

July 10, 2020

The Honorable 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-1735-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 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals: Proposed Rule (Vol. 85, No. 104), May 29, 2020.

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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) 2021. We are submitting separate [comments](#) on the agency's proposed changes to the long-term care hospital PPS.

We support a number of the inpatient PPS proposed rule's provisions, including utilizing FY 2017 Worksheet S-10 data to determine FY 2021 Medicare Disproportionate Share Hospital (DSH) payments and modifying the definition of displaced resident for the purposes of graduate medical education (GME) slot transfers after hospital or residency program closures. At the same time, we have serious concerns with other proposals. In particular, we do not believe CMS's proposals to collect and apply payer-specific charge data are lawful and urge CMS not to finalize them. We also strongly urge CMS to withdraw its proposals to retroactively apply certain policies related to Medicare bad debt. A summary of our key recommendations follows.



“Market-based” MS-DRG Data Collection and Weight Calculation

CMS proposes to require hospitals to include on their Medicare cost report what the agency calls “market-based payment rate information.” Specifically, hospitals would be required to report, by Medicare-severity diagnosis-related group (MS-DRG), the median payer-specific negotiated charge for Medicare Advantage (MA) organizations and the median payer-specific negotiated charge for all of the hospital’s third-party payers. The agency also is considering incorporating this information in the inpatient PPS MS-DRG relative weights beginning in FY 2024. **We believe both proposals are unlawful and urge CMS not to finalize them.** CMS does not cite authority on which to base the payer-specific data collection requirement or the MS-DRG weight recalculation. In addition, the rule on which CMS relies remains under legal challenge.

Worksheet S-10 Data

We believe audited S-10 data – and, by extension, ongoing refinements to the audit process – result in data that are more appropriate for use in Medicare DSH payments. **Therefore, we support the use of FY 2017 S-10 data to determine each Medicare DSH hospital’s share of uncompensated care payments in FY 2021.** However, we are concerned that CMS’s proposal to continue to use the most recent single year of cost report data for FY 2022 and all subsequent years would prevent opportunities to assess and comment on any peculiarities in the data. **Thus, we urge CMS to only propose and finalize the DSH data and methodology for the upcoming fiscal year.** We also recommend, in light of the potential for undue fluctuations when utilizing a single year of data, that CMS monitor payments over time and, if necessary, consider utilizing more than one year of data after FY 2021.

Medicare Bad Debt

The Medicare Provider Reimbursement Manual outlines actions that providers are encouraged or required to take in order for an unpaid amount to be considered a bad debt for Medicare purposes. CMS proposes to clarify, modify and codify into regulation the activities related to bad debt, in addition to proposing new requirements. **The AHA is concerned that CMS is proposing to retroactively apply a number of its bad debt policy proposals. Retroactive implementation of CMS’s bad debt proposals is not warranted, and we urge CMS to withdraw retroactive policy implementation.** We also have concerns with other proposals, including the proposed requirement for providers to take into account a beneficiary’s total resources when determining whether the patient may be deemed indigent.

Chimeric Antigen Receptor T-cell (CAR T) Therapy

CMS proposes to develop a new MS-DRG for CAR T. **We appreciate the agency’s approach to constructing the new MS-DRG for CAR T, which would be more representative of resource use for providing the therapy than its previous assignment. However, the DRG payment is still inadequate in addressing the extraordinary level of resources necessary to provide this life-saving therapy.** Without additional steps to more accurately capture the cost of CAR T, hospitals and

health systems will be forced to continue to take on unsustainable losses in order to provide these life-saving therapies. We, therefore, continue to urge CMS to consider an alternative method of determining the cost of the CAR T therapy as delineated in our detailed comments. Doing so would facilitate more accurate information for determining new technology add-on payments (NTAPs) and outlier payments, as well as future weight-setting or a pass-through payment. For example, we recommend that CMS develop a CAR T-specific cost-to-charge ratio (CCR), which could be calculated if the agency were to create a dedicated cost center on the Medicare cost report. We also continue to urge CMS to consider carving out these very costly new technologies from the MS-DRG and paying for them on a pass-through basis.

Finally, we have [requested](#) that CMS take certain actions related to the current COVID-19 crisis that could exist in the context of the FY 2021 inpatient PPS final rule. For example, we have recommended that CMS suspend critical access hospitals' (CAH) final settlement payments until 12 months after the public health emergency has ended to mitigate unintended cash flow implications and concerns. We also have requested that the agency temporarily permit providers to treat relief funds and other emergency funding mechanisms as grants for cost reporting purposes to avoid unintended financial offsets, which would have financial implications for CAHs and other hospitals' cost-based reimbursements. We urge the agency to consider setting forth these policies alongside the final rule, if not sooner.

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 Erika Rogan, AHA senior associate director for policy, at (202) 626-2963 or erogan@aha.org.

Sincerely,

/s/

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

**American Hospital Association (AHA)
Detailed Comments on the Inpatient Prospective Payment System
(PPS) Proposed Rule for Fiscal Year (FY) 2021**

Table of Contents

“Market-based” MS-DRG Data Collection and Weight Calculation	5
Medicare Disproportionate Share Hospital (DSH) Payment.....	7
Area Wage Index (AWI)	10
Chimeric Antigen Receptor T-cell (CAR T) Therapy.....	13
Graduate Medical Education (GME).....	17
Medicare Bad Debt.....	17
Rural Hospital Provisions	24
Changes to MS-DRG Classifications.....	25
Hospital Inpatient Quality Reporting (IQR) Program	34
Hospital Value Programs.....	39
PPS-exempt Cancer Hospital Quality Reporting Program (PCHQRP).....	39
Promoting Interoperability Program.....	40

“MARKET-BASED” MS-DRG DATA COLLECTION AND WEIGHT CALCULATION

In its FY 2021 Inpatient Prospective Payment System (IPPS) proposed rule, CMS proposes to require hospitals to include on the annual Medicare cost report what the agency calls “market-based payment rate information.”¹ Specifically, every hospital would be required to report “(1) The median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations ... by MS–DRG; and (2) the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA organizations, by MS–DRG.”² The agency also requests comment on incorporating this information in the IPPS MS-DRG relative weights beginning in FY 2024. **The AHA believes that both proposals are unlawful and urges CMS not to finalize them.**

CMS cites no authority to require hospitals to furnish median payer-specific negotiated charge information by MS-DRG. Instead, CMS relies exclusively on a rule the agency promulgated in 2019, denominated by CMS as the “Hospital Price Transparency Final Rule,”³ to require disclosure of negotiated charge information by MS-DRG. CMS explains that “[t]he payer specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency Final Rule (84 FR 65524) that can be crosswalked to an MS–DRG. We believe that because hospitals are already required to publically report payer-specific negotiated charges, in accordance with the Hospital Price Transparency Final Rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.”⁴

The Hospital Price Transparency Final Rule is scheduled to go into effect on Jan. 1, 2021, but it has been challenged by the AHA and other hospitals on statutory, procedural and constitutional grounds. Although the district court denied hospitals’ motion for summary judgment,⁵ the hospitals have appealed that decision to the United States Court of Appeals for the District of Columbia Circuit. The appeal will be fully briefed by the end of August, and the parties are requesting oral argument as soon after that as possible. Because the information to be furnished under the proposed rule would be derived from information collected under the Hospital Price Transparency Final Rule, the new information collection requirement suffers from the same legal infirmities: It is not authorized by statute and violates both the Constitution and Administrative Procedure Act.

¹ 85 Fed. Reg. 32,460, 32,464 (May 29, 2020).

² 85 Fed. Reg. at 32,791.

³ 84 Fed. Reg. 65,524 (Nov. 27, 2019).

⁴ 85 Fed. Reg. 32,460, 32,465 (May 29, 2020). We note that, because there is no comparator in the statement, it is not clear what CMS means when it says that reporting median payer-specific negotiated charges is “less burdensome for hospitals.”

⁵ *American Hospital Assn, et al. v. Azar*, No. 19-CV-3619 (D.D.C. June 23, 2020).

Moreover, if the hospital price transparency final rule is found unlawful, then CMS's requirement for disclosure of median payer-specific charge information by MS-DRG would similarly be unlawful.

The same is true as to the potential approach to change the method of calculation for MS-DRG relative weights beginning in FY 2024. CMS says that it is considering adopting in the FY 2021 IPPS final rule a "change to the methodology for calculating the IPPS MS-DRG relative weights to incorporate this market-based rate information, beginning in FY 2024. . . ."⁶ But if it is unlawful to require disclosure of median payer-specific negotiated charge information by MS-DRG, then CMS could not use that information to change relative weights.

In addition, it would be arbitrary and capricious to use median payer-specific negotiated charge information by MS-DRG to change relative weights. As set forth in section 1886(d)(4)(A) of the Act, relative weights are intended to reflect "the relative hospital resources used with respect to discharges classified within that group" and not the relative price paid. CMS currently uses "a cost-based methodology to estimate an appropriate weight for each MS-DRG."⁷ In proposing to use median payer-specific negotiated charges to set MS-DRG relative weights, CMS has not adequately explained why it thinks market price rather than costs is a better measure of hospital resources used. Instead, the agency appears to *conflate market price with cost*.

The rationales CMS uses for basing MS-DRG relative weights on price (e.g., promoting transparency, bringing down the cost of health care, wanting to move beyond the chargemaster, etc.) have nothing to do with whether median payer-specific negotiated charges are a measure of "hospital resources used" as the Medicare statute requires. Rather, CMS proposes to use this information to "advanc[e] the critical goals of [Executive Orders] 13813 and 13890, and to support the development of a market-based approach to payment under the Medicare FFS system."⁸ But that is not the statutory test. Simply put, we believe CMS has not adequately explained why basing IPPS MS-DRG relative weights on market price would result in relative weights being based on hospital resources used. As such, it would be arbitrary and capricious to adopt this proposal. See *Motor Veh. Mfrs. Ass'n v. State Farm Ins.*, 463 U.S. 29 (1983).

The AHA is hopeful that the appeals court will rule on the challenge to the hospital price transparency final rule before the end of this year.⁹ Should the hospital price transparency final rule be found unlawful, CMS would have no legal basis for requiring hospitals to disclose their median payer-specific negotiated charges by MS-DRG. **If, despite the**

⁶ 85 Fed. Reg. 32,460, 32,465 (May 29, 2020).

⁷ *Id.* at 32,791.

⁸ *Id.*

⁹ If the court does not make its final decision by the end of the year, we have [urged HHS and CMS](#) to delay implementation of the hospital price transparency rule in light of the ongoing litigation and the undue burden on hospitals due to the COVID-19 public health emergency.

AHA's concerns about CMS's proposals to collect data and base IPPS MS-DRG relative weights on median payer-specific negotiated charges, the agency nevertheless elects to finalize them, it should not do so unless and until (1) the court upholds the hospital price transparency final rule, (2) the agency has adequately explained the basis for concluding that payer-specific negotiated charges by MS-DRG reflect resources used, and (3) stakeholders have had another opportunity to comment on the proposal.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENT

Under the DSH program, hospitals receive 25% of the Medicare DSH funds they would have received under the former statutory formula (described as “empirically justified” DSH payments). The remaining 75% flows into a separate funding pool for DSH hospitals. This pool is reduced as the percentage of uninsured declines and is distributed based on the proportion of total uncompensated care each Medicare DSH hospital provides.

The estimated DSH amount determined by the former statutory formula is derived from historical data, including the number of Medicaid enrollees.¹⁰ According to a Kaiser Family Foundation analysis, the economic downturn and increased unemployment related to the coronavirus has resulted in approximately 12 million people who experienced job loss by May 2020 becoming eligible for Medicaid. That number is expected to rise to nearly 17 million people by January 2021, as unemployment benefits expire and more individuals are no longer able to receive subsidies for marketplace insurance plans.¹¹ Furthermore, some models have projected as many as 21 million new Medicaid enrollees if unemployment rises to 20%.¹² **At the time the DSH estimates for FY 2021 were developed, the Actuary could not have anticipated the stark economic changes resulting from the COVID-19 public health emergency. It is imperative that the Office of the Actuary (OACT) update its estimate of the Medicare DSH amount in the final rule to more accurately reflect increased Medicaid enrollment for 2020 and 2021.** Revising the estimated DSH amount will improve the accuracy of both the empirically justified payments and the uncompensated care pool and more closely account for the additional costs associated with providing care to a larger portion of low-income patients.

In addition, as noted above, CMS adjusts the 75% pool to reflect changes in the percent uninsured. Since FY 2018, CMS has applied the percent uninsured estimated by OACT and based on National Health Expenditure Accounts (NHEA) data. According to the proposed rule, the NHEA historical data currently run through 2018. However, the ongoing

¹⁰ CMS Office of the Actuary. (2018). Estimate of Medicare DSH payments used in development of factor 1. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2019-CMS-1694-FR-OACT.pdf>

¹¹ Kaiser Family Foundation. (2020). Eligibility for ACA Health Coverage Following Job Loss. <https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/>

¹² Urban Institute. (2020). How the COVID-19 Recession Could Affect Health Insurance Coverage. <https://www.rwjf.org/en/library/research/2020/05/how-the-covid-19-recession-could-affect-health-insurance-coverage.html>

COVID-19 emergency has highlighted severe limitations of the use of historical data. Specifically, the 9.5% uninsured percentage that OACT has estimated for both FY 2020 and FY 2021 does not account for extensive unemployment and economic hardship resulting from the COVID-19 crisis. For example, according to Pew Research Center and the Bureau of Labor Statistics, unemployment increased markedly, from 3.8% in February to as high as 16.3% in May.¹³⁻¹⁴ Accordingly, some recent estimates indicate that 5-9 million individuals³ could lose their health insurance due to the effects of COVID-19, leaving as many as 40 million individuals uninsured.¹⁵ Inputting these estimates into the NHEA projection results in approximately 11-12% uninsured, and would lead to more than \$1 billion in additional funds in the 75% pool for uncompensated care payments. Thus, current OACT projections significantly underestimate the percent of individuals that are uninsured and would lead to artificially reduced DSH payments in FY 2021. Hospitals across the country have been – and continue to be – on the front lines of the COVID crisis, providing essential care to those who need it, including those that may not be insured. **Given the serious impact that the pandemic has had on the U.S. economy and unemployment, we strongly urge CMS to use more recent and representative data or otherwise apply an upward adjustment to estimate a more appropriate percent uninsured for the FY 2021 75% DSH pool in the final rule.**

Use of Worksheet S-10 Data. CMS proposes to utilize FY 2017 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2021. The agency states that the FY 2017 data are the best available because 1) they are from the most recent year for which CMS has conducted an audit of worksheet S-10 and 2) they reflect improvements to the S-10 instructions. **The AHA has a longstanding position supporting the use of audited S-10 data to promote accuracy and consistency. We continue to believe that audited data – and, by extension, ongoing refinements to the audit process – result in data that are more appropriate for use in Medicare DSH payments. We, therefore, support the use of FY 2017 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2021.**

CMS also proposes, for FY 2022 and all subsequent years, to use the most recent single year of cost report data that have been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to determine DSH payments. While we support the use of audited S-10 data, we are concerned that finalizing such a proposal would prevent opportunities to assess and comment on any peculiarities

¹³ Pew Research Center. (2020). Unemployment rose higher in three months of COVID-19 than it did in two years of the Great Recession. <https://www.pewresearch.org/fact-tank/2020/06/11/unemployment-rose-higher-in-three-months-of-covid-19-than-it-did-in-two-years-of-the-great-recession/>

¹⁴ Washington Post. (2020). "A 'misclassification error' made the May unemployment rate look better than it is. Here's what happened." <https://www.washingtonpost.com/business/2020/06/05/may-2020-jobs-report-misclassification-error/>

¹⁵ Health Management Associates. (2020). COVID-19 Impact on Medicaid, Marketplace, and the Uninsured, by State. <https://www.healthmanagement.com/wp-content/uploads/HMA-Estimates-of-COVID-Impact-on-Coverage-public-version-for-April-3-830-CT.pdf> and <https://www.healthmanagement.com/blog/hma-updates-forecast-of-covid-19-impact-on-medicare-marketplace-uninsured/>

in the data. **Because it is impossible to foresee what potential shortcomings in the data or concerns with the audit process could arise, we urge CMS to only propose and finalize the DSH data and methodology for the upcoming fiscal year.** We believe it would be appropriate, however, for CMS to indicate in the final rule which data the agency expects to audit, as it did in the FY 2020 final rule. This would provide hospitals with predictability for planning purposes, while also providing opportunity to examine and comment on the data to be used.

Finally, as we have commented previously, utilizing a single year of S-10 data may increase the potential for anomalies and undue fluctuations in uncompensated care payments – especially when hospitals experience unforeseen circumstances such as a pandemic. Thus, we continue to recommend that CMS monitor payments over time and, if necessary, consider utilizing more than one year of data after FY 2021. Doing so also would provide a clear pathway to audit all DSH hospitals over time, as recommended below.

Recommendations for Future Audits. We greatly appreciate CMS's efforts to implement and refine the audit process. Based on our members' experiences, they shared suggested improvements that could be made to promote clarity, consistency and completeness of S-10 audits. As such, we continue to recommend that CMS:

- Establish a standardized process across auditors, including standard timelines for information submission and acceptable documentation to meet information requirements;
- Consider targeting particular information/data elements for audit;
- Develop a transparent timeframe for the audit, with adequate lead time and communication to providers about expectations;
- Establish a process for timely appeals; and
- Consider approaches to audit all DSH hospitals over time.

To further maximize available audit resources, we also recommend that CMS focus its audits on only those hospitals to which DSH payments would apply. For example, sole community hospitals that receive their hospital-specific rate, rather than inpatient PPS reimbursement, do not receive DSH payments and could therefore be excluded from the DSH audit in order to improve efficiency and reduce burden.

Technical Proposals Related to S-10. CMS makes several technical proposals related to the S-10 data.

First, as in the past, if a hospital has a cost report that does not equal 12 months of data (in other words, are more or less than 365 days), CMS proposes to annualize Medicaid days and uncompensated care data. **We support this proposal.**

CMS proposes to continue its approach to handling multiple cost reports, as adopted in the FY 2019 inpatient PPS final rule. Thus, CMS proposes to continue to use data from cost

reports that are 12 months in duration; if no such cost report exists for a particular hospital, the longest cost report would be used and its data would be annualized. **We support this proposal.**

CMS calculates an interim DSH payment amount per discharge for each DSH hospital, based on the hospital's estimated DSH total uncompensated care payment divided by the hospital's most recently available three-year average number of discharges. The interim payments are then reconciled at the end of the year to match the total uncompensated payment amount. In some cases, discharge growth discrepancies could lead to overestimated interim payments, which could cause unstable cash flows. In light of this concern, CMS proposes to allow hospitals to request a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the FY and/or once during the FY. **We support this proposal to provide an option for hospitals to request a lower interim uncompensated care payment.**

In addition, CMS proposes to continue to trim data to control for data anomalies. For FY 2021, CMS would substitute information from the 2018 cost report in the event of a hospital reporting extremely high uncompensated care costs that cannot be justified. **We support this proposal.**

We also support the following DSH proposals related to merged hospitals, including:

- Annualizing the newly merged (surviving) hospital's cost report data for determining the hospital's proportion of total uncompensated care;
- Utilizing the newly merged (surviving) hospital's CMS Certification Number (CCN) available the time of the development of the final rule (FY 2017 CCN) to base interim uncompensated care payments for the hospital; and
- Applying a multiplier to the acquired hospital's unannualized data to determine the acquired hospital's uncompensated care costs that should be added to that of the surviving hospital for the purposes of determining the newly merged hospital's proportion of total uncompensated care. The multiplier would be calculated to reflect the acquired hospital's uncompensated care costs incurred prior to the merger's effective date, but after the start of the surviving hospital's current cost reporting period.

AREA WAGE INDEX (AWI)

The area wage index is intended to recognize differences in resource use across types and location of hospitals. It is important for the Medicare prospective payment systems to adequately account for these resource differences to prevent providers from being either inappropriately rewarded or put under fiscal pressure. CMS determines and assigns wage index values based on a hospital's labor market area, using the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB).

Low-wage Hospital Policy. CMS proposes to continue its policy to increase wage index values for low-wage hospitals, which was finalized in FY 2020. Specifically, for hospitals with a wage index value below the 25th percentile, the agency would increase the hospital's wage index by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals. Last year, CMS finalized that this policy would be effective for at least four years, beginning in FY 2020, in order to "allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation." The agency proposes to continue to make this policy budget neutral by adjusting the national standardized amount for all hospitals.

Hospitals have repeatedly expressed concern that the wage index is greatly flawed in many respects, including its accuracy, volatility, circularity, and substantial reclassifications and exceptions. Members of Congress and Medicare officials also have voiced concerns with the present system. To date, a consensus solution to the wage index's shortcomings has yet to be developed. **The AHA appreciates CMS's recognition of the wage index's shortcomings and supports continuing to improve the wage index values for low-wage hospitals. However, we maintain that budget neutrality is not a requirement of the statute which provides CMS the authority to increase the wage index for hospitals in the lowest wage index quartile. Therefore, we support increasing the wage index values of low-wage hospitals, but continue to urge the agency to use its existing authority to do so in a non-budget-neutral manner.**

In addition to the lack of statutory requirement, the AHA continues to believe there also is strong policy rationale for not making the low-wage hospital policy budget neutral. Medicare continues to reimburse inpatient PPS hospitals less than the cost of care. According to an analysis of AHA Annual Survey data, hospitals receive payment of only 87 cents for every dollar spent caring for Medicare patients.¹⁶ Moreover, in 2018, the Medicare Payment Advisory Commission (MedPAC) found that hospitals' aggregate Medicare margin was -9.3%, continuing the longstanding trend of substantially negative Medicare margins.¹⁷ In fact, Medicare has not fully covered the costs of caring for Medicare patients since 2002.¹⁸ Taken together, these observations strongly suggest that there is a need to *add* funds into the system – not to take them away from hospitals that are already operating in a below-cost reimbursement environment.

Wage index increases for low-wage hospitals provide these facilities with sorely needed funds that will begin to address chronic Medicare underfunding. However, CMS is not bound by statute to make such increases budget neutral and reducing

¹⁶ American Hospital Association. (2020). Fact Sheet: Underpayment by Medicare and Medicaid. <http://67.59.137.244/documents/Jun10DataBookEntireReport.pdf>

¹⁷ MedPAC. (2020). March 2020 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch3_sec.pdf?sfvrsn=0

¹⁸ MedPAC (2010). Databook, Chart 7-14 Overall Medicare margin, 1997-2008. <http://67.59.137.244/documents/Jun10DataBookEntireReport.pdf>

the standardized amount of all PPS hospitals intensifies historical Medicare underpayment. The AHA urges CMS to not impose budget neutrality on the low-wage hospital policy.

Wage Index Area Reclassifications. By statute, hospitals must submit applications for reclassification requests to the Medicare Geographic Classification Review Board (MGCRB) 13 months before the fiscal year for which the hospital requests the reclassification. Applications are therefore due on Sept. 1, 2020 for reclassifications intended to begin on Oct. 1, 2021 (the beginning of FY 2022). Typically, final wage index values are available on Aug. 1 each year, allowing hospitals to assess their wage index and determine whether it would be appropriate to apply for reclassification for the following fiscal year. However, this year the final rule could be released as late as Sept. 1, leaving little or no time for hospitals to base the reclassification decision on pertinent data. **Thus, we urge CMS to:**

- **Grant an extension for the reclassification deadline under Section 1135 waiver authority, as the agency has previously done¹⁹ for hospitals affected by public health emergencies such as hurricanes;**
- **Make the final wage index data available by Aug. 1, regardless of the timing of the FY 2021 final rule release, in order to provide ample time for providers to examine wage data and, if desired, submit a timely application; or**
- **Allow hospitals to submit incomplete reclassification applications to the MGCRB by the Sept. 1 deadline, and then supplement their applications with official data from the final 2021 wage index once it is published.** CMS has previously approved this approach in 2006 (71 FR 28644)²⁰ when wage index data were not available by Aug. 1.

In addition, CMS proposes to apply a 5% cap in FY 2021 on any decrease in a hospital's wage index compared to its final wage index for FY 2020. In some cases, because of the timing of a hospital's MGCRB approval for reclassification, the final rule may not contain a hospital's final reclassified wage index for the fiscal year. Thus, we recommend that CMS consider the hospital's final reclassified wage index value, which may be identified from the Provider Specific File, when applying the 5% cap, even if that value is finalized after the issuance of the final rule.

Occupational Mix Survey. Occupational mix adjusts the area wage index for the effect of the hospital's employment choices. By statute, CMS must collect data every three years on occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. The 2016 occupational mix survey data has been applied to wage index values from FY 2019 to FY 2021. For the FY 2022 wage index, CMS is collecting

¹⁹ CMS. (2017). MLN Matters. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17021.pdf>

²⁰ 71 Fed. Reg. 28,651 (May 17, 2006).

data from the 2019 occupational mix survey. Initially, the deadline to submit these data to CMS was set for July. Due to the public health emergency, CMS extended the deadline to Aug. 3. While the delay is appreciated, the extension may not be sufficient time to allow hospitals to gather, review and finalize labor mix information to submit. Data required to complete the survey largely rely on hospital staff who are focused on critical activities related to COVID-19. Given that the 2019 occupation mix survey will be applied to wage index data for the next three years, beginning in 2022, it is especially important to ensure accuracy of the information. **Thus, we urge CMS to further extend the deadline for the occupation mix survey to the end of calendar year (CY) 2020.** Such an extension would support accurate occupational mix data collection and reporting while maintaining an appropriate timeframe for the agency to incorporate the information into wage index calculations for FY 2022.

CHIMERIC ANTIGEN RECEPTOR T-CELL (CAR T) THERAPY

CAR T-cell therapy is a cell-based gene therapy in which a patient's own T-cells are genetically engineered in a laboratory and administered to the patient by infusion to assist in the patient's treatment to attack certain cancerous cells. For FY 2021, CMS proposes to develop a new MS-DRG for CAR T, MS-DRG 018. The proposed relative weight for MS-DRG 018 is 37.1412.

The AHA continues to remain concerned about beneficiary access to CAR T and similar forthcoming technologies given their extreme costliness. While the proposed new MS-DRG for CAR T would be more representative of resource use for providing the therapy than its previous assignment, the current reimbursement system continues to exhibit limitations with regard to appropriate rate setting and payment for CAR T. Without additional steps to more accurately capture the cost of CAR T, hospitals and health systems will be forced to continue to take on unsustainable losses in order to provide these life-saving therapies. In addition to our comments on proposals set forth in the rule, we provide several recommendations below that would promote beneficiary access to these therapies, establish the data needed to more accurately determine cost of CAR T, and preserve opportunities for additional payment options in the future.

AHA also continues to urge CMS to consider carving out these very costly new technologies from the MS-DRG and paying for them on a pass-through basis. Doing so would help ensure not only the integrity of the budget-neutral inpatient PPS, but also, more importantly, beneficiary access to these life-saving technologies. As we have previously noted, ***this is especially necessary given that both new and existing therapies are expected to be approved for additional indications.*** The current payment systems – of any payer, not just Medicare – were not built to sustain access to therapies with costs of these magnitudes. As technology continues to advance, therapies such as these will become more and more prevalent. For example, this year, two additional CAR T products have gone to market. Moreover, according to the IQVIA 2019

Global Oncology Report, 24 additional CAR T therapies are in late-stage development.²¹ It is critical that a precedent is set that ensures beneficiary access to care. We look forward to working with CMS to develop a long-term solution.

New MS-DRG for CAR T. CMS utilized FY 2019 claims data to determine the relative weight for MS-DRG 018. **We agree with the agency's approach to constructing the new MS-DRG for CAR T and believe that the proposed MS-DRG would be more representative of resource use for providing the therapy than its previous assignment.** We appreciate that, when calculating the relative weight, CMS included CAR T cases that would have been considered statistical outliers for the previous MS-DRG 016, but are not outliers when examining CAR T-cell therapy claims only.

We also appreciate that CMS excluded clinical trial CAR T cases when developing the relative weight for the new MS-DRG, since such cases do not include the cost of the therapy itself and would therefore greatly underrepresent relative resource utilization. CMS states in the rule that it identified CAR T clinical trial cases as those cases with a Z00.6 (clinical trial) code or cases with "standardized drug charges" of less than \$373,000. We request that CMS provide more detail regarding how the agency determined standardized drug charges for the purposes of identifying CAR T clinical trials. Specifically, we believe that the revenue code associated with CAR T, revenue code 0891, may not have been incorporated as a component of standardized drug charges. We believe this may have occurred because revenue code 0891 would be included, along with revenue code 081x, in a grouping called "Organ Acquisition Charges" as described in the MedPAR data dictionary documentation.

Typically, costs associated with the 081x and 089x codes in this grouping are excluded from weight-setting, because the 081x codes represent organ acquisition costs, which are reimbursed outside of the DRG payment. However, revenue code 0891 is indeed a pharmacy code as established by the National Uniform Billing Committee (NUBC). Because important drug charge information for the CAR T therapy would be contained in revenue code 0891, omitting it during the weight-setting process would overestimate the number of clinical trial cases and underestimate the resource utilization for non-clinical trial CAR T cases. **We therefore request that CMS describe how it derived "standardized drug charges" and identify an approach to include charges associated with revenue code 0891 if those charges were in fact excluded during weight-setting for MS-DRG 018 for FY 2021.**

While the MS-DRG payment for CAR T is an improvement, it is still inadequate in addressing the extraordinary level of resources necessary to provide this life-saving therapy. According to our analysis of FY 2019 cases, we project that the mean adjusted payment (inclusive of GME, DSH, wage index adjustments) for MS-DRG 018 as proposed would be approximately \$360,000, on average, in FY 2021. However, (non-clinical trial)

²¹ IQVIA Institute for Human Data Science (May 2019). Global Oncology Trends 2019.
<https://www.iqvia.com/institute/reports/global-oncology-trends-2019>

CAR T cases have an average cost \$507,000. **Thus, the new MS-DRG payment is still almost 30% below the cost of CAR T cases.** In fact, the payments do not even cover the costs of the therapy itself, which is \$373,000. Moreover, our analysis reveals that roughly 80% of CAR T case would receive outlier payments – \$112,000 on average – indicating that without a more adequate payment mechanism, these cases will continue to rely on the budget-neutral outlier pool. As more CAR T therapies come to market, the strain on the outlier pool will be exacerbated, and extremely costly non-CAR T cases will no longer have access to these funds. Below, we urge CMS to make several technical changes in the immediate term in order to improve the precision of the clinical and cost information to more accurately determine cost of CAR T for rate setting, and preserve opportunities for alternative payment options in the future.

Additional CAR T Recommendations. The AHA urges CMS to consider an alternative method of determining the cost of CAR T therapy to ensure the agency captures cost accurately. Doing so will facilitate more precise information for determining outlier payments, refining weight-setting for the CAR T MS-DRG or developing a pass-through payment. Without an alternative, the standard method of calculating CAR T costs greatly underestimates the cost of this therapy. Specifically, if a hospital's overall cost-to-charge ratio (CCR) is 0.25, when applied to the list price for one of the CAR T products, it results in a calculated cost of \$93,250, whereas the actual cost is \$373,000. If a hospital with an overall CCR of 0.25 were to adjust the charge of the CAR T product, it would need to set a charge of almost \$1.5 million in order to generate an accurate cost calculation (for determining outlier payments, for example). To prevent such a scenario, we recommend that CMS develop a CAR T-specific CCR, which could be calculated if the agency were to create a dedicated cost center on the cost report, as noted below. Because the cost of these therapies is so uniquely high, a dedicated cost center for CAR T would prevent the underestimates in weight setting that arise because the national average CCR for drugs used in the weighting methodology does not appropriately represent CAR T costs. It also would support more accurate outlier and new technology add-on payments (NTAPs) as applicable. In the interim, CMS could utilize the therapy's average sales prices as a proxy for cost, or the actual acquisition cost as reported by hospitals on claims by requiring use of the NUBC value code 90 (described further below). Either option would allow the full cost of the therapy to be appropriately considered, free from charge compression.

In addition, we recommend that CMS consider approaches to differentiating distinct CAR T products on CAR T claims. Recently, ICD-10-PCS codes have been utilized for this purpose; however, we expect that ICD-10-PCS will have capacity issues in the near term and be unable to accommodate unique drug names. Alternatives, such as National Drug Codes, would provide visibility to the specific therapy being administered without overwhelming the procedure coding system.

The AHA also believes that several technical changes would help support a more accurate cost estimate of CAR T. Specifically, the NUBC last year approved a series of new revenue codes associated with cell/gene treatments. The AHA recommends that CMS require utilization of these codes in addition to the procedure codes, not only for

processing claims, but also for refinements to the Medicare cost report. We recommend CMS make the following technical changes:

- Require hospitals to submit their invoice cost using value code 90;
- Instruct hospitals to utilize the new revenue codes approved by the NUBC;
 - Revenue code 0891 – indicating the cell therapy product charge; and
 - Revenue code category 087x – indicating charges for procedures performed by staff for the collection, processing and infusion/injection of genetically modified cells.
- Create a new line for CAR T and similar immunotherapies in the Medicare cost report, comparable to CMS's development of line 0077 for stem cell transplant. This dedicated cost center would allow CMS to isolate the costs of CAR T in the cost report in order to calculate an accurate, CAR T-specific CCR that would apply in future MS-DRG weight-setting, as well as outlier payment and NTAP calculations.
- Implement a Medicare Code Editor edit requiring either the presence of a clinical trial diagnosis code Z00.6 and condition code 30 or a non-zero dollar value (including a token charge) in new NUBC revenue code 0891 when either of the ICD-10-PCS CAR T administration codes (XW033C3 or XW043C3) is on the claim.

CAR T Clinical Trial Payments. As noted above, CMS identified clinical trial CAR T cases in order to exclude them from CAR T weight setting. In the rule, CMS describes the process for determining payment for clinical trial cases since the resources used for those cases do not include the costs of the therapy. Specifically, CMS proposes to adjust the CAR T MS-DRG payment by multiplying the amount by 0.15, which was calculated by dividing the costs associated with clinical trials by costs associated with non-clinical trial cases. CMS also proposes to identify clinical trial CAR T cases by the Z00.6 code. However, because the Z00.6 code is not unique to CAR T cases, the code alone may not be sufficient in identifying CAR T clinical trials. Thus, there is potential for a CAR T case to be in a clinical trial for a separate intervention and as a result, the Z00.6 could be present despite the full cost of the therapy contributing to the cost of the case. To prevent inappropriate underpayment for such a scenario, we recommend that CMS take additional steps to ensure precise identification of CAR T clinical trial cases, such as confirming that the drug charges for the case are less than \$373,000 – as the agency did to identify cases to exclude for weight-setting – or examining the clinical trial number associated with the case. Since 2014, CMS has required reporting of a clinical trial identifier number on claims for items and services provided in clinical trials;²² reviewing clinical trial numbers for MS-DRG 018 cases that contain a Z00.6 code on the claim will support a more precise identification of clinical trial CAR T cases.

²² CMS. (2013). MLN Matters: Further Information on Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1344.pdf>

GRADUATE MEDICAL EDUCATION (GME)

Medicare graduate medical education (GME) funding is critical to maintain the physician workforce and sustain access to care. However, such funding is insufficient in its current scope. For example, the Balanced Budget Act of 1997 imposed caps on the number of residents for which each teaching hospital is eligible to receive GME reimbursement. These caps have held except for certain limited and one-time adjustments; they are a major barrier to reducing the nation's significant physician shortage. **We urge CMS to support legislative efforts to lift the cap on the number of Medicare-funded residency slots, which would expand training opportunities and help address health professional shortages across the country.**

When a teaching hospital closes a residency program or the hospital closes entirely, Medicare regulations permit the hospital to temporarily transfer a portion of its hospital-specific direct GME and indirect medical education FTE resident slots to other hospitals that are willing to accept and train the displaced resident(s). The receiving hospital(s) may then receive a temporary adjustment to its FTE cap for the duration of the displaced resident's training. CMS has previously defined "displaced resident" as one that is *physically present* at the hospital training *on the day prior to or the day of hospital or program closure*. However, the agency proposes to modify this definition to be based on the day that the closure was publicly announced. In addition, CMS proposes to include as "displaced" those residents that were not physically present at the closing program or hospital, but had intended to train at – or return to training at – the closing program/hospital. **We greatly appreciate CMS's recognition of the efforts made by hospitals that accept and train residents from closed programs and hospitals. We believe that its proposed policy would more accurately account for displaced residents training at receiving hospitals, and therefore support it. We further urge CMS to apply this new policy to all current residents that would meet the new definition of displaced resident, even if the program or hospital closure occurred before FY 2021.** Applying the new definition to displaced residents currently training at receiving hospitals would more accurately and appropriately account for FTE slots at those hospitals for the purpose GME.

CMS also would require that hospitals applying to accept displaced residents only include the last four digits of each resident's social security number, as opposed to the full social security number. **We support this proposal.**

MEDICARE BAD DEBT

The Medicare program reimburses providers for a percentage of their allowable bad debts, which result from unpaid, uncollectible deductibles and coinsurance amounts. Currently, Medicare reimburses 65% of the allowable bad debt for PPS hospitals and critical access hospitals. The Medicare Provider Reimbursement Manual (PRM) outlines actions that providers are recommended or required to take in order for an unpaid amount to be

considered a bad debt for Medicare purposes. CMS is proposing to clarify, modify and codify into regulation the activities related to bad debt, in addition to proposing new requirements.

The AHA is very concerned that CMS proposes to retroactively apply a number of bad debt policy proposals. The agency offers insufficient, unclear and, in some cases, contradictory justification for retroactive application, as described below. We do not agree that retroactive implementation is warranted, and we strongly urge CMS to withdraw retroactive implementation in its rulemaking. In addition to retroactivity, we also have concerns with the substance of several of the proposals, which are outlined further below.

The standard set forth in section 1871(e)(1)(A)(ii) of the Social Security Act on which CMS is relying to make the changes retroactive requires that “failure to apply the change retroactively would be contrary to the public interest.” While the agency states that applying the policies before the upcoming fiscal year would serve the public interest, it provides neither clear nor adequate support for this conclusion. **Indeed, we strongly disagree with CMS and believe that it actually would be *contrary* to the public interest to apply the proposals retroactively.**

CMS claims that, unless the policies are applied retroactively, providers could have confusion regarding the cost reporting periods to which the regulations apply. The agency states that such confusion among providers would cause many of them to resubmit cost reports, leading to an increased and inappropriate use of provider and government resources. CMS asserts that applying the proposals retroactively would prevent this from occurring. However, this is incorrect. Retroactive implementation would actually have the opposite effect – providers would likely request re-opening and re-submitting cost reports out of an abundance of caution to ensure compliance with retroactive rules. Indeed, providers would feel compelled to re-assess all previous cost reports if policies were made retroactive. This is especially the case for any clarified, modified or new requirement.

As a specific example of this, CMS is proposing to retroactively require hospitals to retain a Medicaid remittance advice for services provided to dually eligible beneficiaries in order to claim allowable bad debt for those services. If this were to be finalized, providers would have to possess Medicaid remittance advices for all previous Medicare-Medicaid crossover bad debts in order to prevent any reductions to prior bad debt amounts – even if the provider had indeed billed the state, but the state had not been able or willing to issue a timely remittance advice. Expecting providers to retroactively obtain remittance advice is unreasonable. Not only would this be extremely burdensome for both the providers and state agencies to carry out, but providers would wish to re-submit cost reports in order to supplement previously filed reports with Medicaid remittance advices.

In addition, in its discussion of retroactive rulemaking, CMS does not acknowledge that several of the bad debt proposals would transform *recommended* activities into *mandated*

actions, such that new requirements would be applied to past behavior. This fact alone would make retroactive application inappropriate since a retroactive effective date could put providers out of compliance by default, despite them having followed applicable conventions of an earlier time period. It is unreasonable and illogical to expect hospitals to have historically met new requirements that were not compulsory at the time. Retroactively changing hospital bad debt practices from recommended to required would affect the standard to which prior actions are held, ultimately calling into question the validity of previously submitted cost reports; imposing additional burdens on providers, government, and in some cases, beneficiaries; and adversely affecting prior bad debt reimbursements.

For example, CMS proposes to alter the guideline that “the provider *should* [emphasis added] take into account a patient's total resources” (PRM Chapter 3, Section 312) when determining whether the beneficiary is considered indigent, to a regulation that states that a provider “*must* [emphasis added] do the following:...(2) take into account a beneficiary's total resources.” Retroactive application would therefore hold providers to a standard that had not been in place for past indigence determinations, and could ultimately disallow previously reimbursable bad debt because the requirements for deeming bad debt for unpaid amounts differs for indigent and non-indigent beneficiaries. This retroactive change likely would trigger cost report re-submissions to prevent bad debt losses. **In addition, it could cause significant burden on beneficiaries who could be called upon to submit financial documentation to providers for an ex post facto examination of total resources.** Again, it would not be reasonable to consider such onerous activities – especially for beneficiaries – to be in the public interest.

The AHA opposes retroactive application of the bad debt policies described in the proposed rule. A retroactive effective date would induce additional burden and usage of provider and government resources, and as a result, would be contrary to the public interest, failing the 1871(e)(1)(A)(ii) test for imposing retroactivity. **We strongly urge CMS to withdraw its proposals to retroactively apply proposed policies related to Medicare bad debt. Instead, the agency should only apply any finalized bad debt proposals to cost reporting periods ending on or after Oct. 1, 2020.**

Our concerns on the individual proposals are discussed below.

Policy for Determining Indigence. According to Chapter 3, Section 312 of the PRM, “once indigence is determined and the provider concludes that there had been no improvement in the beneficiary's financial condition, the debt may be deemed uncollectible.” Determining indigence is therefore a crucial component of bad debt activity because providers do not have to engage in “reasonable collection efforts” for debts associated with indigent beneficiaries.

The PRM guidance discusses two methods by which a provider can identify a Medicare beneficiary as indigent: by determining that the beneficiary is also eligible for Medicaid, or by applying “its customary methods for determining the indigence of patients” under a

number of guidelines. One such guideline is that the provider “should take into account a patient’s total resources which would include, but are not limited to, an analysis of assets (only those convertible to cash, and unnecessary for the patient’s daily living), liabilities, and income and expenses.” CMS proposes to make this component of the indigence determination required by regulation. As indicated above, this proposal would change aspects of indigence determination from a recommendation or guideline to a regulatory requirement.

We have several concerns related to changing this policy from a guideline that providers should consider to a requirement that providers would be obligated to carry out; we urge CMS to not finalize its proposal. According to the regulations governing Medicare bad debt (42 CFR § 413.89(e)), providers must utilize “sound business judgment” to determine that there is no likelihood in recovering an unpaid amount. The guideline in the PRM in its current form affords providers the opportunity use “sound business judgment” in this manner because it gives providers flexibility to make adjustments in their consideration of indigence for each patient. As the Provider Reimbursement Review Board (PRRB) has previously attested, “each determination of indigence must take into consideration each patient’s circumstances. In some instances, that will require an asset test while other circumstances may obviate the need for that test.”²³ However, this flexibility disappears when guidelines are put into regulation. These regulations have the force of law and, as such, no longer allow providers to take into consideration each patient’s circumstances per the PRRB. We describe our specific concerns below.

First, the agency does not provide a clear threshold or endpoint for the analysis of the beneficiary’s total resources. Thus, it is unclear when a provider would acquire sufficient information such that it would meet the regulatory requirement and could rightfully deem the patient indigent for Medicare bad debt purposes. Similarly, it is unclear whether any one particular data point would be sufficient to prohibit a beneficiary from being considered indigent. In addition, we have heard from several AHA members that Medicare Administrative Contractors (MACs) may differ in their assessment of providers’ conclusions on indigence, with some MACs denying bad debt amounts due to considering the hospital’s customary methods to be too generous. **Without further clarification of what would be considered to be an adequate amount or a variety of information for identifying indigent beneficiaries, there is a considerable likelihood that bad debt could inappropriately be denied, with variation across regions.**

Second, if the proposal is finalized, the level of information required to identify a beneficiary as indigent for Medicare bad debt purposes would be more restrictive than many hospitals’ charity care or financial assistance policies. This would not only cause confusion and burden for providers, since debts associated with charity care services would possibly not qualify for Medicare bad debt, but it would expose financially vulnerable beneficiaries to a potentially lengthy and challenging collections process. **Clearly, the**

²³ PRRB Dec. No 2008-D12. (June 20, 2007). <https://www.cms.gov/Regulations-and-Guidance/ReviewBoards/PRRBReview/downloads/2008D12.pdf>

Medicare program does not intend for providers to engage in collections for patients with few resources, in light of Chapter 3, Section 312 quoted above. However, requiring the total resource analysis would undermine this position by increasing restriction on who could be deemed as indigent. Many providers utilize presumptive eligibility tools to appropriately and efficiently identify indigent patients, in accordance with their charity care or financial assistance policies. CMS should consider presumptive eligibility as a sufficient indication of indigence for the purpose of Medicare bad debt.

Third, a Medicare requirement to evaluate assets, liabilities and other elements of total resources directly conflicts with some state-level policies and requirements related to national programs. For example, some states prohibit or greatly restrict health care providers from performing asset tests as part of indigence determination. Given this constraint, the proposal would result in substantial reductions in the amount of allowable bad debt that could be written off by hospitals in these states. In addition, other hospitals could be restricted by participation requirements for national programs. Specifically, in order for CAHs to participate in the National Health Service Corps (NHSC) program – which addresses clinical workforce shortages in underserved communities – they must not consider patient assets when offering certain discounted care. **Thus, CMS’s proposal conflicts with certain state laws and could also threaten CAHs’ participation in the NHSC program by compelling them to conduct asset evaluations in order to claim bad debt. In light of the concerning trend of rural hospital closures and ongoing workforce challenges, CMS should not take any steps that could jeopardize opportunities for rural or other hospitals to recruit and retain clinicians in their communities.**

Fourth, requiring an analysis of total beneficiary resources puts extraordinary burden on both beneficiaries and providers. In order for the provider to fully examine total resources, beneficiaries could be called upon to furnish personal documents (e.g., tax returns, bank statements) for providers to assess. Requesting potentially intrusive information at a time when a beneficiary is medically – and potentially financially – vulnerable is inappropriate and counter to the spirit of many charity care/financial assistance policies. Furthermore, the amount of documentation that providers would have to collect and maintain to meet the proposed requirement would be extremely burdensome and clearly contradicts CMS’s Patients Over Paperwork initiative.

Implicit Price Concession as Bad Debt. In 2014, the Financial Accounting Standards Board (FASB) issued its Accounting Standards Codification Topic 606 (“Revenue from Contracts with Customers”), which directs hospitals and other organizations to report their revenue in external financial statements in accordance with Generally Accepted Accounting Principles (GAAP). Specifically, Topic 606 characterizes most bad debts and uncollectible amounts as “implicit price concessions” rather than bad debt. While the FASB differentiation of implicit price concession and bad debt does not change the economic value of bad debts for Medicare purposes, implicit price concessions must be reported as reductions of net patient revenue, rather than operating expenses, in external financial statements. CMS proposes to “recognize that bad debts, also known as ‘implicit price

concessions,' are amounts considered to be uncollectible from accounts that were created or acquired in providing services."

We appreciate CMS's efforts to better align its documentation requirements with existing accounting standards. However, it is crucial that CMS issue guidance to both providers and MACs to clarify that implicit price concessions are a component of bad debt for Medicare purposes. We also recommend that CMS develop a line in Worksheet S10 to properly document and account for implicit price concessions for calculating uncompensated care. CMS should make the proposed policy effective only after appropriate guidance and documentation have been made available to providers.

"Crossover" Bad Debt Reporting. Medicare-Medicaid "crossover" bad debt includes the unpaid deductible and coinsurance amounts associated with dually-eligible beneficiaries. State Medicaid programs may reimburse providers for none, some, or all of these amounts, in accordance with the state's Medicaid policy. As discussed in Chapter 3, Section 322 of the PRM, "any portion of the deductible or coinsurance that the State does not pay that remains unpaid by the patient, can be included as a bad debt under Medicare, provided that the requirements of Section 312 [indigence determination] or, if applicable, Section 310 [reasonable collection efforts] are met."

Providers have generally written off this crossover bad debt to a contractual allowance account. A contractual allowance is a GAAP concept that refers to the difference between a provider's charge and the contractual discounted payment. Historically, crossover bad debt has been considered to be a contractual allowance because providers are bound by their Medicaid provider agreements to accept the amounts paid by the state plan as payment in full. **According to discussions with our members, MACs have historically found this contractual allowance classification to be acceptable, and considered these crossover balances as part of reimbursable bad debt for Medicare purposes.** On external financial statements, crossover bad debts – and all other uncollectible amounts – are applied as reductions to net patient revenue, in accordance with GAAP.

CMS proposes to require providers to write off Medicare-Medicaid crossover bad debts to an expense account for uncollectible amounts (bad debt) and not to a contractual allowance amount. Although this policy change would not affect the value or treatment of the crossover bad debt, as we have [previously written](#) to the agency, it would require providers to create a unique methodology for recording "crossover" bad debt – a methodology that would only be utilized for and necessary because of CMS. **We continue to believe that this would result in substantial, unnecessary administrative burden for providers without any benefit to the accuracy or efficiency of bad debt reporting.** Moreover, the proposal conflicts with the implicit price concession policy described above. Specifically, it would create inconsistency between the FASB standard that would be adopted by CMS per above – i.e., crossover bad debt as implicit price concession – and a new CMS requirement– i.e., crossover bad debt as bad debt expense. **Thus, we urge CMS to clarify its bad debt reporting policies, including those for crossover bad debt, such that they would be aligned with FASB standards in a sensible manner.**

Bad Debt Related to Dual-eligible Beneficiaries. State policies may require Medicaid programs to pay part or all of the enrollee's deductible and coinsurance for certain services. According to Section 322 of the PRM, "where the State is obligated either by statute or under the terms of its plan to pay all, or any part, of the Medicare deductible or coinsurance amounts, those amounts are not allowable as bad debts under Medicare." The proposed rule outlines actions that providers must take in order to satisfy the "reasonable collection effort" requirement for dual-eligible beneficiaries. Specifically, CMS proposes to require providers to bill the state and submit the Medicaid remittance advice to Medicare as evidence of the state's Medicare cost sharing liability (the "must bill" provision), so that any state Medicare cost sharing liability can be deducted from the Medicare bad debt reimbursement.

In some cases, the Medicaid program will not process crossover claims, leaving the provider without a remittance advice. CMS states that in this circumstance, the provider would have to acquire alternative documentation from the state that demonstrates the Medicaid program's Medicare cost sharing liability (or lack thereof). Under this construct, the burden remains on the provider to work with the state to determine the state's cost sharing amounts, and CMS would not accept the provider's estimate of the state's cost sharing responsibility. **The AHA is concerned by the burden that this policy would put on providers that serve dually eligible beneficiaries, including those in rural and underserved areas.** We recommend that CMS accept a provider's estimate of the state's cost sharing when the provider submits documentation that it has billed the state but the state does not provide a remittance advice. In addition, our recommendation should be extended to crossover bad debts related to care that may not be covered by the state's Medicaid program, including certain psychiatric services. We have heard from our members that such crossover bad debts are often disallowed because, when the service is not covered by the state's program, it is not possible to enroll a provider into Medicaid and therefore not possible to receive a remittance advice.

Issuance of a Bill. In order to deem an unpaid amount to be bad debt, providers must first demonstrate that they have made a "reasonable effort" to collect the amount. According to Section 310 of the PRM, reasonable effort must involve the issuance of a bill "on or shortly after discharge or death of the beneficiary to the party responsible for the patient's personal financial obligations." CMS proposes to clarify and modify this provision such that a provider must issue the bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the date of the remittance advice from Medicare or from the beneficiary's secondary payer, whichever is latest. **We appreciate CMS's efforts to clarify this requirement and support the proposed modifications.** We also request that CMS make two clarifications if the agency finalizes the provision. First, we request clarification that the provision requires the provider's attempt to issue the bill, and not the receipt of the bill. Second, because the secondary payer may not send a remittance advice, we also recommend that the agency clarify that a notice of no payment (or other similar documentation) would substitute for a secondary payer's remittance advice if applicable.

120-day Time Period for Collection. Currently, Section 310.2 of the PRM stipulates that a bill cannot be considered uncollectible until at least 120 days have passed since the provider first attempted to receive payment. In the rule, CMS proposes that the 120-day clock restart when the provider receives a partial payment. We understand and support the intent of this policy, which is to allow an appropriate timeframe for patients to make progress toward payment before a provider deems an unpaid amount to be uncollectible. Moreover, many of our members establish extended payment schedules for patients that require more flexibility in light of personal financial circumstances. However, we have heard from our members that nominal partial payments can unintentionally stretch the period for collection efforts for an unreasonable amount of time – even years in some cases. This scenario exposes the beneficiary to a drawn out collections process that can cause ongoing financial strain. It also worsens stability in hospital finances and drains administrative resources because conclusion of the collection efforts remains unknown. **Thus, we recommend that CMS consider setting a minimum threshold for the level of partial payment that is sufficient to restart the 120-day clock. Having a threshold of some kind would allow patients to continue to make good faith payments toward an unpaid amount, while also providing more predictability for providers.**

RURAL HOSPITAL PROVISIONS

The rule discusses several proposals with specific impact on rural hospitals.

Hospitals Applying for Rural Referral Center (RRC) Status. One way in which a hospital can qualify for RRC status is based on a combination of discharge volume and case mix criteria, in comparison to other providers in the hospital's region. To meet the discharge criterion in this circumstance, a hospital must use the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting period used to compute the regional median discharges. CMS proposes that, in a case where the hospital's applicable cost reporting period is shorter or longer than 12 months, the number of discharges would be annualized. **We support this proposal.**

Critical Access Hospitals (CAHs). CMS continues to evaluate the Frontier Community Health Innovation Project (FCHIP), which is a Center for Medicare and Medicaid Innovation (CMMI) demonstration that tests several models of health care delivery for rural CAHs in the most sparsely populated states. The FCHIP program is budget neutral. In previous rulemaking CMS had finalized that, in light of the small number of CAHs participating in the model, it would reduce payment to all CAHs if the aggregate payments for the model were to exceed the amount that would have been paid if the demonstration had not been implemented. Based on analysis of recent cost report settlements, CMS expects that the project would likely yield net savings. However, the agency notes in the proposed rule that it has not yet completed its data analysis to determine the aggregate FCHIP payments. CMS therefore proposes to delay any potential budget neutrality

adjustment for CAHs and revisit this policy in FY 2022 rulemaking when the agency expects to have complete data. **We support this proposal.**

CHANGES TO MS-DRG CLASSIFICATIONS

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

However, in looking forward to CMS’s inpatient PPS rulemaking for FY 2022, we urge the agency to consider the impact of the pandemic on the MedPAR data. Specifically, volumes for DRGs not related to COVID-19 will be atypical since hospitals and patients have been postponing or cancelling elective surgeries.

PRE-MAJOR DIAGNOSTIC CATEGORY (MDC)

Bone Marrow Transplant. CMS proposes to redesignate the MS-DRGs where bone marrow transplant procedures are assigned from surgical to medical MS-DRGs:

- MS-DRG 014 (Allogeneic Bone Marrow Transplant),
- MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy), and
- MS-DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) from surgical MS-DRGs to medical MS-DRGs.

CMS considered bone marrow transplant procedures to be similar to blood transfusion procedures, because they do not utilize the resources of an operating room, and are not surgical procedures. **While we agree that bone marrow transplant procedures are not surgical in nature, the resources utilized for bone marrow transplants are much higher than those for blood transfusions.** Unlike patients receiving blood transfusions, autologous bone marrow transplant patients require a series of daily injections of growth factor to increase stem cell projection as well as apheresis procedures to collect blood stem cells. Both autologous and allogeneic bone marrow transplant patients go through a process called “conditioning” which includes adjustments to radiation and chemotherapy treatments prior to transplants. They also are at risk for a variety of side effects.

MDC 6 (Diseases and Disorders of the Digestive System): Acute Appendicitis. CMS is proposing to reassign diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) from MS-DRGs 338, 339 and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for clinical consistency.

In addition, CMS is proposing to remove diagnosis code K35.32 from the complicated principal diagnosis list in MS-DRGs 338, 339, and 340. CMS's clinical advisors believe that cases reporting ICD-10-CM diagnosis codes describing "with abscess" are associated with higher severity of illness and resource consumption compared to "without abscess" because of extended lengths of stay and treatment with intravenous antibiotics.

We urge CMS to reconsider reassigning diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess). Our members' clinical advisors disagree with CMS's assessment. Specifically, they believe that the presence of appendiceal perforations resulting in peritonitis (with or without abscess) requires intense resources including peritoneal washings and intravenous antibiotics, as well as longer patient stays.

MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

- *Cervical Radiculopathy.* Currently, diagnosis codes describing radiculopathy in the cervical/cervicothoracic area of the spine are assigned to MDC 01 and the procedure codes describing a cervical spinal fusion procedure are assigned to MDC 01 in MS-DRG 028 (Spinal Procedures with MCC), MS-DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS-DRG 030 (Spinal Procedures without CC/MCC). Diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine (M54.14, M54.15, M54.16 and M54.17) are currently assigned to MDC 08 and therefore, group to MS-DRGs 471, 472, and 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively) in MDC 08.

We recommend that all cervical fusion procedures be classified to the same MS-DRGs (471, 472 and 473) regardless of the diagnosis for which the procedure is performed. The main driver for resource utilization is the surgical procedure. Radiculopathy is one of the indications for cervical fusion. The ICD-10-CM diagnosis codes for radiculopathy of the cervical/cervicothoracic spine would need to be classified to MDC 8, in order to group to clinically similar cases under MS-DRGs 471, 472 and 473.

- *Hip Replacements.* CMS is proposing to create two new MS-DRGs for hip replacements: MS-DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively). Currently, those cases fall under MS-DRGs 469 and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement and without MCC, respectively) which are included in the Comprehensive Care for Joint Replacement (CJR) model.

We urge CMS not to finalize its proposal to create the two new MS-DRGs (521 and 522) until it can further analyze and determine why its proposed weights

for these DRGs are not in line with clinical experience and underlying data.

Specifically, the proposed rule indicates, and we agree, that patients undergoing hip replacement due to hip fracture have higher average costs and longer lengths of stay than those undergoing elective hip replacements. However, the recovery statistics and process for a hip fracture patient is typically more complex than an elective procedure. Given this, and that most of the hip replacements due to hip fracture would be shifting from MS-DRG 469 to MS-DRG 521, we would expect MS-DRG 521 to have a weight that is substantially higher than MS-DRG 469. However, it has a weight that is 1.01% lower. This is even more confounding when considering that the geometric mean lengths of stay (GMLOS) and arithmetic mean lengths of stay (AMLOS) are 3.1 and 4.2, respectively, for MS-DRG 469, but substantially higher, 6.2 and 7.2 respectively, for MS-DRG 521. Our analysis has been unable to resolve the contradictions between the clinical, GMLOS and AMLOS data and the resulting weights. We believe a pause in the proposal is in order until this can be resolved.

Given the proposal to create proposed new MS-DRG 521 and MS-DRG 522, CMS seeks comment on the effect this proposal would have on the CJR model and whether to incorporate MS-DRG 521 and MS-DRG 522, if finalized, into the CJR model's proposed extension to December 31, 2023. Beneficiaries undergoing a hip replacement due to a hip fracture typically have surgeries that are unplanned. They also tend to be more medically complex and functionally impaired than beneficiaries undergoing a hip replacement for other reasons. As such, removing these beneficiaries from the CJR and Bundled Payments for Care Improvement (BPCI) Advanced target DRGs would have clear implications for risk adjustment, and it would be critical for CMS to ensure that actual and historical episode spending targets are adjusted so they reflect comparable patient populations. In addition, given the differing weights of the two new MS-DRGs compared to the existing MS-DRGs, adjustments to the actual and historical episode spending targets would also be necessary if hip fractures continue to be included in CJR and BPCI Advanced.

MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Inferior Vena Cava Filter Procedures. CMS is proposing to remove three ICD-10-PCS codes (06H00DZ, 06H03DZ, and 06H04DZ) describing the insertion of an inferior vena cava filter from the ICD-10 MS-DRG O.R. Procedures list. Under this proposal, these procedures would no longer impact MS-DRG assignment. CMS's clinical advisors believe that these procedures do not require anesthesia nor the resources of an operating room (O.R.), and they are comparable to the related ICD-10-PCS procedure codes that describe the insertion of infusion devices into the inferior vena cava that are currently designated as Non-O.R. procedures.

We urge CMS to reconsider its proposal to remove the ICD-10-PCS codes for insertion of an inferior vena cava filter from the ICD-10 MS-DRG O.R. Procedures list. While it may be true that at some hospitals the procedure may be done at bedside similar to the insertion of infusion devices, this is not universally true and facilities incur

significant costs beyond those for infusion devices. In some hospitals, the insertion of vena cava filters require the use of specialized interventional radiology suites and in other hospitals without such specialized suites, the procedure may be performed in a multi-purpose operating room. The procedure requires specialized equipment and is typically performed by physicians such as vascular specialists, and in some instances specialized nurse practitioners. In all instances, the cost of vena cava filters are higher than infusion catheters because filters can easily add over \$4,000 to the cost of the procedure.

OPERATING ROOM (O.R.) AND NON-O.R. ISSUES

Overview. Given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, CMS plans to conduct a comprehensive, systematic review of the ICD-10-PCS procedure codes. During this multi-year project, CMS also will review the process for determining when a procedure is considered an O.R. procedure. For example, CMS notes it may leverage the detail that now is available in the ICD-10 claims data. CMS further indicates that determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD-10-PCS classification, as well as changes in medical practice.

CMS has typically evaluated procedures on the basis of whether or not they would be performed in an O.R. CMS believes that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD-10. CMS is soliciting public comments on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system for future consideration.

We recognize that reviewing O.R. and non-O.R. designations is a significant undertaking that may significantly restructure many MS-DRGs. **We recommend that CMS proceed cautiously and provide advanced notice of its proposed methodology along with transparent data for each ICD-10-PCS procedure code considered for change. We caution CMS that the data for FY 2020 related to procedures will not be representative of typical procedures performed by facilities in light of the COVID-19 pandemic impact which resulted in many hospitals and patients postponing or cancelling elective surgeries.**

In addition, we reiterate the following general recommendations submitted in response to the FY 2020 proposed rule:

- CMS should allow sufficient time for provider review.
- Thorough data analysis with provider input is critical to allow for appropriate insight in provider comments.

- CMS should consider resources surrounding the entire procedure and not only O.R. charges.
- CMS should assemble a technical advisory panel (TEP) made up of clinical, coding and financial stakeholders and experts to review methodologies for O.R. determination.
- CMS should address procedures performed in all settings as there may be variations based on geographical differences, hospital size, resources and physician specialty availability. Specifically, while large hospitals may have hybrid O.R.s or specialized procedure rooms (e.g., interventional radiology suites), many smaller community hospitals may have multi-purpose O.R.s where the same room may be used for invasive general surgeries as well as procedures that may be performed in specialized procedure rooms in large hospitals.

COMPREHENSIVE CC/MCC ANALYSIS

Overview. In the FY 2008 inpatient PPS/LTCH PPS final rule (72 FR 47159), CMS described its process for establishing three severity levels of Complications or Comorbidities (CC) into which it would subdivide the diagnosis codes. The categorization of diagnoses as a Major Complications or Comorbidities (MCC), a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use.

In the FY 2018 inpatient PPS final rule, CMS provided public notice of its plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. This is similar to the FY 2008 inpatient PPS comprehensive review of the CC list performed to better recognize severity of illness that ultimately resulted in the implementation of MS-DRGs. CMS is using the same methodology used in FY 2008 to conduct this analysis. For FY 2020, CMS recommended (but did not implement) a change in the severity level designation for 1,492 ICD-10-CM diagnosis codes.

For FY 2021, CMS notes its internal workgroup developed a set of guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. CMS plans to use a combination of mathematical analysis of claims data and the application of these guiding principles, to continue a comprehensive CC/MCC analysis and present the findings in future rulemaking. CMS is seeking public comment on the guiding principles below as well as other possible ways they can incorporate meaningful indicators of expected resource use and clinical severity by a secondary diagnosis:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.

- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We appreciate the opportunity for comment on the guiding principles that would be used in combination with the mathematical criteria. **However, application of these guiding principles would represent a substantial revision to the definition of a CC, is inconsistent with current CMS standards, and would result in major implications for hospital reimbursement.** Specifically, MS-DRG Definition Manual, Version 37.1 provides the following definition: “A substantial complication or comorbidity was defined as a condition that because of its presence with a specific principal diagnosis would cause an increase in length of stay by at least one day in at least 75 percent of the patients.” To our knowledge, CMS has not applied any other definition until now.

Our concerns and requests with CMS’s proposed guiding principles include:

- A lack of insight on how the mathematical criteria would be used in conjunction with the proposed guiding principles to arrive at decision making for the severity levels. It is important for commenters to know if the conditions must meet both mathematical criteria and principles, or, only one of the two for consideration. For example, CMS does not state how it will handle conditions that would not fit any guiding principles, such as obstetrical diagnoses or congenital conditions, but would meet the mathematical calculation and therefore should be considered MCC/CC.
- The requirement that every specific code meet all guiding principles and the mathematical criteria. Some guiding principles appear overly strict and beyond the conventional definition of CC/MCCs; others appear to be too lax and duplicative of coding requirements for reporting of secondary diagnoses.
- A lack of detailed definitions and criteria for applying the guiding principles. Without such transparency, the principles are vague, subjective and open to interpretation. For example, it is unclear what “impedes patient cooperation and/or management of care” means. Potentially, it could capture every single psychiatric condition, chronic condition, and form of dementia, confusion, paralysis, and loss of sight/hearing.
- Use of the same guiding principles for identification of CCs vs. MCCs.

- The fact that the guiding principles may be applied *before* the mathematical analysis is applied. Instead, they should be applied after, as well as clearly and consistently applied for any proposed changes to the designation of CC/MCCs. Theoretically, the results of applying the mathematical analysis and any guiding principles should be duplicative or supportive of each other.
- Many of the guiding principles are too strict and could potentially eliminate CCs, leaving only MCCs, thus inadvertently eliminating the current 3-tier severity levels currently in the MS-DRG system.
- The principle requiring a “chronic illness with susceptibility to exacerbations or abrupt decline” cannot be applied across the board, as many ICD-10-CM diagnosis codes do not distinguish exacerbation. Only a handful of ICD-10-CM codes specify “acute on chronic” as part of the code descriptor. For example, the ICD-10-CM code for congestive heart failure unspecified as to whether systolic or diastolic, does not distinguish between chronic or acute on chronic.
- Principles such as “reflects systemic impact” introduce a new requirement that CC/MCCs have not had to meet. Many existing CC/MCCs are limited to a single body system. Therefore, it is unclear what the guideline means by “systemic impact.”
- There is a lack of transparency on the priority or process for decision making for diagnosis severity levels as this would impact comments.
- The principle “Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay)” overlaps in many respects with Section III of the *ICD-10-CM Guidelines for Coding and Reporting* regarding what is a reportable secondary diagnosis which states:
 - For reporting purposes, the definition for “other diagnoses” is interpreted as additional conditions that affect patient care in terms of requiring:
 - clinical evaluation; or
 - therapeutic treatment; or
 - diagnostic procedures; or
 - extended length of hospital stay; or
 - increased nursing care and/or monitoring.

In addition, it is unclear how CMS would determine when a condition required a “greater number of caregivers” or what type of caregivers would be considered, as this information would not be available in claims data.

1. We question whether the post discharge environment should be added as a principle. For example, if homelessness is found to be a factor for requiring additional resources in the mathematical formula (as it was noted in the FY 2020 inpatient PPS proposed rule), it is unclear how it would be recognized under the existing principles.
- We question how the principle of “post-operative condition/complication impacting recovery” would be applied. There are challenges associated with capturing all post-operative conditions with ICD-10-CM codes as the codes do not always include the terms “post-operative” or “post-procedural” nor are the conditions within a specific ICD-10-CM chapter. For example, for FY 2020, we disagreed with CMS’s proposed change in severity level from MCC to CC for Acute postprocedural respiratory failure (J95.821). However, acute respiratory failure is a life threatening organ failure which consumes significant resources and, as such, other acute respiratory failure codes are designated as MCCs (Code J95.822, Acute and chronic postprocedural respiratory failure; subcategories J96.0-, Acute respiratory failure, J96.2-, Acute and chronic respiratory failure and J96.9-, Respiratory failure, unspecified). We question how the guideline would apply to in situations where all other respiratory failures are MCC conditions but the guiding principle would or would not support this condition as a CC/MCC. It is also unclear how a determination would be made whether the condition or complication impacts recovery using the ICD-10-CM code.
 - We question the validity of the principle related to “recent (last 10 years) change in best practice, or in practice guidelines” and consider that most medical conditions have potentially had some changes in best practices in the last 10 years.
 - The principles are open to many different interpretations. For example, two different member hospital systems shared their analysis of applying the principles to current common CCs/MCCs and came back with different interpretations of whether the same condition would meet at least one guiding principle. We believe this speaks to the lack of clarity and subjectivity of the principles when there are no definitions or measurable criteria. For example, one system considered body mass index (BMI) over 40 to meet one of the guiding principles, the other one did not.
 - One system evaluated the top 50 CC/MCCs treated at their facility and had difficulty determining whether one of the principles would apply to 15 of those CC/MCCs. Some of those conditions included pleural effusion, ascites, body mass index (BMI) over 40 or under 19, malnutrition, and atelectasis.
 - Another system evaluated the entire list of CC/MCCs and found it difficult to answer a definitive “yes” with most of the guiding principles. Please consider the following application examples to demonstrate some of the challenges encountered:
 - For CC conditions such as acute exacerbation of COPD (J44.0 or J44.1), various atrial fibrillation codes (I48.-), angina codes (I25--, I20-) or

thrombophlebitis codes (I80.--) all meet the mathematical calculation for CC and were not considered for any revisions in their severity designations in the proposed FY 2020 inpatient PPS rule. The same is true for MCC conditions such as pneumonias (J15-J18--). With the exception of the guiding principle involving “typically requires higher level of care” which is measured with the math, could a definitive “yes” be answered for any of the principles or would it be subjective to the patient or a “maybe”?

- The following conditions had a proposed revision for FY 2020 in regards to severity but it appears “yes” could be answered to at least one of the guiding principles in pancytopenia, malnutrition, ST-elevation myocardial infarction, ventricular flutter/fibrillation, infectious gastroenteritis, most neoplasms, BMI 45.0-49.9, ventilator dependence, major depression recurrent, cardiac arrest, sickle cell disease, etc. We question how this would impact the severity consideration for these conditions that met mathematical calculations.
- The proposed FY 2020 inpatient PPS rule outlined many changes in the neoplasm codes; however, many would meet the guiding principles. The neoplasms seem to capture all of the following guiding principles regarding, “involves chronic illness with susceptibility to exacerbations or abrupt declines”, “organ instability”, “systemic”, “impact management of care”.

Proposed Changes to the MS-DRG Diagnosis Codes for FY 2021. We agree with the changes to the severity level designations as proposed in Tables 6I.1, 6I.2, 6J.1 and 6J.2 for FY2021. **However, we request that CMS reconsider the non-CC designation of the six new ICD-10-CM diagnosis codes for cytokine release syndrome (D89.831, D89.832, D89.833, D89.834, D89.835, and D89.839) effective Oct. 1, 2020.** While the codes will not affect the MS-DRG assignment for CAR T cases, cytokine release syndrome (CRS) can occur in other clinical conditions such as infections like COVID-19 and will require significant resources, especially for grades 3 and 4 which include organ failure and are life threatening.

REDUCTIONS IN MS-DRG PAYMENTS

CMS proposes several significant reductions to the relative weights of certain MS-DRGs – a move that could potentially limit patients’ access to these vital services. For example, CMS’s calculations of the relative weight for MS-DRG 215 (Other Heart Assist System Implant) would lead to a *nearly 26.4% reduction* in FY 2021. Decreases of this magnitude over a short time period will negatively impact hospitals that care for critically ill patients who require the implantation of a heart pump in the O.R. or cardiac catheterization laboratory after heart attacks or decompensating heart failure. Other examples of significant reductions include MS-DRG 796 (Vaginal delivery with sterilization/D&C with MCC) and MS-DRG 933 (Extensive Burns or Full Thickness Burns with Mechanical Ventilation > 96 Hours without Skin Graft) with proposed reductions of 46% and 26% respectively. Although MS-DRG 796 may not be significant for the Medicare population, the MS-DRG GROUPER is used by other payers such as Medicaid and some commercial

payers. **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 appreciated that the agency stemmed the payment decrease for MS-DRG 215 for FY 2020, and we urge CMS to again consider such an approach in this situation or when the relative weight for any MS-DRG is drastically reduced in a given year, particularly when it follows a significant decline in recent years.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Hospitals are required to report quality measure data and meet the administrative requirements of the IQR program to avoid a quarter reduction of their annual market basket update. The IQR also includes requirements to report electronic clinical quality measures (eCQMs) that align with the eCQM reporting requirements in the Promoting Interoperability Program.

CMS retains the current IQR measure set and most of the program's existing administrative requirements. However, CMS proposes changes to the IQR's eCQM reporting requirements, and to the measure validation process used in the IQR and other CMS hospital value programs.

COVID-19 Quality Measurement and Value-program Flexibility. **The AHA applauds CMS for using the extraordinary circumstances exception (ECE) policies in the IQR and its other quality reporting and value programs to exempt all hospitals from reporting data from Q4 2019, Q1 2020 and Q2 2020.** This blanket waiver policy provides important administrative burden relief, and ensures that data from the time of the COVID-19 public health emergency – which may not reflect true hospital performance – are not used in hospital programs.

However, we encourage CMS to consider additional reporting exceptions for Q3 and/or Q4 of 2020. The pandemic remains highly dynamic, and at times, extremely unpredictable. While some hospitals are beginning their transition back to more normal operations, hospitals will continue to balance this recovery and rebuilding with COVID-19 response. In addition, the federal government has asked hospitals across the country to report a variety of data to help inform its pandemic response efforts. As CMS assesses whether to exempt additional quarters of data, we ask the agency to be mindful that these other federal data reporting efforts can draw time from the same hospital personnel who also support their organizations' quality reporting efforts.

In addition, removing quarters of data from reporting has implications for measure reliability and accuracy in future public reporting, hospital star ratings and pay-for-performance programs. **We strongly urge CMS to conduct measure reliability analyses using truncated performance periods to ensure it has sufficient data to calculate performance accurately, and to make any results of such an analysis**

public. While it was appropriate for CMS to invoke its ECE policy for the COVID-19 pandemic, basing public reporting on unreliable data would be highly problematic.

eCQM Overview and General Considerations. CMS proposes two key changes to eCQM requirements. First, CMS would increase the number of quarters required for data reporting to two self-selected quarters for CY 2021 reporting period (FY 2023 payment), three self-selected quarters for CY 2022 reporting (FY 2024 payment), and four quarters for CY 2023 reporting (FY 2025 payment). Second, CMS proposes to begin reporting eCQM measure results publicly in late 2022, starting with data from CY 2021.

In general, the AHA believes in the potential for eCQMs to result in timelier, more clinically relevant assessments of hospital quality, with less administrative burden. However, setting realistic and sustainable eCQM policy is a challenging task constrained by a number of realities. In the first place, the development and implementation of eCQMs on a national scale is relatively novel. In fact, 2017 was the first time that hospitals were required to submit eCQM data to CMS. While the field continues to gain valuable experience with eCQMs, numerous questions remain about their accuracy and feasibility, so much so that many hospitals continue to report that they largely do not rely on eCQMs to track their quality improvement efforts.

Furthermore, as detailed in the Promoting Interoperability Program section of this letter, eCQMs are one of many electronic health record- (EHR) related mandates for hospitals. All of these mandates draw upon finite staff time and budgets of many of the same hospital departments, including quality, health IT, pharmacy, medical records and finance. For these reasons, CMS must pace any increase to eCQM reporting requirements appropriately, and implement only those program changes that meaningfully advance the ability of eCQMs to achieve their potential.

eCQM Reporting Quarters. **The AHA urges CMS to delay its proposed increase of the number of quarters required for eCQM reporting by at least one calendar year, to begin no earlier than CY 2022 reporting.** We understand that CMS wants additional quarters of eCQM data in an effort to increase case volume, thereby improving the reliability and accuracy of eCQM measure results. Yet, we believe that increasing the number of reporting quarters in CY 2021 is unrealistic, especially in light of the COVID-19 pandemic. EHR vendors need time during a reporting year to complete upgrades that help them meet CMS's eCQM reporting requirements. The current policy of requiring only one quarter of data is less problematic because the hospital could simply choose to report Q4 data. However, the needs of the COVID-19 pandemic have understandably delayed work on many of these upgrades to such an extent that hospitals may not be ready to report two full quarters of data in 2021. This would be true even if they choose to report the latest possible quarters (Q3 and Q4). We believe CY 2022 is the very earliest CMS should consider asking for two quarters of data. The agency should continue to monitor the progress of the pandemic, and the extent to which hospitals have recovered, to inform the exact timeframe to begin increasing reporting requirements.

Compounding these challenges further, CMS finalized significant policy changes for the Promoting Interoperability Program earlier this year, all of which will draw upon the same hospital resources as eCQMs. We discuss the challenges of these new policies in the Promoting Interoperability Program section of this letter. **Without a delay, the AHA is very concerned that many hospitals will face an untenable situation in which they could lose their entire annual payment update – ¼ for the IQR, and ¾ for the Promoting Interoperability Program – for failing to meet an eCQM mandate that their EHR vendors cannot deliver because of the pandemic and other competing federal EHR-related mandates.**

Improving eCQM reliability and accuracy is critically important. However, CY 2021 is not the time to increase the number of reporting quarters.

eCQM Public Reporting. **The AHA urges CMS not to finalize its proposal to report eCQM data publicly beginning with the CY 2021 reporting period.** As noted above, we oppose CMS's proposal to require two quarters of data during the CY 2021 reporting period, and would strongly oppose any policy in which CMS publicly reports only one quarter of eCQM data. Indeed, one of CMS's justifications for proposing public reporting of CY 2021 data is its intention to require submission of two quarters of data.

However, we encourage CMS to undertake foundational work that could support the potential for future public reporting of eCQMs. First, we recommend CMS make improvements to its eCQM measure validation process. We have detailed those recommendations in the next section of this comment letter. Given that the current validation process provides limited insight into eCQM accuracy, it would be premature to deem the eCQMs in the IQR ready for public reporting.

Second, we strongly urge CMS to conduct “dry runs” of all eCQMs it intends to report publicly. CMS has extensively used dry runs in its quality measurement programs, and they enable hospitals to preview their own performance and national comparison data confidentially before the data are made public. It helps hospitals better grasp measure methodology, and understand where their baseline performance is relative to others across the country. Generally, the agency provides dry run results to hospitals nine to 12 months before any data appear publicly, and we believe that would be appropriate for eCQMs. Given the novelty of eCQMs, CMS should consider conducting two dry runs – one based on a single quarter of data from CY 2020 or CY 2021, and another based on two or more quarters from CY 2022 or later.

Lastly, before setting a date certain for public reporting of eCQMs, we urge CMS to conduct reliability analyses to determine what minimum volumes of cases are needed for public reporting of eCQMs, and to make those analyses public. As with other measures in CMS's programs, the minimum volume threshold could vary by

measure, so CMS should provide analyses for each of the eCQMs it intends to publicly report.

IQR Validation Process. Hospitals are required to meet CMS's measure validation requirements to avoid the IQR's payment reduction penalty of one quarter of the annual market basket update. CMS proposes changes to the IQR's measure validation process that would be implemented gradually starting in 2021, and begin affecting payment in FY 2023. This includes combining the validation process for chart-abstracted measures and eCQMs by requiring all hospitals selected for validation to submit records for both chart-abstracted measures and eCQMs, and calculating a single validation score reflecting both measure types. CMS also would require hospitals to submit records selected for validation using electronic-file submissions, and reduce the maximum number of hospitals selected for validation from 800 to 400.

The AHA supports several aspects of CMS's IQR validation proposals, including a reduction in the number of validated hospitals, alignment of the timeframes of chart-abstracted and eCQM data and the use of electronic file submission for records selected for validation. However, we recommend CMS delay implementation of combining eCQM and chart-abstracted validation processes and scores by at least one year (to begin no earlier than 2022) while taking steps to improve the meaningfulness of the eCQM validation process.

As CMS acknowledges in the proposed rule, the eCQM validation process does not score hospitals on how accurately they collect their eCQM data. Rather, to pass eCQM validation, hospitals must simply submit the records of the patients that CMS's contractor requests within a prescribed timeframe. This falls far short of the rigor of the process for chart-abstracted measures, in which reviewers carefully review whether hospitals obtained the same result, and there must be 75% agreement between the contractor and the hospital's results. Hospitals undergoing eCQM validation do receive reports indicating whether the contractor obtained the same abstracted result (labeled as "matched" or "mismatched") on each measure as the hospital. However, hospitals have expressed frustration that the reports they receive back are highly inconsistent in providing detail about how the contractors obtained their results.

The AHA appreciates that, initially, CMS would weight eCQM validation results as 0% of the combined validation score. We believe that would be appropriate in the initial years of a consolidated validation process. However, we are concerned that CMS could increase the weight of the eCQM score – and tie the score to the accuracy of eCQM abstraction – without ensuring the eCQM validation process has a level of rigor and transparency comparable to that of chart-abstracted measures. To improve the meaningfulness of eCQM validation, we recommend that CMS take a number of steps, including those listed below. The AHA would be glad to engage with the agency on further work to improve the eCQM validation process:

- *Provide more detailed information in validation reports about the causes of a mismatch.* Hospitals have expressed frustration that the reports do not always specify the source of a mismatch, and provide little insight into whether the mismatch is caused by initial data capture, an issue with the Quality Reporting Data Architecture-1 (QRDA-1) file, or some other cause.
- *Develop transparent, consistent criteria for where CMS's validators look for information in the medical record.* Hospitals submit their eCQM data in QRDA-1 files, which draw upon structured fields in EHRs. Yet, validators review a PDF of the entire medical record, including free text. As a result, members have reported that validators have scored measures as a mismatched based on information from free text fields.
- *Ramp up any requirement for eCQM accuracy slowly over time.* Given the novelty of eCQMs, it would be unrealistic to expect the same agreement rate (75%) as chart-abstracted measures initially. When CMS is ready to score hospitals on the accuracy of their eCQM capture, the agency should consider starting at a much lower match rate.

In addition to improving the eCQM validation process, we urge CMS to clarify whether any exclusion criteria apply to a consolidated validation process. Under current policy, CMS excludes hospitals from eCQM validation if they have fewer than five cases for any one eCQM, and if a hospital has been granted an ECE. Yet, the proposed rule would eliminate these exclusions. If CMS is intent on finalizing a consolidated validation process, the agency should specify how it will handle those hospitals who do not have sufficient eCQM data to undergo validation, as well as those hospitals whose either eCQM or chart-abstracted data were not reported because of an ECE.

Hybrid Measure Reporting Requirements. In the FY 2020 inpatient PPS final rule, CMS finalized the required reporting of a hybrid hospital-wide 30 day readmissions measure in which hospitals submit certain “core data elements” from EHRs to supplement the Medicare claims data used to calculate the measure. In this rule, CMS proposes that future hybrid measures would use the same reporting requirements as the hybrid hospital-wide readmission measure. That is, hospitals must use the 2015 Edition of certified EHR technology, and submit data using the quality reporting document architecture (QRDA) currently used for hospital eCQMs (specifically, the patient-level QRDA-I standard).

While the AHA supports this proposal, we encourage CMS to monitor the experience of voluntarily reporting the hybrid measure, and make amendments in future rulemaking as necessary. Hospitals have still had limited experience with reporting the hybrid readmission measure on a voluntary basis, and many EHR vendors are still building out the functionality to report reporting.

HOSPITAL VALUE PROGRAMS

CMS proposes minimal changes to the Hospital Readmission Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, and Hospital Value-based Purchasing (VBP) Program. For the most part, CMS proposes to carry forward existing policies, and codify changes it previously made. **The AHA thanks CMS for keeping the number of changes to these programs minimal in the midst of the COVID-19 pandemic.**

Furthermore, as we noted in the IQR section of this letter, we thank CMS for invoking the ECE policies for these programs to provide administrative burden relief, and remove non-representative time periods of data. However, we also urge the agency to conduct **reliability analyses using truncated performance periods to ensure it has sufficient data to calculate performance accurately, and to make any results of such an analysis public.** Such an analysis also should include an assessment of whether any particular hospital types, or any geographic areas, are disadvantaged by the exclusion of particular data reporting periods. While it was appropriate for CMS to invoke its ECE policy for the COVID-19 pandemic, basing bonuses or penalties on unreliable or biased data would be highly problematic.

For the HAC Reduction program, CMS proposes changes to the validation process for the health-care associated infection (HAI) measures aligned with those in the IQR program. **The AHA believes CMS should continue to align the validation process for the HAC and IQR programs. However, we have concerns about the proposed changes to the IQR's validation process.** Please see the previous section of this letter for additional information.

PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM (PCHQRP)

The Affordable Care Act mandated the establishment of a quality reporting program for PPS-exempt cancer hospitals (PCHs). As with CMS's value programs, the number of proposals for the PCHQRP is small.

The AHA supports CMS's proposal to re-baseline the catheter-associated urinary tract infection (CAUTI) and central-line associated blood stream infection (CLABSI) measures, and use it in public reporting. The AHA strongly agrees that HAIs are an important topic for all hospitals – including PCHs. Conceptually, the AHA agrees with publicly reporting HAI measure data, and has supported doing so in other hospital quality and value programs. However, the patient population of PCHs is very different from other acute care facilities. Cancer diagnoses and treatments often leave patients far more immunocompromised and, therefore, more likely to contract HAIs. For a number of years, we have asked CMS to take steps to ensure PCHs are compared to an appropriate peer group. The re-baselining effort undertaken by the HAI measure steward – the Centers for Disease Control and Prevention – created a baseline unique to cancer hospitals that can

be used in the calculation of the standardized infection ratio. We believe this approach should allow for a more representative comparison of performance. However, we encourage CMS to remain engaged with the PCH community, and assess whether further changes to the CAUTI and CLABSI risk adjustment approaches may be needed.

In addition, we encourage CMS to conduct dry runs of the new unplanned readmissions and palliative care measures before they are publicly reported. The agency indicated it intended to perform such a dry run in the FY 2020 inpatient PPS rule, but it does not appear the dry run has yet taken place. As we noted in the IQR section, dry runs are helpful for hospitals to understand measure methodology and their baseline performance compared to other hospitals.

PROMOTING INTEROPERABILITY PROGRAM

Reporting Period. The AHA appreciates that, particularly in light of the ongoing COVID-19 pandemic, CMS proposes to continue certain policies that offer stability to the program and reduce burden for eligible hospitals and CAHs. **AHA consistently has advocated for an EHR reporting period of any continuous 90-day period and strongly supports CMS's proposal to continue this policy for CY 2022.**

Query of PDMP Measure. As noted in previous comments, PDMP integration with certified EHRs continues to pose a number of challenges for eligible hospitals and CAHs. **The AHA supports CMS's proposal to retain the query of prescription drug monitoring program (PDMP) measure under the electronic prescribing objective as optional worth five bonus points.** We further support mitigating burden on providers by continuing to require only a "yes/no" attestation vs. a numerator/denominator for this measure. This appropriately recognizes that technical capabilities to count PDMP queries vary across EHRs and can be impacted by state laws prohibiting integration and storage of PDMP data.

We concur with CMS's lengthy review and description of considerations that supports additional time to address challenges including EHR-PDMP integration, variation in implementation of PDMP queries into health information technology (IT) and clinical workflows, and lack of robust certification specifications and standards. Key federal and private sector efforts are currently underway aimed at improving technical approaches to EHR-PDMP integration, addressing stakeholder concerns around readiness, implementing key PDMP-related provisions of the SUPPORT for Patients and Communities Act (P.L. 115-271) and assessing alternative measure approaches.

Health Information Exchange Objective. CMS proposes to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to better reflect the measure's intent. The new proposed name would be Support Electronic Referral Loops by Receiving and *Reconciling* Health Information. **The AHA supports this change and concurs with CMS that including the concept of "reconciling" vs. "incorporating" health information will reduce confusion among eligible hospitals**

and CAHs. In addition, we continue to support CMS's policy that for cases in which an eligible hospital or CAH determines that no update or modification is necessary within the patient record based on the clinical information received, and eligible hospital or CAH may count the reconciliation in the numerator of the measure without completing a redundant or duplicative update.

Clinical Quality Measurement. CMS proposes to make several changes related to eCQM reporting. These changes align with proposals in the Hospital IQR Program to progressively increase the number of quarters for which hospitals are required to report eCQM data and to begin publically reporting eCQM data beginning with the CY2021 reporting period. **The AHA has significant concerns with these proposals that are described in detail in the IQR section of our comments.**

Future Direction of the Promoting Interoperability Program. The proposed rule solicits feedback on how CMS can support a variety of established Health & Human Services' (HHS) goals including reducing administrative burden, supporting alignment with the Quality Payment Program, supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. Specific to the 21st Century Cures Act, CMS identifies areas of overlap with the Office of the National Coordinator for Health Information Technology (ONC) final rule on interoperability, information blocking and the ONC health IT certification program.

The AHA urges CMS to approach the future direction of the Promoting Interoperability Program and alignment with the 21st Century Cures Act and other programs based on a holistic view of the full range of regulations that require IT development, upgrades, testing and end-user training. As it stands today, there is an inherent conflict between the department's goal of burden reduction and the reality of the health IT regulatory environment. Over the next several months, hospitals and health systems will require upgraded IT infrastructure to comply with, at a minimum:

- Appropriate Use Criteria (AUC);
- New e-prescribing requirements;
- Compliance with information blocking;
- Implementation of admission/discharge/transfer notifications under the Conditions of Participation;
- Deployment of IT tools to facilitate disclosure of negotiated rates;
- Upgrades for the Promoting Interoperability Program; and,
- New eCQM requirements, particularly if proposals to expand the number of quarters of reporting are finalized.

We have significant concerns regarding EHR vendor capacity to deploy, and hospitals' and health systems' capacity to implement, such a high volume of IT system changes on a short timeline, especially in light of the redirection of resources to support technology and data needs specific to the COVID-19 public health emergency.

Once upgrades are deployed, a period of testing is required to identify and resolve problems with the software and provide necessary training to end users. These activities are critical to ensuring patient safety is not compromised.

As we have seen from past experience with the Promoting Interoperability Program (formerly Meaningful Use), under unrealistic timelines, small hospitals in particular often end up last in line for IT upgrades. Additionally, when EHR vendors are forced to work on condensed timelines driven almost solely by regulatory mandates, other critical pieces of the IT infrastructure that support the continuum of care can be left behind.

With these considerations in mind, **the AHA urges CMS to take an aggregate view of upcoming IT-related requirements, particularly in light of the ongoing PHE, and provide much needed regulatory relief through delayed compliance dates or enforcement discretion.** Moving forward, the recently established CMS Office of Burden Reduction and Health Informatics also should prioritize this issue of “stacking” of IT requirements and emphasize staging of compliance dates as it assesses “the impact of new regulations on health care system operations.”

Finally, with regards to information blocking specifically, there is confusion on the part of hospitals and health systems regarding the relationship between the information blocking attestations in the Promoting Interoperability Program and the information blocking requirements and definitions set forth in the ONC final rule. This is especially true in the absence of final rulemaking to establish the “appropriate disincentives” health care providers will face if they are determined to have engaged in information blocking by the HHS Office of the Inspector General. **We urge CMS to clarify any overlap that may exist for the CY2021 EHR reporting period between the Promoting Interoperability Program attestations and the definition of information blocking under the ONC final rule.**