

June 24, 2019

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–1716–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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospital: Proposed Rule (Vol. 84, No. 86), May 3, 2019.***

Dear Ms. 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) 2020. 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 increasing the wage index values for low-wage hospitals and implementing a 90-day reporting period for attestation for the Promoting Interoperability Program. At the same time, we have serious concerns with other proposals. In particular, we strongly urge CMS not to apply budget neutrality to increases in wage index values for low-wage hospitals, as the agency is not bound to do so by statute. In addition, we strongly urge CMS not to finalize its proposed Complication or Comorbidity (CC) / Major Complication or Comorbidity (MCC) changes and, instead, work towards providing more information and transparency regarding its methodology and data in future rulemaking. A summary of our key recommendations follows.**



### **Area Wage Index**

CMS proposes to increase the wage index values of hospitals with a wage index below the 25th percentile, and also proposes to make such increases budget neutral by decreasing the wage index values of hospitals with a wage index above the 75th percentile. The AHA appreciates CMS's recognition of the wage index's shortcomings and supports improving the wage index values for low-wage hospitals. However, this should not be accomplished by penalizing other hospitals, especially in light of the fact that Medicare currently reimburses all inpatient PPS hospitals below the cost of care. Importantly, CMS is not bound by statute to apply budget neutrality for wage index modifications as proposed. **As such, we support increasing the wage index values of low-wage hospitals, but urge the agency to use its existing authority to do so in a non-budget neutral manner.**

### **Worksheet S-10 Data**

The AHA has a longstanding position supporting audits of the S-10 data in order to improve its accuracy and consistency, and we greatly appreciate CMS's efforts to do so. We continue to believe that audits – and, by extension, ongoing refinements to the audit process – result in data that are more appropriate for use in Medicare disproportionate share hospital (DSH) payments. **Thus, we support the use of FY 2015 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2020.** Furthermore, given the improvements made to the S-10 instructions for the FY 2017 cost report, we strongly recommend that CMS audit the FY 2017 data in the near term and utilize it in determining FY 2021 uncompensated care payments. In addition, we believe that there is room for improvement in the audit process and have outlined several recommendations that support clarity, consistency and completeness in audit implementation. 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.

### **CC/MCC List Analysis**

Following a review of CC/MCC lists, CMS proposes to change the severity level designation for a staggering 1,492 ICD-10-CM diagnosis codes. Eighty-seven percent of the changes (1,301 codes), would be shifted down in severity. According to CMS, these proposals are based on review of the data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses. **We strongly urge CMS not to finalize its proposals because the agency: provides insufficient information to adequately explain its changes; provides inaccurate information in certain instances; and applies its methodology and treats similar codes inconsistently. Together, these shortcomings have rendered us unable to meaningfully comment on the proposals. We urge the agency to instead work toward providing more information and transparency on their methodology and data in future rulemaking. CMS also should strongly consider phasing in any future changes given the impacts such modifications would have on hospitals and the patients they care for.**

### **Chimeric Antigen Receptor T-cell (CAR T) Therapy**

CMS proposes to increase the rate of new technology add-on payments (NTAPs) for all new technologies from 50% to 65% of the marginal cost, which would apply to CAR T given CMS's proposal to continue NTAPs for both CAR T products. **We appreciate the proposed change in NTAP rate, and believe this proposal is a step in the right direction. However, we continue to believe that a higher NTAP for CAR T is needed to ensure beneficiary access to these therapies. We, therefore, urge CMS to make NTAPs for CAR T at a uniform rate of 100%.** While it is not a permanent solution, a uniform NTAP of 100% of the cost of the CAR T product would provide much needed support to bolster provider efforts in meeting patient needs.

**We also urge CMS to consider an alternative method of determining the cost of the CAR T therapy.** Doing so will facilitate more accurate information for determining NTAPs and outlier payments, as well as future weight-setting for a potential CAR T Medicare-severity diagnosis-related group (MS-DRG) or a pass-through payment.

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](mailto:erogan@aha.org).

Sincerely,

/s/

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

*Enclosure*

**American Hospital Association (AHA)  
Detailed Comments on the Inpatient Prospective Payment System  
(PPS) Proposed Rule for Fiscal Year (FY) 2020**

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## **AREA WAGE INDEX (AWI)**

The area wage index is intended to recognize differences in resource use across types and location of hospitals. If these resource differences are not adequately accounted for, hospitals are either inappropriately rewarded or put under fiscal pressure. Taking this into account, 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 not yet been developed.

In the FY 2020 rule, the Centers for Medicare & Medicaid Services' (CMS) proposes to increase wage index values for low-wage hospitals – those with a wage index value below the 25th percentile. The agency also would make this policy budget neutral by decreasing the wage index for hospitals with values above the 75th percentile. The agency proposes that this policy 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 AHA appreciates CMS's recognition of the wage index's shortcomings and supports improving the wage index values for low-wage hospitals. However, this should not be accomplished by penalizing other hospitals, especially in light of the fact that Medicare currently reimburses all inpatient PPS hospitals below the cost of care. As such, we support increasing the wage index values of low-wage hospitals, but urge the agency to use its existing authority to do so in a non-budget neutral manner.**

25th Percentile Policy Proposal. For hospitals with a wage index value below the 25th percentile, CMS 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. Doing so would address an inherent flaw in the wage index that penalizes low wage hospitals. Given the wage index is calculated on a budget neutral basis nationally, the inpatient PPS payments for low wage hospitals do not fully recognize their labor costs, and provides insufficient funding for such hospitals to elect to increase their wages and meet other operational needs. This is a significant contributor to the financial difficulties faced by many rural hospitals.

**In addition, CMS's policy would help address “circularity” in the wage index – an important step toward addressing its long-standing flaws and one which we support.** Under the concept of circularity, for example, a hospital with low wages reports those wages, which informs their future wage index and results in a low-wage index value. Then, in light of its low-wage index value, this hospital may not have the funds needed to raise its wages at a rate that is competitive with other hospitals nationally. CMS's proposal

would aim to halt this spiral by providing an influx of funds via higher wage index values for these hospitals.

CMS also states that having an opportunity to raise wages may assist rural hospitals in addressing the many challenges they face. **However, it is critical that the agency recognize that wage index improvements alone are not sufficient to solve the multitude of complex problems facing rural providers.** Indeed, since 2010, 107 rural hospitals have closed – ten of them this year alone – a number that is expected to continue to rise. Highlighting the concerning trend in rural closures, AHA released our [Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care](#), which describes the many persistent, recent and emergent challenges that rural hospitals face and outlines policy recommendations to address them. The report calls for new federal investments and policy updates in order to tackle the numerous, widespread challenges of rural health care. Previously, in our [Task Force on Ensuring Access in Vulnerable Communities Report](#), we outlined a set of nine strategies to ensure access to essential services in rural areas and other vulnerable communities. Both reports acknowledge the multi-faceted challenges of rural health care and underscore the importance of tackling these issues with multi-pronged approaches. **Improving the wage index for certain rural and other low-wage hospitals is one such investment, but more policy solutions are needed. Specifically, we have recommended new models of care for rural communities, as well as appropriate reimbursement, additional regulatory relief, resources for telehealth and targeted workforce programs. The AHA remains an advocate supporting efforts by CMS and Congress to advance rural health care; we especially look forward to the Administration’s efforts in carrying out CMS’s Rural Health Strategy.**

75th Percentile Policy Proposal. CMS proposes to reduce the wage index values of hospitals above the 75th percentile in order to make its 25th percentile policy budget neutral. However, CMS itself acknowledges that it is not *required* to make this proposed downward adjustment to the wage index of the hospitals in the highest wage index quartile budget neutral. Rather, CMS states that “it would be *appropriate* to maintain budget neutrality” for the policy.<sup>1</sup> (emphasis added). **The AHA does not believe that it would be “appropriate to maintain budget neutrality” by selectively reducing the wage index for high-wage index hospitals. Rather, the AHA believes CMS should not apply budget neutrality at all, as it is not required. We, therefore, strongly urge CMS not to apply budget neutrality to the increases in wage index values for low-wage hospitals in the FY 2020 inpatient PPS final rule.**

CMS cites two provisions of the Medicare statute as support for its policy choice to address wage index disparities in a budget-neutral manner: sections 1886(d)(3)(E) and 1886(d)(5)(I) of the Social Security Act (the Act).<sup>2</sup> The first statutory provision on which CMS relies, section 1886(d)(3)(E) of the Act, gives CMS authority to adjust the proportion

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<sup>1</sup> 84 Fed. Reg. 19,158, 19,162 (May 3, 2019) at 19,395-96.

<sup>2</sup> 84 Fed. Reg. 19,158, 19,162 (May 3, 2019) at 13,396.

of hospital costs attributable to wages by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. It does not give the agency authority selectively to reduce a hospital's wage index simply to ensure budget neutrality. CMS said it wants to reduce the disparity between high- and low-wage index hospitals by increasing the wage index for certain hospitals and decreasing the wage index for others. **Yet, nothing in section 1886(d)(3)(E) of the Act provides authority for CMS to make a wholesale decrease in wage indices where that reduction is not based on a comparison of the wage level in each hospital's geographic area with the national average. In other words, reducing disparities is not a valid reason for a budget neutrality adjustment under the statute.**

More importantly, CMS states that it could increase the wage index for hospitals in the lowest wage index quartile under section 1886(d)(5)(I) of the Act. **We note that this section does not require budget neutrality.** Accordingly, to the extent CMS relies on section 1886(d)(5)(I), it should not reduce the wage index values of the hospitals in the highest quartile to pay for the increase in the wage index values of the hospitals in the lowest quartile in service of budget neutrality.

In addition, the AHA believes there are strong policy reasons for not reducing the wage index of the hospitals in the highest quartile. Chief among them is that Medicare currently reimburses inpatient PPS hospitals less than the cost of care. In fact, according to analysis of our annual survey data, hospitals receive payment of only 87 cents for every dollar spent caring for Medicare and Medicaid patients.<sup>3</sup> This discrepancy is further demonstrated by declining Medicare margins over the past five years; most recently, in 2017, hospitals' aggregate Medicare margin was -9.9%. Notably, MedPAC projects that the overall Medicare margin will continue its downward trend to -11% for 2019, the lowest margin in Medicare's history.<sup>4</sup> These findings 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.

Further, while CMS describes this proposal as necessary to support rural hospitals, it actually penalizes certain rural hospitals. Specifically, the 75th percentile policy would reduce payments to 5% of rural IPPS hospitals. Such a reduction in funding is a heavy burden for these small providers, who rely on Medicare and Medicaid for a majority of their revenue. Indeed, more than 70% of rural inpatient PPS hospitals have negative Medicare margins.<sup>5</sup> Reductions to Medicare payments for these providers would exacerbate the challenges they already face, putting them at even more financial risk and likely worsening financial health and access concerns in certain rural areas.

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<sup>3</sup> Analysis of 2017 AHA Annual Survey Data.

<sup>4</sup> MedPAC. (2019). Report to Congress: Medicare Payment Policy. [http://medpac.gov/docs/default-source/reports/mar19\\_medpac\\_entirereport\\_sec.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0).

<sup>5</sup> Based on analysis of FY2017 Medicare Cost Report data from 1st quarter 2019 HCRIS release.

In addition, CMS does not indicate or provide evidence to show that wage index values above the 75th percentile are *inaccurate* or that those values do not reflect the wages paid by those hospitals. The agency does not make any claims that these higher wage hospitals have wage index values that are unrepresentative of real wage information. Indeed, that is because they are not – they are based on extensively audited financial data that has been annually reported to CMS since at least 1993. A policy that penalizes certain hospitals simply because of where they fall in the wage index distribution is not based on evidence – it is based on an arbitrary cut-off point. This contradicts the efforts that both hospitals and CMS make in order to have consistent and accurate wage data reporting, including regular data submissions, revisions and audits.

**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. The agency should not penalize hospitals given the below-cost reimbursement that all inpatient PPS hospitals face and the lack of evidence to justify reductions to wage index values.**

AWI Exclusions. In the rule, CMS states that in reviewing the Worksheet S-3 data it identified as aberrant the data from more than 80 hospitals. The agency excludes these data from the wage index calculations, but notes that it intends to include corrected data from some providers in the final wage index for FY 2020.

**The AHA supports CMS's efforts to improve the quality of wage information contained in the Worksheet S-3. We are concerned however, that CMS may be excluding data that is both accurate and representative of the local labor market.** For example, CMS discusses the exclusion of data from a number of hospitals within a single system that negotiates salaries with unionized employees. It contends that the data for these hospitals should be excluded from the wage index not due to inaccuracy or inadequate documentation, but because the negotiated wages do not vary across labor markets and are notably higher than other hospitals in their respective core-based statistical areas (CBSAs). However, CMS does not provide any criteria, standards, thresholds or trim methodologies that substantiate such exclusions. Neither does the agency offer any rationale that would support the claim that data from these hospitals is not reflective of the actual wages paid to employees. While the average wages for these providers may exceed those of other nearby hospitals, the hospitals in question are indeed geographically located in their CBSAs, making their wages an integral component of the local labor market in practice.

**We recommend that CMS include in the wage index those data that are accurate and representative of actual wage information. In addition, we also urge CMS to outline its criteria for determining whether data are aberrant, and thoroughly describe a data-driven rationale for excluding certain hospitals' data.** Such transparency is critical not only for our ability to meaningfully comment, but also for educating providers on



a significant component of their Medicare reimbursement. It is especially important to provide transparent information on the construction of the wage index in light of its use across Medicare payment systems including those for inpatient and outpatient hospital services, inpatient rehabilitation and psychiatric hospital services, and post-acute care, as well as its use in Medicare Advantage plans.

## **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.

Use of Worksheet S-10 Data. CMS proposes to utilize FY 2015 S-10 data to determine each Medicare DSH hospital’s share of uncompensated care in FY 2020. The agency states that the FY 2015 data are the best available because they are from the most recent year for which CMS has allowed data to be resubmitted; CMS previously used these data to determine uncompensated care payments, making the data subject to public comment and scrutiny; and they were recently audited by CMS. However, the agency also sets forth the use of unaudited FY 2017 data as an alternative in response to provider concerns about the accuracy and consistency of the FY 2015 data audit.

**The AHA has a longstanding position supporting audits of the S-10 data in order to improve its accuracy and consistency.** We greatly appreciate CMS’s efforts to do so, as well as the agency’s resolution of a particular issue regarding “expected payments” that was identified during the audit. **We continue to believe that audits – and, by extension, ongoing refinements to the audit process – result in data that are more appropriate for use in Medicare DSH payments. Thus, we support the use of FY 2015 S-10 data to determine each Medicare DSH hospital’s share of uncompensated care in FY 2020.**

In addition, as CMS moves forward with additional audits of the S-10 data, we have several suggestions, outlined below, that would help further support clarity, consistency and completeness to assist both CMS and the field. **Furthermore, given the improvements to the S-10 instructions that were made for the FY 2017 cost report, we strongly recommend that CMS audit the FY 2017 data in the near term and utilize it in determining FY 2021 uncompensated care payments.** Doing so not only allows for the continued use of audited data, but also provides another year of public scrutiny of FY 2017 data and shortens the lag between data collection and its application. We recommend that CMS provide clarity regarding its plan for S-10 data to be used for FY 2021.

Finally, as CMS moves from a three-year average to a single year of S-10 data, the potential for anomalies and undue fluctuations in uncompensated care payments increases. We, therefore, recommend that CMS monitor payments over time and, if necessary, consider utilizing more than one year of data after FY 2021. Doing so would also provide a clear pathway to audit all DSH hospitals over time, as recommended below.

Recommendations for Future Audits. As noted above, we greatly appreciate CMS's recent efforts in auditing the S-10 data. Throughout the process, our members shared suggested improvements that could be made in the spirit of further promoting clarity, consistency and completeness. As such, we 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 hospitals over time.

Technical Proposals Related to S-10. CMS also 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 finalized in FY 2019. 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 cost report that is closest to 12 months would be used and its data would be annualized. **We support this proposal.**

In addition, CMS proposes to continue to trim data to control for data anomalies. For FY 2020, CMS would substitute information from an alternative year's cost report in the event of a hospital reporting extremely high uncompensated care costs that cannot be justified. CMS proposes to use FY 2016 data as substitute for FY 2015 data in these cases. Instead, we recommend that CMS utilize FY 2014 data as substitute for FY 2015 data in such circumstances because FY 2014 data has been previously available for public scrutiny and previously utilized in determining uncompensated care payments.

As finalized in FY 2014, new hospitals do not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. For FY 2020, CMS proposes to modify this policy such that new hospitals that appear to be eligible for Medicare DSH payments would receive interim empirically justified payments, but still not receive interim uncompensated care payments. **We support this proposal.**

## 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 2020, CMS proposes to keep CAR T assigned to Medicare-severity diagnosis-related group (MS-DRG) 016 (see "Changes to MS-DRG Classifications" below). However, the agency invites public comments on a number of questions to consider if CMS decides to develop a CAR T-specific MS-DRG in future rulemaking. CMS also proposes to increase the rate of new technology add-on payments (NTAPs) for all new technologies, including CAR T, from 50% to 65% of the marginal cost. Finally, the agency invites public comments on payment alternatives for CAR T therapies, including a higher NTAP rate for it alone.

**The AHA remains concerned about beneficiary access to CAR T and similar forthcoming technologies given their costliness. It is clear that the current system does not ensure appropriate rate-setting or payment for CAR T, forcing hospitals and health systems to take on unsustainable losses in order to provide these life-saving therapies.** Thus, in order to tackle both nearer-term and longer-term reimbursement challenges, we address the proposals and requests for comment set forth in the proposed rule, as well as provide additional recommendations that promote beneficiary access to these therapies, set appropriate precedents for how they are handled in rate setting and preserve opportunities for additional payment options in the future.

**In addition to the recommendations below, AHA 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. ***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. In fact, according to the IQVIA 2019 Global Oncology Report, 24 CAR T therapies are in late-stage development.<sup>6</sup> 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.***

NTAPs for CAR T. NTAPs are intended to "recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system"<sup>7</sup> by providing additional payments for eligible cases until CMS has sufficient data for MS-DRG rate setting. These payments are not budget neutral and NTAPs may be provided for two to

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<sup>6</sup> IQVIA Institute for Human Data Science (May 2019). Global Oncology Trends 2019.

<https://www.iqvia.com/institute/reports/global-oncology-trends-2019>.

<sup>7</sup> 42 CFR § 412.87.

three years “after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology.”<sup>8</sup>

In the rule, CMS proposes to continue its NTAP approval for both CAR T products, KYMRIA<sup>™</sup> and YESCARTA<sup>™</sup>, in FY 2020. **We strongly support this proposal. In addition, we appreciate the proposed change in NTAP rate from 50% to 65% for new technologies, including CAR T.** However, while this proposal is a step in the right direction, we continue to believe that a higher NTAP for CAR T is needed to ensure beneficiary access to these therapies. **Thus, we continue to urge CMS to make NTAPs for CAR T at a rate of 100%, for the reasons below. In addition, we urge CMS to make these NTAPs uniform such that eligible CAR T cases would receive a uniform rate of 100% of the cost of the CAR T product, rather than a rate applied to the “lesser of” the marginal cost of the case or the cost of the CAR T product.**

First, the agency has previously limited the NTAP rate in order “balance the desirability of using the new technology versus the old” and prevent “a large and perhaps inappropriate incentive to use the new technology.”<sup>9</sup> However, we maintain that this rationale does not apply to CAR T. First, for patients eligible for this treatment, there is no balancing “the desirability of using the new technology versus the old” because these patients have either relapsed or not responded to conventional cancer treatments and are using CAR T as a last measure. Indeed, this is by definition – at the time of this writing, CMS has proposed to limit coverage to CAR T for only those patients who have relapsed or refractory cancer.<sup>10</sup> Second, the losses hospitals continue to face when administering this technology mean that there is no need to provide additional incentives for “continued cost-effective behavior” and, likewise, there is no “inappropriate incentive to use the new technology.” Information from some of our member hospitals indicates that for CAR T cases outside of clinical trials, patient care costs alone may exceed \$200,000. In addition, data from one of our members indicates that in FY 2019, the hospital’s average loss per CAR T case exceeded \$180,000. Even with the maximum NTAP under the 65% proposal, the losses that hospitals incur will not be sustainable over the long run as the use of CAR T and similar forthcoming technologies increases, potentially jeopardizing beneficiary access. While it is not a permanent solution, a uniform NTAP of 100% of the cost of the CAR T product would provide much needed support to bolster provider efforts in meeting patient needs.

In addition, we continue to believe that an increased payment rate for CAR T would not result in an excessive amount of NTAPs being made as related to the agency’s historical targets. Specifically, when implementing NTAPs, CMS set a target limit for these payments at 1% of total operating prospective payments.<sup>11</sup> Yet, agency spending on NTAPs has

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<sup>8</sup> 84 *Federal Register* 19,276 (May 3, 2019).

<sup>9</sup> 66 *Federal Register* 46918.

<sup>10</sup> Proposed Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N), February 2019. <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=291>.

<sup>11</sup> 66 *Federal Register* 46920.

never come close to this amount. For example, we analyzed NTAP levels from FY 2013 through 2018 and found that CMS made payments as low as \$8.4 million in FY 2018 and as high as \$47 million in FY 2016. This equates to less than 0.0001 and 0.03% of total operating prospective payments, respectively – at least 33 times less than the agency’s target. This indicates that accommodating a 100% uniform rate for CAR T product NTAPs within CMS’s original target is practicable.

Finally, we urge CMS to consider extending NTAP approval for CAR T beyond FY 2020 if a new MS-DRG – or pass-through payment – is not developed at the time CAR T “newness” expires. As they were envisioned, NTAPs offer a temporary respite from the high costs associated with providing access to new technologies, until the time at which sufficient data are available to incorporate those technologies into the Medicare DRG system. Specifically, CMS states that a technology “may continue to be considered “new” for purposes of new technology add-on payments within two or three years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology.... [The agency uses] the earliest market availability date submitted as the beginning of the newness period.”<sup>12</sup> CMS considers CAR T’s “newness period” to have begun on Nov. 22, 2017, which limits its eligibility for NTAPs to FY2019 and FY 2020.

As noted above, the NTAP timeframe was put in place to allow a sufficient amount of time to collect data and develop codes that accurately represent the cases utilizing the new technology. In the case of CAR T, data availability may continue to be low in light of a small eligible patient population, a lengthy certification process for hospitals to be permitted to provide the service, and the inadequate reimbursement to date. In FY 2018, there were just over 150 cases of CAR T in Medicare claims data, with less than half of those cases occurring outside of clinical trials. Taking this into account, if representative data for CAR T cases is not available or satisfactory at the end of the product’s “newness period”, it would be appropriate to continue NTAPs after FY 2020. It would not be appropriate, however, to put the onus on providers to continue covering the expense of these extremely costly technologies until a suitable reimbursement approach is determined. **Specifically, if hospitals are left without NTAPs, pass-through payment, and a CAR T MS-DRG, these therapies will draw large sums from the budget-neutral outlier pool as a matter of course, reducing the opportunity for other high-cost outlier cases to be adequately reimbursed and leaving hospitals to shoulder the heavy financial burden of CAR T despite not having any control over the manufacturer prices.** According to our analysis of CAR T claims from FY 2018, a year when CAR T was assigned to a DRG with exceedingly inadequate payment and not yet eligible for NTAPs, the mean outlier payment was greater than \$246,000 per case. In the future, if there is no NTAP, pass-through payment or adequate MS-DRG for CAR T cases, similarly high outlier payments are to be expected. As CAR T products become more prevalent, such cases would likely take up a substantial portion of outlier funds and

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<sup>12</sup> 84 *Federal Register* 19,279 (May 3, 2019)

increase the fixed loss threshold, making it more difficult for other high-cost cases to receive outlier payments.

**Potential New MS-DRG for CAR T. While CMS does not propose to create a new MS-DRG for CAR T for FY 2020, AHA recommends that CMS continue exploring this approach as additional data is collected.** A new MS-DRG would potentially allow for much more accurate reimbursement of these treatments since the weight of this new MS-DRG would directly reflect the extremely intensive resources involved since they would not be averaged together with much less resource-intensive treatments. However, as discussed in the rule, there are a number of considerations, addressed below, that are related to the development of such a MS-DRG in light of CAR T's unique characteristics.

**First, we recommend that CMS exclude clinical trial CAR T cases in the development of a new MS-DRG, given the substantial differences in costs between trial and non-trial cases.** As CMS notes in the rule, clinical trial cases typically do not include the costs of the products under investigation; as a result, including such cases would dramatically skew the weight of a new CAR T MS-DRG downward. For example, according to our analysis of FY 2018 CAR T cases (without using statistical trimming), non-trial CAR T cases (n= 75) had nearly *18 times higher* drug costs (standardized) and five times higher total costs (standardized) than clinical trial CAR T cases (n=84). This striking dissimilarity indicates that the two types of cases are categorically different, with the non-trial cases being more representative of realistic resource use for CAR T in practice. In the event that CMS determines that the number of non-trial cases alone is not sufficient to develop a new MS-DRG, we recommend that clinical trial CAR T cases be included on the condition that they are augmented by the list price of CAR T – \$373,000 – to adequately account for the full product cost.

**In addition, based on our analysis, we also recommend that CMS refrain from trimming the CAR T data when determining the weight for a potential DRG.** Trimming is typically intended to remove cases that are not representative. However, doing so for CAR T would omit a substantial number of cases, making the resulting weight unrepresentative. For example, we found that, due to their high, but not anomalous costs, more than 20% of CAR T cases (35 of 159 cases) were trimmed out of MS-DRG 016 in FY 2018. In addition, all of the 35 trimmed cases were non-clinical trial cases. Thus, relying on the trimmed data alone would lead to inappropriate weighting and significant underpayment.

**Further, AHA supports the application of indirect graduate medical education (IME) and Medicare DSH adjustments to the full DRG payment under a new MS-DRG for CAR T, in recognition of the purpose and usage of the two programs.** According to the Medicare Payment Advisory Commission (MedPAC), teaching hospitals “have always had higher Medicare inpatient costs per discharge” compared to other hospitals. While some portion of this cost is due to direct costs of medical education, other reasons for higher costs among teaching hospitals include: “unmeasured differences in patients’

severity of illness, inefficiencies in the use of services associated with residents' learning by doing, and greater use of emerging technologies."<sup>13</sup> Since the IME program was intended to address the higher provider costs associated with these characteristics, these payments are relevant for *all* cases and are especially applicable to CAR T cases, which represent both high severity of illness as well as the use of emerging technology. Similarly, the goals of the Medicare DSH program – to address higher costs associated with serving lower income populations and provide relief for uncompensated care – support the application of DSH adjustment to all discharges. The IME and Medicare DSH programs were intended to address the overall resource use in a hospital that supports medical training and/or patient care for low-income individuals; neither were meant to be selectively applied on a case-by-case basis.

Finally, we urge CMS to make several technical changes, as outlined below, in the immediate term in order to improve the precision of the clinical and cost information for a potential MS-DRG in FY 2021.

**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 accurate information for determining NTAPs and outlier payments, as well as weight-setting for a potential CAR T MS-DRG or a pass-through payment. Without an alternative, the standard method of calculating CAR T costs could vastly underestimate 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. 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. This would lead to a more accurate calculation of the cost of CAR T. 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 National Uniform Billing Committee (NUBC) value code 86 (described further below). Either option would allow the full cost of the therapy to be appropriately considered, free from charge compression.

**Furthermore, the AHA believes that several technical changes also will help support a more accurate cost estimate of CAR T, in addition to facilitating the development of a new CAR T MS-DRG.** Specifically, NUBC has approved a series of new revenue codes associated with cell/gene treatments. The AHA recommends that CMS utilize 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:

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<sup>13</sup> MedPAC. (2007). Report to Congress: Medicare Payment Policy. [http://www.medpac.gov/docs/default-source/reports/Mar07\\_EntireReport.pdf](http://www.medpac.gov/docs/default-source/reports/Mar07_EntireReport.pdf).

- Require hospitals to submit their invoice cost using value code 86 (available as of April 1, 2019).
- Instruct hospitals to utilize the new revenue codes approved by NUBC, available as of April 1, 2019:
  - Revenue code 0891 (from new category 089x) – indicating the cell or gene 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, similar 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. Since these claims exclude the product cost, CMS also should consider excluding them from NTAPs (but they would continue to qualify for outlier) and excluding these claims when CMS is evaluating a new MS-DRG for CAR T and other cell and gene therapies.

CAR T Reimbursement for PPS-exempt Cancer Hospitals. AHA also urges CMS to ensure an appropriate and timely solution for CAR T therapy for PPS-exempt cancer hospitals. These hospitals are reimbursed under the Tax Equity and Fiscal Responsibility Act (TEFRA) and have comprised nearly half of all CAR T treatments to date, despite representing only 14% of hospitals currently qualified to provide the therapy. Under TEFRA, cancer hospitals are paid based on reimbursement rates derived from the historic cost of treating cancer patients during base periods that are 12-15 years old and do not take into account innovative therapies such as CAR T. Therefore, CMS effectively provides no reimbursement for CAR T to cancer hospitals at this time. Both PPS hospitals and PPS-exempt cancer hospitals require an adequate reimbursement solution.

PPS-exempt cancer hospitals have the ability to request that the agency take into account the cost of new therapies into reimbursement. However, this process is extremely burdensome and takes years to complete. In the proposed rule, CMS solicits comments on how TEFRA processes could be improved to account for changes in the current environment. We recommend that CMS automatically recognize CAR T as a reasonable cost directly related to patient care under TEFRA, and provide clear direction to ensure appropriate CAR T reimbursement for all providers of the therapy.



## **CRITICAL ACCESS HOSPITAL (CAH) AMBULANCE SERVICES**

Currently, CAHs are reimbursed for ambulance services at 101% of costs, as long as the CAH is the only supplier of ambulance services located within a 35 mile drive of the CAH. Otherwise, the CAH is reimbursed per the ambulance fee schedule. CMS proposes to modify this policy such that the 35-mile criterion would exclude ambulance suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. **We support this proposal.**

## **GRADUATE MEDICAL EDUCATION (GME) AND RESIDENTS PRACTICING AT CAHS**

Hospitals with GME programs may include residents that train in “nonprovider” settings in their full-time equivalent (FTE) count for GME and IME payments. Currently, CAHs are not considered nonprovider settings and as a result, residents training at CAHs are not included in a hospital’s FTE count. (CAHs may, however, operate their own residency programs, which receive cost-based reimbursement.) In order to support training of residents in rural areas, CMS proposes to permit a hospital to include residents training at a CAH in its FTE count as long as the CAH meets nonprovider setting requirements. As noted in AHA’s [\*Rural Report: Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, Affordable Care\*](#), workforce shortages are a persistent challenge for rural providers; only 10% of U.S. physicians practice in rural areas despite nearly 20% of Americans residing in these communities. **While more policies are needed to fully address workforce gaps in rural America, the AHA believes that this proposed policy may increase opportunities for residents to work in rural communities and facilitate CAH recruitment efforts. We support the proposal.**

In addition, we recommend that CMS permit hospitals that are currently within their cap-building period to count the time residents spent training at CAHs at any point during their cap-building period. This would facilitate rotations at CAHs as these teaching hospitals build their GME programs, promoting future opportunities for residents to train in rural areas each year.

## **CHANGES TO MS-DRG CLASSIFICATIONS**

**The AHA supports a number of CMS’s proposed changes to the MS-DRG classifications, but we also have concerns with several changes as outlined below.**

Pre-major Diagnostic Category (MDC).

*Peripheral Extracorporeal Oxygenation (ECMO).* In FY 2019, new procedure codes were implemented to distinguish peripheral from central ECMO. In the FY 2019 inpatient PPS final rule, CMS designated percutaneous (peripheral) ECMO procedures as non-operating room (O.R.) procedures and reassigned cases involving the use of peripheral ECMO from pre-MDC MS-DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation >96 Hours or

Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedure) to the following MS-DRGs:

- MS-DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral ECMO),
- MS-DRG 291 (Heart Failure and Shock with Major Complication or Comorbidity (MCC) or Peripheral ECMO),
- MS-DRG 296 (Cardiac Arrest, Unexplained with MCC or Peripheral ECMO), and
- MS-DRG 870 (Septicemia or Severe Sepsis with Mechanical Ventilation>96 Hours or Peripheral ECMO).

**We strongly agree with CMS that recent data analysis and stakeholder feedback, including AHA input, on the resource use associated with percutaneous (peripheral) ECMO support reassigning percutaneous ECMO cases back to Pre-MDC MS-DRG 003.** Additional revisions to the ICD-10-PCS codes for ECMO were proposed at the March 5, 2019 ICD-10-CM/PCS Coordination and Maintenance Committee meeting. At the time of the meeting, we believed it was too early to make changes to the ECMO codes as they are so new that there is little or no data on their usage. We note that new codes for intraoperative ECMO are included in the ICD-10-PCS addenda released May 31, 2019 for Oct. 1, 2019 implementation. These codes are not included in the FY 2020 proposed rule, Table 6B—New Procedure Codes, as codes presented at the March meeting are normally not available for inclusion in the proposed rule. **We recommend that the new codes for intraoperative ECMO also should be considered using the same logic and grouped to MS-DRG 003 regardless of whether the procedures are performed in the O.R. or at bedside until their impact on resource utilization can be analyzed.**

**We request that CMS revisit Tables 7a and 7b that show a decline for MS-DRG 003 when comparing V36 and V37 (15,749 vs 15,164).** Since the proposal will shift cases to MS-DRG 003 from MS-DRGs 207, 291, 296, and 870 for the peripheral ECMO, we ask that CMS revisit these Tables and provide insight regarding a potential issue with the surgical hierarchy since peripheral ECMO codes are not recognized OR procedures.

*CAR T Therapy.* In FY 2019, CMS finalized the assignment of the CAR T ICD-10-PCS procedure codes listed below to Pre-MDC MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell immunotherapy):

- XW033CS - Introduction of engineered autologous CAR T immunotherapy into peripheral vein, percutaneous approach, new technology group 3, and
- XW043C3 - Introduction of engineered autologous CAR T immunotherapy into central vein, percutaneous approach, new technology group 3.

We support CMS's proposal not to modify the current MS-DRG assignment to MS-DRG 016 for FY 2020 given the relatively newness of CAR T therapy, the low number of claims availability in the FY 2018 Medicare Provider Analysis and Review (MedPAR) data file,

the wide variability of cost data due to differences in provider billing and charging practices, and CMS's proposal to continue new technology add-on payments for FY 2020 for the two CAR T therapies.

MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Knee Procedures with Principal Diagnosis of Infection. We agree with CMS's proposal to add ICD-10-CM diagnosis code M00.9 (Pyogenic arthritis, unspecified) to the list of principal diagnoses of infection for MS-DRGs 485, 486 and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively). **We recommend the addition of diagnosis code A54.42 (Gonococcal arthritis) to the same list as both codes may correctly identify infections of the knee.** The fact that the code is not specifically indexed to include the knee does not preclude its application to the knee as both codes are intended for any joint.

MDC 22 (Burns): Skin Graft to Perineum for Burn. CMS received a request to add seven ICD-10-PCS procedure codes that describe a skin graft to the perineum to MS-DRG 927 (Extensive Burns Or Full Thickness Burns with MV >96 Hours with Skin Graft) and MS-DRGs 928 and 929 (Full Thickness Burn with Skin Graft Or Inhalation Injury with CC/MCC and without CC/MCC, respectively). CMS disagreed believing that the procedure codes were more clinically aligned with the other procedures in MS-DRGs 746 and 747 (Vagina, Cervix and Vulva Procedures with CC/MCC and without CC/MCC, respectively), to which they are currently assigned. None of the cases in the MedPAR data analyzed by CMS had a principal or secondary diagnosis of a burn, which suggested that these perineal skin grafts were not performed to treat a burn.

**We urge CMS to reconsider this request and add the seven ICD-10-PCS codes describing skin graft to the perineum to MS-DRGs 927-929.** Currently, when principal diagnosis codes T21.37XA, Third degree burn of (female) perineum, and T21.36XA, Third degree burn of the (male) perineum, are assigned in combination with one of the ICD-10-PCS codes for skin graft to the perineum, the cases incorrectly group to non-surgical MS-DRG 934, Full Thickness Burn without Skin Graft or Inhalation Injury.

Review of Procedure Codes in MS DRGs 981 through 983 and 987 through 989. Each year, CMS reviews cases assigned to determine whether it would be appropriate to change the procedures and/or principal diagnosis codes assigned among MS-DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively) and MS-DRGs 987, 988 and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). MS-DRGs 981 through 983 and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS-DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. CMS is proposing to move the procedures and/or principal diagnosis codes described

below from MS-DRGs 981, 982, and 983 and 987, 988 and 989 into one of the surgical MS-DRGs for the MDC into which the principal diagnosis is assigned.

- *Bone Excision with Pressure Ulcers.* CMS proposes to add the ICD-10-PCS procedure codes describing excision of the sacrum, pelvic bones, and coccyx to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), in MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively). Under this proposal, cases reporting a principal diagnosis in MDC 9 (such as pressure ulcers) with a procedure describing excision of the sacrum, pelvic bones, and coccyx would group to MS-DRGs 579, 580, and 581. **We strongly disagree with CMS's proposal and urge the agency not to finalize it. It is not appropriate for procedures performed on bones to be grouped to MS-DRGs for procedures on skin and subcutaneous tissue. Bone excisions are more clinically significant, with higher risk and higher resources than excisions of skin and subcutaneous tissue.** We realize that CMS may have selected MDC 9 as it includes all pressure ulcers. However, MDC 9 also includes ICD-10-CM diagnosis code L89.154, Pressure ulcer of sacral region, stage 4, which has the inclusion term "Pressure ulcer with necrosis of soft tissues through to underlying muscle, tendon, or bone, sacral region." The higher severity and intensity for these ulcers is determined by the procedure on bone.
- *Lower Extremity Muscle and Tendon Excision.* CMS proposes to add the procedure codes describing excision of lower extremity muscles and tendons to MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders). Cases reporting these procedure codes with a principal diagnosis in MDC 10 would group to MS-DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with MCC, with CC, and without CC/MCC, respectively). **We strongly disagree with CMS's proposal and urge the agency not to finalize it. It is not appropriate for procedures performed on muscles and tendons to be grouped to DRGs for skin and subcutaneous tissue. Excisions of muscles and tendons are more clinically significant, with higher risk and higher resources than excisions of skin and subcutaneous tissue.**
- *Kidney Transplantation Procedures.* CMS proposes to add ICD-10-PCS procedure codes describing transplantation of kidneys to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 5 (Diseases and Disorders of the Circulatory System). Kidney transplantation is performed for end stage renal disease (ESRD). The ESRD may be due to a circulatory system disorder like hypertension (code I12.0, Hypertensive chronic kidney disease with stage 5 chronic kidney disease or ESRD) or due to an endocrine system disorder like diabetes (codes E10.22, E11.22, E13.22, Diabetes with chronic kidney disease). All these diagnosis codes are currently in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). **We strongly disagree with CMS's proposal and urge the agency not to finalize**

**it. It is illogical and clinically incongruent to assign resource intensive procedures such as kidney transplantations to MCD 5 when the procedure is a procedure performed on the urinary system. Kidney transplantations should continue to group to MS-DRGs 981 through 983.**

Adding Diagnosis or Procedure Codes to Major Diagnostic Categories.

- *Stage 3 Pressure Ulcers of the Hip.* CMS proposes to add ICD-10-PCS procedure codes 0KXP0ZZ (Transfer left hip muscle, open approach) and 0KXN0ZZ (Transfer right hip muscle, open approach) to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). Under this proposal, cases reporting ICD-10-PCS procedure code 0KXP0ZZ or 0KXN0ZZ with a principal diagnosis in MDC 9 would group to MS-DRGs 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, with CC and without CC/MCC, respectively). **We strongly disagree with CMS's proposal and urge the agency not to finalize it. It is not appropriate for procedures performed on muscles to be grouped to DRGs for skin and subcutaneous tissues. Transfer procedures for muscles are more clinically significant, with higher risk and higher resources than grafts of the skin and subcutaneous tissues.**
- *Finger Cellulitis.* CMS proposes to add the procedure codes describing excision and resection of phalanx to MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively). Under this proposal, cases reporting one of the phalanx excision or resection procedures in conjunction with a principal diagnosis from MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) such as cellulitis of the right finger would group from MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 579, 580, and 581.

**We request that CMS reconsider this proposal as it does not appear clinically appropriate for bone procedures to be grouped to Skin or Subcutaneous Tissue MS-DRGs.** Clinically, an infection deeper than cellulitis of the skin would warrant removal of the phalanx bone. The small volume of cases (17) CMS reported as within MS-DRGs 981, 982, 983 may represent a coding problem.

O.R. and Non-O.R. Issues.

*Overview.* CMS has announced that 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. This will be a multi-year project during which CMS also will review the process for determining

when a procedure is considered an operating room 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 operating room. 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.**

In addition, we have the following general recommendations:

- CMS should provide a test MS-DRG GROUPER to allow hospitals the ability to determine the impact;
- 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; and
- CMS should address procedures performed in all settings as there may be variations based on geographical differences, hospital size, resources and physician specialty availability.

remedē® System Coding. CMS approved the remedē® System for NTAPs for FY 2019. According to the rule, cases involving the use of the remedē® System that are eligible for NTAPs are identified by ICD-10-PCS procedure codes 0JH60DZ and 05H33MZ in combination with procedure code 05H03MZ (Insertion of neurostimulator lead into right innominate vein, percutaneous approach) or 05H43MZ (Insertion of neurostimulator lead into left innominate vein, percutaneous approach). **However, these codes are incorrect; we request that a correction to the codes along with the appropriate payment be made retroactively for the following reasons:**

- The code proposal presented at the March 2018 ICD-10 Coordination and Maintenance meeting described the system as “the sensing lead is inserted into the azygos vein. The stimulation lead is inserted unilaterally, either into the right innominate (brachiocephalic) or into the left pericardiophrenic veins, which are anatomically adjacent to the right and left phrenic nerve, respectively.” This describes the system as having a single sensing lead.
- The remedē® system uses a single array stimulator generator. Therefore the correct code should be 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) which is used for single array stimulator generators, rather than code 0JH60DZ which is for multiple array stimulator generators.
- The code descriptor listed for code 05H03MZ in the proposed rule is incorrect – that code is not for insertion of neurostimulator lead into the right innominate vein, but rather for insertion of neurostimulator lead into azygos vein, percutaneous approach.
- *Coding Clinic for ICD-10-CM and ICD-10-PCS* published information on the procedure in the Fourth Quarter 2016 issue, pages 97-98. The explanation indicated that for coding purposes, the sensing lead is designated as a monitoring device to differentiate between what monitors the respiratory activity and the electrode that delivers the electrical stimulation. The following codes were published and have also been subsequently incorporated in all major encoder programs:
  - 0JH60MZ, Insertion of array stimulator generator into chest subcutaneous tissue and fascia, open approach) and
  - 05H032Z, Insertion of monitoring device into azygos vein, percutaneous approach, in combination with
  - 05H33MZ, Insertion of neurostimulator lead into right innominate vein, percutaneous approach or
  - 05H43MZ, Insertion of neurostimulator lead into left innominate vein, percutaneous approach.

## REDUCTIONS IN MS-DRG PAYMENTS

In the proposed rule, 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 30% reduction* in FY 2020, which is on the heels of a 20% reduction in FY 2018. 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. **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 2019, 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.**

## **COMPREHENSIVE CC/MCC ANALYSIS**

In the FY 2008 inpatient PPS final rule, CMS described its process for establishing three different levels of severity into which it would subdivide the diagnosis codes. The categorization of diagnoses as Major Complications or Comorbidities (MCC), Complications or Comorbidities (CC), or a non-CC used 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. Since then, CMS has reviewed the CC/MCC lists periodically to better recognize severity of illness.

For FY 2020, the agency is conducting another comprehensive review of the CC/MCC lists, applying the same methodology used in FY 2008. As such, it proposes a change in the severity level designation for a staggering 1,492 ICD-10-CM diagnosis codes.<sup>14</sup> Eighty-seven percent of the changes (1,301 codes), would be shifted down in severity. CMS says these proposals are based on a review of the data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses.

**The AHA strongly urges CMS not to finalize its proposals because it: provided insufficient information to adequately explain its changes; provided inaccurate information in certain instances; and applied its methodology and treated similar codes inconsistently.**

**Together, these shortcomings have rendered us unable to meaningfully comment on the proposals. We urge the agency to instead work toward providing more information and transparency on their methodology and data in future rulemaking. CMS also should strongly consider phasing in any future changes given the impacts such modifications would have on hospitals and the patients they serve.**

### ***Information Provided Is Insufficient and May Be Inaccurate***

We have major concerns about the sufficiency and accuracy of information provided in the proposed rule, as illustrated in the following examples.

Ventricular Fibrillation and Cardiac Arrest. The diagnoses for ventricular fibrillation and cardiac arrest (I46.2, I46.8, I46.9) are proposed to no longer be MCCs. However, all of these codes have “charge ratios” that would support MCC designation under the quantitative methodology that CMS purports to use. Indeed, CMS’s FY 2008 analysis

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<sup>14</sup> See Table 6P.1c at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-IPPS-Proposed-Rule-Tables.html>.



indicated that ventricular fibrillation and cardiac arrest impacted the patient's mortality and were important to consider vis-a-vis the resources used. **The proposed rule does not present any similar alternative analysis; as a result, the basis of CMS's proposal remains unclear.**

Chronic Kidney Disease. CMS proposes to change the severity level designation for seven kidney-related diagnosis codes from CC to non-CC and for ESRD from MCC to CC. We disagree with this shift given the high level of clinical complexity and resources required to treat these conditions. ESRD patients have high resource consumption, as they require dialysis during the inpatient stay. **We do not understand the basis for this proposal, and CMS does not provide rationale or additional information to support this proposed change.**

Neoplasm Chapter Codes. This set of codes represents more than half of all proposed severity level changes. Specifically, CMS proposes to change all 767 codes currently designated as a CC to non-CC. **Yet, this change is not at all supported by the detailed quantitative methodology that CMS purported to use to evaluate the CC/MCC lists.** Instead, it appears to be based solely on CMS's clinical advisers' recommendation that when a neoplasm is reported as a secondary diagnosis, it does not significantly impact resource use because it is not the condition that occasioned the patient's admission to the hospital. **However, this assertion is inaccurate.** All cancer patients generally require more resources in terms of nursing, monitoring, nutrition, medications, pain management and ancillary services, such as imaging – regardless of the specific reason for admission. Patients also may be immunocompromised, anemic or dehydrated because of their chemotherapy or radiation therapy, requiring extra precautions and medications.

#### Factors Influencing Health Status and Contact with Health Services.

- *Body Mass Index.* CMS proposes to change the severity level designation from CC to non-CC for three ICD-10-CM codes specifying adult body mass index (BMI) ranges. **We do not understand the basis for this proposal and it is not explained in the rule.** These patients require more intense resources because they are physically harder to manage requiring additional assistance from nursing staff and ancillary staff with lifting, turning and ambulation. The additional resource use may not be fully recognized by non-nursing clinical advisers unfamiliar with the complexity involved in physically managing these patients. A variety of medical studies have provided data on the fact that morbid obesity is linked to increased use of hospital resources and increased length of stay, especially in relation to joint replacements.
- *Ventilator Status.* CMS proposes to downgrade diagnosis codes Z99.11, Dependence on respirator [ventilator] status, and Z99.12, Encounter for respirator dependence during power failure, as these codes indicate status only with no current complication. **We do not understand the basis for this proposal given**

**that the status codes indicate higher resources involved with the need for mechanical ventilation, which is a costly resource. CMS does not explain its rationale in the rule.**

### ***CMS's Proposals Are Inconsistent***

The proposed rule contains numerous inconsistencies, demonstrating our concern about how the CC/MCC analysis has been applied across codes.

- *Myocardial Infarction.* CMS proposes to change the severity level designation for 13 ICD-10-CM diagnosis codes from categories I21 (Acute myocardial infarction (AMI)) and I22 (Subsequent ST elevation [STEMI] and non-ST elevation [NSTEMI] myocardial infarction) from an MCC to a CC. According to CMS, the data suggest that for patients for whom any of the myocardial infarction codes are reported as a secondary diagnosis, the resources involved in their care are not aligned with those of an MCC. **Yet, it maintains the MCC category for four other similar AMI codes without explaining the inconsistency.** Specifically, it is unclear why STEMI (ICD-10-CM codes I21.0 to I21.4) would be handled differently than NSTEMI (I21.4), unspecified AMI (ICD-10-CM code I21.9), type 2 AMI (I21.A1), or other MI type (ICD-10-CM code I21.A9).

AMIs are life-threatening conditions requiring immediate attention including specialized intensive care units (ICUs), telemetry and significant nursing care. In addition, consideration should be given to whether the AMIs have a Present on Admission (POA) indicator of “Yes” or “No” as this may demonstrate a difference in acuity and resources if the AMI is in the healing phase and still receiving care, but perhaps not in the ICU. According to the ICD-10-CM Tabular instructions, codes in category I21, Acute myocardial infarction, include “myocardial infarction specified as acute or with a stated duration of 4 weeks (28 days) or less from onset.”

- *Respiratory Diseases.* CMS proposes a 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). **Again, CMS does not explain the inconsistency or its rationale for these differences.**
- *Malnutrition.* CMS proposes that code E43, Unspecified severe protein-calorie malnutrition, be shifted from an MCC to a CC. Yet, the clinically less severe condition, code E44.0, Moderate protein-calorie malnutrition, would be shifted from a CC to an MCC. However, both codes are associated with a “charge ratio” that indicate them as an MCC for the most complex patients (“C3” group) according to the data provided by CMS: severe malnutrition has 345,682 cases with a ratio of 3.3797 and the moderate

malnutrition has 183,680 cases with a ratio of 3.2746. **CMS does not explain its rationale or the inconsistency.**

- *Pressure Ulcers.* CMS proposes a change to the severity level for 150 diagnosis codes describing pressure ulcers. Specifically, it would designate as CCs both the 50 ICD-10-CM diagnosis codes that are currently designated as MCCs and the 100 ICD-10-CM diagnosis codes currently designated as non-CCs. The ICD-10-CM classification includes codes that describe pressure ulcers across various anatomical regions and across the various possible stages based on the depth of the ulcer (stages 1 through 4, unspecified stage, and unstageable). Currently, all stage 3 and 4 pressure ulcers are designated as MCCs, while stage 1, stage 2, unspecified stage, and unstageable pressure ulcers are currently designated as non-CCs. However, the proposed rule states that CMS's clinical advisers believe that the fact that the ulcer developed in the first place is more important than the stage of the ulcer in determining the impact on the costs of hospitalization. According to CMS's advisers, the presence of a pressure ulcer may indicate an increase in resource use, but that increase is similar regardless of the stage of the ulcer.

**The assertions of CMS's advisers run contrary to historical International Classification of Diseases (ICD) coding, CMS's own methodology, and widely accepted clinical convention. And, yet again, these consistencies are not explained.** ICD coding has distinguished pressure ulcers by stages since FY 2009. The rationale provided at the September 2007 ICD-9-CM Coordination and Maintenance Committee meeting for the creation of the codes was that "the most important element in quality measurement, workload and clinical services is the depth of the lesion . . . using stages."

Indeed, according to National Pressure Ulcer Advisory Panel, stage 1 and stage 2 pressure ulcers are superficial wounds that are often treated with established guidelines for bedside staff. Due to the greater extent of tissue damage in stage 3 (full thickness skin loss involving damage or necrosis of subcutaneous tissue), and stage 4 (soft tissues through to underlying muscle, tendon, or bone) pressure ulcers, there is greater intensity of care and resource expenditure. The presence of stage 3 and 4 pressure ulcers is a significant risk factor for developing additional full-thickness pressure injuries. Therefore, these patients require a multidisciplinary approach for treatment and prevention. According to a member hospital's wound care specialist, the multidisciplinary approach includes a group of professionals that collaborate for care management. The medical team typically includes:

- A certified wound ostomy and continence nurse specialist to provide direction in treatment and to enhance care coordination and health outcomes;
- A Surgeon To Assist In Debridement Methods And Surgical Interventions To Divert Fecal And Urinary Contamination;

- Infectious Disease Specialists To Assist In Treating The Specific Organism Infecting These Wounds;
- Registered Dieticians To Address Increased Nutritional Needs And Supplements;
- Physical Therapists To Promote Mobility And Repositioning Of Patients;
- Case Managers And Social Workers To Collaborate With Facilities And Determine The Continued Needs Of The Patient;
- Endocrinologists And Diabetes Specialists To Assist In Managing Hyperglycemia, A Condition That May Delay Healing And Prolong Infection If Left Unaddressed; And
- Other Services Professionals Such As Palliative Care And Pain Management Specialists.

Stage 4 pressure ulcers often have bone involvement and require imaging to evaluate the bone infection. They often require six to eight weeks of intravenous antibiotics and radiology placement of a long-term intravenous access device. Specialty support surfaces are a national standard for treatment of stage 3 and 4 pressure ulcers. This includes mattresses that often incur rental costs, mattress overlays, integrated bed systems, and specialty seat surfaces. In addition, there is increased nursing time due to the necessity of dressing changes, turning/ repositioning, offloading of bony prominences and incontinence management.

Moist wound management is the gold standard for treatment of stage 3 and 4 pressure ulcers. Dressings require packing which consists of a contact layer (placed on the base of the wound), filler dressings (fill dead wound space, address moisture balance and insulate the wound), and cover dressing (keeps filler dressings in place and protects the periwound (fragile skin surrounding the wound)). Wounds also may benefit from active therapies (i.e., negative pressure wound therapy, larvae, ultrasounds) which also have an impact on costs. Dressing changes require re-inspection and reassessment of the wound. Dressing changes can take place anywhere from three times weekly to twice daily. In light of this, we do not understand the basis for CMS's proposal and the agency does not provide sufficient rationale in the proposed rule for these changes.

***The Impact of These Changes is Consequential, But Not Thoroughly Discussed***

The impact of CMS's proposal to recategorize the severity levels of 1,492 codes cannot be overstated. At the very least, hospitals coding and billing departments will require substantial staff education and training. We also believe that the financial impact would be considerable – according to our own analysis, we estimate a decrease of millions of dollars in reimbursement to some hospitals in FY 2020 alone. This could very well, in turn, impact beneficiary access to care. However, there is little information provided in the proposed rule as to the net effect on the inpatient PPS or to specific hospitals and whether and how this is accounted for in the budget neutral adjustment.

In addition, it is unclear if the data analysis provided took into consideration the changes related to the principal diagnosis acting as its own MCC or CC that went into effect for

FY2019. That change would impact the MS-DRG assignment on data used for the proposed FY 2020 severity analysis and may under-estimate the impact of these proposals.

Furthermore, CMS has not explicitly identified the impact of its proposed changes on other aspects of the Medicare program, including quality programs such as the Hospital-Acquired Conditions (HAC) Reduction Program. For example, pressure ulcers are addressed differently in the payment system depending on when they arise; not all ulcers develop within the hospital stay as some patients have an ulcer present at the time of admission. Currently, the inpatient PPS differentiates the two types by a Present on Admission (POA) indicator or a HAC indicator. However, CMS proposes to include all pressure ulcers into the existing HAC, without regard to whether these codes have a POA indicator of Yes or No, and contrary to the current system, which only includes stages 3 and 4 into the HAC. As discussed above, the clinical treatment of the lower stage ulcers are not as intensive as the higher stages. Thus, it is unclear if this proposed change would create challenges for long-term review of this established HAC or the HAC Reduction Program. We recommend that CMS provide a thorough description of the impact of its proposed changes on other aspects of the Medicare program including the HAC Reduction Program.

**Taking these issues into account, we are unable to meaningfully comment on CMS's proposed changes to the CC/MCC lists and strongly urge the agency not to implement them.** CMS should instead work toward providing more information and transparency on their methodology and data in future rulemaking, and strongly consider proposals that would phase in the impact any changes would have on hospitals.

#### Requested Changes to Severity Levels.

- *Heart Failure.* CMS considered and denied requests to change codes for acute right heart failure, and acute on chronic right heart failure from a non-CC to an MCC, and for chronic right heart failure from a non-CC to a CC. CMS also proposes to downgrade chronic systolic, diastolic and combined heart failure from CCs to non-CCs. This decision is inconsistent with how other heart failure codes are handled. These conditions can adversely affect fluid status and the care of the patient, as they require increased nursing care, including care provided by ancillary staff. **We recommend CMS designate acute right heart failure, and acute on chronic right heart failure as MCCs. The resources required are similar to existing heart failure codes, which are classified as MCCs.**
- *Ascites in Alcoholic Liver Disease and Toxic Liver Disease.* CMS received a request to change the severity level for ICD-10-CM diagnosis codes K70.11 (Alcoholic hepatitis with ascites), K70.31 (Alcoholic cirrhosis with ascites), and K71.51 (Toxic liver disease with chronic active hepatitis with ascites) from a non-CC to a CC. CMS's clinical advisers reviewed this request and believe that the resources involved

in caring for a patient with this condition are not aligned with those of a CC. We recommend CMS reconsider its decision; these conditions should be considered CCs in recognition of the additional resources used to treat ascites. The change is consistent with the severity level designation of other ascites codes, such as R18.0, Malignant ascites and R18.8, Other ascites.

- *Obstetrics Chapter Codes.* CMS reviewed a request to change the severity level for 94 ICD–10–CM diagnosis codes in the Obstetrics chapter of the ICD-10-CM diagnosis classification that describe a variety of complications of pregnancy, childbirth and the puerperium. The requestor stated that the reclassification of the 94 obstetric diagnosis codes would more appropriately reflect severity of illness and accurate MS-DRG grouping after CMS’s FY 2019 creation of new obstetric MS-DRGs subdivided by severity level (with MCC, with CC, and without CC/MCC). CMS was unable to utilize the approach used elsewhere in this section to evaluate requested changes to severity levels, because the number of obstetric patients in the Medicare data was insufficient to perform evaluation using statistical methods. Instead, CMS’s clinical advisers used their judgment to evaluate the requested changes to the severity levels for the 94 obstetrics diagnosis codes. As a result, CMS proposes a change to the severity level for 14 ICD–10–CM diagnosis codes on the advice of their clinical advisers.

We understand that Medicare data does not have a sufficient volume for the obstetric population to make a meaningful data analysis. However, it remains important to make clinically and financially sound changes, not the least of which is because MS-DRGs are utilized in limited patient populations. Our analysis of the data support current severity designations in most cases. **Given the lack of sufficient Medicare data on obstetrical patients, we recommend that CMS postpone its decisions and instead work with a panel of provider stakeholders that utilize Obstetrical MS-DRGS and input from the American College of Obstetrics and Gynecology to reach consensus.**

Changes to the Medicare Code Editor (MCE). In general, we agree with all proposed MCE changes.

## **HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP)**

The HRRP imposes penalties of up to 3.0% of base inpatient PPS payments for having “excess” readmissions rates for selected conditions when compared to expected rates. CMS proposes mostly minor updates to the program in the proposed rule. Additionally, CMS will continue to implement the socioeconomic adjustment approach mandated by the 21<sup>st</sup> Century Cures Act of 2016 that it adopted in the FY 2018 inpatient PPS final rule.

**General Considerations. America's hospitals and health systems continue to agree that avoiding unnecessary hospital readmissions is an important goal. Hospitals' efforts to reduce readmissions are improving care and achieving significant savings for the Medicare program.** MedPAC's June 2018 *Report to Congress* showed that both unadjusted and risk-adjusted readmission rates across all conditions measured in the HRRP have declined significantly since 2010. In addition, MedPAC found that the decline in readmissions saved Medicare \$2.04 billion in spending on readmissions. Underlying these encouraging data are innumerable examples of how hospitals have enhanced their care by strengthening care transitions, connecting patients with community resources to enhance recovery, and improving in-hospital care processes to avoid complications that could result in readmissions.

**However, the AHA urges CMS to monitor and respond to ongoing concerns about the HRRP that threaten the fairness and sustainability of the program. First and foremost, the agency should engage with the field to evolve its approach to socioeconomic adjustment.** In FY 2019, CMS took an important step toward improving the HRRP's fairness by implementing the congressionally mandated socioeconomic adjustment approach that places hospitals into dual-eligible peer groups to calculate their penalties. This adjustment provided some much-needed relief to hospitals caring for the nation's poorest communities. But Congress intended for this adjustment to be a *starting* point and granted CMS the ability to update the approach beginning in FY 2021. As we [wrote](#) in our FY 2019 inpatient PPS comment letter, it is essential that CMS's socioeconomic adjustment approach keeps up with the evolving measurement science around accounting for social risk factors.

Recent studies underscore the need to consider enhancements to the adjustment approach. For example, data from one study showed that hospitals in states with less generous Medicaid programs – including those that did not expand Medicaid – are not helped as much by the adjustment as other hospitals.<sup>15</sup> Another study demonstrated the feasibility of using other social risk factor adjusters directly in measures, such as poverty, disability, housing instability and residence in a disadvantaged neighborhood.<sup>16</sup>

**The AHA also urges CMS to work with a range of stakeholders – including hospitals, patients and health services researchers – to assess whether the HRRP has had a negative impact on hospital mortality rates.** MedPAC's 2018 *Report to Congress* suggested that hospital readmission rates and mortality rates are largely uncorrelated. But emerging research<sup>17</sup> suggests that the HRRP's strong incentive to reduce readmissions could be associated with higher mortality rates. Given the divergent nature of the evidence around the link of readmissions to mortality, it is critical for CMS to examine this issue

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<sup>15</sup> See Joynt Maddox KE et al. Association of Stratification by Dual Enrollment Status with Financial Penalties in the Hospital Readmissions Reduction Program. *JAMA Internal Med.* Published online Apr. 15, 2019.

<sup>16</sup> See Joynt Maddox KE et al. Adjusting for social risk factors impacts performance and penalties in the hospital readmissions reduction program. *Health Services Research.* 2019; 54:327–336.

<sup>17</sup> For example, see Gupta A et al. Association of the Hospital Readmissions Reduction Program implementation with readmission and mortality outcomes in heart failure. *JAMA Cardiol.* 2018;3(1):44-53.

further to assess what changes to measure design and/or program implementation might be needed to the measures to avoid such an association.

**Lastly, the AHA is concerned that at least some of the measures in the program may be approaching “topped out” status, and urges CMS to consider phasing out these measures.** Commendably, CMS has proposed new measure removal criteria for the HRRP, as detailed in the next section of this letter. Yet, by the numerical criteria CMS has used in other programs, it appears that the measures in the HRRP may be “topped out” in performance, raising questions about the benefit of keeping the measures in the program.

**New Measure Removal Policy. The AHA strongly supports CMS’s proposal to add the same measure removal criteria to the HRRP that are used in other CMS hospital quality measurement programs. However, we also encourage CMS to strengthen these criteria by considering the use of numerical criteria to determine “topped out” performance.**

To date, the HRRP has lacked measure removal criteria, and CMS has never removed measures from the HRRP. The AHA is pleased that CMS recognizes the need to assess whether the measures in the HRRP have sufficient performance variation, relevance and value to patient care for retention in the program. The use of the same eight measure removal factors in the HRRP that already are in other CMS programs also should foster alignment and consistency.

**However, we believe CMS should enhance the objectivity and consistency of the “topped out” measure criterion by adopting the same numerical criteria that it uses in the hospital inpatient quality reporting (IQR) and value-based purchasing (VBP) programs.** When a measure is topped out, performance is so high and unvarying across providers that meaningful distinctions are no longer possible. But, in the absence of numerical criteria, this important concept could be applied somewhat subjectively. Fortunately, CMS already has adopted numerical criteria for “topped out” performance in both the IQR and VBP programs, which are as follows:

- The difference in performance between the 75th and 90th percentile is statistically indistinguishable. In general, this means that the 75th and 90th percentile scores differ by less than two standard deviations.
- The truncated coefficient of variation (TCV) is less or equal to 0.10. CMS’s definition of “truncated” is to remove the top and bottom 5% of hospitals before calculating the CV.

**Applying these two criteria to current data shows that the program’s measure set may already be “topped out” in performance.** The AHA analyzed the most recent data available on each measure from *Hospital Compare* (see Table 1 below). All six of the program measures would meet both criteria for being “topped out.” On the first criterion,



the 75th and 90th percentiles were separated by no more than 1.1 standard deviations. And the TCV values for all measures were 0.084 or less, well below the cut of 0.10.

**Table 1: Application of “Topped Out” Measure Criteria to Current HRRP Program Measures**

Measure	Number of Hospitals Reporting Data	90th Percentile	75th Percentile	Standard Deviation (SD)	Number of SDs between 75th and 90th Percentiles	Difference between 75 <sup>th</sup> and 90 <sup>th</sup> Percentiles > 2 SDs?	Truncated Coefficient of Variation (TCV)	TCV >= 0.10
AMI	2,109	17.3 %	16.7 %	1.08253	0.6	Yes	0.053	Yes
CABG	1,010	14.9 %	14.1 %	1.34455	0.8	Yes	0.08	Yes
COPD	3,602	21.0 %	20.3 %	1.11956	0.7	Yes	0.043	Yes
Heart Failure	3,595	23.7 %	22.6 %	1.63337	1.1	Yes	0.058	Yes
Hip-Knee	2,762	4.8 %	4.4 %	0.48418	0.4	Yes	0.084	Yes
Pneumonia	4,035	18.5 %	17.5 %	1.33411	1.0	Yes	0.061	Yes

Source: Hospital Compare Feb. 2019 release, Unplanned Hospital Visits file. The truncated coefficient of variation is calculated after removing hospitals with the top and bottom 5% of scores.

The results of this analysis call into question the long-term desirability of keeping measures in the HRRP that may not reflect significant differences in performance. Using measures with limited variation means that hospitals can experience significantly different readmission penalties based on only small differences in performance. Moreover, retaining “topped out” measures in the HRRP could detract from quality improvement efforts because hospitals would spend resources attempting to improve performance on the current HRRP measures, rather than on other measures with greater opportunity to improve. As a practical matter, Congress requires CMS to implement the HRRP, so any effort to remove or update the current measure set would require time. Nevertheless, given the significant implications of the program, CMS should begin to assess whether other clinical conditions with more variation would be more appropriate to assess in the program. It can use this assessment to develop suitable program measures and seek endorsement of them by the National Quality Forum.

**Look Back Period for Dual-eligible Status. The AHA supports CMS’s proposal to implement a one-month “look back” period to assess patients’ dual-eligible status.**

We agree that the step should improve the overall accuracy of the adjustment approach. CMS identifies dual-eligible patients using the state Medicare Modernization Act (MMA) file, which states submit to CMS monthly. Currently, a patient counts as “dual-eligible” if they had full-benefit status in both Medicare and Medicaid *for the month the beneficiary was discharged from the hospital*. However, CMS identified two circumstances in which its current definition of dual-eligible may lead to the underreporting of the number of dual-eligible beneficiaries – 1) the dual-eligible status is not recorded in the month a patient dies; and 2) a patient’s status changes from dual-eligible to non-dual eligible during the

month of death. Thus, CMS would modify the definition of “dual-eligible” who die in the month of discharge by identifying their dual-eligible status using the previous month’s MMA file.

Subregulatory Process for Non-substantive Changes. In prior rulemaking, CMS adopted a subregulatory approach for minor updates to the HRRP’s measure specifications. It now proposes to use a subregulatory approach for updates to the calculation of HRRP payment adjustment factors, such as minor changes to data sourcing. CMS would judge what constitutes a nonsubstantive change on a case-by-case basis. CMS believes the proposed dual-eligible look back period is an example of the type of change it would make on a subregulatory basis. But other changes, such as the program measure set, or a broader definitional change to dual-eligibility, would continue to follow a notice and comment process.

**The AHA urges CMS to add a safeguard to its final policy in which it explicitly states that any programmatic changes that impact hospital performance must go through notice and comment rulemaking.** In concept, adopting very minor programmatic updates without notice and comment rulemaking is reasonable and administratively efficient. Certainly, a subregulatory process would be appropriate if CMS were adopting a change such as changing the name of a file used to determine the payment adjustment factor. However, the AHA strongly believes that all of CMS’s programs – especially those like the HRRP that have a significant impact on provider payment – should operate on a transparent, “no surprises” basis. Any changes that have an impact to individual hospital performance, and/or to the program performance distribution, should be communicated in advance of their implementation. The annual inpatient PPS rulemaking process provides an ideal mechanism for this communication because of its predictable and widely known schedule. Contrary to CMS’s belief, the AHA believes it was entirely appropriate for CMS to use notice and comment rulemaking to adopt its dual-eligible “look back” period; this definitional change actually could have impact on hospital performance.

## **HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM**

The HAC Reduction Program imposes a 1% reduction on all Medicare inpatient payments for hospitals in the top quartile of certain risk-adjusted national HAC rates. The HAC Reduction Program’s measure set and scoring methodology are unchanged. However, CMS proposes two updates to the program. First, CMS proposes to adopt the same measure removal criteria that are proposed for the HRRP. Second, CMS proposes several minor updates to the HAC Reduction Program’s healthcare-associated infection (HAI) measure validation process.

Measure Removal Criteria. **The AHA supports CMS’s proposal to add new measure removal criteria to the HAC reduction program. However, we also encourage CMS to consider adopting quantitative criteria for assessing whether a measure is “topped out.”** We refer the agency to our discussion of measure removal criteria for the HRRP for more information.

Measure Validation Process Updates. **The AHA supports CMS's proposed clarifications and updates to the HAC Reduction Program measure validation process.** Each year, CMS randomly selects 400 hospitals for validation of both their HAI measures in the HAC program, and chart-abstracted measures from the hospital IQR program. In addition, the agency selects an additional 200 hospitals to undergo "targeted" validation of their HAI and IQR measures. CMS proposes two updates to the validation process. First, CMS would now select up to 200 hospitals for its "targeted sample." CMS believes this policy would allow it to remove hospitals that do not have a sufficient volume of HAI measure data from the targeted sample. Second, CMS would not validate HAI measure cases in which all positive blood or urine cultures are obtained on the first or second day following hospital admission. CMS has found that, for the most part, cases fitting this criterion are community-acquired infections rather than "true" HAIs.

Toward a Better HAC Reduction Program. **America's hospitals and health systems remain deeply committed to eliminating avoidable harm, but continue to have significant concerns about the design and implementation of the HAC Reduction Program.** The AHA has long opposed the arbitrary statutory design of the HAC Reduction Program, which imposes penalties on 25% of hospitals each year, regardless of whether hospitals have improved performance, and regardless of whether performance across the field is consistently good. In addition, the HAC Reduction Program's measure set overlaps with that of the hospital VBP program, leading to the possibility of divergent performance on the two programs, or double payment penalties under both. Lastly, results from the program's first five years show that large teaching hospitals, large hospitals, some smaller hospitals, and hospitals caring for larger number of poor patients are at much higher risk for payment penalties. We believe this is a result of flawed measurement rather than true "poor" performance.

We understand that CMS cannot change the statutory requirements of the HAC Reduction Program. **However, we continue to urge CMS to take a number of steps to improve the program's fairness.** This includes the following:

- Phase out the Patient Safety Indicator (PSI) measure. The AHA has long urged CMS to remove the deeply flawed PSI measure from the HAC Reduction Program and all other hospital quality reporting and pay-for-performance programs. Simply put, PSIs lack the accuracy, validity and usefulness to be suitable for any public reporting and pay-for-performance use. For additional information on the shortcomings of PSIs, we refer the agency to our FY 2019 inpatient PPS proposed rule comment [letter](#).
- Require that measures newly added to the HAC Reduction Program be publicly reported for at least a year before tying the measure to hospital payment. By statute, CMS is required to publicly report hospital performance on all measures in the HAC program. However, the program does not currently require that CMS

publicly report new program measures *before tying the measures to hospital payment*. The AHA believes public reporting is an essential step before tying a measure to payment that allows for all stakeholders to ensure there are no adverse unintended consequences of reporting a measure.

- Removing the measure overlap between the VBP and HAC Programs. CMS proposed to remove the measure overlap between these two programs in last year's inpatient PPS proposed rule, and the AHA is disappointed the agency chose not to move forward. We believe that using the same measures in programs with different scoring methodologies and data reporting periods simply creates confusion for hospitals, rather than a stronger incentive to improve performance.

## **HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM**

As required by the Affordable Care Act (ACA), CMS proposes to fund the FY 2020 VBP program by reducing base operating DRG payment amounts to participating hospitals by 2.0%. The VBP program is budget neutral; all funds withheld must be paid out to hospitals. CMS does not propose changes to the VBP program's measure set or scoring methodology. However, CMS proposes to adopt the same administrative requirements for submitting, reviewing, correcting and validating HAI data that it uses in the HAC Reduction Program. The requirements would take effect with data reported starting Jan. 1, 2020, and therefore affect FY 2022 payments.

**The AHA supports CMS's proposal to use the same HAI measure administrative requirements across the VBP and HAC programs. However, we ask CMS to clarify how failing HAI measure validation would affect hospital scoring and participation in the VBP program.** Prior to last year's inpatient PPS final rule, HAI measure validation was a requirement of the hospital IQR program. By statute, those hospitals that do not meet all IQR requirements – including measure validation – are not permitted to participate in the hospital VBP program. However, in last year's rule, CMS removed the HAI measures from the IQR, and transferred all HAI measure administrative requirements to the HAC Reduction Program. In addition, any hospitals that fail HAI measure validation now automatically receive the lowest possible HAC Reduction Program score for the measure(s) on which they fail validation.

In the proposed rule, CMS does not address how it will score those hospitals that fail HAI measure validation in the VBP program. The agency has a number of complex issues to consider. The VBP program has both baseline and performance periods, meaning that failed measure validation could impact two different FYs. Furthermore, the VBP program's administrative requirements would now be linked to both the HAC Reduction Program and the IQR. The VBP statute expressly excludes hospitals failing IQR administrative requirements, but it does not speak to the HAC Reduction Program.

**Thus, we urge CMS to engage with stakeholders to determine a fair, transparent process for scoring hospitals that fail HAI measure validation in the VBP.** We do not object to CMS moving forward with the non-validation portions of its proposed policies. But we urge CMS to consider issuing either an interim final rule or proposed rule as soon as possible to lay out how it will address this issue.

## **HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM**

Hospitals are required to report measures and meet the administrative requirements of the IQR program to avoid having their annual market basket update reduced by one quarter. 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 proposes three new measures for the IQR program, two of which are eCQMs, and one of which is a “hybrid” measure that combines electronic health record (EHR) data with Medicare claims data. CMS also proposes updates to eCQM submission requirements and discusses potential future new measures.

Proposed New eCQMs. CMS proposes to add two new eCQMs related to the safety of opioid prescribing and administration to the menu of eCQMs available for hospitals to report. These two eCQMs could be reported beginning with the calendar year (CY) 2021 reporting period for FY 2023 payment:

- *Safe use of opioids – concurrent prescribing*, which reports the proportion of discharged patients who were prescribed either (1) two or more opioids, or (2) opioids and benzodiazepines; and
- *Hospital harm – opioid-related adverse events*, which assesses the proportion of patients who received naloxone (an opioid reversal agent) either (1) at least 24 hours after hospital arrival; or (2) within the first 24 hours of hospital arrival with evidence of hospital opioid administration prior to the naloxone administration. The measure excludes naloxone administered for O.R. procedures.

**The AHA supports adding these two measures to the menu of available eCQMs, and we appreciate the agency’s interest in opioid-related measures.** Hospitals have reported that these two measures generally would draw upon data that are available from EHRs. Furthermore, these measures also could help with provider efforts to monitor opioid prescribing patterns. While the measures in and of themselves do not provide everything one would need to know about opioid prescribing, the data sources that it draws upon are the same ones that hospitals would use to evaluate prescribing patterns.

CMS also proposes to require the reporting of the concurrent prescribing eCQM starting with the CY 2022 reporting period. However, we believe a few improvements to the measure are necessary before CMS mandates its reporting. We detail those

recommendations later in this section in conjunction with our comments on other eCQM administrative requirements.

Required Reporting of Hybrid Hospital-wide, All-condition Readmission Measure. For FY 2026 payment, CMS proposes to require hospitals to report the hybrid hospital-wide all-cause readmissions measure it adopted previously for voluntary reporting. The first required reporting period would be July 1, 2023 – June 30, 2024. The hybrid readmission measure would combine Medicare fee-for-service claims data with certain data elements reported from EHRs to calculate performance. CMS would remove the claims-only hospital-wide readmission measure from the IQR.

**The AHA agrees that hybrid measures hold considerable promise for the future. However, the AHA urges CMS to keep the reporting of the hybrid readmission measure voluntary at this time.** In concept, the use of EHR data has the potential to bring much more precise clinical information to measures than using claims data alone. It could enhance risk adjustment approaches, and make the measure much more accurate.

**Experience with reporting such measures has been far too limited for CMS to deem the measure ready for the more than 3,500 hospitals that would be required to report it.** As CMS notes in the proposed rule, only 80 hospitals chose to voluntarily report the hybrid readmissions measure in 2018. Furthermore, those hospitals were required to report only two quarters worth of data, rather than the full year of data CMS would require of hospitals. And as of the writing of the proposed rule, CMS had yet to provide the participating hospitals with reports on how they actually performed on the measure. Lastly, hospitals have reported that only one major EHR vendor offers a module to its customers to support reporting. While it may have been appropriate for CMS to start voluntary reporting on a smaller scale, it is far from clear that the results of the voluntary reporting show that the measure is ready for use on a broad scale.

**Furthermore, the AHA is not confident that the current QualityNet system would be up to the task of accepting the very large amount of data that hospitals would have to submit to meet the requirements of the measure. If CMS is intent on requiring the hybrid readmission measure – or any other significant increases in eCQM reporting – in future years, it must enhance its infrastructure to accept such data.** Hospitals have reported significant issues with submitting eCQM data in each of the years eCQM reporting has been required. In fact, CMS has had to delay the submission deadlines because of these issues. Reporting a full year of data on the hybrid readmission measure entails the creation of very large QRDA-1 files. Without improvements, the required reporting of the hybrid readmission measure could put an unsustainable strain on CMS's data systems. Thus, the AHA strongly recommends that CMS improve the capacity of the QualityNet portal to receive test and production QRDA-I files and send submission summary and performance reports. If CMS finds that updates to QualityNet are not feasible, we recommend that CMS work with hospitals and other stakeholders to identify

alternatives for future reporting: a new QualityNet portal, use of an existing eCQM reporting portal or an alternative to electronic submission of eCQM data files.

**In addition, CMS must ensure that the reporting specifications of the hybrid measure remain stable throughout the reporting period.** Hospitals have expressed frustration at the frequency with which the specifications of eCQMs are changed during the reporting year. These changes make prospective measure performance tracking far more challenging. If CMS is intent on requiring a full year of measure data to be reported, it would be very challenging to track the measure if the specifications change too frequently.

**Lastly, the AHA is concerned about the capacity of EHR vendors to support significant new eCQM reporting at a time when CMS has proposed other significant changes to its meaningful use policies.** In other rulemaking, CMS and the Office of the National Coordinator for Health Information Technology (IT) have proposed sweeping new policies to promote the exchange of health information across the continuum. This includes a requirement for hospitals to transmit admission, discharge and transfer notifications, as well as new requirements around information blocking. We do not yet know which of these policies will be finalized, but implementing any of them would require significant resources from health IT vendors. This would not only impinge upon any work to prepare for the reporting of the hybrid measure, but also on hospitals' other efforts to enhance the ability of their EHRs to support patient care.

eCQM Data Reporting and Submission Requirements. **The AHA strongly supports CMS's proposal to require that certified EHRs be able to report all eCQMs.** The AHA previously advocated for such a policy to ensure that hospitals can select eCQMs that reflect their patient population and quality improvement goals, rather than being forced to select eCQMs based on what the EHR vendor makes available.

**The AHA also strongly supports CMS's proposal to retain current eCQM reporting requirements for CY 2020 and 2021 reporting, which are tied to payment in FY 2022 and FY 2023, respectively.** This means that hospitals would be required to submit one, self-selected calendar quarter of data on four self-selected eCQMs for the CY 2020 and CY 2021 reporting periods.

For CY 2022 reporting (FY 2024 payment), CMS also proposes that hospitals would be required to report one self-selected calendar quarter of the proposed Safe Use of Opioids – Concurrent Prescribing eCQM, plus three additional self-selected eCQMs. CMS believes requiring the concurrent prescribing measure is appropriate in light of the opioid crisis. **We appreciate the concept of using eCQM reporting to augment hospital activities to address the opioid crisis. However, before requiring the measure to be reported by all hospitals, we encourage CMS to consider additional measure exclusions.** Hospitals have expressed concern that the measure should exclude additional patient types for whom the concurrent prescribing of an opioid and a benzodiazepine is appropriate. For example, some patients may be being tapered off of one or the other

medicine at the time of discharge. But since the measure does not exclude such patients, there may be an inadvertent incentive to remove patients from the medicine sooner than they would be otherwise.

We encourage CMS to use the CY 2021 reporting period in which reporting the concurrent measure will not be required to inform its efforts to assess the measure. In practice, this may mean that required reporting of the measure is pushed back by one year, to CY 2023.

Potential Future Quality Measures. In the proposed rule, CMS solicits input on three eQMs it is considering for future years of the IQR. We briefly comment on each measure.

*Hospital harm – Severe hypoglycemia eCQM.* **While the AHA agrees that hypoglycemia can have significant patient safety ramifications, we urge CMS to consider several potential issues with this measure.** First, it is not entirely clear from available information whether hypoglycemia is an issue of sufficient scale across all hospitals to warrant inclusion in a national reporting program. At a time when CMS is rightly focused on “Meaningful Measures,” we urge CMS to ensure the measure is not focused on an overly narrow issue. We also urge CMS to use the feedback it received in discussing the measure with the Measure Applications Partnership (MAP) earlier this year. For example, there was some disagreement about the definition of “low glucose” – whether the level should be 40 mg/dL or 70 mg/dL.

*Hospital harm – Pressure injury eCQM.* **The AHA agrees that pressure injuries are an important potentially preventable patient safety issue. At the same time, this particular measure needs significant work before use in the IQR.** This measure is similar to that recently implemented in the various post-acute care quality reporting programs, and calculates the proportion of hospital encounters with a newly developed stage 2, 3 or 4 pressure injury or an unstageable pressure injury during hospitalization. In the notice and comment cycles in which that measure was proposed and finalized, several organizations raised issues with the measure that are also apparent in this inpatient measure.

First, this measure relies heavily on documentation of injuries within the first 24 hours of arrival at the hospital, which is a major challenge. Documentation of injuries of the various stages during this very busy period is extremely difficult, and it is unclear whether this measure relies upon physician documentation alone or whether nurse notes also would contribute to identification of these injuries. Even though there are guidelines on how to determine the stage of pressure injuries, there is still room for subjectivity. Performance on quality measures should be influenced only by the care provided, not on the variable documentation of that care.

Second, the measure does not adequately adjust for the various risk factors associated with pressure injuries, including proportion of ICU patients, frailty, nutrition, ECMO patients and multiple injuries. Teaching hospitals and safety net hospitals care for patients more



susceptible to pressure injuries, so their performance on this measure would likely be comparably low through no fault of the providers.

*Cesarean birth (PC-02) eCQM.* Cesarean birth (CB) is a procedure that can save the lives of mothers and babies. Given the potential risks of the procedure, the AHA agrees that CBs should not be performed more than is medically necessary. Yet, the AHA is concerned that the measure lacks risk adjustment, which could lead to inappropriate performance comparisons between referral centers for high-risk deliveries and other hospitals. The measure also fails to exclude patients with eclampsia or pre-eclampsia, for whom CB may be indicated. As specified, the measure likely is detecting differences in patient populations rather than differences in quality performance. In other words, the measure does not capture inappropriate or unnecessary procedures, and the use of the measure would go against optimal treatment for patients for whom CB is a protective option.

Further, we question the feasibility of implementing PC-02 as an eCQM. The data elements necessary to calculate the measure are not available in a structured format within current EHRs, and it is unclear whether they would capture data as accurately as through chart-abstraction. We understand that hospitals can currently choose which eCQMs to report under the Promoting Interoperability Program; however, CMS could easily change this policy in the future, which would put providers in the difficult position of sacrificing accuracy for compliance. Because of these logistical and conceptual issues as well as the overall importance of measures regarding maternal health, the AHA recommends that CMS seek other ways to surveil quality of care on this issue.

## **PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM (PCHQRP)**

The ACA mandated the establishment of a quality reporting program for PPS-exempt cancer hospitals (PCHs). CMS proposes a number of changes to the PCHQRP's measure set and proposes to publicly report additional measure data from the program.

### **The AHA supports many of CMS's proposals for the PCHQRP. This includes:**

- The removal of the external beam therapy for bone metastases measure given the significant data collection burden and challenges associated with it;
- The public reporting of the outpatient chemotherapy patient admission and ED visits measure; and
- The proposed confidential "dry run" of the unplanned readmission and palliative care measures planned for future public reporting.

**The AHA also supports CMS's proposed new measure assessing complications from the surgical treatment of prostate cancer. However, we urge CMS to clarify how it would publicly report the measure data.** The measure calculates the risk adjusted rate of the occurrence of urinary and erectile dysfunction following surgical treatment for prostate cancer using Medicare claims data. Outcomes data in this area would be useful given that prostate cancer is a common disease, and that, for some patients, surgery is the most appropriate course of treatment. However, we urge CMS to clarify how it would publicly report the measure. The proposed rule suggests the measure should be stratified by the type of surgical treatment used (i.e., open versus closed prostatectomy). However, we urge CMS to assess whether the sample sizes are actually large enough to report these rates. If they are not, we recommend that CMS simply report a single rate.

**The AHA also supports the proposed removal of the communication about pain questions from the version of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey used for PCHs.** This proposal aligns with CMS's decision to remove these same questions from the version of the HCAHPS used for other hospitals. As we have previously noted, we believe the removal of these questions is prudent until we can better understand the relationship between these questions and opioid prescribing. At the same time, CMS should continue engaging with hospitals, clinicians, measure developers and researchers to explore a range of approaches to assessing how well hospitals are addressing pain management in the hospital setting. These approaches could include further revisions to the pain questions in HCAHPS, or the use of other measurement approaches.

**The AHA also supports CMS's proposal to begin publicly reporting health care personnel influenza vaccination rates for PCHs. However, we continue to be concerned that publicly reporting the other HAI measures in the PCHQRP may have unintended consequences.** 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. We believe benchmarking the *MRSA* and *C Difficile* rates of PCHs against other hospitals may lead to unfair performance comparisons. Furthermore, given the small number of PCHs (n=11), we are not confident that the sample sizes will be large enough to accurately capture performance differences across PCHs. Thus, we encourage CMS to work with the Centers for Disease Control and Prevention and PCHs to determine the most appropriate way of capturing and publicly reporting measure results.

## HOSPITAL-WITHIN-HOSPITAL REGULATIONS

In 2003, CMS created “hospital-within-hospital” (HwH) regulations, in part, to address patient shifting, where patients began their care in an inpatient PPS hospital and then were discharged to a co-located non-inpatient PPS for a second stay. CMS elected to include children’s hospitals under these regulations. Existing hospitals were grandfathered in, but were prohibited from increasing their Medicare-certified beds beyond the number they had in a specified year.

In recent discussions with our members, it has become clear that the bed moratorium is having a negative impact on patient access to care with regard to the nation’s one grandfathered children’s HwH. For example, it has been unable to expand the size of its medical education residencies to increase the number of physicians trained to treat diseases and injuries of childhood. **Therefore, we request that CMS amend the HwH regulations to remove the restriction on grandfathered children’s HwHs’ ability to expand their number of Medicare-certified beds.** As noted, we believe that there is only one grandfathered children’s HwH in the nation. Less than one percent of their reimbursement comes from the Medicare program and this change will not increase Medicaid expenditures. Further, the patient-shifting issue that the HwH regulations sought to address does not apply – there are no patients who are admitted to the parent inpatient PPS hospital and then discharged to the children’s hospital, or vice versa for that matter.

## PROMOTING INTEROPERABILITY PROGRAM

As strongly advocated by the AHA, CMS proposes a reporting period of a minimum of any continuous 90-day period in CY 2021. **CMS believes that this is an appropriate length of time and that the proposal offers stability to the program.**

**In addition, the AHA supports CMS’s proposal to convert the Query of Prescription Drug Monitoring Program (PDMP) E-prescribing bonus measure “query of PDMP” from numerator/denominator performance scoring to an attestation measure.** As we noted in our comments last year, PDMP integration with certified EHRs is not widespread and many eligible hospitals and CAHs are likely to need to enter data manually into the certified EHR to document the completion of the query and conduct manual calculation of the measure. We understand that laws in several states do not permit PDMP data to be brought into and stored within a certified EHR, thereby extending the need for manual data entry and manual calculation of the measure indefinitely. We believe moving to a “yes/no” attestation will significantly lessen administrative burden.

**Lastly, the AHA supports CMS’s proposal to remove the Verify Opioid Treatment Agreement measure from the Promoting Interoperability Program.** As we noted in our FY 2019 inpatient PPS proposed rule comments, this measure lacks a standard that specifies the data to be included in the agreement. Without such standards, and accompanying certification requirements, it is unclear how a provider’s certified EHR technology could support this activity.