



June 13, 2017

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

Re: CMS-1677-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 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; Proposed Rule (Vol. 82, No. 81), April 28, 2017.

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, 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) 2018. We have submitted separate comments on the agency's proposed changes to the long-term care hospital (LTCH) PPS and CMS's request for information related to administrative burden.

We support a number of the inpatient PPS proposed rule's provisions, including those intended to reduce regulatory barriers for hospitals, health systems and the patients they serve, as well as those related to electronic clinical quality measures (eCQMs) and the Electronic Health Record (EHR) Incentive Program. At the same time, we have concerns about CMS's provisions related to changes to disproportionate share hospital (DSH) payments, the documentation and coding reduction and the implementation of many of CMS's quality programs. A summary of our key recommendations follows.



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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, the AHA continues 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 hospital uncompensated care costs. However, while we appreciate CMS's analysis that shows that the S-10 data have improved over time, we still have concerns over the accuracy and consistency of the data. Accordingly, we urge the agency to take the following actions:

- Delay use of the Worksheet S-10 in calculating DSH payments by one year only. That is, we urge the agency to begin using the S-10 data in FY 2019, rather than FY 2018. The agency should use this year to further educate hospitals about how to accurately and consistently complete the S-10, including allowing them to correct their data retroactively if necessary. We also emphatically urge the agency to have an audit process for the S-10 data in place by this time.
- Continue to use Medicaid and Medicare Supplemental Security Income (SSI) days from FY 2011-2013 (pre-Medicaid expansion), for purposes of calculating uncompensated care payments to hospitals in FY 2018. Using these data during the one-year delay would avoid including FY 2014 post-Medicaid expansion data in the DSH payment calculation. CMS also should continue using a three-year average of data reported on a hospital's cost reports to calculate that hospital's uncompensated care payment.
- Implement a phase-in approach of at least three years when transitioning to the Worksheet S-10 data.
- Implement a stop-loss policy to protect hospitals that lose more than 10 percent in DSH payments in any given year as a result of transitioning to the Worksheet S-10. This stop-loss should extend beyond the transition to help hospitals with decreasing uncompensated care payments adjust to their new payment levels.

DOCUMENTATION AND CODING ADJUSTMENT

The American Taxpayer Relief Act of 2012 (ATRA) requires CMS make adjustments to inpatient PPS rates 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. The agency instituted these cuts in FYs 2014 through 2017. When completing its final ATRA recoupment in FY 2017, CMS finalized a cut of 1.5 percentage points to inpatient PPS payments. This was almost two times what it had planned and what lawmakers had expected. Yet, the agency did not propose to correct for this discrepancy when instituting this year's restoration of these one-time cuts. As a result, hospitals would now be left with a larger permanent cut than Congress intended when legislating the restorations. **The AHA urges the agency to restore the excess cut and help ensure that hospitals have sufficient resources to care for their communities.**

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HOSPITAL READMISSION REDUCTION PROGRAM (HRRP) CHANGES

CMS proposes to implement a vitally important, congressionally directed, first step to improving the fairness of readmission penalties by proposing to implement socioeconomic adjustment in the HRRP. Indeed, the AHA has long urged CMS to implement socioeconomic adjustment in the HRRP because of the significant body of research showing that readmissions performance is impacted by poverty, availability of resources and other social risk factors beyond hospitals' control. At the same time, the AHA also recommends that CMS take steps to improve the transparency of the proposed approach by making more data available on how it determines peer groupings. We also urge CMS to continuously evaluate its adjustment approach and to engage with the field on ensuring its adjustment approach keeps up with the evolving science around capturing and adjusting for socioeconomic factors.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM CHANGES

The AHA appreciates CMS's proposals to reduce the number of eCQMs hospitals are required to report and to shorten the data reporting period. However, we recommend that CMS instead retain the FY 2018 reporting requirement, in FY 2019 and FY 2020, permitting hospitals to submit data for a minimum of four eCQMs and do so for a minimum of one self-selected calendar quarter. While the AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting, there remain far too many questions about eCQMs for CMS to mandate an expanded reporting requirement in the IQR for FY 2020. In addition, we continue to urge CMS to streamline further and focus the measures in the IQR program around high-priority quality and safety issues.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Priya Bathija, AHA senior associate director for policy, at (202) 626-2678 or <u>pbathija@aha.org.</u>

Sincerely,

/s/

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

Enclosure

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American Hospital Association (AHA) Detailed Comments on the Inpatient Prospective Payment System (PPS) Proposed Rule for Fiscal Year (FY) 2018

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

The American Taxpayer Relief Act of 2012 (ATRA) required 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. In FYs 2014 through 2016, the agency projected that these cuts would equate to a 3.2 percentage point cut that would spread over the mandated four-year period. CMS then instituted a 0.8 percentage point cut in each of FYs 2014, 2015 and 2016. Instead of acting in accordance with its projections and instituting a 0.8 percentage point cut for FY 2018, however, the agency finalized a cut of 1.5 percentage points to inpatient PPS payments. This was almost two times what it had originally planned and what lawmakers had expected.

The ATRA cuts were recoupment cuts; as such, Congress intended that the cumulative 3.2 percentage point cut projected by CMS (0.8 percentage points for each of FYs 2014-2016, plus 0.8 percentage points in FY 2017) would 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 the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA). Specifically, relying on CMS's actuaries' estimate that the final ATRA cut would be 0.8 percentage points in FY 2017, Congress dedicated 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 were to 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. The 21st Century Cures Act then modified this restoration slightly, but the intent remained.

Because CMS implemented 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 and the 21st Century Cures Act allow for only 3.0 percentage points to be returned to hospitals by FY 2023. Consequently, CMS's cut leaves hospitals with a permanent cut of 0.9 percentage points instead of the 0.2 percentage point cut that Congress intended. This additional 0.7 percentage point cut is inconsistent with Congress' intent in the ATRA, MACRA and 21st Century Cures Act, which, together, required restoration of most of the documentation and coding cuts. The AHA reiterates the <u>comments</u> we made on this issue in the inpatient PPS proposed rule for FY 2017. This excessive cut will take effect in FY 2018, and we urge the agency to restore these funds to help ensure that hospitals have sufficient resources to be able to care for their communities.

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DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT CHANGES

BACKGROUND

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 FYs 2014-2017, the agency used inpatient days of Medicaid beneficiaries plus inpatient days of Medicare SUPlemental Security Income (Medicare SSI) beneficiaries as a proxy for measuring the amount of uncompensated care each hospital provides.

CMS'S PROPOSED DSH CHANGES FOR FY 2018

For FY 2018, CMS estimates that the total amount of Medicare DSH payments that would have been made under the pre-FY 2014 formula is \$16.003 billion. Therefore, it proposes that hospitals would initially receive 25 percent of these funds, or \$4.001 billion, as empirically justified DSH payments. The remaining \$12.002 billion would flow into the 75-percent pool. To calculate what portion of the 75-percent pool is retained, CMS determined that the percentage of uninsured for FY 2018 would be 8.15 percent. After inputting that rate into the statutory formula, it proposed to retain 58.21 percent – or \$6.962 billion – of the 75-percent pool in FY 2018. This amounts to an increase of about \$1 billion in Medicare DSH payments in FY 2018 compared to FY 2017. We are supportive of this proposal.

TRANSPARENCY RELATED TO DSH CALCULATION

The AHA continues to be 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 should 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 the total DSH pool (the total amount of Medicare DSH payments that would have been made under the pre-FY 2014 formula), which is discussed on page 19944 of the rule. There, CMS includes a table explaining the factors applied for FYs 2015 – 2018 to estimate Medicare DSH expenditures. CMS states:

The figures for FY 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 figures for FYs 2017 and 2018 are assumptions based on recent trends recovering back to the long-term trend and

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assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans.

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

CMS also includes an "Other" column in the rule that it says shows the increase in other factors that contribute to the Medicare DSH estimates, including the difference between the total inpatient hospital discharges and the inpatient PPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns. The "Other" column also includes a factor for Medicaid expansion due to the ACA. However, while CMS provides the categories included in this factor, it fails to include detail as to how this factor is actually calculated. As such, we request that CMS include a detailed explanation, including calculations, of how 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.

NATIONAL HEALTH EXPENDITURES ACCOUNT (NHEA) DATA

CMS proposes to change its data source for calculating the uninsured rate from the Congressional Budget Office (CBO) to estimates produced by OACT as part of the development of the National Health Expenditures Account (NHEA). The agency considered a variety of data sources before selecting the NHEA data, but indicates it believes the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured. For FY 2018, the NHEA data produces a significantly smaller reduction in the uninsured, thereby increasing the total available dollars for uncompensated care. **The AHA agrees with the agency's determination regarding the attributes and quality of the NHEA data. As such, we support CMS's proposal to change its data source for calculating the uninsured rate from CBO to NHEA data.**

TRANSITION TO WORKSHEET S-10

For several years, CMS discussed using the cost report's Worksheet S-10 data on hospital charity care and bad debt to determine the amount of uncompensated care each hospital provides, in place of the current formula of Medicaid and Medicare SSI days. However, because of concerns regarding variations in and the completeness of these data, CMS had stated that it was premature to propose the use of Worksheet S-10.

In the FY 2017 inpatient PPS final rule, the agency addressed the issue again and indicated that it planned to institute certain additional quality control and data improvement measures, including

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an audit process, to the Worksheet S-10 instructions and data. CMS also stated that it intended to begin incorporating Worksheet S-10 data into the DSH computation once these additional measures were in place (but no later than FY 2021) and that the agency would re-propose a policy related to incorporation of these data prior to that time. However, for a variety of reasons, CMS now believes it has reached a "tipping point" with respect to the use of Worksheet S-10 data and proposes, starting in FY 2018, to begin a three-year phase in of incorporating hospitals' Worksheet S-10 data into the methodology for determining uncompensated care payments.

The AHA reconvened our Medicare DSH Advisory Committee to discuss the agency's specific proposals. This committee is comprised of a cross-section of AHA members, including representatives from hospitals with different ownership, teaching and Medicaid expansion statuses, different geographic locations and different sizes, as well as two state association representatives. Our comments below reflect the work of this committee, as well as the AHA Board and our members at large. Generally speaking, the AHA continues 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 hospital uncompensated care costs. However, while we appreciate CMS's analysis that shows that the S-10 data have improved over time, we still have concerns over the accuracy and consistency of the data. Accordingly, we urge the agency to take the following actions.

- Delay use of the Worksheet S-10 in calculating DSH payments by one year only. That is, we urge the agency to begin using the S-10 data in FY 2019, rather than FY 2018. The agency should use this year to further educate hospitals about how to accurately and consistently complete the S-10, including allowing them to correct their data retroactively if necessary. We also emphatically urge the agency to have an audit process for the S-10 data in place by this time.
- Continue to use Medicaid and Medicare SSI days from FY 2011-2013 (pre-Medicaid expansion), for purposes of calculating uncompensated care payments to hospitals in FY 2018. Using these data during the one-year delay would avoid including FY 2014 post-Medicaid expansion data in the DSH payment calculation. CMS also should continue using a three-year average of data reported on a hospital's cost reports to calculate that hospital's uncompensated care payment.
- Implement a phase-in approach of at least three years when transitioning to the Worksheet S-10 data.
- Implement a stop-loss policy to protect hospitals that lose more than 10 percent in DSH payments in any given year as a result of transitioning to the Worksheet S-10. This stop-loss should extend beyond the transition to help hospitals with decreasing uncompensated care payments adjust to their new payment levels.

<u>One-year Delay</u>. The AHA urges the agency to delay, by one year only, using the Worksheet S-10 data in calculating DSH payments. That is, we urge the agency to begin using the S-10 data in FY 2019, rather than FY 2018. Because, as noted below, the AHA continues to have concerns about the Worksheet S-10 data, we believe such a delay would provide CMS with an

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important opportunity to further educate hospitals about how to accurately and consistently complete the S-10, including allowing them to correct their data retroactively if necessary. We also emphatically urge the agency to have an audit process for the S-10 data in place by this time to ensure the data are sufficiently accurate and consistent.

<u>AHA Concerns Related to the Worksheet S-10 Data</u>. **The AHA continues to have concerns over the accuracy and consistency of the Worksheet S-10 data**. Specifically, the form and its instructions are unclear in some places and lack specificity in others. Hospitals' attempts to reconcile the instructions for the Worksheet S-10 with their obligation to accurately reflect their financial circumstances often lead to inconsistencies in reporting of this data.

In April, AHA provided the agency with an <u>analysis</u> of the Worksheet S-10 data that identified examples of reporting inconsistencies. For example, when we analyzed FY 2014 data, we found a 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. Another had bad debt expenses (Line 28) that were more than 2000 percent of its total expenses. Such data inaccuracies and inconsistencies can have a critical impact on the distribution of Medicare DSH payments. That is, because the 75-percent pool is a fixed amount, inaccurately reported data by one hospital will affect the DSH payments of all other hospitals.

Additional Changes to Ensure the Accuracy and Consistency of the Worksheet S-10 Data. We have communicated our major concerns and suggestions regarding the Worksheet S-10 to CMS on multiple occasions, including in a stakeholder discussion group lead by Dobson DaVanzo & Associates LLC, in January 2014 and in our <u>comments</u> on the FYs 2015, 2016 and 2017 inpatient PPS proposed rules, and in an additional <u>letter</u> to the agency in April. While many of those concerns still apply, we specifically urge CMS to take the following steps to ensure the accuracy and consistency of the Worksheet S-10 data. We also urge CMS to make clarifications to the Worksheet S-10 and instructions as soon as possible to ensure that hospitals are reporting data in a consistent manner.

• 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. However, the agency also proposes that Medicaid shortfalls (i.e., 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 would *not* be included in the definition of uncompensated care. The AHA continues to recommend that the definition of uncompensated care costs, including not only charity care and bad debt but also the unreimbursed costs of Medicaid, SCHIP, and other state and local government indigent care 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

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unreimbursed costs, and it will ensure the most appropriate basis for calculating future uncompensated care payments.

- Discounts. The ACA directed the uncompensated care 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 has indicated in previous rulemaking, 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 run contrary to the underlying intent of uncompensated care payments under the ACA.
- Revisions to the Cost-to-Charge Ratio (CCR) for Worksheet S-10. The ratio of costto-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.
- Indian Health Services (IHS) Facilities that Receive DSH Payments. Certain IHS and tribal hospitals receive Medicare DSH payments; however, these hospitals are not required to and do not complete the Worksheet S-10. The agency should propose an alternative and meaningful procedure for these hospitals to account for the costs they incur in treating the uninsured prior to transitioning to the Worksheet S-10.

<u>Technical Comments Related to the Worksheet S-10</u>. CMS also makes two proposals to address technical comments it has received from the hospital field related to the current Worksheet S-10 and its instructions. First, CMS proposes to annualize cost reports for hospitals that have cost

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reports that do not equal 12 months of data (in other words, are more or less than 365 days) in any given year. CMS also proposes to combine data from multiple cost reports beginning in the same fiscal year before annualizing these cost reports. **On previous occasions, the AHA has urged CMS to account for both of these issues. Accordingly, we appreciate CMS's proposal to address these issues.**

Second, rather than proposing to audit the Worksheet S-10 data in FY 2018, CMS proposes to 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. In addition, as a first step in its trimming methodology, CMS would remove Maryland hospitals, all-inclusive rate providers and providers that did not report a CCR on Worksheet S-10, Line 1. Those hospitals would be assigned the statewide average CCR. 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.

Specifically, CMS indicates that the statewide average CCR would be applied to 140 hospitals, of which 117 are all-inclusive rate providers (we note that we analyzed the FY 2014 cost report data and identified 86 all-inclusive providers according to line 115, column 1 of Worksheet S-2, Part I). If CMS uses another method of identifying all-inclusive providers, we urge CMS to share its method. While 64 of these all-inclusive providers did not report CCRs on Worksheet S-10, 22 of them did. A majority of these providers did not report CCRs or uncompensated care costs that appear erroneous and it is our understanding that these providers use approved alternative methods of cost accounting. Trimming these CCRs raises doubts about the soundness of CMS's trimming methodology. Since their CCRs were trimmed, their uncompensated care costs also were trimmed substantially. Accordingly, we urge CMS to revise its trim methodology so that it does not penalize providers that use alternative methods of cost apportionment.

<u>Cost Report Revisions and Worksheet S-10 Audits</u>. CMS states that it has developed a process for auditing the S-10 data, and instructions will be provided to the Medicare Administrative Contractors (MACs) as soon as possible. The agency expects that cost reports beginning in FY 2017 will be the first cost reports for which the Worksheet S-10 data will be subject to a desk review. The agency plans to wait until these Worksheet S-10 data have been submitted, the audits have been performed, and the data are available for review before it considers making any further revisions to the Worksheet S-10 instructions.

As indicated above, we urge CMS to audit the S-10 data <u>prior</u> to transitioning to Worksheet S-10 to verify that they are correct and complete. For example, the agency could conduct a side audit to expedite the process, similar to audits for the occupational mix survey data. We note that hospitals are eager to learn how auditors will interpret the Worksheet S-10, and greater clarity of CMS's expectations would ensure hospitals are in a much better position when they fill out the Worksheet S-10. CMS has indicated that tying the S-10 to payment and requiring its regular use will inherently improve its accuracy. However, given the inaccuracies and inconsistencies discussed above, we do not believe that simply tying these together will improve the S-10 data. Ms. Seema Verma June 13, 2017 Page 12 of 51

Data Used in Uncompensated Care Calculation. The AHA urges CMS to continue to use Medicaid and Medicare SSI days from FY 2011-2013 (pre-Medicaid expansion), for purposes of calculating uncompensated care payments to hospitals in FY 2018. Using these data during the one-year delay in Worksheet S-10 would avoid including FY 2014 post-Medicaid expansion data in the DSH payment calculation. The members of AHA's Medicare DSH Advisory Committee had significant discussion related to the differential impact the transition to Worksheet S-10 would have on those states that expanded Medicaid and those states that did not expand Medicaid under the ACA. Some believed that maintaining the current method would unfairly impact states that did not expand Medicaid. This concern would be ameliorated by continued use of pre-expansion data in FY 2018.

In addition, CMS proposes to continue using a three-year average of data reported on a hospital's cost reports to calculate that hospital's uncompensated care payment. Specifically, for FY 2018, CMS would use FY 2014 Worksheet S-10 data in combination with FYs 2012 and 2013 Medicaid days and FYs 2014 and 2015 SSI ratios to determine the distribution of uncompensated care payments. CMS indicates that an additional year of Worksheet S-10 data would be incorporated into the calculation in FY 2019, and the use of Medicaid and Medicare SSI days would be phased out by FY 2020. Notwithstanding our positions regarding Worksheet S-10 implementation and Medicaid data above, AHA supports using three years of data to limit unpredictable swings and anomalies in DSH payments.

<u>Phase-in Approach</u>. When CMS transitions to the Worksheet S-10 data in FY 2019, we urge the agency to implement a phase-in approach of at least three years. Medicare has a longstanding history of transitioning policies with significant impacts on providers in order to help maintain predictability and reliability in the PPS, which we are supportive of given the major payment changes involved.

<u>Stop-loss Policy</u>. We also believe the agency should consider additional transition policies that would limit the losses of those hospitals that face significant decreases in payment as a result of the transition to the Worksheet S-10. **Specifically, we urge CMS to implement a stop-loss policy to protect hospitals that lose more than 10 percent in any given year as a result of transitioning to the Worksheet S-10.** Such a policy is critical given the large number of hospitals that face substantial losses in moving to the Worksheet S-10. Specifically we found that the following percent of hospitals would lose at least 10 percent in DSH payments over the course of the initial three-year transition:

	% Hospitals Qualifying for
FYs	10% Stop Loss
2017-2018	6.8%
2018-2019	17.5%
2019-2020	21.8%

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In addition, the number of hospitals that would lose at least 20 percent of their DSH payments is consequential. While this stop-loss is necessary during any transition period proposed by the agency, we believe it should extend beyond a three-year transition to help hospitals with decreasing uncompensated care payments adjust to their new payment levels.

We look forward to working with CMS to improve the Worksheet S-10 and the associated methods for calculating uncompensated care payments to hospitals. The AHA also would be pleased to work with CMS to educate hospitals on how to accurately and consistently complete the Worksheet S-10.

96-HOUR CERTIFICATION REQUIREMENT

As a condition of payment for inpatient services provided at a critical access hospital (CAH), current law requires that a physician certify that an individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. CAHs also are required to comply with a Medicare Condition of Participation (CoP) that requires CAHs to provide acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

While CAHs typically maintain an annual average stay of 96 hours per patient, in order to ensure access to certain critical services in their communities, they do offer some medical services that have standard lengths of stay greater than 96 hours. In those cases, however, CAHs would not satisfy the condition of payment because a physician would be unable to reasonably certify that the beneficiary's stay will be less than 96 hours. As such, if this condition of payment is enforced, CAHs would no longer receive payment from CMS for medical services requiring a beneficiary stay of longer than 96 hours – an untenable situation for providers and patients alike. Patients would no longer be ensured access to critical services that have standard lengths of stay greater than 96 hours. In addition, Medicare payments account for roughly 47 percent of total revenues for CAHs, and any changes in these payments are difficult to absorb. The resulting financial pressure on CAHs would severely affect their ability to operate and care for beneficiaries in rural communities.

In response to concerns raised by the AHA, CMS indicates it has reviewed the CAH 96-hour certification requirement to determine if there are ways to reduce its burden on providers. As a result of that review, in the proposed rule, CMS states that it will direct Quality Improvement Organizations (QIOs), MACs, the Supplemental Medical Review Contractor (SMRC) and Recovery Audit Contractors (RACs) to make the requirement a low priority for medical record reviews conducted on or after Oct. 1, 2017. This means that, absent concerns of probable fraud, waste or abuse of the coverage requirement, these contractors will not conduct medical record reviews to determine compliance with the CAH 96-hour certification requirement. The AHA appreciates CMS's recognition that this condition of payment could stand in the way of promoting essential, and often lifesaving, health care services to rural America. We urge CMS to finalize this proposal on a permanent basis to provide CAHs with certainty that the agency will not begin to audit the 96-hour certification requirement in the future.

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In addition, while this moratorium offers some comfort, it does not remove the 96-hour certification requirement from the statute, and the AHA remains concerned that CAHs may still be at risk for penalties. For example, noncompliance with this payment requirement could trigger liability under the False Claims Act – leaving CAHs subject to unscrupulous relators in those cases. There also is potential for auditors outside CMS's control to use this requirement to target and penalize CAHs. As a result, the AHA will continue to advocate for a legislative solution that permanently removes the 96-hour physician certification requirement as a condition of payment for CAHs and we urge CMS to work with us to support that effort.

EXTENSION OF RURAL COMMUNITY HOSPITAL (RCH) DEMONSTRATION PROGRAM

The RCH Demonstration Program was established to test the feasibility and advisability of reasonable cost reimbursement for rural hospitals with fewer than 51 beds. This program has provided stability to certain rural hospitals that are too large to qualify for CAH status, but too small to remain financially viable under Medicare's inpatient hospital PPS. While originally authorized for five years, the program was extended by the ACA for an additional five years. The 21st Century Cures Act extended this program for an additional five years.

CMS proposes to begin implementation of the 21st Century Cures Act extension on a hospital's first cost-reporting period beginning on or after Oct. 1, 2017, following the announcement of the selection of additional hospitals to the RCH Demonstration Program. However, this would result in a gap in the reasonable cost-based payment methodology paid to hospitals that previously participated in the program. While the length of the gap in payment will vary for each previously participating hospital, all ended their performance long before Oct. 1, 2017.

We are concerned that CMS's proposal to implement the 21st Century Cures Act extension is inconsistent with both congressional intent and past CMS approaches. Specifically, Section 15003 of the 21st Century Cures Act changed the language in the ACA regarding length of the extension from "five years" to "ten years." The language also explicitly states that this extension is to begin on the date *immediately following* the last day of the initial five-year period. Further, CMS's proposal is inconsistent with its previous approach – the agency implemented the first five-year extension of this program continuously without a gap in the reasonable cost payment methodology. In addition, CMS has implemented extensions of other critical rural payment programs, including the Medicare-dependent hospital program and the enhanced lowvolume adjustment, in a seamless manner.

In addition, this proposal would cause financial hardship for the hospitals that have been participating in the RCH Demonstration Program. For example, a gap in reasonable costbased payments would harm these hospitals' ability to recruit specialty health care services, prevent development of virtual care and transportation services and force them to reevaluate ongoing capital projects. As a result, we are concerned that they would be forced to reduce or Ms. Seema Verma June 13, 2017 Page 15 of 51

eliminate the services they offer to their communities, thereby further threatening access to health care services for individuals living in these rural communities.

CMS acknowledges this gap in payment in the proposed rule and indicates that it also considered an "alternative approach" where each previously participating hospital would begin the second five years of the 10-year extension period immediately following the end of their first five-year period. For example, if a hospital's first five-year period ended on June 30, 2015, the extension period would begin July 1, 2015. Accordingly, under this alternative approach, there would be no gap in the reasonable cost-based payment methodology.

The AHA urges CMS to implement the "alternative approach" instead of its proposal, thereby continuing the RCH Demonstration Program in a seamless manner. Doing so would align with congressional intent, remain consistent with CMS's past practice and help allow previously participating hospitals to continue delivering essential health care services to their communities.

EXPIRATION OF THE IMPUTED FLOOR POLICY

In FY 2005, CMS temporarily adopted an "imputed" rural floor policy by establishing a wage index floor for those states that did not have rural hospitals. CMS subsequently has extended this policy through FY 2017. However, CMS does not propose to extend the policy again, expressing concern that the methodology creates a disadvantage in the application of the wage index to hospitals in states where rural hospitals but no urban hospitals receive the rural floor. Absent any new wage index policies that address the original need for the imputed rural floor, the AHA asks CMS to extend the current policy.

LABOR-RELATED SHARE

Current law requires CMS to adjust the proportion of the standardized amount that is attributable to wages and wage-related costs (the labor-related share) by a factor that reflects the relative difference in labor costs among geographic areas (the area wage index). For FYs 2014-2017, CMS used the labor-related share of 69.6 percent for those hospitals with wage indices greater than 1.0. For FY 2018, CMS proposes to rebase and revise the inpatient PPS market basket to reflect 2014 data. As a result, the agency proposes a labor-related share of 68.3 percent for those hospitals with wage indices greater than 1.0 – this is approximately 1.3 percentage points lower than the current labor-related share of 69.6 percent. The labor share for hospitals with wage indices less than 1.0 will remain at 62 percent, as specified in current law.

We are concerned about the methodology CMS used to remove a portion of professional fees from the labor-related share. To estimate the proportion of professional fees that are labor-related, CMS relies on a hospital survey it conducted in 2008 regarding the proportion of those fees that go to companies that are located beyond their own local labor market (and are therefore, not labor-related). Based on the weighted results of that survey, CMS determined that

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hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services;
- 30 percent of engineering services;
- 33 percent of legal services; and
- 42 percent of management consulting services.

CMS believes these survey results are appropriate to use for the 2014-based inpatient PPS market basket as they empirically determine the proportion of contracted professional services purchased by the field that is attributable to local firms and the proportion that is purchased from national firms. However, these data are woefully out-of-date and if the agency's intention is to update its labor share to account for recent changes, it should also update this survey data. It is inappropriate for the agency to be using data gathered in 2008 to adjust payments made in 2018. In addition, as the AHA noted in our previous comments, CMS received only 108 responses to this survey. It is statistically impossible for these 108 hospitals to constitute a representative sample. Further, the agency failed to share data on the characteristics of the hospitals that responded, possible selection bias or survey methodology.

The AHA urges CMS not to use the statistically dubious results of this survey to estimate the proportion of professional fees that are labor-related. Rather, CMS should ensure this data is up-to-date and reflects current trends and practices of the hospital field. In addition, we urge the agency to continue to investigate alternative methodologies for determining the proportion that is labor-related. The agency also should consider an approach that will mitigate significant decreases in inpatient payments to hospitals as a result of the decreased labor share.

Lastly, CMS should provide all information necessary for the hospital field to replicate the agency's calculation of the labor-related share, including, but not limited to, greater clarity of data sources used; case counts at different points, such as number of providers after trimming; and provider data illustrating what information CMS used in the calculation. 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.

LOW-VOLUME HOSPITAL PAYMENT ADJUSTMENT RELATED TO HOSPITALS OPERATED BY IHS OR A TRIBE

In order to qualify for the low-volume hospital payment adjustment, a hospital must meet, among other criteria, a requirement that it be located more than a specified number of miles from the nearest subsection (d) hospitals. Section 1886(d)(1)(B) of the Social Security Act defines 'subsection (d) hospital' as *a hospital located in one of the 50 States or District of Columbia, other than the specified excluded types of hospitals*. CMS indicates in the proposed rule that, in its prior rulemaking, the agency considered IHS and Tribal hospitals to be subsection (d)

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hospitals. While the AHA does not believe that has always been the case for purposes of the lowvolume hospital payment adjustment, CMS has recently used this standard to deny eligibility for the low-volume payment adjustment if a hospital is located less than the specified mileage from an IHS or Tribal hospital.

The AHA has urged CMS to reconsider its recent interpretation, given the unique nature of IHS and Tribal hospitals and the populations they serve. Except for emergencies and a few other limited special cases, those individuals who are not members of a federally recognized Tribe are not eligible for treatment at IHS or Tribal hospitals. Therefore, such a hospital is not a valid option for the general Medicare population, including local residents who are not eligible for IHS services. The AHA had requested that the agency allow additional flexibility in determining eligibility for the low-volume hospital payment adjustment for IHS and non-IHS hospitals and Tribal hospitals that are located less than the specified mileage from one another.

In the proposed rule, CMS addresses this flexibility by proposing the following for FY 2018 and after:

- For an IHS or Tribal hospital, only its proximity to other IHS or Tribal hospitals would be used to determine if the mileage criterion is met; and
- For a non-IHS hospital, only its proximity to other non-IHS hospitals would be used to determine if the mileage criterion is met.

The AHA supports this proposal. However, given the uncertainty CMS's recent position has caused for hospitals that were denied the low-volume payment adjustment, we urge the agency to consider applying this flexibility retroactively to those hospitals that were denied the low-volume payment adjust and are currently in the process of appealing those denials.

PROPOSED CHANGE TO VOLUME DECREASE ADJUSTMENT FOR SOLE COMMUNITY HOSPITALS (SCH) AND MEDICARE-DEPENDENT, SMALL RURAL HOSPITALS (MDH)

CMS is required to make a volume decrease adjustment (VDA) to certain SCHs and MDHs that experience a decrease of more than 5 percent of their total number of inpatient discharges from one year to the next due to circumstances beyond its control. This adjustment is intended to compensate the hospital for the fixed costs it incurs in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

Under the current methodology, the MAC calculates the VDA by subtracting the hospital's total MS-DRG revenue for inpatient operating costs, including outlier payments and indirect medical education (IME) and DSH payments, in the cost-reporting period in which the volume decrease occurred, from fixed costs in the cost-reporting period in which the volume decrease occurred, minus any adjustment for excess staff. If the result of that calculation is greater than zero and less than the cap, the hospital receives that amount in a lump-sum payment. If the result of that

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calculation is zero or less than zero, the hospital does not receive a volume decrease payment adjustment.

The AHA has expressed concern regarding the calculations used by MACs when determining the VDA. Specifically, we believe it would be more appropriate for the MACs to only consider the MS-DRG revenue estimated to be attributable to fixed costs. To do so, they should adjust the hospital's total MS-DRG revenue from Medicare by multiplying it by the ratio of a hospital's fixed costs to its total costs (as determined by the MAC). They would then subtract that estimate of the fixed portion of MS-DRG payments from the hospital's total fixed costs. In this way, the calculation would compare estimated Medicare revenue for fixed costs to the hospital's fixed costs when determining the volume decrease adjustment.

In this rule, CMS proposes to prospectively change how the MACs calculate the VDA and require that MACs compare estimated Medicare revenue for fixed costs to the hospital's fixed costs to ensure that a hospital that qualifies for the volume decrease adjustment will be fully compensated for fixed costs as a result of the application of the adjustment. The AHA strongly supports this proposal. However, numerous hospitals around the country currently have pending appeals related to CMS's previous calculation. As such, we ask CMS to apply this proposal retroactively for all properly pending SCH and MDH appeals.

REQUEST FOR COMMENTS ON PAYMENT DIFFERENTIALS FOR SIMILAR SERVICES PROVIDED IN INPATIENT AND OUTPATIENT SETTINGS

CMS previously requested public comment on potential payment policy options to address the issue of payment differentials between services provided in the inpatient and outpatient settings. It now seeks additional public comment on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.

The AHA previously provided the agency with comments in this area. Specifically, we provided an analysis of potential short-stay <u>models</u> that could supplement the agency's original twomidnight policy. However, while our models reduced payment differentials between inpatient stays and similar outpatient stays, we found that new payment differentials between short-stay and non-short stay inpatient cares were created. We also provided <u>comments</u> to the Medicare Payment Advisory Commission (MedPAC) as it considered similar outpatient stays in the context of the two-midnight policy. In addition, the outpatient PPS proposed rule for calendar year (CY) 2016, CMS made significant modifications to the two-midnight policy, and the AHA provided comments in support of those changes. We reiterate all of these comments to the extent that they are still relevant under CMS's modified two-midnight policy.

All of these comments were provided to the agency prior to implementation of CMS's revised two-midnight policy. Hospitals around the country are currently implementing the revised policy and it appears to be working smoothly. We believe more time must pass before the full effect of

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those modifications is reflected in the publicly available data. In the meantime, however, the AHA continues to believe that hospitals must be appropriately and adequately reimbursed for the care they provide to beneficiaries, and we support efforts to better align payment rates to the resources used to furnish services. We encourage CMS to consider maintaining an ongoing dialogue with hospitals, physicians, beneficiaries, skilled nursing facilities and other stakeholders on this issue.

OUTLIER PAYMENTS

In order to estimate the proposed FY 2018 outlier fixed loss threshold, CMS inflated the charges in the FY 2016 MedPAR file by two years, from FYs 2016 to 2018. To estimate the one-year average annualized rate-of-change in charges per case for FY 2018, CMS proposes to compare 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) to the average covered charge per case from the second quarter of FY 2017 (Jan. 1, 2016 – Dec. 31, 2016). CMS finds a one-year rate-of-change of 5.1 percent (1.05074) or 10.4 percent (1.104055) over two years.

However, the publicly available FY 2016 MedPAR dataset contains claims only through Sept. 30, 2016. Therefore, we do not have access to claims in the first quarter of FY 2017 (Oct. 1 – Dec. 31, 2016) 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 2017 (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 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.

HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)

The HRRP imposes penalties of up to 3 percent of base inpatient PPS payments for having "excess" readmissions rates for selected conditions when compared to expected rates. CMS proposes only minor updates to the HRRP for FY 2018. For FY 2019 penalties, however, CMS proposes to implement the socioeconomic adjustment approach mandated by the 21st Century Cures Act of 2016.

PROPOSED FY 2018 PERFORMANCE PERIOD

The AHA is concerned that the proposed FY 2018 HRRP performance period – July 1, 2013 through June 30, 2016 – combines data collected under both ICD-9 and ICD-10. We urge CMS to provide further empirical analysis in the final rule demonstrating that measure reliability and validity are not compromised by using these two different coding systems. We also urge CMS to ensure that the ICD-10 versions of the measures in the HRRP are endorsed by the National Quality Forum (NQF).

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ICD codes are integral to collecting and calculating quality measures in CMS's programs, especially those measures like readmissions that are based solely on Medicare claims data. The codes define the patient population included in the measure, identify the outcome being measure (e.g., a readmission), and are used to perform risk adjustment. There are significant differences between ICD-9 a ICD-10 codes, and as a result, the agency is in the process of re-specifying measures previously collected in ICD-9 so the specifications work in an ICD-10 environment. However, as CMS revises the measures, it is imperative for the agency to examine how coding changes may affect measure performance, and to consider whether it is appropriate to combine or compare data collected using the different coding systems.

CMS appears to have undertaken a systematic process for re-specifying the HRRP measures in ICD-10, but we urge CMS to make the results of its underlying analyses public. The March 2017 readmissions technical specifications report on QualityNet describes how CMS's measure developer (Yale Center for Outcomes Research and Evaluation, or Yale/CORE) updated the code sets and accounted for differences between ICD-9 and ICD-10 data.¹ Among other analyses, Yale/CORE appears to have compared the measure rates for each hospital obtained using ICD-9 to ICD-10, and assessed how frequently hospitals were in the same quintile of measure performance. Based on these analyses, Yale/CORE suggests it updated the ICD-10 version of measure to ensure that "the performance of the risk adjustment model was as similar as possible to the performance of the previously-specified model, and that the hospital-level results were as similar as possible." However, the report does not share the underlying data showing how differently the ICD-9 and ICD-10 versions of the data may have performed. We believe making such data public would provide the field with greater confidence that combining ICD-9 and ICD-10 data is appropriate.

Furthermore, while it may be appropriate during this time of transition to make the results collected under ICD-9 and ICD-10 as consistent as possible, obtaining the same measure results should not be CMS's long-term measure development goal. ICD-10 codes provide more granular levels of detail about diagnoses and underlying conditions than ICD-9, which may help improve the reliability and accuracy of measure results. Once more data have been collected under ICD-10, CMS should examine ways of taking advantage of the broader set of codes to improve the readmission measures.

Lastly, the AHA strongly urges CMS to undertake analyses of any performance differences resulting from the transition to ICD-10 for *all* of the measures used in all of its public reporting and pay-for-performance programs. The results of those analyses should be made available publicly. Such data would help inform the field about any potential unintended biases and measure performance changes resulting from the use of the new codes. The data also would provide insight on whether it is actually appropriate to mix data collected using ICD-9 with data collected using ICD-10.

¹ See Yale-Center for Outcomes Research and Evaluation, 2017 Condition-Specific Measures Updates and Specifications Report: Hospital-Level 30-Day Risk-Standardized Readmission Measures, March 2017. The report is available on <u>QualityNet</u>.

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FY 2019 SOCIOECONOMIC ADJUSTMENT

For the FY 2019 HRRP, CMS proposes to implement the socioeconomic adjustment approach mandated by the 21st Century Cures Act. Starting in FY 2019, the agency must implement a budget-neutral methodology in which readmission penalties are based on hospitals' performance relative to other hospitals with a similar proportions of patients who are dually eligible for Medicare and Medicaid. CMS proposes to place each HRRP-eligible hospital into five peer groups (or quintiles) based on the proportion of Medicare fee-for-service (FFS) and Medicare Advantage (MA) dual-eligible patients it treats. The agency would then calculate each hospital's readmissions performance relative to the median of its quintile, applying a budget-neutrality modifier to ensure aggregate penalties across all hospitals are equivalent to the current approach. CMS has the authority to move away from a peer-grouping and use other risk-adjustment approaches after FY 2020.

The AHA applauds Congress for mandating a vitally important first step to improving the fairness of readmission penalties. Indeed, the AHA has long urged CMS to implement socioeconomic adjustment in the HRRP because of the significant body of research showing that readmissions performance is impacted by poverty, availability of resources and other social risk factors beyond hospitals' control. We believe the proposed approach will provide relief to many hospitals caring for large numbers of patients facing socioeconomic challenges.

However, the AHA also recommends that CMS take steps to improve the transparency of the proposed approach by making more data available on how it determines peer groupings. In addition, the 21st Century Cures Act affords CMS and all stakeholders the opportunity to improve the adjustment approach after FY 2020. This flexibility will be especially useful as the science of capturing and adjusting for socioeconomic and other social risk factors continues to evolve. We urge CMS to continually evaluate its adjustment approach, and to engage with the field on ensuring its adjustment approach keeps up with the science.

Improving Transparency. The AHA urges CMS to make more information available to the public on the Medicare Modernization Act (MMA) file it uses to determine dual-eligible patients. In the proposed rule, CMS suggests that the MMA file is the most accurate data source for identifying dual-eligible patients because states submit the data to CMS monthly. Unfortunately, the agency did not make any of the data from the file publicly available, making it more difficult to replicate and evaluate CMS's proposed approach. While we recognize there are patient privacy issues that might preclude CMS from sharing the entirety of the MMA file, we believe CMS could take several steps that appropriately balance the need to protect sensitive information with providing greater transparency:

• CMS should conduct a "dry run" of its finalized dual-eligible peer grouping approach in which hospitals are provided with confidential preview reports based on FY 2018 performance period data (that is, July 1, 2013 through Jun. 30, 2016). CMS has used dry runs when it plans to implement major changes to measures or methodology, and hospitals have appreciated the opportunity to use the reports to familiarize themselves with the calculation details and get a sense of their baseline performance. The dry run reports should provide estimates of the proportion of dual-eligible patients hospitals treat

based on the MMA file; the cut points for quintiles; the median excess readmission ratio for each condition in each quintile; and, if possible, an estimated payment adjustment factor.

• As a part of the FY 2019 proposed rule HRRP impact table, CMS should include information on each hospital's proportion and quintile of dual-eligible patients based on the MMA. We would encourage CMS to adopt this approach for all subsequent proposed and final rules.

<u>Keeping Up With Measurement Science</u>. The AHA urges CMS to view its proposed dualeligible peer grouping approach as the starting point in a longer term effort to refine and update its approach to socioeconomic adjustment. Indeed, we believe this is precisely what Congress envisioned when it provided CMS with the ability to implement a different socioeconomic adjustment approach in the HRRP after FY 2020. Going forward, CMS should consider both whether it should continue to use dual-eligibility as the adjustment variable, and whether to move from the current peer grouping approach to one in which it incorporates one or more socioeconomic variables into the risk-adjustment models of the HRRP measures (i.e., direct risk adjustment).

The ideal data for use in either peer groupings or direct risk adjustment should: 1) have a conceptual and statistical relationship to readmission rates; 2) use a readily available data source; and 3) be collected in a consistent way using standardized definitions. Dual-eligible status has all three of these characteristics, which is why we remain supportive of its use in adjusting readmission penalties.

Nevertheless, dual-eligible status also has important limitations as a risk adjustor. Most notably, there is variation in the generosity of state Medicaid program benefits and, in the long run, the adjustor may be sensitive to differences in state-level decisions to expand Medicaid. Dual-eligible status also may not fully reflect the poverty in communities. For example, it would not reflect the proportion of undocumented immigrants in communities, as such individuals would not be eligible for either Medicare or Medicaid.

The use of peer groups – in this case, quintiles based on the proportion of dual-eligible patients – obviates the need to change the risk-adjustment models for underlying quality measures. However, the use of peer groupings involves somewhat subjective choices about where to set the cut points of a particular group. Those hospitals at the upper end of one quintile and those at the lower end of the next quintile would have similar proportions of dual-eligible patients, but would be placed into different quintiles for performance comparison purposes. This is true regardless of the number of peer groups one chooses to use to evaluate performance.

The science of quality measurement is dynamic, and there are a number of options that we encourage CMS to evaluate for improving the risk adjustment approach. The NQF and National Academy of Medicine both have reports identifying the types of socioeconomic and social risk factors that may influence performance on readmissions. One particularly promising set of data are census-tract data on poverty rates and income. Census variables like poverty rate and income

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are readily available, and could be mapped to a hospital's patient population using zip codes. Moreover, census data could be a more direct measurement of poverty than dual-eligible status, and would not be sensitive to differences in state Medicaid programs.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM

As required by the ACA, CMS proposes to fund the FY 2018 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. CMS proposes to change the scoring approach for the cost/efficiency measure domain for FY 2021, add one new cost measure to the FY 2022 VBP program and update the claims-based patient safety indicator (PSI) measure for the FY 2023 program.

GENERAL VBP CONSIDERATIONS

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 score providers on the better of 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, we remain concerned about the overlap of measures between the VBP and Hospital-Acquired Conditions (HAC) Reduction programs given the different construction and goals of each program. 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. 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, but not both.

WEIGHTING OF MEASURES WITHIN EFFICIENCY/COST DOMAIN FOR FY 2021 The AHA continues to urge CMS not to use condition-specific payment measures in the VBP's efficiency and cost domain. We believe the overlap between the condition-specific measures and the Medicare spending per beneficiary (MSPB) measure may lead to mixed signals for hospitals. However, if CMS retains the condition-specific measures, the AHA urges the agency to weight them as 20 percent or less of the domain score.

Last year, CMS adopted two condition-specific episode-based payment measures (acute myocardial infarction and heart failure) for the FY 2021 VBP program, adding to the MSPB measure already in the program. As a result, CMS proposes how it will weight MSPB and the condition-specific measures in the program towards a hospital's efficiency/cost domain score. In general, MSPB would comprise 50 percent of a hospital's domain score, while the condition-specific measures, weighted equally, would comprise the other 50 percent of the score. The AHA believes that reducing the weight of the condition-specific measures to 20 percent, while not

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ideal, would somewhat mitigate the mixed signals hospitals may receive from the two sets of measures.

EPISODE-BASED PAYMENT MEASURES FOR FY 2022

The AHA does not support CMS's proposal to add the pneumonia condition-specific episode-based payment measures to the FY 2022 VBP. While we continue to 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 the MSPB measure may lead to unnecessary confusion among hospitals.

The designs of the MSPB and condition-specific measures are similar in that they capture riskadjusted 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 pneumonia. 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 for hospitals to score well in the resource use category of VBP.

Yet, the overlap between MSPB and the condition-specific measure may 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 MedPAC has noted, not all hospitals will have sufficient volume to be scored on each condition-specific payment measure, and the statistical reliability of conditionspecific measures will likely be far weaker than the MSPB measure. As a result, the conditionspecific measures would provide a less useful picture of performance.

Finally, 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 were reviewed in 2016 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 major 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.

PSI 90 MEASURE CHANGES

Starting with the FY 2019 VBP program, CMS proposes to remove the current ICD-9 based version of the claims-based PSI composite because it does not yet have the software to calculate

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it in ICD-10. However, CMS would reintroduce a revised version of the PSI composite based on ICD-10 data as part of the FY 2023 VBP program. In addition to being based on ICD-10 data, the updated composite would include revisions to the underlying component PSI indicators.

The AHA continues to oppose the use of any version of the PSI measure in hospital payfor-performance programs and urges CMS to simply remove the measure from the VBP program altogether. Furthermore, CMS's proposed removing and then reintroducing PSI measures only creates additional confusion. The PSI indicators fail to provide accurate, meaningful data on hospital safety performance.

We appreciate that the revised PSI 90 measure proposed for FY 2023 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 limited for use in public reporting and pay-for-performance applications.

Examples of the inconsistency of the results of PSI component measures with clinical reality abound.² 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.³ And another recent study showed that performance on the PSI measures is more a

² 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 in 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.

³ 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.

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function of bed size than of underlying quality performance.⁴ 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.⁵

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 in the December 2016 update of the Agency for Healthcare Research and Quality's HAC scorecard, a composite measure of 28 different HACs fell nationwide by 21 percent between 2010 and 2015, from 145 to 115 per 1,000 discharges. The steadfast efforts of hospitals to make care safer also have led to 125,000 fewer deaths, and saved nearly \$28 billion in health care costs.⁶ 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. 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.

For these reasons, the AHA applauds CMS for exploring ways to improve the fairness of the HAC Reduction Program within its statutory authority. For example, we are pleased that CMS is considering how to respond to the findings of the Assistant Secretary for Planning and Evaluation's (ASPE) that safety-net hospitals are more likely to be penalized under the HAC program. The linkage between socioeconomic factors and performance in the HAC Program is complex because the program's measures – healthcare-associated infections (HAIs) and serious safety events – largely reflect the actions taken within a hospital. This is in contrast to other outcome measures such as readmissions, cost or patient experience, where

⁴ Koenig L et al. Complication rates, hospital size and bias in the CMS Hospital-Acquired Condition Reduction Program. American Journal of Healthcare Quality. Dec. 19, 2016.

⁵ See <u>http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf</u>

⁶ Source: Agency for Healthcare Research and Quality. Saving Lives and Saving Money: Hospital-Acquired Conditions Update. Available at: <u>https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html</u>

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socioeconomic factors like poverty and access issues can clearly affect outcomes. Thus, socioeconomic adjustment for the measures in the HAC program may be unwarranted.

However, we agree with the findings of the ASPE report that patient disability and complexity have a significant impact on patient outcomes, and may not be adequately captured in the HAC program's measures. For example, patients with significant disabilities may be more susceptible to infections, and it would be important that the HAI measures adequately capture those risk factors. We also encourage CMS to examine whether there are any broader community environmental factors that may impact a patient's risk for infections or other complications. For example, poorer communities also can have environmental pollution, reduced access to resources to manage chronic conditions, food desserts that impact nutrition and so forth.

The AHA also urges CMS to consider other actions to improve the HAC Reduction

Program. As noted in the VBP section of this letter, the AHA has long recommended that CMS eliminate the measure overlap between the HAC and VBP programs to reduce the likelihood of mixed signals on performance. **We also urge CMS to phase out the PSI 90 composite measure.** 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.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Hospitals are required to report measures and meet the administrative requirements of the IQR program to avoid having their annual market basket update 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 the FY 2019 IQR program, CMS proposes to reduce the number of electronic clinical quality measures (eCQMs) hospitals must report and to shorten the data reporting period. CMS also proposes to re-word the pain management questions in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey beginning with surveys in 2018. In addition, the agency proposes the voluntary reporting of a "hybrid" hospital-wide 30-day readmission measure in which hospitals would submit certain data elements from EHRs to supplement the claims data used to calculate the measure.

STREAMLINING AND FOCUSING THE IQR PROGRAM

The AHA applauds CMS for not proposing any new mandatory measures for the IQR program. However, opportunities remain for ensuring the IQR achieves its foundational goals – that is, to provide the public and hospitals with *accurate* and *comparable*

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information for improving quality on *the most important* areas. The AHA stands ready to work with CMS and all other stakeholders to streamline and focus the measures in the IQR and all other measurement programs on "measures that matter."

To provide a starting point for this vital effort, the AHA has engaged hospital leaders in efforts to identify high priority hospital measure topics. In 2014, the AHA Board of Trustees approved a list of 11 hospital measurement priority areas. That list was updated in July 2016 and is provided below.

AHA-identified Priority Measurement Areas

- 1. Patient Safety Outcomes
 - Harm Rates
 - Infection Rates
 - Medication Errors
- 2. Readmission Rates
- 3. Risk-adjusted Mortality
- 4. Effective Patient Transitions
- 5. Diabetes Control
- 6. Obesity
- 7. Adherence to Guidelines for Commonly Overused Procedures
- 8. End-of-Life Care According to Preferences
- 9. Cost per Case or Episode of Care
- 10. Behavioral Health
- 11. Patient Experience of Care / Patient Reported Outcomes of Care

Hospital leaders believe using well-designed measures in these 11 areas in national measurement programs would most effectively promote better outcomes and better health for the patients they serve. We also note that these 11 priority measurement areas are well aligned with the 15 "core measure" topics identified by the National Academy of Medicine's *Vital Signs* report. The *Vital Signs* report also urged that multiple stakeholders come together to identify priority measurement topics and use them to align the efforts of health care providers, payers and communities to drive greater improvement in quality.

However, having measures addressing the right topics is only part of the success – the particular measures also must be methodologically sound, reliable, accurate and actionable. Moreover, hospital leaders also understand the list of priority areas will evolve over time, "retiring" areas where sufficient progress has been achieved and replacing them with new core areas that address emerging issues. To provide a strategic grounding for ongoing discussions about measurement priorities and specific measures, the AHA Board also approved a list of seven strategic principles for selecting measures that was developed with extensive input of hospital leaders.

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AHA Principles for Measures to be Included in Hospital Payment and Performance Systems

- 1. Provider behavior must influence the outcome(s) being measured;
- 2. Measures must have strong evidence that their use will lead to better care and outcomes;
- 3. Measures should be used in programs only if they reveal meaningful differences in performance across providers, although some may be retained or re-introduced to reaffirm their importance and verify continued high levels of importance;
- 4. The measures should be administratively simple to collect and report, and to the greatest extent possible, be derived from electronic health records data;
- 5. Measures should seek to align the efforts of hospitals, physicians and others along the care continuum, and align with the data collection efforts of the other providers;
- 6. Measures should align across public and private payers to reduce unnecessary data collection and reporting efforts; and
- 7. Risk adjustment must be rigorous and account for all factors beyond the control of providers, including socioeconomic factors where appropriate. In addition, adjustment methodologies should be published and fully transparent.

To provide a "proof of concept" of how the 11 priorities and the measure selection principles for selection might be applied, AHA staff reviewed the approximately 90 measures in CMS's inpatient and outpatient quality reporting programs. While some of the extant measures are inline with these principles and the priority areas that were identified, most were not. The attached appendix provides more detail on the measures the AHA recommends for retention, and how they map to our 11 measurement priority areas. With respect to the IQR, the AHA believes that 25 measures would be best for retention, with many of them needing significant modifications to improve their reliability and accuracy.

UPDATED HCAHPS PAIN MANAGEMENT QUESTIONS

For FY 2020 payment determination and onward, CMS proposes to change the existing painrelated questions in the HCAHPS survey. A composite measure of three questions that emphasize communication about pain would become part of the survey and be publicly reported beginning in October 2019. Specifically, the proposed questions ask:

- "During this hospital stay, did you have any pain?"
- "During this hospital stay, how often did hospital staff talk with you about how much pain you had?" and
- "During this hospital stay, how often did hospital staff talk with you about how to treat your pain?"

Pain management is an important part of patient experience and the healing process. Undertreatment of pain can have a significant impact on individuals' quality of life even during a shortterm hospital stay. Thus, the AHA believes that the HCAHPS survey should include a component on pain management. Ms. Seema Verma June 13, 2017 Page 30 of 51

We commend CMS for its responsiveness to stakeholder concerns about the current pain-related questions. In light of opioid epidemic, we wholeheartedly agreed with CMS's decision last year to remove the pain questions from the VBP calculations. We appreciate that the agency has worked to develop and test new questions that focus less on pharmacotherapy to address pain.

The urgency and tragic outcomes associated with the opioid crisis necessitate careful review of the newly proposed pain questions. **CMS should complete the multi-stakeholder, consensus-based review process for this composite measure before incorporating it into the HCAHPS survey and the IQR program.** Although the law envisions a robust evaluation of measures before their inclusion in pay-for-reporting programs, a comprehensive analysis has yet to occur for this measure due to the unavailability of testing data. The MAP briefly discussed the proposed questions in December 2016, but it recommended that they be refined and resubmitted prior to rulemaking. Additionally, these questions have not been reviewed or endorsed by the NQF. We note that the testing results were not included in the proposed rule, further complicating the ability of stakeholders to provide comprehensive feedback on the measure through the notice-and-comment rulemaking process.

At the very least, the MAP and NQF should have the opportunity to examine the testing data on reliability and validity, which could help them understand:

- how the questions will be perceived by patients and providers;
- whether CMS's proposal will ultimately provide accurate data about pain management or improve outcomes;
- whether the new composite could potentially have unintended consequences; and
- how these questions compare to others CMS may have tested, including further explanation about the incorporation of the term "how often" in two of the questions.

Given the compelling need for a more comprehensive review of the proposed pain-related questions, we ask CMS not to finalize the proposed Communication About Pain composite at this time. CMS should give the MAP and NQF time to review and deliberate the appropriateness of the new questions for the long-term.

We also urge CMS to do more to address the current pain questions in the HCAHPS

survey. De-coupling the current pain management questions from VBP payments was a vitally important step to mitigating the potential pressure to use opioids to manage pain. However, concern remains about the negative unintended consequences of publicly reporting the current pain management composite. Thus, the AHA recommends that CMS suspend the reporting of individual facility performance on the pain management composite on *Hospital Compare*. This approach would enable hospitals to use any collected HCAHPS survey data to inform their internal pain management efforts if they choose to, but without the pressure of implementing pharmacological interventions that may be created from using the current questions for public accountability purposes.

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UPDATED STROKE MORTALITY MEASURE FOR FY 2023

The AHA applauds CMS for proposing to incorporate an adjustment for stroke severity into the stroke mortality measure. However, we urge CMS not to finalize the revised measure until it has been endorsed by the NQF. Given that stroke severity is perhaps the most important predictor of stroke outcomes, the AHA and numerous other stakeholders have long urged that CMS incorporate an adjustment for stroke severity into its 30-day stroke mortality measure. However, because the field only transitioned to ICD-10 on Oct. 1, 2015, CMS has not yet had the opportunity to complete field testing of the measure using the new codes. We urge that such testing be completed, and that the measure changes are reviewed and endorsed by the NQF prior to its inclusion in the IQR.

VOLUNTARY HYBRID READMISSIONS MEASURE

While the AHA does not object to the voluntary reporting of the proposed hybrid readmission measure, we urge CMS not to set any date certain for either mandatory submission or public reporting of the measure. This hybrid measure combines claims data with certain data abstracted from EHRs to calculate performance. CMS has long been interested in moving toward the use of EHRs to collect and submit quality data, and views "hybrid" measures combining EHR-derived data with claims data as a way of improving the risk adjustment of outcome measures. This is because EHR data has the potential to include more precise clinical information than using claims alone.

The AHA agrees with the potential value of hybrid measures. Given the continued concerns about the extent to which eCQMs provide accurate and reliable data, and the extent to which existing EHR products can support all measure reporting requirements, we also support CMS's decision not to mandate the collection of the hybrid measure.

However, CMS should not make any proposals to mandate the hybrid measure until it has reviewed the experience of hospitals submitting the measure on a voluntary basis. To make the reporting of this or any other "hybrid" measure viable in the long run, CMS will need the input of the field on the feasibility of abstracting the EHR data and the accuracy of measure results. CMS also will need experience to set appropriate minimum data completeness standards, and to ensure its own systems (such as the QualityNet secure portal) have sufficient capacity to accept eCQM data. Many hospitals reported significant technical issues in submitting eCQM data in early 2017 and found they were unable to run reports verifying that their data had been appropriately submitted to CMS. These technical issues would need to be resolved

Reporting of Data Stratified by Socioeconomic Factors

The AHA strongly supports efforts to identify and eliminate health care disparities and appreciates CMS's interest in providing data to hospitals and the public to inform these efforts. We urge CMS to provide data in a way that minimizes the risk of providing divergent signals to hospitals.

CMS is considering reporting the pneumonia readmission and mortality measure performance for each hospital stratified by dual-eligible status. CMS would provide confidential feedback

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reports (perhaps in 2018) prior to public reporting. To stratify the data, CMS would use one of two approaches:

- Approach 1 Reporting a measure rate adjusted for the proportion of dual-eligible patients hospitals treat alongside the unadjusted rate. This approach would require CMS to change the underlying risk-adjustment model of the pneumonia and mortality measures; or
- Approach 2 Report two rates for each measure one for dual-eligible patients and one for non-dual eligible patients. CMS would not change the underlying risk-adjustment approach.

The AHA encourages CMS to use approach 2 for now, as we believe it minimizes the risk of mixed signals on measure performance. CMS also should align its stratification approach with the socioeconomic adjustment methodology in the HRRP. The AHA has long believed that directly adjusting the readmission and mortality measures for socioeconomic factors is warranted, and so we understand the appeal of the first approach. However, this approach would be inconsistent with the socioeconomic adjustment approach that will be used in the HRRP starting in FY 2019, in which measure rates are not adjusted and hospitals are placed into quintiles based on the proportion of dual-eligible patients they treat. Furthermore, the risk-adjustment approach CMS proposed does not appear to have been reviewed by the NQF, and we simply do not know how the revised risk adjustment model would perform.

Approach 2 also is not perfectly aligned with the socioeconomic adjustment methodology in the HRRP. However, it would provide hospitals with useful information about how the measure performance varies between the dual eligible and non dual-eligible patient populations. It also would avoid providing hospitals with overall measure performance score that they would not recognize in their readmissions penalty. Should CMS choose to modify the HRRP adjustment approach and directly adjust measures in the program, then CMS could consider using stratification in approach 1.

ECQMS IN THE IQR PROGRAM

For the FY 2019 and the FY 2020 IQR program, CMS proposes to decrease the number of eCQMs for which hospitals must submit data and proposes to decrease the number of calendar quarters for which hospitals are required to submit data.

eCQM Reporting for the FY2019 IQR Program. For FY 2019, CMS proposes that hospitals electronically submit data for a minimum of six of the 15 eCQMs available for the IQR program, a reduction from the current FY 2019 requirement to submit data for eight eCQMs. CMS also proposes that hospitals report on two self-selected calendar quarters of data, a reduction from the current requirement to report four quarters of data. The AHA supports the proposal for FY 2019 to decrease the number of eCQMs for which hospitals must submit data and a reduction in the number of calendar quarters for which data is reported and urges CMS to finalize additional flexibility for FY 2019. We recommend that CMS retain the FY 2018 Ms. Seema Verma June 13, 2017 Page 33 of 51

reporting requirement, permitting hospitals to submit data for a minimum of four eCQMs and do so for a minimum of one self-selected calendar quarter. Maintaining the FY 2018 eCQM reporting requirements will provide hospitals, certified health IT vendors and CMS with additional time to work on measure specification, data validation, technology readiness and system issues. Failure to successfully electronically submit eCQMs places hospitals at risk for an annual payment reduction equal to the applicable market basket update in a future payment year (25 percent reduction under the IQR program and 75 percent reduction under Medicare EHR Incentive Program). Additionally, the AHA recommends that CMS finalize the FY 2019 requirements as soon as possible to provide clarity for hospitals concerning the current CY 2017 reporting year requirements.

eCQM Reporting for FY 2020 IQR Program. For FY 2020, CMS proposes that hospitals electronically submit data for a minimum of six eCQMs of the 15 eCQMs available for Hospital IQR, a reduction from the current FY 2020 requirement to submit data for eight eCQMs. CMS also proposes that hospitals report on the first three calendar quarters of CY 2018, a reduction from the current FY 2020 requirement to report four quarters of data. The AHA recommends that CMS retain the FY 2018 reporting requirement, permitting hospitals to submit data for a minimum of four eCQMs and do so for a minimum of one self-selected calendar quarter. While the AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting, there remain far too many questions about eCQM for CMS to mandate an expanded reporting requirement in the IQR for FY 2020. The long-term challenges associated with eCQMs – accuracy, reliability and efficiency when compared to manual abstraction and the value delivered to the organization when compared to outcome based measures - will not be resolved by the start of or during the CY 2018 reporting period. The entire eCQM process - from measure specifications updates through data file submission - must mature and provide evidence that eCQMs are feasible and valid measures of the quality of care before a mandatory increase in eCQM data reporting requirements.

Additionally, a reporting period of one calendar quarter will align the eCQM reporting requirement in the IQR with a 90-day reporting period proposed for the Medicare and Medicaid EHR Incentive Programs for CY 2018. Hospitals will be transitioning to the 2015 edition of certified EHR technology, and the process to transition to a new edition or a new technology takes 19 months to conduct safely. At this time, the certified health IT product list reflects a scarcity of available 2015 edition certified EHRs for the inpatient setting, which makes data gathering and reporting eCQMs for the first three calendar quarters of 2018 extremely unlikely.

Hospital experience with the use of EHRs for eCQM reporting indicates significant work has occurred, yet more work is necessary before eCQMs represent data that is reliable and valid for use in hospital quality reporting programs. **The AHA urges CMS to help build the knowledge base about eCQM reporting by collaborating with hospitals in the identification and sharing of successful practices in data mapping, data validation, and test production file submission**. The AHA also recommends that CMS address the diverse challenges to successful eCQM reporting:

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Inability of CMS QualityNet Security Portal to Manage the Size of Incoming ORDA-I files and Requests for Validation Reports. Hospitals and health systems reported several system issues that challenge their successful eCQM submissions for the CY 2016 reporting period. These issues included QRDA-I files that are too large to be accepted in the QualityNet secure portal, system down time because of the number of hospitals attempting to access the portal, and the receipt of vague error messages that required assistance from QualityNet or the QualityNet contractor to understand. Hospitals also reported vendor issues, including certified technology that supported test file submission but not production file submission and receipt of last minute software patches that yield inaccurate measure data. Additionally, some hospitals that electronically submitted eCQMs and attested to meaningful use indicated their meaningful use attestation submission status shifted from "in progress" to "pending eReporting" and back to "in progress" without any action on their part. A reversion in submission status for hospitals with a documented attestation and a submission receipt created concern, as hospitals with an "in progress" status could be considered unsuccessful in meeting meaningful use and, therefore, subject to financial penalties. Impacted hospitals resubmitted eCQM data to the already taxed QualityNet secure portal. We appreciated the extraordinary measures CMS took to improve the functioning of its systems, including temporarily disabling access to eCQM submission summary and performance summary reports at the QualityNet secure portal. The AHA urges CMS to improve the capacity of the OualityNet system to receive ORDA-I files and send submission summary and performance reports before increasing the number of ORDA-I data files that hospitals must submit.

Ensure that EHR Vendors Support any Proposed Requirement that Hospitals Use EHRs Certified to All eCQMs. CMS proposes to require hospitals to have their EHR technology certified to all eCQMs that are available for hospitals to report in order to meet the eCQM reporting requirements. This would be applicable for the CYs 2017 and 2018 reporting periods and applicable for 2014 edition and 2015 edition certified technology. **The AHA urges CMS not to require hospitals to have 2014 edition EHRs that are certified to support all of the eCQMs available for IQR reporting for FY 2019.** This places an unreasonable burden on hospitals to identify health IT vendor solutions solely because the certified EHRs do not support all reporting options within this CMS program. We recommend that CMS work with the Office of the National Coordinator for Health Information Technology (ONC) and health IT vendors to ensure that the 2015 edition certified EHRs are capable of supporting hospitals eCQM reporting, including reporting any of the eCQMs that are available to report in IQR.

Refrain from Adding New eCQMs in the IQR. CMS seeks public input of the possible addition of 13 new eCQMs in the IQR for reporting in a future year. CMS expresses concern that the current number of eCQMs does not offer the variety of measures that hospitals might wish to report based on their patient population. However, during the MAP consideration of the proposed eCQMs, endorsement for inclusion in the IQR was not provided and recommendations were made for additional evidence sufficient to establish clinical importance and links to improved patient outcomes. The AHA concurs with the MAP's recommendations and urges CMS to consider additional evidence from the measure developers and the appropriateness of the measures for inpatient reporting before proposing eCQMs for the IQR.

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Communicate the Future Plans for eCQMs Including Public Reporting of eCQMs. Hospitals that report eCQMs also are reporting the manually chart-abstracted counterpart measures. As a result, they have processes and documentation workflows for chart-abstracted measures and eCQM guidelines. To minimize the potential interruption in vetted and quality workflows, hospitals are spending significant time in reviewing and including flexibility in data collection. However, this process is time intensive, particularly as eCQM measure specifications can change in substantive ways from one year to the next and multi-disciplinary teams are engaged in the data mapping and data capture. Given limited time and resources, hospitals would benefit from the ability to focus on measures expected to be retained and publically reported.

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

IPFQR MEASURE-RELATED CHANGES

To align with other quality reporting programs, CMS proposes to adopt specific factors to consider in removing or retaining IPFQR measures, as well as criteria for determining when a measure is "topped-out." The AHA agrees with the list of measure removal factors found on page 20122 of <u>the rule</u>. However, we ask CMS to clarify or add that a measure also will be removed if its implementation puts patients at greater risk of harm. Further, we urge CMS to add an additional factor, "Measure has not been specified or tested in the IPF setting." The AHA believes that measures should only be included in CMS pay-for-reporting and pay-for-performance programs when they have been specified for, and tested in, the specific site of service for which they are proposed. Without fully vetting a measure for use in a proposed care setting, CMS risks increasing the burden and confusion associated with its implementation. Further, the agency risks creating a new requirement for collection of data that is ultimately inaccurate in evaluating facility-level performance.

The AHA does not support the proposed retention factors to consider after a measure has met one or more of the removal factors. CMS proposes to retain a measure that has met one or more of the removal factors when it aligns with Health and Human Services (HHS)/CMS policy goals or programs or supports the move to e-measures. We do not believe these are strong enough reasons to justify keeping measures that no longer align with clinical guidelines, lead to negative unintended consequences, are not feasible to implement, do not lead to better outcomes or produce good data, or can be replaced by a better measure. On rare occasion, CMS may be able to articulate a reason to retain a measure that has met one or more of the removal criteria. But we do not believe the proposed factors are sufficient in most cases.

The AHA supports the proposed criteria for determining that a measure is "topped-out." That criteria states that a measure is "topped-out" if there is statistically indistinguishable performance at the 75th and 90th percentiles and the truncated coefficient of variation is less than or equal to 0.10.

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NEW QUALITY MEASURE

The AHA does not support CMS's proposal to add the measure, Medication Continuation following Inpatient Psychiatric Discharge, for the FY 2020 payment determination and onward. This is a Medicare FFS claims-based measure that identifies whether patients admitted to IPFs with diagnoses of major depressive disorder (MDD), schizophrenia or bipolar disorder filled at least one evidence-based outpatient medication within two days prior to discharge through 30 days post-discharge. At the very least, CMS should not finalize this measure unless and until it has been recommended for inclusion in the IPFQR program by the MAP and endorsed by the NQF.

Medication adherence is critical to ensuring positive outcomes, and we agree that hospitals have an important role to play in ensuring that patients can obtain, and actually do take, their postdischarge medications. Hospitals can provide patient education, work with patients and families to create a plan for how they will have their prescriptions filled after discharge, ensure medications are included on the patient's formulary, or potentially fill a prescription for the patient before he or she leaves the hospital.

However, we do not believe that a measure assessing whether patients have their prescriptions filled within a certain time period, including 30 days *post-discharge*, qualifies a hospital (facility) measure. Hospitals can try to influence, but do not have complete control over, events that take place after the inpatient stay. Other influences include Medicare's own rules for covering prescription drugs, the ease with which the patient can access a pharmacy, the patient's living situation, and even other clinicians who might see the patient post discharge and prescribe a different medication regimen. We understand CMS's desire to ensure hospitals are doing as much as possible to promote medication adherence. But we do not believe this measure is the correct one for that purpose. It does not answer the question, "Did the hospital take evidence-based steps to promote post-discharge medication adherence?" A measure could be developed that assesses hospitals on specific, evidence-based facility actions.

Further, to some extent the proposed measure uses the filling of a prescription as a proxy for a patient actually taking his or her medication, which is the ultimate goal. CMS should carefully evaluate the evidence as to whether patients who fill prescriptions within 30 days actually do take their medications and have better outcomes. We note that, at the NQF Behavioral Health Committee in-person meeting in February, 78 percent of members gave this measure only a moderate score for validity.

We agree that one way to ensure that prescriptions for post-discharge medications are filled is for hospitals to fill them before the patient leaves. However, at the NQF Behavioral Health Committee in-person meeting, it was noted that that these medications must come from an ambulatory pharmacy. To the extent that CMS wishes to drive practice change and incentivize hospitals to fill prescriptions before discharge, the agency must first gain an understanding of how many hospitals/IPFs have an outpatient pharmacy, or how feasible it is for hospitals to set up innovative programs with local retail pharmacies. The AHA does not track how many hospitals have outpatient pharmacies but would be willing to work further with CMS to gauge
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the potential of these interventions. Alternatively, CMS could allow hospitals to fill discharge medications under Part A.

ADDITIONAL PROPOSALS

We support CMS's proposed changes related to the data submission periods, Notice of Participation and withdrawals, and the Extraordinary Circumstances Exceptions policy.

CHANGES TO MS-DRG CLASSIFICATIONS

As of Oct. 1, 2015 providers report diagnoses and procedures for hospital inpatient services using the International Classification of Diseases 10th Revision (ICD-10) coding system, which replaces ICD-9-CM and now, serves as the base code set for Medicare's MS-DRGs. With the FY 2016 inpatient PPS/LTCH PPS final rule, CMS implemented ICD-10 MS-DRGs Version 33 as the replacement to ICD-9-CM based MS-DRGs Version 32.

Generally, the AHA supports most of CMS's proposed changes to MS-DRG classifications. The changes seem reasonable given the data associated with the ICD-10-CM/PCS codes and information provided. There are however a few exceptions as noted below.

• Major Diagnostic Category (MDC) 1 (Diseases and Disorders of the Nervous System) *Precerebral Occlusion or Transient Ischemic Attack with Thrombolytic*. CMS proposes to add ICD-10-CM diagnosis codes currently assigned to MS-DRGs 067 and 068 (Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC, respectively) and MS-DRG 069 (Transient Ischemia) to the GROUPER logic for MS-DRGs 061, 062 and 063 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) when those conditions are sequenced as the principal diagnosis and reported with an ICD-10-PCS procedure code describing use of a thrombolytic agent (for example, tPA). CMS also is retitling MS-DRGs 061, 062 and 063 as "Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC and without CC/MCC" respectively, and MS-DRG 069 as "Transient Ischemia without Thrombolytic."

The change is needed to better account for the subset of patients who were successfully treated with tPA to prevent a stroke, to identify the increase use of thrombolytics at the onset of symptoms of a stroke, to further encourage appropriate physician documentation for a precerebral occlusion or transient ischemic attack when patients are treated with tPA, and to reflect more appropriate payment for the resources involved in evaluating and treating these patients.

We agree with the above changes for FY 2018. However, for future rulemaking, we ask that CMS create new MS-DRGs specifically to distinguish acute ischemic strokes from precerebral occlusions and transient ischemia, with and without thrombolytics, and, with and without MCC/CC respectively.

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• MDC 14 (Pregnancy, Childbirth and the Puerperium)

Vaginal Delivery and Complicating Diagnoses. We agree that the MS-DRG logic involving a vaginal delivery under MDC 14 is technically complex. In response to CMS's solicitation of public comments on diagnosis and procedure codes for consideration for possible further refinement of MS-DRGs 767, 768, 774, 775 and 781, the AHA plans on convening a workgroup of member hospitals and will provide a separate comment letter since this is outside of the inpatient PPS comment period deadline.

• MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services): Updates to MS-DRGs 945 and 946 (Rehabilitation with and without CC/MCC, Respectively)

In our FY 2016 inpatient PPS comment letter, the AHA requested CMS 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. This is mostly due to changes in the ICD-10-CM codes and the corresponding guidelines for admissions/encounters for rehabilitation. 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). 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, then the case is not assigned to MS-DRGs 945 or 946. Instead it is assigned to an MS-DRG within the MDC where the principal diagnosis code is found.

CMS's analysis for this proposed rule indicates there was a decrease of 3,320 MS-DRG 945 cases (from 3,991 to 671) from FY 2015, when submitting claims with ICD-9-CM codes, to FY 2016, when using ICD-10 codes. There was a decrease of 1,027 MS-DRG 946 cases (from 1,184 to 157) from FY 2015 to FY 2016. The average length of stay increased 0.5 days (from 10.3 to 10.8 days) for MS-DRG 945 and decreased 0.7 days (from 8.0 to 7.3 days) for MS-DRG 946. CMS also examined possible MS-DRGs where these cases may have been assigned in FY 2016 based on increases in the number of claims. Because there is not a diagnosis code which would indicate if the admissions were for rehabilitation services, CMS was unable to determine if these were cases admitted for rehabilitation that moved from MS-DRGs 945 and 946 because of the lack of a code for encounter for rehabilitation, or if there was simply a change in the number of cases.

In June 2016, the AHA submitted a proposal to the Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, the federal agency responsible for the creation and maintenance of the ICD-10-CM code set, 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. The proposal was discussed at the March 7-8, 2017 meeting of the ICD-10 Coordination and Maintenance Committee. The CDC has made no decision yet on our proposal.

It is important to replicate the ICD-9-CM MS-DRG logic for MS-DRGs 945 and 946 using ICD-10 MS-DRG logic. Since the adoption of the ICD-10 coding, patients previously grouped to MS-DRGs 945 and 946 using ICD-9-CM are now affecting case-mix and

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outcomes for several MDCs where the principal diagnosis code for the medical condition that required rehabilitation. It is not simply a problem affecting Medicare payments, but important assumptions and interpretations regarding patient populations for commercial payers, managed care contracting, patient safety and quality indicators that use MS-DRGs. For example, all diagnosis codes from ICD-10-CM category I69, Sequelae of cerebrovascular disease, group to MS-DRG 056-057 Degenerative Nervous System disorders. Such MS-DRG groupings result in overpayment for rehabilitation services for any new or existing inpatient rehabilitation facility (IRF) paid by Medicare under the MS-DRG system that does not qualify for the IRF PPS. Many hospitals employ less-than-perfect manual workarounds to address the DRG shift and reproduce the rehabilitation DRGs for Medicaid, commercial and Workmen's Compensation cases, which is extremely burdensome.

If a single new ICD-10-CM diagnosis code for encounter for rehabilitation therapy is approved, we recommend that CMS consider adding the new code as a principal diagnosis to the MS-DRG logic for MS-DRGs 945 and 946. On the other hand, should the CDC decide not to grant the unique ICD-10-CM diagnosis code, we urge CMS to consider assembling a technical advisory panel (TEP) made up of stakeholders, such as rehabilitation providers and other representation to conduct an evaluation and recommend options to improve the DRG logic and changes for FY 2019.

<u>Medicare Code Editor (MCE) Changes</u>. After implementation of the ICD-10 MCE Version 34, CMS received several requests to examine specific code edit lists that the requestors believed were incorrect and affected claims processing functions.

Age Conflict Edit. This edit detects inconsistencies between a patient's age and any diagnosis on the patient's record. CMS received a request for clarification regarding the overlapping age ranges for Pediatric (age 0 to 17 years inclusive) and Adult (age 15 to 124 years inclusive) patients. CMS noted that the age ranges defined within the Age Conflict edits were established with the implementation of the inpatient PPS. The adult age range includes the minimum age of 15 years for those patients who are declared emancipated minors. CMS also noted that it has not provided coding advice in rulemaking with respect to policy. CMS collaborates with the AHA through the *Coding Clinic for ICD-10-CM and ICD-10-PCS* to promote proper coding. We are grateful for the long-standing collaboration with CMS to promote accurate coding through *Coding Clinic*. However, while *Coding Clinic* addresses proper coding, it cannot address issues related to payer-specific edits or definitions, such as this one.

Sex Conflict Edit. This edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record. We have no objections to the proposed new edits for Diagnoses for Males Only or Diagnoses for Female Only. **However, we recommend that CMS consider developing a process for handling claims for transgender patients as the sex conflict edits require cumbersome workarounds to bypass the edits for this community.**

• Operating Room Procedures to Non-Operating Room Procedures. For FY 2018 CMS continues to address the recommendations for changing the designation of specific ICD-10-PCS procedure codes. CMS proposes to change the designation of 867 ICD-10-PCS

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procedure codes from operating room (O.R.) to non-O.R. procedures. CMS further states that the procedures generally would not require the resources of an operating room and can be performed at bedside.

We are concerned with the large number of broad changes made to the list of procedures without having a more in-depth analysis of the impact to specific DRGs. It is imperative that more detailed analysis and research be conducted by CMS prior to implementing all of the proposals involving changing the O.R. to non-O.R. designation. Many of the FY 2018 proposed changes go beyond last year's changes when the changes from O.R. to non-O.R. were carried out in order to replicate the logic of the ICD-9-CM MS-DRG Grouper. For example, some of the FY 2018 proposed changes mapped back to ICD-9-CM codes recognized as O.R. procedures. The procedures may have initially mapped to surgical DRGs based on the intensity of the procedure and risk to the patient.

<u>Percutaneous Transfusion</u>. We oppose the shift of 20 autologous, nonautologous, bone marrow and stem cell transplants, and embryonic stem cell transplants from O.R. to non-O.R. procedures unless they retain their pre-MDC status as transplants. Neither the patients requiring these transplants nor the resources required for these transplants, have changed. Therefore, reassignment of these codes from MS-DRGs 014 (Allogeneic Bone Marrow Transplant), 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC, and without CC/MCC respectively) into as many as 70 different MS-DRGs based on the principal diagnosis is inappropriate. Such drastic changes result in significantly lower reimbursement simply based on a change in the codes.

While we agree that these procedures are performed at bedside, changing their status based of a change in the coding nomenclature is inappropriate. It appears that only the codes for percutaneous transfusion of bone marrow and stem cells have been proposed for the change thus leaving only the codes with open approach in MS-DRGs 016 and 017. The open approach codes exist for this range of ICD-10-PCS codes for the sake of parity to provide all possible approach options. However, clinically, these transfusions would rarely, if ever, be performed using the open approach. Thus, removing the proposed codes in effect leaves behind the corresponding codes for procedures that are not performed thereby making MS-DRGs 014, 015 and 016 less clinically meaningful. As a result, we strongly urge CMS to reconsider this proposal as the significantly lower reimbursement rates will certainly affect patient access to care.

REDUCTIONS IN MS-DRG PAYMENTS

In the proposed rule, CMS proposes a number of significant reductions to the relative weights of certain MS-DRGs, which could potentially limit access to these necessary services for Medicare beneficiaries. For example, CMS has proposed a 34.8 percent reduction in the relative weight for MS-DRG 215 for FY 2018. This would have a significant negative impact on hospitals which care for critically ill cardiovascular patients who require the implantation of a heart pump in the operating room or cardiac catheterization laboratory after heart attacks or decompensating heart failure. CMS also proposed a reduction of between 20-25 percent for several gastrointestinal-

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related DRGs, including MS-DRGs 326, 327, 332, 333, 334, 344 and 346. The AHA has previously urged the agency to phase in substantial fluctuations in payment rates in order to promote predictability and reliability for the hospital field. We urge CMS to consider such an approach in this situation or when any MS-DRG is drastically reduced in a given year.

REQUEST FOR INFORMATION ON PHYSICIAN-OWNED HOSPITALS

CMS requested feedback from stakeholders on "the appropriate role of physician-owned hospitals in the delivery system" and "how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery," including the impact on Medicare beneficiaries. The statute bans new physician-owned hospitals from participation in Medicare and sets very clear limits on expansion of grandfathered physician-owned hospitals.

The AHA opposes any changes that would allow additional physician-owned hospitals to participate in Medicare or allow grandfathered hospitals to expand or increase their capacity beyond what is currently allowed. Congress enacted strict restrictions on physician-owned hospitals to address physicians' clear incentive to steer the most profitable patients to facilities in which they have an ownership interest, potentially devastating the health care safety net in vulnerable communities and jeopardizing communities' access to full-service care.

Further, it has been well demonstrated, by entities including CBO and MedPAC, that physician self-referral leads to greater utilization of services and higher costs for the Medicare program. Specifically, the Government Accountability Office (GAO), CMS and MedPAC have all found that physician-owned hospitals' patients tend to be healthier than patients with the same diagnoses at general hospitals. Further, MedPAC and GAO found that physician-owned hospitals treat fewer Medicaid patients. This trend creates a destabilizing environment that leaves sicker and less-affluent patients to community hospitals. It places full-service hospitals at a disadvantage because they depend on a balance of services and patients to support the broader needs of the community. For example, the current payment system does not explicitly fund standby capacity for emergency, trauma and burn services, nor does it fully reimburse hospitals for care provided to Medicaid and uninsured patients. Community hospitals rely on crosssubsidies from the well-reimbursed services targeted by physician-owned hospitals to support these and other essential but under-reimbursed health services. Revenue lost to specialty hospitals can lead to staff cuts and reductions in subsidized services such as inpatient psychiatric care, as well as lower operating room utilization, which decreases efficiency, strains resources and increases costs. Siphoning off the most financially rewarding services and patients threatens the ability of community hospitals to offer comprehensive care - and serve as the health care safety net for all patients.

Finally, we note that the statute does provide grandfathered physician-owned hospitals the opportunity to expand if they meet certain qualifications. Specifically, a physician-owned hospital can expand to up to double its capacity if it can demonstrate that it has a higher percentage of Medicaid inpatient admissions than other hospitals in its county, or that it is

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located in an area with significant population growth and high bed occupancy rates (i.e., that it would be creating needed beds). To date, five hospitals have applied for an expansion, and CMS has not denied expansion to any hospital that has applied. This indicates that the exceptions process is working as Congress intended, and therefore needs no changes.

PROPOSED CHANGES TO HOSPITAL-WITHIN-HOSPITAL REGULATIONS

Under current rules, hospitals-within-hospitals (HwH) must meet certain separateness and control standards. Among other provisions, they must have separate governing bodies, medical staffs, chief executive officers, and chief medical officers. In the rule, CMS proposes to apply these rules only when an HwH is an inpatient PPS-excluded hospital that occupies space in the same building as an inpatient PPS hospital, or that occupies space in one or more separate buildings on the same campus as those used by an inpatient PPS hospital. CMS states that its concerns about patient shifting are sufficiently moderated when inpatient PPS-excluded hospitals are co-located with one another but not inpatient PPS hospitals.

The AHA supports removing these regulations and providing more flexibility with regard to hospital governance and medical staff frameworks. Additionally, we believe the separateness rules should be modified for co-located inpatient PPS and inpatient PPSexcluded hospitals. In recent years, CMS amended the hospital CoPs to allow health systems with separately certified hospitals to have unified governing boards and medical staffs. Aligning the HwH regulations with the CoPs would allow co-located hospitals to examine whether combining certain functions would benefit patients, especially with regard to quality improvement. For example, while either a unified or separate medical staff structure could work best depending on the circumstances, some health systems have enhanced quality and patient safety by integrating their medical staffs. Improved peer review and on-call coverage, standardization of safety policies and best practices, and more efficient sharing of information are examples of the potential benefits of an integrated medical staff.

We refer CMS to page 27116 of the May 12, 2014 <u>final rule</u> allowing unified medical staff structures, where the agency discusses the impact on quality of care in its reasoning. Specifically, CMS stated in that rule, "We agree that it appears to be evident that a unified system medical staff would usually be better suited to standardizing best practices and implementing quality improvements than would the more fragmented structure of separate medical staffs." We also note that CMS built important safeguards into the final regulations to protect unique patient populations.

The 2014 <u>final rule</u> adopting flexibility in hospital governing board structures similarly echoed the potential for quality improvement. In that rule, CMS observed that, "...multi-hospital systems might gain important efficiencies and achieve significant progress in quality programs under the governance of a single governing body" The agency indicated that it would not endorse one model of hospital governance over the other given the lack of evidence that either worked best.

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Removing the separateness criteria for inpatient PPS and inpatient PPS-excluded co-location arrangements would not automatically result in the blending of governing board or medical staff structures across all HwHs. Especially with regard to medical staff integration, *such changes must be voluntary*, and we expect that hospitals and medical staffs would evaluate numerous factors and points of view in making such sweeping decisions. Nevertheless, giving hospitals the opportunity to evaluate whether care could be delivered in a more integrated, safer and efficient way is appropriate and aligned with CMS's broader goals related to quality and coordination of care.

CMS also proposes to remove other HwH requirements related to performance of basic hospital functions. We support these changes and appreciate CMS's efforts to align and remove the **overlap between the HwH rules and the CoP interpretive guidance.** However, we ask CMS to clarify in the final rule that it is removing 412.22(e)(1)(v)(A), 412.22(e)(1)(v)(B), *and* 412.22(e)(1)(v)(C). In other words, we urge CMS to clarify it is removing 412.22(e)(1)(v) altogether.

Currently hospitals have a choice of three options for meeting requirements at § 412.22(e)(1)(v). The proposed regulatory text indicates that those three choices, described in paragraphs (A), (B) and (C), will bet sunsetted. However, the preamble only discusses removal of (A) and (B). We believe all three should be removed.

MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS

CMS proposes to modify the Medicare and Medicaid EHR Incentive Program reporting period in CY 2018 to a minimum of any continuous 90-day period within CY 2018. This is a reduction in the current requirement that participants attest for a full year. The proposed reduction would be applicable for new and returning participants attesting to CMS or their state Medicaid agency. The AHA strongly supports the proposal for a reporting period of any continuous 90-day period within CY 2018. We share CMS's view that eligible hospitals (EHs), CAHs and eligible professionals (Eps)will benefit from additional time to implement and optimize the 2015 edition certified EHR and review workflows. Experience to date indicates that the transition to new editions of certified EHRs is challenging due to lack of vendor readiness, the necessity to update other systems to support the new data requirements, mandates to use immature standards, an insufficient information exchange infrastructure and a timeline that is too compressed to support successful change management. Additionally, each new certification edition has corresponded with a decline in the number of vendors offering certified products. Provider decisions to switch vendors within a shrinking marketplace may intensify the lack of certified product readiness seen in prior years. To address some of these challenges, the AHA recommends a reporting period of any continuous 90-day period for CY 2018 and subsequent reporting periods.

Hospitals Require Greater Flexibility to Meet CY 2018 Reporting Requirements. To increase the opportunities for EHs, CAHs and EPs to successfully meet Medicare and Medicaid EHR

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Incentive Program requirements, the AHA recommends several additional program changes for CY 2018:

- Cancel Stage 3 by removing the 2018 start date from the regulation. Hospitals face extensive, burdensome and unnecessary "meaningful use" regulations from CMS that require significant reporting on the use of EHRs with no clear benefit to patient care. These excessive requirements are set to become even more onerous when Stage 3 begins in 2018. We believe the level of difficulty associated with meeting all of the Stage 3 current measures is overly burdensome. Some of the measures require the use of certified EHRs in a manner that is not supported by mature standards, technology functionality or an available infrastructure. They also will raise costs by forcing hospitals to spend large sums upgrading their EHRs solely for the purpose of meeting regulatory requirements.
- Expand the reporting options by allowing EHs, CAHs and EPs to choose the certified technology to use to meet meaningful use in CY 2018. Specifically, permit the choice to use 2014 edition certified EHR to report modified Stage 2 or use a combination of the 2014 and 2015 edition certified EHR to report modified Stage 2. While complex, this flexibility would enable EHs, CAHs and EPs to successfully meet meaningful use while taking into account their unique implementation circumstances. However, current requirements that leave Medicare EHs and CAHs with insufficient time to fully implement certified EHRs increase the possibility of a negative payment adjustment for FY 2020 through no fault of their own. Flexibility also supports additional opportunities for more providers to test and implement the new application programming interface (API) functionality supporting Stage 3 requirements for coordination of care and patient electronic access. Although ONC finalized three certification criteria in support of APIs in the 2015 Edition Certification Rule, ONC specifically did not recognize a standard for APIs, citing standards immaturity. Additionally, ONC finalized the API requirements without specifying a certification approach or framework applicable to the apps that would extract data from the EHR.

Additionally, the structure of the EHR Incentive Program remains largely unchanged since its inception, resulting in requirements that compel EHs, CAHs and EPs to count the number of times the EHR functionality is used for a particular purpose rather than citing the availability of the functionality to successfully support the delivery of care and the engagement of patients. Stage 3 raises the bar for several measures, particularly those supporting health information exchange. The experience using the consolidated clinical data architecture (C-CDA) standard to exchange summary of care records illustrates the problems with using standards that have not been adequately specified. Hospitals that receive summary of care documents find they are too large, and it is difficult to find what is relevant and pertinent to ongoing management of the patient. Acceleration of efforts to improve the information exchange infrastructure and support for providers with limited experience participating in information exchange should be prioritized.

Furthermore, hospitals and health systems have significant concerns about the security ramifications of the API requirement, and particularly the need to connect any app of the patients' choice. Given the current cyber threat environment, including daily ransomware attacks and sophisticated cyber attacks such as the WannaCry attack that crippled Britain's National Health Service, hospitals and health systems must be afforded the ability to control connections to their systems. In general, smaller providers, including CAHs and physician offices, have even fewer resources to address these challenges. Providers of all sizes could be faced with an unfair choice of complying with the API requirement to avoid a financial penalty, or deciding to protect their systems at the cost of the significant financial penalties.

In September 2014, during the transition to a new version of certified EHRs, CMS finalized similar flexibility, modifying the Medicare and Medicaid EHR Incentive Program for 2014 to provided 10 different pathways to meet meaningful use. We urge CMS to offer comparable flexibility for the CY 2018 reporting year and recommend that CMS finalize the CY 2018 requirements in a time frame that enables EHs, CAHs and EPs to take advantage of the flexibility finalized.

- Make reporting Stage 3 voluntary should CMS decide to move forward with the final stage of meaningful use in CY 2018. A voluntary start of Stage 3 in CY 2018 would be available for those EHs, CAHs and EPs that have 2015 edition certified EHRs implemented and optimized to meet Stage 3 requirements reporting requirements. EHs, CAHs and EPs should retain the option to report modified Stage 2.
- Align the eligible hospital and CAH required start of Stage 3 and requirements in other programs to use 2015 edition certified EHRs. The CMS Quality Payment Program (QPP) includes the advancing care information category, a set of requirements that are derived from the objectives and measures included in Stage 3 that require the use of 2015 edition certified EHRs. The AHA recommends that CMS align the timeline for required use of 2015 edition certified EHRs in the Merit-based Incentive Program, the Advanced Payment Model program and other CMS programs that have objectives, measures or reporting requirements that are dependent on the use of implemented 2015 edition certified EHRs in CY 2018 with the Medicare and Medicaid EHR Incentive Programs timelines for required use of 2015 edition certified EHRs. Specifically, we recommend that these programs also allow flexibility in technology used and make any requirements derived from Stage 3 voluntary efforts. The barriers cited earlier to a safe and successful implementation of 2015 edition certified EHRs exist for eligible clinicians. Alignment is essential to the effective exchange of clinical information in support of care coordination across the continuum and the engagement of patients.
- Permit CAHs to attest to eCQM reporting requirements in the CY 2018 reporting period. Under the current regulation, CAHs will be required to electronically submit eCQM data to CMS for the CY 2018 reporting period to meet Medicare meaningful use.

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Some CAHs attempted to electronically submit eCQMs in 2016 but others were unable to do so because their certified EHRs did not support QRDA-I file generation necessary for electronic submission of eCQMs. In all instances, the effort to validate the eCQM data due to the small number of patient cases is not minimal. The AHA recommends that CMS not require CAHs to electronically submit eCQMs in CY 2018 and provide additional time for the validation necessary to successfully submit eCQMs data.

ACCREDITING ORGANIZATION WITH DEEMING STATUS

CMS proposes to require that accrediting organizations with deeming status publish the survey reports and health care facilities' plans of corrections for addressing any violations that have been found during the survey. These reports and corrective action plans would be published on the accrediting organization's website. CMS indicates that this proposal is in further support of its initiative to promote transparency about quality in health care delivery.

The AHA fully supports the need for transparency around quality and safety. In fact, in 2003, the AHA first proposed the coordinated voluntary effort to publicly report a set of valid and reliable quality measures that led to the creation of the *Hospital Compare* website that is now the foundation of CMS's transparency and VBP programs for hospitals. Since 2003, we have sought to work closely with CMS and others to identify the most useful, valid and reliable information for the public to have in assessing the quality provided by hospitals and other organizations, and we will continue that work.

We agree with CMS that compliance with standards, such as the CoPs or the even more demanding standards of some of the accrediting organizations, are an important part of ensuring the quality in hospitals, but believe the publication of the survey reports and plans of correction is not the right mechanism to help the public gain better insight into quality.

The AHA does not support CMS's proposal to require the accrediting bodies to publish on their own websites the survey reports and corrective action plans for all surveyed organizations:

• First, the Mandated Publication of Survey Reports Could Have a Chilling Effect on Quality and Safety Improvement. Since the publication of the Institute of Medicine Report *To Err is Human* in 1999, some accrediting organizations have undertaken major efforts to change from simply looking at compliance with standards to partnering with health care provider organizations in their efforts to fundamentally improve quality and safety. This work involves creating a culture in which every member of the staff trusts that he or she can raise questions or identify areas where risks are present and can be mitigated. Surveyors contribute to this work in many ways, including noting areas where no standard has been violated, but there may be an opportunity for a different approach that is safer or more likely to lead to high-quality results. Creating that culture of trust takes time, but it can evaporate quickly if confidential inquiries are disclosed. The kind of public disclosure proposed by CMS is likely to have a chilling effect on conversations between hospital staff and surveyors – conversations that lead to safer, more effective care for the public. The survey reports prepared by accrediting bodies provide a confidential, detailed assessment of opportunities for improvement that are of great value to the hospitals that contract for the surveys and to the communities they serve.

• <u>Second, CMS's Proposal Will Not Provide Meaningful Transparency</u>. To achieve transparency, information must be presented to the public in a clear, understandable and useable manner that would support the decisions patients and their family members are trying to make. However, the survey reports are not designed to communicate to patients. The length and nature of the survey reports is likely to obscure rather than enlighten patient decision-making. The survey reports focus on issues of keen interest to those who operate health care organizations and are responsible for day-to-day operations, but not on issues identified by patients or their families as critical to decision-making.

Moreover, the reports are written to communicate effectively with an internal audience that is knowledgeable about both the standards and the organization being surveyed. They are written in a manner that requires sufficient context in which to understand the implications of the citation for the patients and community served. In the alternative, some might try to use the number of citations as a proxy for quality, but the number of citations can vary depending on the nature and size of the organization, the age of the physical plant, the number of different services provided, and the composition and training of the survey team rather than differences in quality. Thus, we believe this approach is likely to mislead patients and families.

Further, CMS's proposal would mean that the surveys for hospitals and other providers would appear on various accrediting organization websites. This will make it hard for the public to find information on the organization(s) in which they have an interest. Anyone wanting to locate the survey for a particular hospital or other organization would have to know the names and websites of the organizations to which CMS has granted deeming authority for that type of provider, and be willing to search each of those organizations' websites to discover which organization accredits the hospital or hospitals in which the patient has an interest.

In addition, the survey reports may be outdated very quickly. Every hospital and other organization that seeks accreditation does so because it wants to be in compliance with the standards. As soon as defects are identified on a survey, the hospital will launch efforts to correct them. In many cases, hospitals fix issues spotted during the survey within days or weeks of the survey – even before the official survey report is received. This means the survey report could be obsolete even before it is posted. Yet, the majority of hospitals will not be surveyed again for three years or longer. The public should not be misled by out-of-date surveys as if they were current reflections of the care provided.

• <u>Third, CMS's Proposal is Contrary to Congress's Limits on Public Disclosure of</u> <u>Accrediting Organization Reports</u>. The proposal is directly at odds with the limited Ms. Seema Verma June 13, 2017 Page 48 of 51

> authority Congress granted the HHS secretary to disclose accrediting organization reports. The HHS secretary must treat accrediting organization reports as confidential, with two narrowly drawn exceptions (accrediting organization reports related to a home health agency or disclosure in connection with an enforcement action), neither of which is relevant here.

The AHA concurs with the legal analysis in The Joint Commission's comment letter. We want to underscore several points. Section 1865(b) of the Social Security Act focuses specifically and exclusively on the confidentiality of accrediting organization reports. CMS contends that it has the authority to require public reporting of accreditation surveys by accrediting organizations because Section 1865(a)(2) permits the Secretary to consider "other factors" when determining whether an accrediting organization should be granted deeming authority. CMS's defense of its proposal effectively treats 1865(b) as superfluous. It claims authority – to regulate the confidentiality of accrediting organization can carry out the functions of surveying and monitoring the performance of a provider (Section 1865(a)(2)).

The legislative history reinforces the limitation on the secretary's authority to regulate disclosure. Prior to Section 1865, the secretary did not have access to accrediting organization reports. The trade-off for obtaining access was the duty of the secretary to maintain confidentiality. The existence of the provision and its continued presence through many years and various amendments makes sense only if Congress intended that accrediting organizations be able to keep reports confidential. Thus, CMS's proposal contravenes Congress's clear intent to protect the confidentiality of accrediting organization reports from broad public disclosure.

For these reasons, the AHA urges CMS not to finalize its proposal to require accrediting organizations to publish survey reports and corrective action plans. Instead, we urge CMS to work with accrediting organizations, hospitals and other health care provider organizations, and experts on transparency to determine what information, if any, can be derived from surveys that would be useful to patient and family decision-making and how it might best be added to the vast amount of data and other information CMS provides on *Hospital Compare* and other similar websites to create a more complete picture of quality for the public without violating the statute or impinging on the culture of safety.

Appendix: Current Inpatient Quality Reporting and Outpatient Quality Reporting Measures for Retention

AHA Measurement Priority Areas	Measures Kept (possible minor modifications)	Measures Kept If Major Modifications Made
Patient Safety Outcomes Harm Rates Infection Rates Medication Errors 	Central-line associated bloodstream infection (CLABSI)Surgical site infection (colon and hysterectomy procedures only)Catheter-associated urinary tract infection (CAUTI)Clostridium Difficile (C Difficile)Methicillin Resistant Staphylococcus Aureus (MRSA)Global influenza vaccinationInfluenza vaccinationInfluenza vaccination coverage among health care personnel (inpatient)OP-27: Influenza vaccination coverage among health care personnel (outpatient)	Risk-standardized complication rate following elective primary total hip and/or total knee arthroplasty Severe sepsis and septic shock management bundle
Readmission Rates Effective Patient Transitions		Acute myocardial infarction (AMI) 30-day risk standardized readmission
		Heart failure (HF) 30-day risk standardized readmission Pneumonia (PN) 30-day risk standardized readmission
		Total Hip / Total Knee Arthroplasty (THA/TKA) 30-day risk standardized readmission COPD 30-day risk standardized readmission

AHA Measurement Priority Areas	Measures Kept (possible minor modifications)	Measures Kept If Major Modifications Made
		CABG 30-day risk standardized
		readmission
		Acute ischemic stroke (STK) 30-
		day risk standardized readmission
		Hospital-wide all cause unplanned
		readmission
		OP-32: Facility 7-day risk-
		standardized hospital visit rate
		after outpatient colonoscopy
mail and an elements		AMI 30-day mortality rate
Risk Adjusted Mortality		Aivit 50-day mortanty rate
		HF 30-day mortality rate
		PN 30-day mortality rate
		FIN SO-day mortality rate
		Coronary artery bypass graft
		, , ,, ,
		(CABG) 30-day mortality
		AMI 30-day risk standardized
		readmission
Dishatas Control		
Diabetes Control	NO MEASURES AVAILABLE IN HOSPITAL	
Obesity	NO MEASURES AVAILABLE IN HOSPITA	
Adherence to Guidelines for		OP-33: External beam
Commonly Overused Procedures		radiotherapy (EBRT) for bone
		metastases
		OP-29: Endoscopy/Poly
		Surveillance: Appropriate follow-
		up interval for normal
		colonoscopy in average risk
		patients
		OP-30: Endoscopy/Poly
		Surveillance: Colonoscopy interval
		for patients with a history of
		adenomatous polyps—Avoidance
		of inappropriate use
		OP-8: MRI lumbar spine for low
		back pain

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AHA Measurement Priority Areas	Measures Kept (possible minor modifications)	Measures Kept If Major Modifications Made
		OP-11: Thorax CT – Use of
		contrast material
		OP-13: Cardiac imaging for
		preoperative risk assessment for
		non-cardiac low risk surgery
End-of-Life Preferences	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Cost Per Case or Episode		Medicare spending per beneficiary
		(MSPB)
Behavioral Health	NO MEASURES AVAILABLE IN HOSPITAL PROGRAMS	
Patient Experience of Care /		
Patient Reported Outcomes of		HCAHPS survey
Care		