the agency's proposed policies.

Hospitals and health systems will need adequate time to develop and operationalize policies and procedures for the NOTICE Act requirements, update and test their medical record system to

[2] The consolidated case *Shands Jacksonville Medical Center, Inc., et al. v. Burwell*, No. 14-263 includes a case brought by the AHA, four hospital associations and four hospital organizations.

include the notice requirements and provide extensive education to their staff on the requirements. For hospitals and health systems that intend to integrate the requirements of the NOTICE Act into their information technology (IT) infrastructure and workflow, the process would involve critical tasks including:

- working with their IT vendor to design, build and test the software to meet the requirements, and integrating it within the workflow of the staff responsible for documenting the required MOON data elements;
- developing and implementing new hospital policies and procedures consistent with the regulatory requirements; and
- providing new software and significant education, training and testing of the new requirements, features and functionality prior to implementation.

Therefore, we ask CMS to institute a transition period, so that hospitals and health systems have the opportunity to operationalize this new policy. This transition period also would have the additional benefit of giving CMS time to issue clear and detailed guidance to hospitals and Medicare contractors.

ENFORCEMENT

The NOTICE Act amends the provider agreement provisions of the Social Security Act. Although CMS does not specify in the proposed rule, it is our understanding that violations of requirements in this section can lead to the termination of a hospital's Medicare provider agreement. However, we believe that defaulting to terminating a hospital's provider agreement in response to a finding of noncompliance with the Act's provisions would be a disproportionate penalty to impose. Instead, **the AHA encourages CMS to develop a graduated process that begins with notifying and educating the provider about the regulatory requirements.** This should allow the hospital to develop and carry out a corrective action plan.

WRITTEN NOTIFICATION VIA THE MOON

CMS proposes that hospitals furnish a new CMS-developed standardized notice, the MOON, to a Medicare beneficiary or enrollee who has been receiving observation services for more than 24 hours. The MOON would include all the required elements specified in the NOTICE Act. **The AHA supports the use of a standardized CMS notice for hospitals' use and appreciates the agency's assistance in designing this form.** However, we recommend that CMS clarify that the hospital may list either the physician who ordered the observation services or the patient's attending physician on the MOON. Observation services are often initiated in a hospital's emergency department by an emergency physician, prior to an attending physician being assigned to the patient. Allowing the hospital to list the ordering physician or the attending would help ensure the timely completion of the MOON.

In addition, we are concerned that supplying specific dates and times in three separate fields on the MOON is unnecessary. The first incidence is the date and time that the MOON was provided to the patient, which should be the same as the date and time of the patient's signature. The second incidence is the date and time at which observation services are initiated. As CMS notes in the proposed rule, this information should already be contained in the patient's medical record

and so it is unnecessarily redundant to provide it on the MOON. **We urge CMS to delete these two fields for date and time from the MOON.**

TIMING OF THE REQUIRED NOTIFICATION

CMS would require that, for beneficiaries receiving outpatient observation services for more than 24 hours, the hospital must provide the written notification and oral explanation no later than 36 hours after observation began (or upon discharge). While it is not clear from the proposed rule, one interpretation of this requirement would be that the hospital could only present and explain the MOON within a 12-hour period between 24 and 36 (or less) hours after observation services have been initiated. Delivering the notice within this window of time could pose significant logistical and operational challenges for hospitals – observation beds can be located in many different units across the hospital, observation care patients are often taken off the unit for purposes of testing and treatment and the appropriate hospital personnel required to present the notice may not be available within this timeframe.

The AHA recommends that CMS clarify that hospitals are permitted to provide the beneficiary with the MOON and its explanation at any point after outpatient observation services are initiated, as long as it takes place within 36 hours or, if earlier, prior to discharge, transfer or inpatient admission. This would be helpful for both the beneficiary and the hospital. Specifically, it would permit beneficiaries to learn about their status as outpatients and the implications of that status earlier in their stay. For the hospital, it would allow the notice to be provided in a timely manner that is in accordance with the workflow of the facility.

ORAL EXPLANATION

In the proposed rule, CMS provides virtually no information about what is required with regard to the oral explanation of the written notice. Instead, the agency states it will provide guidance for the oral notification in forthcoming Medicare manual provisions. The AHA is concerned that the agency plans to issue this guidance outside of a notice-and-comment rulemaking process and, therefore, without an opportunity for public comment. **We encourage CMS to develop the manual section in a transparent manner that allows for public review and comment prior to it being finalized. Further, we note that CMS does not propose to limit which hospital staff may provide the written MOON and its oral explanation to the beneficiary. We agree that hospitals should be permitted to determine which staff are best equipped to provide the notice to beneficiaries in the most appropriate and timely manner.**

BENEFICIARY SIGNATURE REQUIREMENT

The Act provides that, if a beneficiary refuses to provide a signature on the MOON, the notification must be signed and dated by the hospital staff member who presented the written notification. **The AHA recommends that CMS also apply this process in other similar situations – such as when a beneficiary is unable, due to his or her medical or mental condition, to comprehend and sign the notification and there is no family or patient representative available in a timely manner.** In these circumstances, hospitals' ability to obtain a signature is out of their control. They should be able to document that an attempt was made to provide the notice, including efforts to reach family or the patient's representative, and allow the staff member to sign the MOON.

OVERLAP WITH SIMILAR STATE LAWS AND/OR REGULATIONS
A number of states, such as New Jersey, Illinois, Florida, Minnesota and Pennsylvania, have laws and/or regulations that mandate notifications similar to those in the NOTICE Act for outpatients receiving observation services. **We strongly urge CMS to clarify whether state or federal requirements would take precedence or if both requirements must be met simultaneously. In addition, we recommend that CMS address whether a hospital that complies with substantially equivalent requirements imposed by its state could be considered to also be in compliance with the requirements of the NOTICE Act.** We believe that it would be counter-productive to require hospitals in these states to give patients two somewhat different notifications, potentially provided at different times, informing them about generally the same issue.

GRADUATE MEDICAL EDUCATION (GME)

CMS proposes to revise the GME regulations related to rural training track programs (RTT), a change the agency indicates it inadvertently failed to make when it previously amended regulations to provide for a five-year new program growth period and cap-building window. Specifically, the agency proposes to increase, from three to five years, the period of time that urban hospitals are granted to establish RTT direct GME and indirect medical education caps. Under the proposed revisions, an urban hospital's RTT cap would take effect beginning with the hospital's cost-reporting period that coincides with or follows the start of the sixth program year of the RTT's existence. **The AHA supports this proposal.**

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 data show that we are making care safer. As noted by a recent report from the Agency for Healthcare Research and Quality, a composite measure of 28 different HACs fell nationwide by 17 percent between 2010 and 2014, from 145 to 121 per 1,000 discharges. The steadfast efforts of hospitals to make care safer also have led to 87,000 fewer deaths, and saved nearly $20 billion in health care costs.[3] 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.

[3] Source: Agency for Healthcare Research and Quality. Saving Lives and Saving Money: Hospital-Acquired Conditions Update. Available at: http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2014.html?utm_source=HHSPressRelease65&utm_medium=HHSPressRelease&utm_term=HAC&utm_content=65&utm_campaign=CUSP4CAUTI2015

For this reason, we have long opposed the arbitrary statutory design of the HAC Reduction Program, which imposes penalties on 25 percent of hospitals each year, regardless of whether hospitals have improved performance, and regardless of whether performance across the field is consistently good. **In addition, we are concerned that CMS's implementation of the program has unfairly placed teaching hospitals, large hospitals, small hospitals and hospitals caring for larger number of poor patients at greater risk of a penalty as a result of faulty measurement, not bad performance.**

The proposed rule includes several policies intended to address some of the shortcomings of the HAC program, including changes to the scoring methodology and modifications to the patient safety indicator (PSI 90) measure. **The AHA commends CMS's willingness to consider program changes within its statutory authority. However, we do not believe the proposed policy changes are sufficient to remedy the fundamental flaws with the program.** Below we comment on each of CMS's proposed policy changes, and suggest additional steps the agency could take to improve the program. We also stand ready to work with CMS and Congress to improve the HAC program so that it fairly and effectively promotes improvement on patient safety.

PROPOSED SCORING METHODOLOGY CHANGES FOR FY 2018

The AHA does not support CMS's proposal to use Winsorized z-scores to calculate points on HAC measures starting in FY 2018. While we applaud CMS's willingness to explore changes to its current scoring methodology, we do not believe the z-score approach meaningfully improves the fairness of the HAC program.

A z-score is a commonly used statistical formula that compares a hospital's score on a given measure to the national average (i.e., mean) score. Specifically, the z-score calculates the number of standard deviations between a hospital's performance on a measure and the national mean. CMS proposes to calculate z-scores on each measure for each hospital. The remainder of the HAC scoring methodology would remain unchanged – that is, CMS would combine the z-scores on each measure into domain scores, then calculate a weighted sum of the domain scores to create a Total HAC Score.

CMS suggests a number of ways in which the z-score approach may be superior to the current scoring approach in which hospitals receive points on HAC measures based on their decile of performance. The agency estimates that using the z-score approach would result in fewer very large (i.e., 500+ beds) and very small (i.e., less than 25 beds) hospitals receiving penalties. Furthermore, CMS believes the z-score approach is better able to identify meaningful differences in performance across hospitals. For example, two hospitals whose difference in performance is meaningfully different may fall into the same decile. It also is possible that two hospitals whose performance is not statistically different may fall into different deciles of performance. In addition, the agency believes the z-score approach will reduce the number of ties at the HAC penalty threshold, enabling it to penalize a full 25 percent of hospitals.

Unfortunately, it does not appear that the use of z-scores will meaningfully improve the fairness of the program. An AHA-commissioned analysis shows that teaching hospitals, large hospitals, and hospitals caring for large numbers of poor patients still would be

disproportionately more likely to receive penalties using the z-score approach. The AHA worked with KNG Health to estimate the impact of CMS's proposed scoring changes, and compare the proposed scoring approach to the current decile-based approach.

As shown in Table 1 below, the percentages of large hospitals, high-DSH payment hospitals and teaching hospitals penalized under the z-score method is minimally different from the distribution of penalties under the decile-based scoring method. Furthermore, it does not appear that the z-score approach would make it any more likely that CMS would penalize 25 percent of hospitals. In fact, our analysis shows that under either method, 25 percent of hospitals would be penalized in FY 2017. **Given that hospitals have gained an understanding of the decile-based scoring approach, and that there are minimal differences in the distribution of penalties, we see little merit to changing the scoring approach at this time.**

Table 1: AHA/KNG Health Comparison of HAC Penalties using Decile-Based Scoring and Winsorized Z-Scores

	Number of IPPS Hospitals	FY 2017 Parameters (Measures and Weights)						
		IPPS Hospitals Receiving Score	Decile Method			Z Score Method		
			Mean Total HAC Score	Median Total HAC Score	Percent Receiving Penalty	Mean Total HAC Score	Median Total HAC Score	Percent Receiving Penalty
Overall	3,408	3,198	5.1	5.3	25%	-0.1	-0.1	25%
Bedsize Category								
Quartile 1 (fewer than 62 beds)	852	696	4.1	3.9	16%	-0.5	-0.5	15%
Quartile 2 (62 to 133 beds)	852	820	4.7	4.6	18%	-0.2	-0.2	21%
Quartile 3 (134 to 253 beds)	853	833	5.4	5.4	25%	0.0	0.0	27%
Quartile 4 (more than 254 beds)	851	849	6.1	6.1	39%	0.2	0.1	35%
DSH Percent Category								
Quartile 1 (less than 18.2%)	852	752	4.9	5.1	22%	-0.2	-0.1	22%
Quartile 2 (18.2% to 26.8%)	852	804	5.2	5.4	25%	-0.1	-0.1	25%
Quartile 3 (26.8% to 36.1%)	852	827	5.0	5.1	22%	-0.1	-0.1	21%
Quartile 4 (greater than 36.1%)	852	815	5.3	5.5	31%	0.0	0.0	32%
Teaching Status								
Major Teaching	309	300	6.4	6.4	49%	0.3	0.3	51%
Minor Teaching	762	756	5.6	5.7	31%	0.1	0.1	28%
Non Teaching	2,337	2,142	4.7	4.9	20%	-0.2	-0.2	20%

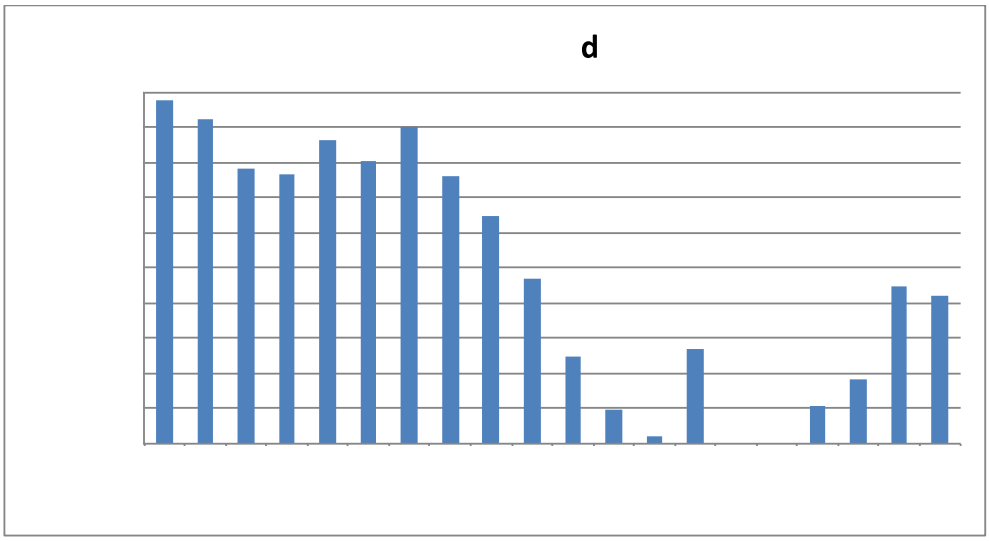
Note: The analysis estimates performance using available measure data from the May 2016 update of *Hospital Compare* and assumes the domain scoring weights (15 percent for Domain 1, 85 percent for domain 2) that CMS adopted for the HAC Reduction Program in FY 2017 and beyond.

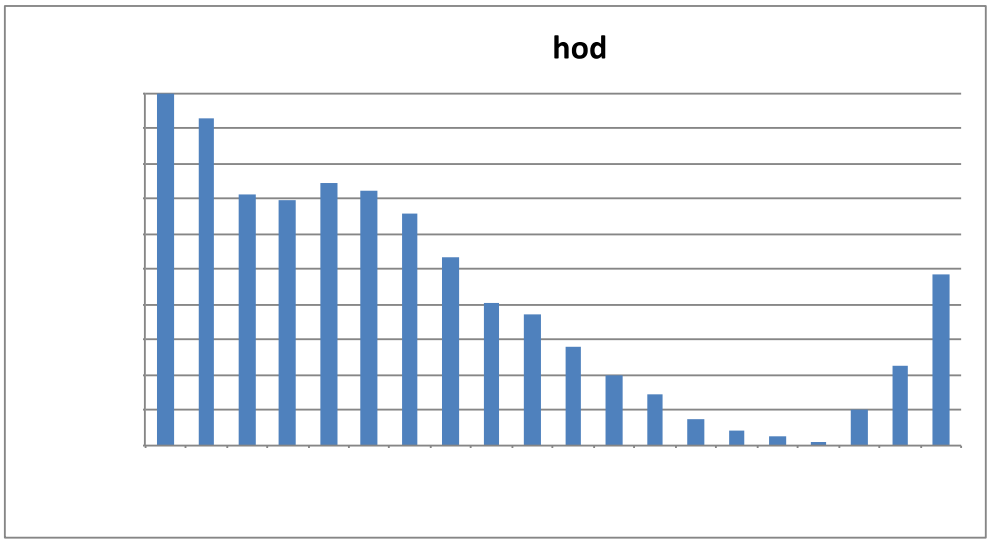
Furthermore, we are concerned that neither the proposed z-score approach nor the current decile-based scoring approach is adequate to the task of identifying meaningful differences in performance across hospitals. Given that the HAC program is a payment penalty program, the fairness of the program hinges on whether the scoring methodology identifies truly meaningful differences in performance across providers. That is, hospitals that receive penalties should have performance scores that are clinically and statistically worse than those that did not receive penalties. Our analysis suggests that both scoring approaches as applied to the HAC Reduction Program appear to fail this basic test, making the assessment of penalties more like a game of chance rather than a meaningful and fair determination of performance.

To quantify the extent to which z-scores and decile-based scoring identify meaningful performance differences, KNG and the AHA conducted a simulation analysis to determine whether hospitals in particular performance categories had total HAC scores that are statistically different from the payment penalty threshold score. Hospitals were placed into ventiles (with higher ventiles indicating worse performance) of total HAC scores, and we then calculated the percentage of hospitals whose performance was statistically different from the penalty threshold score.

As shown in Figure 1 below, as the ventile of performance increases, the percentage of hospitals whose performance scores are statistically different from the performance threshold score declines. In some cases (i.e., the 15th and 16th ventiles under the decile scoring method, and the 17th ventile under the z-score method), virtually no hospitals had Total HAC Scores that were statistically different from the payment penalty threshold score.

Figure 1: Percentage of Hospitals Whose Total HAC Scores are Statistically Different from Penalty Threshold Score under Decile-Based Scoring and Z-Score Approaches





Note: Total HAC scores simulated using data from the May 2016 update of *Hospital Compare*. Hospitals are considered statistically different from threshold if threshold is not inside a 95% confidence interval for Total HAC Score. Confidence intervals derived from simulation, drawing observed complications from a binomial distribution and expected complications from a normal distribution. Simulations only performed on Domain 2 (CDC measures, 85% weight) due to data limitations. Consequently, confidence intervals are conservative.

The findings outlined above are troubling given that CMS must impose penalties on hospitals whose performance is in the worst performing quartile, by law, but the majority of hospitals in that quartile do not have scores that are statistically different than the threshold. Furthermore, the HAC Reduction Program's statutory language constrains CMS's options for scoring approaches. For example, the agency cannot apply penalties on a sliding scale because it is required to impose a 1 percent penalty on all penalized hospitals. The agency also might consider adopting a scoring methodology that recognizes both improvement and achievement, but the legislative language does not permit that kind of flexibility. The AHA welcomes the opportunity to work with CMS and Congress to improve the design for the program.

In the meantime, we recommend that CMS consider other changes to the HAC program that may improve its fairness. **For example, we have long urged CMS to 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. 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.

In addition, as the AHA has recommended previously, 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.

UPDATED VERSION OF PSI 90 FOR FY 2018

The AHA does not object to CMS's proposal to incorporate an updated version of the PSI 90 measure in the HAC Reduction Program starting in FY 2018. However, as noted above, we strongly urge the agency to phase the measure out of the HAC Reduction Program and other programs altogether. CMS proposes to adopt the version of PSI 90 that was recently endorsed by the National Quality Forum (NQF). We appreciate that the revised measure re-weights individual component PSIs so they better reflect the importance and preventability of particular safety events. We certainly agree that there is variability in the preventability and importance of safety events, and appreciate the attempt to improve the measure. Nevertheless, these changes are not sufficient to improve the underlying lack of reliability and accuracy with individual component PSI measures.

Indeed, the AHA has long been concerned by the significant limitations of PSI 90 as a quality measure. PSIs use hospital claims data to identify patients that have potentially experienced a safety event. However, claims data cannot and do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the rates derived from the measures are highly inexact. PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation with the benefit of the full medical record. But, the measures are poorly suited to drawing meaningful conclusions about hospital performance on safety issues. In other words, PSI 90 may help hospitals determine what "haystack" to look in for potential safety issues. But the ability of the measure to consistently and accurately identify the "needle" (i.e., the safety event) is far too suspect to deem it worthy of NQF endorsement, let alone use in public reporting and pay-for-performance applications.

Examples of the inconsistency of the results of PSI component measures with clinical reality abound.[4] One recent study that validated the results generated by PSI 3 (pressure ulcer rates) using direct patient surveillance found that PSI 3 frequently misclassified hospital performance.[5] Our members also have reported significant issues with PSI 15 (accidental puncture/laceration). For example, when surgeons operate with the intention of removing gall bladders and other organs, their surgical note might say something like "sliced the gall bladder

[4] See for example:
Ramanathan R et al. Validity of Agency for Healthcare Research and Quality Patient Safety Indicators at an academic medical center. The American Surgeon. 2013 Jun; 79(6):578-82.

Cevasco M et al. Validity of the AHRQ Patient Safety Indicator "central venous catheter-related bloodstream infections. Journal of the American College of Surgeons. 2011 Jun;212(6):984-90;

Kaafarani H et al. Validity of Selected Patient Safety Indicators: Opportunities and Concerns. Journal of the American College of Surgeons. 2011 Jun; 212(6):924-34.

Utter GH, Zrelak PA, Baron R, et al. Positive predictive value of the AHRQ accidental puncture or laceration patient safety indicator. Ann Surg. 2009;250(6):1041-1045

Rajaram R et al. Concerns About Using the Patient Safety Indicator-90 Composite in Pay-for-Performance Programs. Journal of the American Medical Association. 2015; 313(9):897-898.

[5] Meddings JA et al. Hospital Report Cards for Hospital-Acquired Pressure Ulcers: How Good are the Grades. Annals of Internal Medicine. 519(8):505-13. October 2013.

and removed it." But if the surgeon does not specifically note in the surgical notes that the removal was intentional, it would be coded as an accidental puncture and this would erroneously be included in the calculation of the PSI 90. It is not surprising, then, that a CMS-commissioned study showed that many of the individual components of PSI-90 have low levels of reliability when applied to Medicare claims data.[6]

PSI 90 PERFORMANCE PERIOD FOR FYS 2018 AND 2019

The AHA is concerned by CMS's proposal to shorten the performance periods of the PSI 90 measure to 15 months in FY 2018 and 21 months in FY 2019. While the performance period for PSI 90 generally is 24 months, the agency proposes shorter performance periods to account for the transition from ICD-9 to ICD-10 coding on Oct. 1, 2015. CMS is developing an ICD-10 version of PSI 90, but it will not be finalized until late 2017. Moreover, CMS believes it is not feasible to calculate PSI 90 using a combination of data collected under ICD-9 and ICD-10.

While we agree it is likely inappropriate to mix performance data collected under ICD-9 with data collected under ICD-10, we note that the PSI measure's reliability is compromised when the reporting periods are shortened. We are especially concerned by the 15-month performance period proposed for FY 2018. At a minimum, we would encourage the agency to reduce the domain weight of the PSI 90 measure for FYs 2018 and 2019. CMS also should consider whether it would be feasible to suspend the use of the PSI measure for FY 2018. In addition, the agency could determine whether there are any other available measures that could be incorporated into the program for FY 2018.

OTHER HAC REDUCTION PROGRAM PROPOSALS

The AHA supports CMS's proposed change to the definition of "complete data" for the PSI measure. Under current policy, a hospital has completed enough data to receive a Domain 1 score if it has three or more eligible discharges for at least one component PSI measure. Beginning in FY 2017, CMS proposes to add one additional criterion – that is, a hospital must have 12 or more months of PSI data. We agree with the agency that using less than 12 months of measure data may not provide a statistically valid reflection of hospital performance.

The AHA also supports CMS's proposed Domain 2 healthcare-associated infection (HAI) data submission standards. Specifically, CMS clarifies that all newly opened hospitals that are eligible for the HAC Reduction Program-eligible must submit HAI data, regardless of whether or not they choose to participate in the Hospital Inpatient Quality Reporting (IQR) Program.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

CMS proposes only minor updates to the HRRP, which penalizes hospitals for having "excess" readmission rates when compared to expected rates.

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

SOCIODEMOGRAPHIC ADJUSTMENT

The AHA is disappointed that the agency has once again failed to propose any sociodemographic adjustment for the HRRP. Research continues to show that factors that have nothing to do with the quality of care patients received while hospitalized increase the likelihood that patients will be readmitted. These factors include: living alone; the lack of primary care, home health and rehabilitation services in the community; a dearth of transportation options that enable patients to go to follow up appointments; and challenges adhering to dietary restrictions or health promoting activities; among others. **We remain concerned that hospitals caring for patients from poorer communities, where these kinds of sociodemographic factors are more common, will be disproportionately penalized.**

TIMELINE FOR PUBLIC REPORTING ON *HOSPITAL COMPARE*

CMS clarifies that excess readmission ratios will be posted on an annual basis to the *Hospital Compare* website as soon as is feasible following the review period. CMS notes that this could, but may not always, occur as early as October. We urge CMS to continue to ensure there is an adequate review period of at least 30 days, and to ensure there is adequate time to make necessary corrections between the review period and the public display of data.

HOSPITAL VBP PROGRAM

As required by the ACA, CMS proposes to fund the FY 2017 VBP program by reducing base operating DRG payment amounts to participating hospitals by 2.0 percent. The VBP program is budget neutral; all funds withheld must be paid out to hospitals.

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 continually 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 continue to be concerned about the impact of the transition from ICD-9 to ICD-10 on the measures used in the VBP and other CMS programs. We urge the agency to work with all stakeholders to address this issue.

FY 2021 PNEUMONIA MORTALITY MEASURE UPDATE

The AHA urges CMS not to finalize its proposed update to the pneumonia mortality measure unless and until the measure change has been reviewed and endorsed by the NQF. In the FY 2016 inpatient PPS final rule, CMS expanded the cohort of the pneumonia mortality measure in the hospital IQR program. In addition to including patients with a primary discharge

diagnosis of pneumonia, the measure also includes: (1) patients with a principal discharge diagnosis of aspiration pneumonia; and (2) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission. CMS believes these changes allow the measure to capture a broader spectrum of pneumonia patients, as well as to account for potential differences in coding practices for pneumonia across hospitals.

However, we have urged CMS to seek NQF endorsement of these changes because the endorsement process would allow the field to better understand the potential *causes* of coding differences. Those causes are critically important to understand before including new diagnoses in the measure population. Moreover, clinical leaders from the AHA's membership have expressed concern that the inclusion of the two new groups may inadvertently conflate pneumonia as a discrete medical event with other underlying disease conditions. For example, aspiration pneumonia has symptoms similar to community-acquired pneumonia. However, the causal mechanism – foreign particles entering the airway, often due to swallowing disorders – is different.

EPISODE-BASED PAYMENT MEASURES FOR FY 2021

The AHA does not support CMS's proposal to add the acute myocardial infarction (AMI) and heart failure (HF) condition-specific episode-based payment measures to the FY 2021 VBP. While we agree that well-designed measures of cost and resource use can assist with assessing the value of care, we are concerned that the overlap between these condition-specific measures and Medicare spending per beneficiary (MSPB) measure may lead to unnecessary confusion among hospitals.

The design of the MSPB and two condition-specific measures is similar in that they capture risk-adjusted Medicare Part A and Part B payments during an episode of care than spans 30 days after initial hospital admission. However, while the MSPB measure reflects all patients that can be attributed to a hospital, the two condition-specific measures focus on patients with a primary discharge diagnosis of AMI or HF. As a result, it is possible for the Part A and Part B payments captured in MSPB to overlap with those captured in the condition-specific measures. In the proposed rule, CMS suggests the inclusion of the condition-specific measures will enhance hospitals' focus on resource use, and increase the opportunity to hospitals to score well in the resource use category of VBP.

The AHA is concerned that the overlap between MSPB and the condition-specific measures will instead send mixed signals to hospitals about their resource use performance, rather than facilitate a meaningful assessment of resource use. Indeed, it will be possible for hospitals to score well on MSPB, but poorly on the condition-specific measures, even though the measures will capture many of the same services. The multi-stakeholder Measure Applications Partnership (MAP) shared this same concern, and recommended against the inclusion of both the payment measures in the VBP. Furthermore, as the Medicare Payment Advisory Commission (MedPAC) has noted, not all hospitals will have sufficient volume to be scored on each condition-specific measure, and the statistical reliability of condition-specific measures will likely be far weaker than the MSPB measure. As a result, the condition-specific measures would provide a less useful picture of performance.

Lastly, we strongly urge CMS to continue examining the impact of socioeconomic factors on measure performance, and incorporate adjustment as needed. We acknowledge that these measures recently were reviewed as part of the NQF's "trial period" on socioeconomic adjustment, and that NQF's evaluation suggested that socioeconomic adjustment may not be necessary. However, the AHA joined with three other national hospital associations to raise concerns about the conceptual and empirical approach used to test the measures for the effects of socioeconomic status, as well as the overall evaluation process. We have asked for further review and analysis of the measures. While we look forward to continuing to work with NQF and CMS to improve these measures, we do not believe they should be included in the VBP or other programs until the issues around socioeconomic adjustment are fully resolved.

PROPOSED NEW MEASURE FOR FY 2022

The AHA urges CMS to improve the reliability of the coronary artery bypass graft (CABG) mortality measure it proposes for the FY 2022 VBP program before finalizing it. 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 points to significant reliability concerns with the mortality measures, which raise questions about whether they are an accurate reflection of hospital performance. Indeed, a 2012 CMS-commissioned analysis of claims-based measures demonstrated the AMI, HF and pneumonia mortality measures in the VBP program achieved only the "lower limit" of moderate reliability.[7] When the CABG mortality measure was reviewed for NQF endorsement in 2014, its testing results also showed only "fair" reliability.[8] **The public, CMS and hospitals deserve measures that have more than "fair" 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.

EXPANSION OF CATHER-ASSOCIATED URINARY TRACT INFECTION (CAUTI) AND CENTRAL-LINE ASSOCIATED BLOODSTREAM INFECTION (CLABSI) DATA FOR FY 2019

The AHA supports CMS's proposal to incorporate CAUTI and CLABSI measure data collected from non-ICU locations into hospitals' VBP performance beginning with the FY 2019 program year. The AHA supported CMS's decision to broaden the reporting of CLABSI and CAUTI in the IQR to non-ICU locations beginning in January 2015. We believe it is important for the agency to include these expanded data in its pay-for-performance programs, including the VBP.

[7] See http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf
[8] See http://www.qualityforum.org/QPS/2558

FY 2018 PSI 90 REPORTING PERIOD

The AHA opposes CMS's proposal to shorten the performance period for PSI 90 in the FY 2018 VBP program to 15 months of data. We refer the agency to our discussion of a similar proposal for the FY 2018 HAC Reduction Program. Similar to the HAC program, we are concerned that shortening the performance period will degrade measure reliability. Rather than shortening the performance period, the AHA encourages the agency to consider suspending the use of PSI 90 in the VBP program for FY 2018.

IMMEDIATE JEOPARDY (IJ) CHANGES

The AHA supports CMS's proposal to increase the number of IJ findings needed to exclude a hospital from the VBP program from two to three. Currently, hospitals are not eligible for the VBP program if they have been cited for IJ on at least two surveys during the performance period. CMS points out that the program currently uses measures with 12-month, 24-month and 36-month performance periods. Thus, IJ citations could result in excluding a hospital from the program for several program years. In the rule, CMS proposes to increase the number of IJs needed to exclude a hospital from the program from two to three. Thus, a hospital would need to be cited for IJ on at least three surveys during the performance period in order to be excluded.

ICD-9 TO ICD-10 TRANSITION

The AHA again urges CMS to continue working with hospitals, measure developers and all other stakeholders to address the potential unintended consequences of combining measure data collected under ICD-9 and ICD-10.

ICD codes are integral to collecting and calculating quality measures in CMS's programs. For chart-abstracted measures, ICD codes allow hospitals to identify the patient population (i.e., the denominator) that is included or excluded from data collection. ICD codes are used to generate the initial patient population, to determine performance, and for risk adjustment. There are significant differences between ICD-9 and ICD-10 codes, and as a result, the agency is now re-specifying measures previously collected in ICD-9 so the specifications work in an ICD-10 environment. CMS has updated the specifications for its chart-abstracted measures, and we are aware that the agency has begun to undertake such activity for claims-based measures, such as PSI-90. **Nevertheless, 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.

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. For FY 2019 IQR, CMS proposes to remove two registry participation measures, 13 electronic clinical quality measures (eCQMs), and two chart-abstracted measures, while adding four new Medicare claims-based measures. CMS also proposes refinements to two IQR measures for the FY 2018 IQR program. Lastly, CMS proposes a significant expansion of the requirement that hospitals report certain eCQMs.

STREAMLINING AND FOCUSING THE IQR PROGRAM

The AHA appreciates that CMS's proposals would result in a smaller number of measures in the IQR program, as we have long urged CMS to streamline the measures in the program. However, we remain concerned that the IQR is not achieving its foundational goals – that it, to provide the public and hospitals with *accurate* and *comparable* information for improving quality on *the most important* areas. The measures currently in the program, as well as the four proposed measures, may reflect measures that are available, but they are not those that would advance progress on a defined national quality improvement priority. For example, CMS proposes three episode-based payment measures for aortic aneurysm, cholecystectomy and common duct exploration, and spinal fusion. Certainly, there is broad agreement among many stakeholders that improving the efficiency of care is important. But there is virtually no explanation provided for why the three chosen conditions are more important to measure in a national program than others. Moreover, the measures lack NQF endorsement, providing the public with limited insight on whether the measures are reliable and accurate enough for public reporting.

The AHA also is concerned that the proposal to expand eCQM reporting requirements seems more focused on advancing a particular data collection mechanism than on improving the actual quality of care. We continue to strongly support the long-term goal of using electronic health records (EHRs) to collect timelier, more clinically meaningful quality data in a less burdensome way. However, we question whether the IQR is the most appropriate mechanism to achieve this goal. At its core, the IQR is a *public reporting* program intended to provide data that advance progress on high priority quality topics. Yet, given the ongoing questions about eCQM accuracy and feasibility, CMS does not plan to publicly report eCQM measure results at this time.

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. We continue to urge CMS to consider using the National Academy of Medicine's (NAM) *Vital Signs* report as a uniting framework that will help make all stakeholders be more accountable and engaged in

measurement and improvement. The 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 NAM's core measure areas dovetail well with the list of 11 hospital quality measurement priority areas that the AHA identified in 2014 using input from our membership. We believe these 11 areas best represent the key contributions hospitals can make toward improving the NAM's 15 core areas. A mapping of the NAM core measure areas and AHA priority list is provided in the table below.

Mapping of *Vital Signs* Core Measure Areas and AHA Priority Measures

NAM *Vital Signs* and AHA Priority Lists
Life expectancy Risk Adjusted Mortality
Wellbeing Diabetes Control
Overweight & Obesity Obesity
Addictive Behavior
Unintended Pregnancy
Healthy Communities
Preventive Services
Care Access Readmission Rates Effective Patient Transitions
Patient Safety Harm Rates Infection Rates Medication Errors
Evidence-based Care Adherence to Guidelines for Commonly Overused Procedures
Care Matched to Patient Goals End-of-Life Preferences
Personal Spending
Population Spending Cost Per Case or Episode
Individual Engagement Community Engagement

Blue = NAM Core Measure Area
Red **=** *AHA Priority Measure*

The AHA is eager to work with the agency to help refocus CMS hospital measurement programs on these areas. We 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.

PROPOSED MEASURE REMOVAL FOR FY 2019

The AHA supports CMS's proposal to remove two chart-abstracted measures from the IQR program – STK-4 (Thrombolytic therapy) and VTE-5 (VTE discharge instructions) –

because performance on both measures has "topped out." We also support CMS's proposal to remove two "structural" measures that reflect whether hospitals participate in systematic clinical data base registries for nursing sensitive care and general surgery. We agree with the agency that the measures do not reflect actual performance on process or outcomes, and add little value to the IQR program at this time.

The AHA also supports CMS's proposal to remove 13 eCQMs from the IQR, but has serious concerns about CMS's other eCQM reporting programs. We describe our concerns about the eCQM reporting option elsewhere in this section.

PROPOSED NEW MEASURES FOR FY 2019

CMS proposes four new measures for the FY 2019 IQR program. **The AHA is very disappointed that none of the proposed measures are endorsed by the NQF. Indeed, the MAP did not support three of them, and conditionally supported one of them, urging that it receive NQF endorsement before being placed into the IQR.** Our comments on the specific measures are provided below.

Clinical Episode-based Payment Measures. **The AHA does not support CMS's proposal to add three measures reflecting Medicare "resource use" during episodes of care for aortic aneurysm, cholecystectomy and common duct exploration, and spinal fusion. However, as we suggested when CMS proposed similar measures last year, 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 measure data may be helpful to hospitals as they engage in new models of care.

The measures capture risk-adjusted Medicare fee-for-service (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. Indeed, our members have identified cost per case or episode as a priority measurement area. 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. The measures also lack adjustment for sociodemographic factors, and we believe CMS must assess the measures for the impact of socioeconomic status on performance before adopting them for the program. We also are concerned the measures would be used in the IQR program without corresponding measures of quality. The proposed measures simply report how much was paid by CMS to providers for the care that was rendered to the patients in these categories. Because CMS sets the payment rates for each provider included in this measure – i.e., hospitals, physicians, post-acute care settings – the vast majority of performance variation in these measures reflects differences in services used by the patients. However, the measures do not provide insight on whether the services used were necessary and

appropriate or represent overuse of services. Without concurrent quality measures that help us understand if the outcomes are better in places where more or fewer services are used, the display of these measures tells the public nothing about the value of the care. The AHA believes 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.

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 may be 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 it provides hospitals with confidential reports, and solicits feedback on the usefulness of the information.

Excess Acute Care Days after Pneumonia Hospitalization. **The AHA urges CMS not to adopt its Excess Acute Care Days measures for pneumonia.** The measure is intended to assess excess "all-cause acute care utilization" in the 30-days after discharge for pneumonia. 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."[9] This finding was further confirmed in an April 2016 study published in the *New England Journal of Medicine.*[10]

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.

MEASURE REFINEMENTS FOR FY 2018 IQR

CMS proposes refinements to two IQR measures for FY 2018, PSI 90 and a pneumonia episode-based payment measure. **The AHA does not object to CMS's proposal to use an updated version of PSI 90 starting in FY 2018, but continues to have significant concerns about the measure's accuracy.** We refer the agency to the HAC Reduction Program section of our letter for further information.

CMS also proposes to expand the cohort of the pneumonia episode-based payment measure in a manner similar to the pneumonia mortality measure discussed in the VBP section of this comment letter. **As with the pneumonia mortality measure, the AHA urges CMS not to finalize the expanded cohort for the pneumonia payment measure unless and until it has obtained NQF endorsement of the measure changes.**

FUTURE MEASUREMENT TOPICS

CMS solicits comment on several measures that it may propose in future years, including an antibiotic use measure. **The AHA strongly supports antimicrobial stewardship efforts, which are aimed at minimizing the overuse of antibiotics to preserve their effectiveness and reduce the emergence of drug-resistant bacteria. We are eager to continue working with CMS, the Centers for Disease Control and Prevention and other stakeholders to advance antibiotic stewardship efforts. However, we do not believe the antibiotic measure is appropriate for the IQR program at this time.**

As we understand it, the measure CMS is considering is intended for surveillance and internal improvement efforts. It also may help to create a foundation for future measures assessing the *appropriate use* of antibiotics by capturing information on overall antibiotic use. We agree that a national standard for capturing overall antibiotic use will be helpful to future efforts, but do not believe the measure is appropriate for public reporting or pay-for-performance at this time for two reasons. First, the testing sample used to develop the measure is small, providing limited insight into any potential unintended consequences of reporting the measure on a national scale. Second, the use of the measure in public reporting may result in misleading comparisons of hospital performance. We believe a number of factors can contribute to the differences in

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

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

antibiotic use rates. For example, we would expect that tertiary and quaternary care referral hospitals would have higher rates of antibiotic use than smaller hospitals given the complexity of their patient population.

eCQMs in the IQR Program

For FY 2019, CMS proposes a significant expansion of the requirement that hospitals report certain electronic clinical quality measures (eCQMs). Currently, hospitals must report on four of the 28 eCQMs available. The agency is proposing to reduce the number of eCQMs available to 15, but to require hospitals to report a full year of data on all 15 eCQMs in the IQR program. **While the AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting, we are concerned that there remain far too many questions about eCQM feasibility and accuracy for CMS to mandate an expanded reporting requirement in the IQR.**

eCQMs Available in Hospital IQR. For CY 2017, CMS proposes to remove 13 of the 28 eCQMs available in the measure set for reporting in the Hospital IQR Program. CMS states that eight eCQMs were removed because the chart-abstracted version of the measures were "topped-out" in terms of hospital performance and were removed from the Hospital IQR Program measure set in the FY 2015 or FY 2016 IPPS final rules. CMS also states that five eCQMs were removed because the data capture requirements cannot be represented adequately in the eCQM form due to their conceptual complexity. **The AHA supports the removal of measures because the performance has "topped out" or the measure complexity cannot be captured in electronic form. We support the foundational goals of the Hospital IQR program – to provide the public and hospitals with accurate and comparable information for transparency and for improving quality on important areas – and do not believe focusing on electronic submission of topped out measures achieves these goals.**

eCQM Reporting Requirements. CMS proposes to require hospitals to electronically submit data for 15 eCQMs for CY 2017. However, this would be a near four-fold increase from the CY 2016 requirement to electronically submit data for any four of the 28 eCQMs available in CY 2016. CMS states that hospitals have had several years to submit eCQMs through the Hospital IQR voluntary electronic reporting option created in the FY 2014 IPPS final rule and the EHR Incentive Program.

In 2013, the AHA reported on the early experience of hospitals that attempted to generate eCQM data using their certified EHRs. The hospitals in the study identified several challenges to successful submission of eCQM data, including the inability of EHRs to capture and reuse information gathered during the course of care for eCQM reporting, the difficulty with capture of information from other department information systems, and the need to modify workflows to support data capture for eCQM reporting.[11] In addition to technology or clinical challenges, hospitals have been required to adopt annual sub-regulatory guidance on eCQMs. These specifications are updated annually with changes to vocabularies, value sets and measure logic.

[11] American Hospital Association report: Hospitals Face Challenges Using Electronic Health Records to Generate Clinical Quality Measures. Available at: http://www.aha.org/research/policy/ecqm.shtml.

The changes have been significant and are often accompanied by vendor updates to software to accommodate the eCQM changes. Additionally, CMS requires eCQM data electronically submitted to follow the most recent CMS eCQM implementation guide, which also is updated annually. In advance of the CY 2016 requirement to electronically submit eCQM data, many hospitals have been engaged in an ongoing effort to produce feasible, reliable and accurate eCQM data that accurately depicts the quality of care delivered.

In the FY 2016 inpatient PPS final rule, CMS finalized the requirement for hospitals participating in the hospital IQR program to submit four eCQMs for patients discharged during either the third or fourth quarter of 2016 by February 28, 2017. The Joint Commission partnered with the AHA and the Federation of American Hospitals (FAH) on a survey to obtain an accurate and nationally representative picture of hospitals' experiences and challenges, and learn what can be done to help hospitals meet the 2016 IQR program requirements. The survey was sent to hospitals in mid-March 2016 and responses were received by the end of April. More than 90 percent of hospital respondents said are aware of the reporting requirement and are planning to report eCQM data by the Feb. 28, 2017 deadline. Nearly 70 percent of respondents agreed that the reporting requirement is achievable. However, more than 75 percent of the respondents indicated they need to do some or a lot of work in order to successfully submit eCQM data to CMS, and over 40 percent indicated they have not successfully generated a quality reporting data architecture category 1 (QRDA-I) patient-level data file. Additionally, more than 70 percent of respondents indicated they have not successfully submitted a patient-level data file to CMS in the past. While these responses indicate some optimism, significant challenges remain.

Given the effort underway to successfully meet the CY 2016 eCQM reporting requirement, the AHA urges CMS not to increase the eCQM reporting requirement in CY 2017. We recommend that CMS maintain the current requirement that hospitals electronically submit data for any four of the eCQMs available for reporting in CY 2017. Should CMS seek to expand the opportunity to electronically report eCQMs, we recommend that the agency create a voluntary electronic reporting option for hospitals to electronically submit data for any of the eCQMs available for hospital IQR reporting other than the eCQMs selected for required reporting. A voluntary approach will allow hospitals that choose to report additional measures to do so while not mandating a larger reporting requirement prematurely. It also would allow time to manage the expense of upgrading certified EHRs and other technology to support additional measures specifications.

Moreover, in the proposed rule, CMS shared high-level findings of the 2015 eCQM validation pilot, noting "measure record matching rates (that is, the rates of medical record abstracted values as compared to the values reported in the QRDA I file) of less than 50 percent for all of the measures reported." CMS added that "for all measures, the inconsistencies between abstracted values and values reported in the (quality reporting data architecture) QRDA-I files appear to be mainly due to missing data rather than actual differences in reported versus abstracted values."

The AHA appreciates the insight from the 2015 eCQM validation pilot and recommends that CMS share additional findings. We believe it would be beneficial for stakeholders to know the number of hospitals that were able to successfully submit QRDA I files, the types of

hospitals that were successful and the method of submission selected. Respondents to the TJC/AHA/FAH survey expressed strong interest in additional education on eCQM reporting. More than 90 percent of hospitals indicated interest in additional education on best practices for implementing and reporting eCQMs, strategies to validate and improve eCQM accuracy, and reporting standards and specifications for eCQMs. **The AHA recommends that CMS expand existing eCQM outreach activities to address this significant interest in educational opportunities**.

Finally, AHA recommends that CMS wait to expand eCQM reporting until it can analyze findings and experiences with 2016 reporting. For FY 2016, CMS finalized the alignment of eCQM reporting in hospital IQR program and the EHR Incentive Program to CY reporting and required reporting of one calendar quarter of data for Q3 or Q4 of CY 2016. For CY 2017, CMS proposes to require the electronic submission of a full year of eCQM data. **The AHA is troubled by CMS's proposal, as it would increase the amount of data electronically submitted without the benefit of lessons learned from the first year of the electronic submission requirement. We also are concerned that the proposal is not realistic given the timeline for CY 2016 reporting, the eCQM update experience to date and the competing activities in 2017**.

EHR vendors and third-party data submission vendors generate the QRDA-I file for some hospitals. It is not known if vendors will have the ability to support their hospital customers with successful submissions of a full year of data for CY 2017 immediately following the close of the CY 2016 reporting period. Additionally, all hospitals participating in the EHR Incentive Program will be required to implement the 2015 edition certified EHR in CY 2017. Experience indicates that upgrading to a new edition of certified EHR results in unforeseen implementation challenges. **The AHA urges CMS to refrain from increasing the amount of eCQM data reported for CY 2017 and recommends retaining the current requirement that hospitals electronically submit eCQM data for one calendar quarter for either Q3 or Q4. We also recommend that CMS use the experience from the 2016 data submission to inform proposals to increase in the amount of eCQM data to be submitted and to increase the number in an incremental manner.**

Public Reporting of eCQMs. CMS proposes to continue the policy to not publically report the eCQM data submitted. **The AHA supports the continuation of this policy.** One quarter's worth of data would not provide a statistically valid sample from which to assess a hospital's performance, and the ongoing challenges with the reliability and validity of the electronically submitted eCQM data make public reporting premature.

Extraordinary Circumstances Extensions/Exemptions (ECE) Policy. CMS proposes to establish a submission deadline of April 1 following the end of the reporting calendar year for ECEs related to eCQMs. This timeframe also aligns with the Medicare and Medicaid EHR Incentive Programs' typical annual hardship request deadline. **The AHA supports this proposal, as it provides certainty in the ECE policy. We also recommend that CMS recognize an expansive definition of extraordinary circumstances that would support favorable consideration for an extension or waiver of the eCQM data submission requirement to**

include technology difficulties that present a barrier to compliance, including switching EHR or third-party data eCQM submission vendors during the reporting period.

eCQM Reporting for Eligible Hospitals (EH) and CAHs Participating in the Medicare and Medicaid EHR Incentive Programs in CY 2017

eCQMs Available for Reporting in the Medicare and Medicaid EHR Incentive Programs. CMS proposes to remove the same 13 eCQMs from the Medicare and Medicaid Programs EHR Incentive Programs that it proposes to remove from the Hospital IQR Program. The 15 inpatient eCQMs that CMS proposes to retain in the IQR and the one outpatient eCQM would remain available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. **The AHA supports the proposal to align the eCQMs available for reporting in the EHR Incentive Program and IQR program**.

eCQM Reporting Period and Submission Method. CMS proposes that the Medicare EHR Incentive Program retain the option to submit eCQMs by attestation or electronic submission in CY 2017. **The AHA supports the availability of the attestation option for eCQM reporting for the EHR Incentive Program in CY 2017** and the reporting on the eCQMs available for attestation – 15 inpatient eCQMs and one outpatient eCQM. For reasons stated in our comments on the eCQM reporting requirements proposed for hospital IQR program, we disagree with the proposal that hospitals participating in the EHR Incentive Program and the IQR program electronically submit data for all of the 15 eCQMs that CMS proposes for availability in CY 2017. **We recommend that CMS maintain the current requirement that hospitals electronically submit data for any four of the eCQMs available for reporting in the EHR Incentive Program in CY 2017. Should CMS seek to expand the opportunity to electronically report eCQMs, we recommend that the agency create a voluntary electronic reporting option for hospitals to electronically submit data for any of the eCQMs available for the EHR Incentive Program.** We believe this approach will support the ability to hospitals to report measures of their choice and continue to use their 2014 edition EHR to meet program requirements.

INPATIENT PSYCHIATRIC FACILITY (IPF) QUALITY REPORTING PROGRAM (IPFQR)

New Measures for FY 2019

CMS proposes two new measures for the FY 2019 payment determination and subsequent years. **The AHA does not support the inclusion of *SUB-3: Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge* or the subset measure *SUB-3a: Alcohol & Other Drug Use Disorder Treatment at Discharge* (NQF #1664).** We believe CMS has not adequately explored whether this measure is needed for improvement.

CMS believes that including this measure and its subset would encourage IPFs to offer and provide medication and/or referrals for addictions treatment for patients with co-occurring drug or alcohol use disorders at discharge. IPFs already should provide this service when appropriate

at discharge, and CMS offers no information suggesting that there is variation in performance for this aspect of care. Thus, CMS offers no evidence quality could be improved through the addition of the measure. **To add a quality measure that will increase burden on IPFs, without fully knowing whether it has the potential to improve quality, is premature and misguided.**

Given limited health care resources, **quality measurement is best used to address areas where there is a likely or demonstrated need for quality improvement.** CMS says it is "imperative to assess IPFs' efforts to offer treatment options for patients who screen positive for drug and alcohol abuse." The AHA believes assessments are needed *prior* to requiring the implementation of a new quality measure in a reporting program. Thus, we urge CMS to provide data (even if preliminary) demonstrating that IPFs are not providing these important discharge services before including a measure such as SUB-3 in the program.

Further, an assessment of whether IPFs are providing these services, or whether improvement is needed, can be done in in a much more efficient manner. The required investments of time, money, and labor by CMS and IPFs to implement a new quality measure in the IPFQR program include: (1) establishing and educating the IPF field about the measure specifications, as well as the processes and timeframes for submitting data; (2) training staff on data abstraction to meet the specifications; (3) potentially enhancing EHR systems; (4) conducting the data abstraction and submitting the data; (5) providing preliminary information for IPFs to preview the data; (6) previewing the data; and (7) making corrections where necessary. We do not believe that such an investment by CMS staff and contractors and all IPFs is necessary merely for assessment purposes. This level of time and energy should be devoted to areas where there is a demonstrated need for improvement.

CMS also proposes a readmission measure, *Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF*. **The AHA does not support the inclusion of this measure for numerous reasons, including the fact that it has not been reviewed and endorsed by NQF.**

The AHA believes that identifying and reducing avoidable readmissions – including those related to psychiatric care – has the potential to improve patient safety, improve coordination of care across settings, and reduce healthcare spending. The experience of the field to date suggests that readmissions reduction requires participation from, and collaboration among, all providers – inpatient facilities, post-acute providers and physicians – as well as the patients and communities they serve. Well-designed measures of readmission performance hold the potential to facilitate readmission reduction.

However, we do not believe that the proposed measure should be included in the program until it has been adjusted for sociodemographic factors. As demonstrated in a growing body of research, sociodemographic factors – such as the availability of primary care, physical therapy, easy access to medications and appropriate food, and other supportive services – significantly influence performance on outcome measures like readmissions, mortality and resource use. For the IPF readmission measure, we believe adjusting for sociodemographic factors is significantly important. In many instances, the readmission risk for psychiatric and behavioral health patients

will hinge on whether they have access to outpatient behavioral health services after discharge. However, the U.S. has substantial shortages of behavioral health professionals and outpatient services. Even where some services or professionals are available, we are concerned that long wait times to see an outpatient practitioner could impact readmission rates. For example, recent studies and media reports indicate that, even when patients have coverage through the health care marketplaces, many psychiatrists in their networks may not be able to take new patients or may have wait times of three weeks or longer. **Measures that fail to adjust for sociodemographic factors, when there is a relationship between those factors and the measure outcome, lack credibility, unfairly portray the performance of providers caring for more complex populations, and may serve to exacerbate health care disparities.**

The measure also does not exclude unrelated readmissions. We agree that IPFs should evaluate and treat patients in a holistic way and address their mental as well as physical health needs during the IPF stay. In addition, we believe that IPFs should have robust discharge planning procedures that help ensure a patient's mental and physical health needs are met after the inpatient stay. We are concerned that there may be instances, for example, where the IPF readmissions measure would penalize an IPF because of an unrelated readmission, even if the IPF did everything within its control to ensure a good outcome for the patient. For example, a patient may be discharged from an IPF after an admission for severe depression, and within 30 days be admitted to an acute care hospital for a condition, illness or injury that is not related to the patient's depression. The planned readmissions algorithm addresses some, but not all, of our concerns about unrelated readmissions. Further, we believe the planned readmissions algorithm may need additional analysis with psychiatric patients in mind. In the final rule, we ask CMS to explain in detail how the planned readmissions algorithm applies specifically to readmissions of patients previously discharged from IPFs. Further, we ask CMS to address whether it believes that the chronic nature of some psychiatric and substance use disorders may necessitate readmissions within 30 days in some instances.

PUBLIC DISPLAY AND REVIEW REQUIREMENTS

IPFQR program data is available to the public. Under current policy, CMS displays the data in April of each calendar year following the start of the respective payment determination year. However, CMS proposes to display data as soon as possible, on at least a yearly basis. We urge CMS to continue its policy of allowing for a 30-day review period. In addition, we believe that CMS should allow for enough time between the preview period and the public display of data to make necessary corrections. CMS previously specified that that the preview period would begin approximately 12 weeks prior to publicly displaying the data. In the final rule, CMS should explain how it will ensure enough time between the preview period and the public display of data.

OUTLIER PAYMENTS

In order to estimate the proposed FY 2017 outlier fixed loss threshold, CMS inflated the charges in the FY 2015 MedPAR file by two years, from FY 2015 to FY 2017. To estimate the one-year average annualized rate-of-change in charges per case for FY 2017, CMS proposes to compare

the average covered charge per case from the second quarter of FY 2014 through the first quarter of FY 2015 (Jan. 1, 2014 – Dec. 31, 2014) to the average covered charge per case from the second quarter of FY 2015 through the first quarter of FY 2016 (Jan. 1, 2015 – Dec. 31, 2015). CMS finds a one-year rate-of-change of 4.4 percent (1.043957) or 9.8 percent (1.089846) over two years.

However, the publicly available FY 2015 MedPAR dataset contains claims only through Sept. 30, 2015. Therefore, we do not have access to claims in the first quarter of FY 2016 (Oct. 1 – Dec. 31, 2015) 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 2016 (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

MS-DRG CHANGES

As of Oct. 1, 2015, providers use the ICD-10 coding system to report diagnoses and procedures for Medicare hospital inpatient services as the base code set for MS-DRGs, replacing ICD-9-CM. The majority of the issues being evaluated for the FY 2017 MS-DRGs update continue to relate to the need for the ICD-10 MS-DRGs to accurately replicate the logic of the ICD-9-CM based version of the MS-DRGs. **We appreciate CMS' continued efforts and agree that replication is important because both the logic for the proposed MS-DRGs and the data source used to calculate and develop proposed relative payment weights are based on the same MedPAR claims data.** In addition, it is paramount to maintain the integrity of MS-DRGs, as they are used to identify patient populations for different purposes beyond Medicare reimbursement.

In general, the AHA supports CMS's proposed changes to the MS-DRG classifications, which seem reasonable given the data, the ICD-10-CM/PCS codes and information provided, with the exceptions noted below.

Transcatheter Mitral Valve Repair with Implant. CMS proposes to collapse MS-DRGs 228, 229 and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively) from three severity levels to two severity levels by deleting MS-DRG 230 and revising MS-DRG 229. The title of proposed revised MS-DRG 229 would be "Other Cardiothoracic Procedures without MCC". The title for MS-DRG 228 would remain the same: MS-DRG 228 (Other Cardiothoracic Procedures with MCC).

We oppose this proposed change. As FY 2016 is the first year of ICD-10 data, we suggest that no changes be made to MS-DRG reclassifications other than for purposes of replication of the ICD-9-CM MS-DRG logic. This will allow the coded data to stabilize so that potential changes may be better analyzed and evaluated.

Endovascular Thrombectomy of the Lower Limbs. CMS proposes to restructure the ICD-10-PCS MS-DRG configuration for ICD-10 MS-DRGs 270, 271 and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively). We agree with the reconfiguration of ICD-10-PCS code translations and the MS-DRG classification change to reflect endovascular thrombectomy of the lower limbs. However, of the ICD-10-PCS codes proposed in the table in this section, there appear to be some ICD-10-PCS codes that represent veins of the upper limbs and other areas of the body, as well as lower limbs. **We recommend CMS remove codes that do not represent procedures of the lower limb to align with the intent of this MS-DRG Classification change.** A few examples of incorrect codes included in this table are:

- 03C53ZZ, Extirpation of matter from right axillary artery, percutaneous approach.
- 03C63ZZ, Extirpation of matter from left axillary artery, percutaneous approach.
- 03C73ZZ, Extirpation of matter from right brachial artery, percutaneous approach.
- 03C83ZZ, Extirpation of matter from left brachial artery, percutaneous approach.
- 03C93ZZ, Extirpation of matter from right ulnar artery, percutaneous approach.
- 03CA3ZZ, Extirpation of matter from left ulnar artery, percutaneous approach.
- 03CB3ZZ, Extirpation of matter from right radial artery, percutaneous approach.
- 03CC3ZZ, Extirpation of matter from left radial artery, percutaneous approach.
- 03CD3ZZ, Extirpation of matter from right hand artery, percutaneous approach.
- 03CF3ZZ, Extirpation of matter from left hand artery, percutaneous approach.

Pacemaker Procedures Code Combinations. We agree with CMS's proposal to modify the logic for MS-DRGs 260, 261, and 262 (Cardiac Pacemaker Revisions Except Device with MCC, with CC, and without CC/MCC, respectively) so that cases reporting any one of the ICD-10-PCS codes describing procedures involving pacemakers devices and related procedures and associated devices listed on the Tables on pages 24984- 24985 of the Display Copy of the proposed rule would be assigned to MS-DRGs 260, 261, and 262. However, we noted some inconsistencies in the code titles for some of these codes listed in the table versus the code title in the actual ICD-10-PCS code below. Included below is an example.

The "J" character in the device character field describe cardiac lead, pacemaker (02HK0JZ, 02HK3JZ, and 02HK4JZ) rather than a monitoring device:

- Proposed Rule narrative – 02HK3JZ Insertion of monitoring device into right ventricle, percutaneous approach
- Code book narrative – 02HK3JZ Insertion of Cardiac Lead, Pacemaker, percutaneous approach

We recommended that CMS revise the code titles of the ICD-10 PCS codes, where applicable, to align with the intent and description of the procedure codes for this table.

MS-DRG 945 and 946 Rehabilitation. CMS received several requests to examine the MS-DRG logic for MS-DRGs 945 and 946 (Rehabilitation with CC/MCC and without CC/MCC, respectively) because the logic does not replicate the ICD-9-CM MS-DRGs because of changes

in the ICD-10-CM codes and the corresponding guidelines for admissions/encounters for rehabilitation. As we commented last year, we continue to believe that although inpatient rehabilitation facilities (IRF) are not paid under the MS-DRG system, efforts should continue to be made to replicate the logic of ICD-9-CM MS-DRGs for all ICD-10 MS-DRGs. It is not simply a problem affecting Medicare payments as CMS notes in the rule, but important assumptions and interpretations regarding patient populations that are based on MS-DRGs, including for commercial payers, managed care contracting, patient safety and quality indicators. Due to the coding changes for ICD-10-CM, patients that would have been grouped to MS-DRGs 945 and 946 in ICD-9-CM are affecting case-mix and interpretations for several different MS-DRGs.

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."

In order to be assigned to ICD-10 MS-DRG 945 or 946, a case must first have a principal diagnosis from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services), where MS-DRGs 945 and 946 are assigned. If the case does not have a principal diagnosis code from the MDC 23 list, but does have a procedure code from the list included under the Rehabilitation Procedures for MS-DRGs 945 and 946, the case will not be assigned to MS-DRGs 945 or 946. The case will instead be assigned to a MS-DRG within the MDC where the principal diagnosis code is found. This logic results in many common diagnoses for rehabilitation that were grouped to ICD-9-CM MS-DRGs 945 and 946 to be grouped instead to several different ICD-10 MS-DRGs. For example, all diagnosis codes from category I69, Sequelae of cerebrovascular disease, group to MS-DRG 056-057 Degenerative Nervous System disorders.

In our FY 2016 inpatient PPS comment letter, the AHA recommended 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. Upon further review, a great number of diagnosis codes beyond sequelae of stroke (ICD-10-CM category I69) would need to be added in order to replicate the logic of the ICD-9-CM MS-DRGs. Therefore, we modified our recommendation to designating MS-DRGs 945 and 946 as pre-major diagnostic categories (Pre-MDC) MS-DRGs so that cases are grouped to these MS-DRGs on the basis of the procedure code rather than the principal diagnosis. In addition, we recommended a revision to the ICD-10-PCS Official Guidelines for Coding and Reporting to designate the ICD-10-PCS rehabilitation

codes to be used only for admissions for rehabilitation therapy. CMS reviewed this issue and did not believe the recommendations feasible for a variety of reasons, and, for FY 2017, is proposing to maintain the current structure of MS-DRGs 945 and 946 and reconsider the issue when ICD-10 claims data become available prior to proposing any updates.

We agree that our previous recommendations have been less than perfect workarounds and, if implemented, could have unintended consequences with different MS-DRGs. We recognize that collecting data using the ICD-10-PCS rehabilitation codes could be useful and should not be limited to rehabilitation admissions. We continue to believe it is important to address replication of the MS-DRGs 945 and 946 logic. Therefore, we respectfully propose a multi-step process, which includes creation of a new ICD-10-CM diagnosis code and changes to the MS-DRG GROUPER logic:

1. Work with the ICD-10 Coordination and Maintenance Committee, the federal committee co-chaired by CMS and CDC, to create a single new ICD-10-CM diagnosis code ("Z-code") to replicate the ICD-9-CM code category V57, Care involving use of rehabilitation procedures.

2. Maintain the existing ICD-10-CM Official Guidelines for Coding and Reporting to allow the sequencing of the diagnosis code for the condition for which the service is being performed as the principal diagnosis when the purpose for the admission/encounter is rehabilitation. In addition, recommend revision of the ICD-10-CM Official Guidelines for Coding and Reporting so that the "Z-code" is reported as a secondary diagnosis when the purpose for the admission/encounter is rehabilitation. Our understanding is that in the past providers, researchers and others had expressed an interest in identifying the actual medical condition as the principal diagnosis rather than the generic codes from ICD-9-CM category V57.

3. CMS to consider adding the "Z-code" to MDC 23 and grouping cases to MS-DRGs 945 and 946 on the basis of the secondary diagnosis code using the "Z-code." There is precedence for the GROUPER logic to use the secondary diagnosis to drive the MS-DRG as in MS-DRGs 280 to 285 (acute myocardial infarction) and MS-DRGs 969, 970, and 970-977 (human immunodeficiency virus) which are grouped on the basis of the codes for acute myocardial infarction or human immunodeficiency virus in either the principal diagnosis or secondary diagnoses position.

We believe this "hybrid" approach would satisfy the needs of users that desire more clinically specific diagnosis codes as the principal diagnosis, as well as allow a more accurate replication of the logic for MS-DRGS 945 and 946. **Given that this is of interest to the field, we also recommend that CMS consider the option to assemble a technical advisory panel (TEP) made up of stakeholders, such as rehabilitation providers and other representation to conduct an evaluation and recommend options for potential DRG logic changes for FY 2018.**

MEDICARE CODE EDITOR (MCE) CHANGES

After implementation of the ICD-10 MCE Version 33, CMS received several requests to examine specific code edit lists that the requestors believed were incorrect and that affected claims processing functions. We agree with CMS on the vast majority of MCE changes related to age conflict edits, sex conflict edits, noncovered procedure edits, and unacceptable principal diagnosis edits. We also have no objections to the proposed conversion of O.R. Procedures to Non-O.R. procedures and conversion of Non-O.R. procedure to O.R. Procedures in order to address replication issues. We recognize many of the proposed changes relate to specific requests submitted by us or our members, as well as issues that required review by the *AHA Coding Clinic for ICD-10-CM and ICD-10-PCS* Editorial Advisory Board to determine the correct application of the codes. We believe that many of the issues were the natural result of implementing a new and large code set change and are grateful for CMS' efforts to address the needs of the healthcare field and continue to replicate the MS-DRG logic. **In particular, we agree that CMS should remove all the ICD-10-CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list to address claims processing concerns.**

However, we disagree with CMS's opinion that there may be a conflict between the intent of the chapter-specific guidelines in ICD-10-CM Chapter 16 (Certain Conditions Originating in the Perinatal Period) that specify that "should a condition originate in the perinatal period, and continue throughout the life of the patient, the perinatal code should continue to be used regardless of the patient's age" and the guideline that states that all clinically significant conditions should be coded and that a condition is clinically significant if among other criteria, the condition "has implications for future healthcare needs."

We do not believe that the ICD-10-CM Chapter 16 guidelines contradict each other and therefore disagree with CMS's recommendation that they be examined and potentially be changed. Both of these guidelines are long-standing and exist in both ICD-9-CM and ICD-10-CM. The first guideline explains that the codes in Chapter 16 represent conditions that arise in the perinatal period (defined as before birth through the 28th day), and the reporting is not limited to newborn records. While there may be relatively small number of codes in ICD-10-CM Chapter 16 that may exist only during the perinatal period, the vast majority of the codes represent conditions that persist or continue to affect a patient through his or her life. The second guideline defines the parameters of what is a reportable diagnosis namely that the condition require clinical evaluation; or therapeutic treatment; or diagnostic procedures; extended length of hospital stay; increased nursing care and/or monitoring; (similar to the guideline for adults) with the exception that for newborns collection of information on perinatal conditions may be important for the future care of the patient.

However, we believe that there may be a slight discrepancy between the guidelines and an instructional note in the Tabular List for Chapter 16, which may have inadvertently caused some confusion. The Tabular List note states "Codes from this chapter are for use on newborn records only, never on maternal records," while the guideline simply states "Codes in this chapter are never for use on the maternal record." We do not believe the intent was for ICD-10-CM to restrict use of these codes to ONLY newborn records and will work with the CDC to make a future revision.

CODE FREEZE

The AHA previously supported CMS's recommendations to continue limited code updates to ICD-10-CM/PCS to capture new technologies and diseases through FY 2016. For FY 2017, the partial freeze has been lifted and regular updates to the ICD-10-CM and ICD-10-PCS code set will resume. As a result, 2,000 new diagnosis codes and 3,600 new procedure codes for Oct. 1, 2016 implementation were included in the FY 2017 IPPS proposed rule. **The AHA is very pleased that CMS and CDC provided an early release in March. Providers, vendors, payers and all other stakeholders have used the extra lead time to ensure the additional codes are seamlessly incorporated into the existing systems using ICD-10 codes.**