American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

June 28, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

RE: CMS-1752-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 2022 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program: Proposed Rule (Vol. 86, No. 88), May 10, 2021.

Dear Administrator Brooks-LaSure:

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) 2022. We are submitting separate comments on the agency's proposed changes to the long-term care hospital PPS.

We first thank CMS for its ongoing support for our nation's hospitals, providers and patients during the COVID-19 public health pandemic. The AHA appreciates the continued support, assistance and flexibility that CMS is providing to our members so that they are best positioned to care for their patients and communities. We look forward to continuing to work with you to protect the health of our nation.

We support a number of the inpatient PPS proposed rule's provisions, including the repeal of market-based Medicare severity diagnosis related group (MS-DRG) data collection and the use of FY 2019 data in rate-setting. At the same time, we have concerns with other proposals. In particular, we are concerned about proposals for organ acquisition payments and urge CMS not to finalize them. We also strongly urge

CMS to modify its proposals in distributing residency slots as part of the graduate medical education (GME) program. Finally, we have concerns about several of the agency's proposed new measures for the inpatient quality reporting program. A summary of our key recommendations follows.

"Market-based" MS-DRG Data Collection and Weight Calculation
CMS proposes to repeal the requirements that hospitals include on their Medicare cost report what the agency calls "market-based payment rate information." Specifically, hospitals would no longer be required to report, by MS-DRG, the median payer-specific negotiated charge for Medicare Advantage (MA) organizations. The agency also proposes to repeal the requirement that the information be used to calculate new market-based MS-DRG relative weights. **We strongly support repealing these requirements and thank the agency for its actions.**

Organ Acquisition Payments
The Medicare program reimburses transplant hospitals for organ acquisition costs, the transplant surgery, inpatient and post-transplant costs for Medicare recipients. CMS proposes to clarify, modify and codify into regulation the activities related to organ acquisition payments, in addition to proposing new requirements. **The AHA is concerned with CMS' proposals related to Medicare usable organs and organ acquisition payments.** Specifically, organ tracking capabilities simply do not exist to the degree necessary to obtain the information CMS would require. As such, if enacted, this proposed policy could severely limit patient access to organ transplantations. **Thus, we strongly urge CMS to withdraw its proposal and instead engage with stakeholders in developing any modifications to organ acquisition payment methodologies.**

Graduate Medical Education Program
CMS proposes to implement several provisions of the Consolidated Appropriations Act of 2021 that affect Medicare direct GME and indirect medical education (IME) payments to teaching hospitals. **The AHA is very concerned about CMS' proposed method to award a maximum of one full-time equivalent (FTE) residency slot per hospital per year and its proposal to prioritize slot distribution by health professional shortage area (HPSA) scores.** Such a limitation is unworkable and unproductive and such a prioritization method reflects neither statutory intent nor the reality of teaching hospital service areas. Instead, we urge CMS to provide sufficient FTE slots as appropriate for the length of a residency program and to implement an alternative method for prioritization, which reflects statutory intent in a streamlined and simplified manner. We also have concerns with other proposals, including the criteria to determine hospitals that serve HPSAs.

Hospital Quality and Value-based Programs
The AHA applauds CMS for recognizing the unprecedented impact of the COVID-19 public health emergency (PHE) on its hospital quality measurement and value programs. We support CMS' proposed measure suppression policy and most of the proposed program-specific measure suppressions for FYs 2022 and 2023. The AHA also shares CMS' commitment to advancing health equity and values the opportunity to respond to

the agency's requests for information (RFIs) on this vitally important priority. However, we have concerns about several of the agency's proposed new measures for the inpatient quality reporting program and recommend that CMS reconsider their adoption.

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 Shannon Wu, AHA senior associate director for policy, at (202) 626-2963 or swu@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

American Hospital Association (AHA) Detailed Comments on the Inpatient Prospective Payment System (PPS) Proposed Rule for Fiscal Year (FY) 2022

Table of Contents

"MARKET-BASED" MS-DRG DATA COLLECTION AND WEIGHT CALCULATION

Last year, in its inpatient PPS FY 2021 rule, CMS finalized a requirement that hospitals must include what the agency calls "market-based payment rate information"[1] on their Medicare cost reports for FYs beginning on or after Jan. 1, 2021. Specifically, every hospital was required to report "the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations ... by MS–DRG."[2] CMS planned to use such data for a new market-based methodology to estimate the MS-DRG relative weights beginning in FY 2024.

This year, CMS proposes to repeal both the requirement that hospitals report their median payer-specific charges for MA organizations and that information's use in calculating new market-based MS-DRG relative weights. Instead, the agency would continue using the existing cost-based methodology for calculating MS-DRG relative weights for FY 2024 and subsequent years. **The AHA strongly supports repealing these requirements and appreciates the agency's proposal to do so.** As we have stated previously, basing MS-DRG relative weights on price is not consistent with the statutory requirement that the weights are based on hospital resources used. As set forth in section 1886(d)(4)(B) of the Act, relative weights are intended to reflect "the relative hospital resources used with respect to discharges classified within that group" and not the relative price paid. Currently, CMS uses "a cost-based methodology to estimate an appropriate weight for each MS–DRG."[3] The AHA believes that the agency was conflating market price with cost.

We have stated repeatedly that the hospital field is committed to providing patients with the information they need on their out-of-pocket costs to enable them to be more prudent purchasers of health care services, and we remain focused on that goal. We have long said that privately negotiated rates take into account any number of unique circumstances between a private payer and a hospital, and their disclosure will not further CMS' goals of paying market rates that reflect the cost of delivering care or providing information useful to consumers. The AHA continues to believe that data and methodologies intended to reflect the resources used by hospitals should continue to be the basis in determining relative weights. **Therefore, the AHA supports the continued use of the current cost-based methodology for calculating relative weights for FY 2024 and subsequent years. Further, we urge the agency to focus on transparency efforts that help patients access their specific financial information based on their coverage and care.**

[1] 85 Fed. Reg. 58437 (September 18, 2020).
[2] 85 Fed. Reg. 58437 (September 18, 2020).
[3] 86 Fed. Reg. 25527 (May 10, 2021).

ORGAN ACQUISITION PAYMENTS

The Medicare program reimburses transplant hospitals for organ acquisition costs, the transplant surgery, inpatient and post-transplant costs for Medicare recipients. Currently, Medicare reimburses transplant hospitals for organ acquisition costs under a reasonable cost-based method, using the hospital's ratio of Medicare usable organs to total usable organs. CMS is proposing to clarify, modify and codify into regulation the activities related to organ acquisition payments, in addition to proposing new reporting requirements.

The AHA is very concerned with CMS' proposals related to Medicare usable organs and organ acquisition payments to transplant hospitals. Contrary to the agency's statements, hospitals simply do not have the ability obtain the information that CMS proposes to require they report – either through their own tracking systems or through organ procurement organizations (OPOs). It would be impossible for hospitals to comply with these requirements, and consequently they would have their payments cut for noncompliance. Furthermore, even if hospitals were to attempt to put systems in place to obtain the relevant information, it would be a massive undertaking that would require undue administrative burden and resources. Taken together, such payment cuts and increased costs would endanger transplant programs' ability to provide care and, subsequently, access to organ transplantations for vulnerable patients. We strongly urge CMS to withdraw its proposals related to organ acquisition payments and instead engage with stakeholders in developing any modifications to organ acquisition payment methodologies.

Currently, as part of its reimbursement mechanism, CMS considers Medicare usable organs to include organs that hospitals send to other transplant hospitals or independent OPOs. The agency states that this policy originated because Medicare assumed that all kidney transplant recipients were Medicare beneficiaries, and then applied those assumptions to non-renal organs. CMS contends that this has led Medicare to reimburse transplant hospitals and OPOs for organs that were not transplanted into Medicare beneficiaries.

However, CMS now believes that tracking capabilities exist to allow transplant hospitals and OPOs to determine the identity and payer information of organ transplant recipients, which would allow providers to also know whether the transplant recipient was a Medicare beneficiary. For transplant hospitals that do not use an organ tracking capability, CMS believes that they can contact the OPO, which can report the relevant information. Therefore, CMS asserts that it is possible for transplant hospitals and OPOs to report on their cost reports the number of organs transplanted into Medicare beneficiaries. **However, this assertion is flawed, and, the agency does not provide any support for it. In contrast, our members report that such tracking capabilities simply do not exist to**

the degree necessary, and that obtaining the relevant information from the OPOs is impossible.

First, CMS believes that some transplant hospitals use an organ tracking system. **While this is true, those that do have these systems do not have the capability to accurately collect the information CMS would require.** For example, some of our members report that their tracking system is primarily used to verify safe transport and receipt and custody of an organ shipping from one location to another. However, they are not able to obtain or exchange any information regarding the organ recipient in this process.

Second, CMS states that if transplant hospitals do not have their own tracking system, the OPO to which they donated the organ would be able provide the relevant information, namely the recipient's payer records. **This is also incorrect.** OPOs have neither the responsibility nor the expertise to ascertain recipients' payer information.[4] Instead, OPOs only have the necessary clinical information that is used to coordinate donation and transplantation, such as age, gender, blood type and antibody levels, but not payer information. In addition, donor hospitals cannot compel OPOs to provide even this clinical information about the organ recipient, and OPOs have no incentive to provide such information.

There are also global, systemic issues that stand in the way of hospitals having the ability to report information under CMS' proposal. For example, the hospital staff that care for organ donors have no need, no access and no right to know the demographic information of the patients who receive the allocated donated organs. The current reality for many transplant hospitals is that once the donor organ leaves the hospital, little information is relayed back, let alone specific information regarding recipients' payers. OPOs do not report to the donor hospital the placement details of each organ procured at a donor hospital, including information about the final recipient or recipient hospital of that organ. This, in fact, is by design to ensure fairness and integrity of the organ allocation system.[5] Maintaining anonymity ensures that an equitable allocation system exists and that a fair pattern of distribution occurs, where characteristics such as race, socioeconomic class and gender do not play prominent roles in determining allocations but rather medical and clinical need. Indeed, the current system operates under this framework to restrict information flow between donor and recipient providers so that the allocation of these scarce resources can be fair and equitable.

---

[4] Health Resources and Services Administration (2012). Guidance for Donor and Recipient Information Sharing. https://optn.transplant.hrsa.gov/resources/guidance/guidance-for-donor-and-recipient-information-sharing/.

[5] Health Resources and Services Administration (2010). Ethical Principles in the Allocation of Human Organs. https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/

Third, CMS states that transplant hospitals without tracking capabilities that cannot obtain information from their OPO can use “manual methodologies.” Specifically, the agency states that transplant hospitals could “determine the organ recipient from their records” and verify the insurance payer of the recipient with the transplant recipient’s hospital. **This is again incorrect and, furthermore, unreasonable.** CMS does not clarify what these “records" are and we do not understand what it could be referring to—hospitals do not have medical records or other information for organ recipients who are not their patients. The agency does not suggest any other method for determining the organ recipient, particularly in the case if OPOs do not or will not provide such information.

Further, even if transplant hospitals were able to determine the identities of the organ recipients, expecting them to then manually contact the hospital of each and every organ recipient for each and every organ they donate is entirely unreasonable. For example, a hospital that recovers five organs from each donor and sees 100 donors each year would need to initiate 500 contacts. In doing so, it would need to find the appropriate contacts at recipient hospitals, confirm a match and obtain sensitive recipient information for each of these 500 cases. Hospitals would not only be dealing with local transplant centers but need to establish relationships with transplant centers across the nation to obtain such information. Indeed, confirming a match between hospitals on an organ is in and of itself difficult to do, let alone having to obtain additional payer information. For example, the donor hospital would have a United Network for Organ Sharing (UNOS) donor ID of organs procured at their facility, but recipient hospitals may not be equipped from an electronic medical record standpoint to search for recipients by UNOS donor ID.

In addition, recipient payer information may not be determined and confirmed until months after the transplantation. For example, while payer information may be reported when the patient is listed for transplant on the Transplant Recipient Registration form, this information is not accompanied by source documentation and is not updated again until the patient is transplanted, which could be years later and/or when the patient could have aged into Medicare or otherwise changed insurance status. It would not be unusual for the incorrect payer information to remain listed on the recipient hospital’s registration form. Yet, under CMS’ proposal, donor hospitals would be required to ensure that the recorded payer information is the confirmed and final status. They also would need to develop record-keeping processes that track organs across multiple cost report years—another huge and unreasonable burden. For example, if an organ was excised in year one but not transplanted until year two, transplant hospitals would need to implement new processes to reconcile reported organs on the cost report and maintain sensitive medical information on recipients for cost report audits.

Furthermore, Medicare may share a liability for organ acquisition costs as a secondary payer in certain circumstances, adding even more complication and burden to the hospital’s requirements under CMS’ proposal. Thus, transplant hospitals would need to determine not only a primary payer, but also whether Medicare actually made a payment in its capacity as secondary payer. To seek such evidence, transplants hospitals would need

to determine whether the recipient's transplant hospital primary private insurance contract specifies "accepting payment in full," and compare Medicare's total cost to payment from the primary payer. Only then could the organ be counted as a Medicare usable organ. Obtaining contract information on organ transplantation from other transplant hospitals to verify Medicare secondary payer liability is, as one might imagine, seemingly impossible.

The above examples are not exhaustive, but do illustrate how it would be virtually impossible for hospitals to comply with CMS' proposed policies. And the consequences to transplantation programs and beneficiaries would be devastating. Specifically, because transplant hospitals would be unable to comply and accurately report Medicare usable organs transplanted into Medicare beneficiaries, CMS would presume that none, or very few, of the excised organs were transplanted into Medicare beneficiaries. Instead of ensuring that Medicare only pays for the costs associated with transplanting organs into Medicare beneficiaries, the agency's proposal would no longer reimburse the excising transplant hospital for their allowable organ acquisition costs when an organ is sent to an OPO and subsequently transplanted into a Medicare beneficiary. This presumption would result in massive payment cuts for approximately 200 transplant hospitals, at nearly $550 million in one year.[6] Nearly 30% of these hospitals would see their Medicare transplant reimbursements slashed by half. **Thus, CMS would be financially penalizing transplant hospitals for not complying with a policy that is unattainable.**

These payment cuts, combined with the added costs that transplant hospitals would incur as they struggle to comply with even part of the proposal would, in turn, trigger them to assess the financial sustainability of certain transplant programs. Potential decreases in the number of transplant programs in the future would, of course, be detrimental to the Medicare program and beneficiaries, including end stage renal disease patients who would have to stay on dialysis rather than undergo a kidney transplant. **Thus, this proposed policy could severely limit patient access to organ transplantations and we strongly urge CMS to withdraw it. Instead, the agency should convene stakeholders to develop any future proposals. The AHA urges CMS to start this process by conducting a comprehensive analysis examining issues related to the financial impact of and equitable access to organ donation and transplantation, among other topics.**

GRADUATE MEDICAL EDUCATION (GME)

Medicare graduate medical education (GME) funding is critical to maintaining the physician workforce and sustaining access to care. Current funding is insufficient and limitations to caps on the number of residents for which each teaching hospital is eligible to receive GME reimbursement are a major barrier to reducing the nation's significant physician shortage. CMS proposes to implement several provisions of the Consolidated

[6] Based on analysis of FY 2018 Medicare Cost Report data from the March 31, 2021 quarterly update of the Healthcare Cost Report Information System (HCRIS).

Appropriations Act of 2021 that affect Medicare direct GME and indirect medical education (IME) payments to teaching hospitals.

The AHA is very concerned about CMS' proposed method for distributing new residency slots. Specifically, the agency's proposal to award a maximum of one full-time equivalent (FTE) residency slot per hospital per year is unworkable and unproductive. Instead, we urge CMS to provide, *at the very least*, one FTE slot times the length of the relevant residency program. In addition, CMS' proposal to prioritize slot distribution by health professional shortage area (HPSA) scores reflects neither statutory intent nor the reality of teaching hospital service areas. Instead, the agency should prioritize slot distribution based solely on the four categories included in the law. Finally, we continue to urge CMS to support additional legislative efforts to lift the cap on the number of Medicare-funded residency slots, which would expand training opportunities across the country.

Slot Distribution Limitations for Hospitals. CMS proposes to phase in no more than 200 residency slots each year until 1,000 new Medicare-funded residency slots have been distributed. By statute, there are limitations on the distribution of residency slots – hospitals may not receive more than 25 additional FTE positions in total. Yet, CMS would impose a drastically more severe limitation on hospitals—limiting each individual hospital to no more than one FTE each year. **Such a limitation is not a sustainable framework for any training program that is seeking additional slots; it effectively makes the additional slots unworkable.** For example, depending on the specialty, a resident occupies a slot for three to five years. A hospital receiving one slot would mean it could only bring in one additional internal medicine resident every three years since that resident would occupy the slot for the entire duration of the training program. That is, once the additional resident moves on to training in year two, the program would then have to revert back to its previous number of training slots when bringing in a new cohort of residents because the additional resident is still occupying the one new slot. This would mean that a hospital would need to apply and obtain a slot every year for three consecutive years in order to fully sustain a stable internal medicine residency program and for four or five consecutive years for other specialties. While obtaining a slot every year is possible, it certainly is not guaranteed. And, such a limitation would make recruitment difficult and would not advance toward building sustainable training programs. **We urge CMS to instead provide sufficient FTE slots as appropriate for the length of a residency program. For example, if a hospital were to apply for slots for a three-year residency, it should be able to obtain three FTE positions at once *at the very least* in order to sustain training in the program over time.**

Slot Distribution Methods. By statute, qualifying hospitals for new residency slots must fall in one of the following categories: 1) hospitals located in rural areas, 2) hospitals operating above their resident limits, 3) hospitals in states with new medical schools, or 4) hospitals that serve areas designated as health professional shortage areas (HPSAs). Additionally, at least 10% of the total number of residency slots must be distributed to each of the four

categories. CMS proposes to prioritize applications from qualifying hospitals operating residency programs serving underserved populations by utilizing the Health Resources and Services Administration's HPSA score in allocating FTEs. Specifically, it would allocate one FTE to each hospital with the highest HPSA score and continue to hospitals with the next highest score until all available positions are distributed.

CMS states it is considering an alternative approach. Specifically, CMS is considering that priority be given to hospitals that qualify in more than one of the four statutory categories, with the highest priority given to hospitals qualifying in all four categories. Indeed, we believe that this approach would be less burdensome and offer a much clearer metric for qualifying hospitals. It is also much more consistent with the statutory criteria, which do not place any additional emphasis on HPSA service or scores. Indeed, the use of HPSA scores is concerning given the longstanding issues around the accuracy of HPSA scores. For example, the Government Accountability Office (GAO) has reported on shortcomings of HPSA scores, where certain providers received too low HPSA scores to qualify them for certain federal programs that required minimum scores, but they qualified for other programs that did not have such requirements.[7] We also have previously urged additional actions to refine HPSA scoring that more accurately reflects workforce shortage areas. **Therefore, we urge CMS to instead immediately implement this alternative method for prioritization, which reflects statutory intent in a streamlined and simplified manner, and work with stakeholders to refine the approach for future years.**

Determination of Hospitals that Serve HPSAs. In order to qualify as a hospital that serves areas designated as HPSAs, CMS proposes that a hospital's main campus or provider-based facility must be physically located in a primary care or mental health HPSA and that least 50% of the residents training time over the duration of the program must occur at those locations in the HPSA. While we appreciate CMS' objective to maximize distribution of GME positions to residency programs serving underserved populations, this requirement is too restrictive in serving that goal and in carrying out statutory intent. The law specifies that hospitals must *serve* areas designated as HPSAs— not be located in a HPSA. And, indeed, providers routinely serve these areas even if they are not physically located in a one. This is particularly true given the large size, service line offering and, accordingly, service area that teaching hospitals routinely serve. We also believe that requiring hospitals to track and report if their residents training time occurs at least 50 percent of the time in the HPSA is too restrictive and burdensome. Allowing hospitals to qualify if they are proximate to a primary care or mental health HPSA, rather than physically located in one, and removing the 50 percent restriction would also take on a more expansive view of providers serving underserved populations. **Therefore, we urge CMS to consider a hospital to serve a HPSA if it is either proximate to, or physically located in one, and to remove the restriction that 50 percent of the residents training time must occur in the HPSA.**

[7] Government Accountability Office (2006). Health Professional Shortage Areas: Problems Remain with Primary Care Shortage Area Designation System. https://www.gao.gov/products/gao-07-84.

Resetting Low Per Resident Amount (PRA) and FTE Caps. In order for hospitals to qualify to reset their previously low PRA, CMS proposes to consider hospitals that either have PRA of less than one FTE before Oct. 1, 1997, or a PRA of less than three FTEs after Oct. 1, 1997 and before Dec. 27, 2020. In order for hospitals to qualify to reset their previously low FTE caps, hospitals in either categories above would need to first begin training residents in new residency programs after Dec. 27, 2020. **We support these proposals.**

Rural Training Track (RTT) Proposals.

- *Urban and Rural Hospitals Participating in and/or Adding Additional RTTs.* CMS proposes to provide an adjustment to IME and direct GME FTE resident caps each time an urban and rural hospital establish a RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes. The proposed change would now allow for the rural hospital to also receive adjustments to its resident caps. Furthermore, under previous regulations, after establishing the first RTT, urban hospitals that established additional RTTs (beyond the first RTT) did not qualify for cap adjustment unless these additional RTTs were new for Medicare payment purposes. CMS proposes to change this policy to adjust resident caps for an urban hospital creating additional RTTs after establishing its first RTT. We support these cap adjustment opportunities. However, we believe that CMS should not limit FTE cap adjustment opportunities to only new rural hospital RTTs ("spokes") as opposed to existing rural hospitals who already have worked with urban hospitals ("hubs"). According to CMS, a rural hospital that already participated in an RTT would be held to its already existing Medicare resident cap, but a rural hospital that never participated in an RTT would be permitted to receive a Medicare cap adjustment. **We urge CMS to permit existing rural hospital "spokes" to receive a one-time opportunity for adjustment to their RTT caps.**
- *Separately Accredited RTTs*. Hospitals have not been able to seek additional funding opportunities for rural tracks developed in specialties other than family medicine because the Accreditation Council for Graduate Medical Education (ACGME) only separately accredited family medicine programs. CMS proposes that beginning on or after Oct. 1, 2022, as long as the program is entirely accredited by ACGME, regardless of specialty, and the residents spend more than 50% of the entire program in a rural area, except for family medicine, it may qualify as a RTT and the urban and rural hospitals may receive rural track FTE adjustments. **We support this proposal.**

Extension to Cap Building Period. **The AHA continues to urge CMS to temporarily amend the regulations for teaching hospitals with new medical residency programs that have been unable to build their programs to full size before the cap is established due to the impacts of the ongoing pandemic and public health emergency (PHE).** As we have previously stated, the AHA urges additional actions to help create flexibility in addressing workforce shortages, and we wish to reiterate the

importance of allowing extensions to the five-year cap-building period for new GME programs. Most recently, the GAO has also reported on the importance to extend the five-year cap-building period to increase the overall number of residents trained and to address physician workforce shortages.[8] Throughout the PHE, CMS has implemented numerous waivers and modified many regulations nationwide, including many focusing on the workforce. Such actions have been essential in allowing hospitals and health systems to react and adapt swiftly to new patient care needs, demands and decisions. The agency should extend the five-year cap building window for impacted hospitals by the length of the PHE plus the additional time needed to reach July 1 of that year. Hospitals in hard hit areas will require additional time to align with the July 1 start date of the academic year when residency programs begin. Taking this action would do much to support the long-term sustainability of physician training.

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.

Transparency related to DSH calculation. The AHA continues to be concerned about the agency's lack of transparency with regard to how CMS and the Office of the Actuary (OACT) are calculating DSH payments. This is particularly troubling because Congress has generally foreclosed subsequent review, making the adequacy and completeness of notice-and-comment rulemaking that much more important from a constitutional due process perspective. We highlight below some examples of improvements that should be made to promote transparency related to the DSH calculation; however, this list is not all-encompassing, and **we urge CMS to provide all additional information required for stakeholders to replicate and validate this complex calculation.**

Our biggest concern relates to the calculation of Factor 1, the estimate of what total DSH payments would have been under the former statutory formula.[9] CMS includes in the rule a table explaining the factors it applied for FYs 2019 through 2022 to estimate Factor 1. In this table, the agency includes an "Other" column that it says "shows the increase in other factors that contribute to the Medicare DSH estimates", including the difference between the total inpatient hospital discharges and the inpatient PPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns.

[8] Government Accountability Office (2021). Physician Workforce: Caps on Medicare-Funded Graduate Medical Education at Teaching Hospitals. https://www.gao.gov/assets/gao-21-391.pdf.
[9] 86 Fed. Reg. 25444 – 25446 (May 10, 2021).

However, while CMS provides examples of the categories included in this factor, they are not exhaustive. In addition, it fails to detail how this factor is actually calculated. For example, CMS states that it included the 20% add-on for COVID-19 discharges, as well as changes in Medicaid enrollment due to the Affordable Care Act (ACA) and the COVID-19 pandemic. Yet, the "Other" value for FY 2021 is less than 1 despite continued add-on payments for COVID-19 discharges due to the PHE and an estimated growth in Medicaid enrollment by 1.2%. While CMS has implied that there may have been differences between the total inpatient hospital discharges and the inpatient PPS discharges for FY 2021 that could have accounted for this value, CMS' failure to make a detailed methodology available means that this is simply a guess. In fact, our analysis of FY 2021 data shows that inpatient PPS discharges changed in a similar pattern compared to total inpatient discharges, making particularly the "Other" value of 0.9754 for FY 2021 questionable.[10] Indeed, without CMS' methodology, it severely limits the AHA's ability to comment sufficiently on this issue. **As such, we request that CMS publish a detailed methodology, including how the "Other" values for all years have been calculated by OACT. In addition, the AHA would like to see detailed calculations of the discharge and case mix values for all years. We also request that this information be provided to the hospital field in advance of publication of the final rule and in the inpatient PPS proposed rule each year going forward. This will enable the field to have the data necessary to replicate CMS' DSH calculation and comment sufficiently in future years.**

In addition, in estimating Factor 1, CMS used data based on "the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2021 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule,"[11] in addition to historical and preliminary claims data. The agency further states that the "discharge figures for FY 2020 to FY 2022 reflect the estimated impact of the COVID-19 pandemic." While CMS estimated in its FY 2021 final rule that discharges would increase by 3.6% in FY 2021, it now estimates a decrease of 3.2% in discharges for FY 2021. We disagree with this estimate. While total discharge volume remains low compared to pre-pandemic levels, early signs of volume recovery are starting to emerge. For example, according to a Kaufman Hall study, adjusted national patient volume has increased by 6% year to date.[12] Further, national utilization data from Strata Decision Technology illustrate that total inpatient admissions began to increase starting in February 2021 consistent with declines in COVID-19 inpatient volumes.[13] Indeed, our analysis also shows that non-COVID inpatient discharges began to increase starting in February 2021 when, at the same time, COVID inpatient discharges began to

[10] Analysis based on Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.
[11] 86 Fed. Reg. 25445 (May 10, 2021).
[12] Kaufman Hall (2021). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2021-05/may-2021-national-hospital-flash-report.pdf.
[13] Strata Decision Technology Monthly Report. https://www.stratadecision.com/wp-content/uploads/2021/06/National-Patient-and-Procedure-Volume-Tracker_June_14_2021.pdf.

decrease.[14] Although it appears likely that FY 2021 volumes will remain lower than historic, pre-pandemic levels, the trends indicate that FY 2021 volumes will continue to increase. Given these trends, we urge CMS to carefully monitor changes in discharge volume when estimating Factor 1.

As CMS is using preliminary claims data to estimate the "Discharges" factor that is used to arrive at Factor 1 for FY 2022, it is critically important that these data be updated to reflect the latest discharge information to ensure that hospitals are accurately paid for their uncompensated care costs. While the rule indicates "OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2022 IPPS/LTCH PPS final rule,"[15] **we urge OACT to carefully monitor changes in discharge volume and to update its estimate of the Medicare DSH amount in the final rule to more accurately reflect additional changes in discharge volume for 2021.**

Use of Worksheet S-10 Data. CMS proposes to utilize FY 2018 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2022. The agency states that the FY 2018 data are the best available because 1) they are from the most recent year for which CMS has conducted an audit of worksheet S-10 and 2) they reflect improvements to the S-10 instructions. **The AHA has a longstanding position supporting the use of audited S-10 data in order to promote accuracy and consistency. We continue to believe that audited data and, by extension, ongoing refinements to the audit process result in data that are more appropriate for use in Medicare DSH payments. We, therefore, support the use of FY 2018 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2022.**

As we have commented previously, utilizing a single year of S-10 data may increase the potential for anomalies and undue fluctuations in uncompensated care payments—especially when hospitals experience unforeseen circumstances such as a pandemic. Thus, we continue to recommend that CMS monitor payments over time and, if necessary, consider utilizing more than one year of data after FY 2022. Doing so also would provide a clear pathway to audit all DSH hospitals over time, as recommended below.

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

- Establish a standardized process across auditors, including standard timelines for information submission and acceptable documentation to meet information requirements;
- Consider targeting particular information/data elements for audit;

[14] Analysis based on Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.
[15] 86 Fed. Reg. 25445 (May 10, 2021).

- Develop a transparent timeframe for the audit, with adequate lead time and communication to providers about expectations; and
- Establish a process for timely appeals.

Technical Proposals Related to S-10. CMS makes several technical proposals related to the S-10 data. First, in making DSH payments, CMS calculates an interim amount per discharge for each DSH hospital, based on the hospital's estimated DSH total uncompensated care payment divided by the hospital's most recently available three-year average number of discharges. CMS proposes to modify this calculation for FY 2022 in light of the COVID-19 PHE. The agency proposes to use the average of FY 2018 and FY 2019 discharge data rather than its traditional use of a three-year average. **We support this proposal.**

In addition to the existing uncompensated care (UCC) trim methodology, CMS proposes to apply a new UCC trimming methodology to hospitals that are not projected to be DSH eligible and do not have an audited Worksheet S–10, but may have aberrant amounts of insured patients' charity care costs. CMS would use a ratio threshold of greater than 60% of insured patients' charity care costs to total uncompensated care costs and a dollar threshold of the median total uncompensated care cost reported in FY 2018 cost reports ($7 million). For hospitals that are subject to this proposed trim but ultimately are DSH eligible at cost report settlement, the hospital's MAC would make a final determination of Medicare DSH payments based on its FY 2022 cost report. **We support this proposal.**

We also support the following DSH proposals:

- Newly Merged Hospitals. CMS proposes to continue its policy that interim uncompensated care payments for newly merged hospital would be based only on the data for the surviving hospital's CMS Certification Number (CCN) available the time of the development of the final rule. For FY 2022, this would be the FY 2018 cost report for the surviving hospital's CCN. Per the policy described above, CMS would then determine the final DSH payment for the newly merged hospital based on the FY 2022 during cost report settlement.
- "New Hospitals." CMS proposes to continue its policy for "new hospitals" finalized in FY 2020. Specifically, for those hospitals with a CCN established on or after Oct. 1, 2018, the hospital's Medicare Administrative Contractor (MAC) would make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2022 cost report. New hospitals would not receive interim uncompensated care payments before cost report settlement because Worksheet S-10 data for FY 2018 would not be available.
- Puerto Rico Hospitals. CMS proposes to continue to use a low-income patient proxy, rather than FY 2018 Worksheet S-10 data, to determine the share of uncompensated care provided by Puerto Rico hospitals for FY 2022. Specifically, CMS would utilize Medicaid days from FY 2013 and the most recent update of Supplemental Security Income (SSI) days. For Puerto Rico hospitals, SSI days

would be equivalent to 14% of a hospital's Medicaid days, as finalized in the 2017 inpatient PPS/LTCH PPS final rule.

- Indian Health Service (IHS) and Tribal Hospitals. CMS proposes to continue to use a low-income proxy for IHS and Tribal hospitals, which consists of Medicaid days from FY 2013 and the most recent update of SSI days.

USE OF FY 2020 OR FY 2019 DATA IN RATE SETTING

CMS states that both the FY 2020 claims and the FY 2019 cost report data, which would have been typically used for FY 2022 rate setting, were impacted by the COVID-19 PHE and are highly unusual compared to past years. Specifically, their use results in an aberrant outlier fixed-loss amount, MS-DRG relative weights and case mix. For example, the fixed loss threshold was nearly 20% higher based on 2020 data compared to 2019 data. Accordingly, CMS proposes to use FY 2019 claims and FY 2018 cost report data where ever it would have ordinarily used FY 2020 claims and FY 2019 cost reports. **The AHA supports CMS' proposal to use FY 2019 claims and FY 2018 cost report data for FY 2022 rate setting and appreciates its recognition of the unusual nature of the FY 2020 data. That said, AHA's support of this methodology only pertains to the proposed FY 2022 rates and weights. The data used in future years' rulemaking should be revisited on a year-by-year basis.**

AREA WAGE INDEX (AWI)

Low-wage Hospital Policy. CMS previously finalized a policy to increase wage index values for low-wage hospitals, beginning in FY 2020 and effective for at least four years, in order to "allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation." As such, CMS proposes to continue this policy in FY 2022. Specifically, for hospitals with a wage index value below the 25th percentile, the agency would continue to 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. The agency proposes to continue to make this policy budget neutral by adjusting the national standardized amount for all hospitals.

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

we support increasing the wage index values of low-wage hospitals, but continue to urge the agency to use its existing authority to do so in a non-budget-neutral manner.

In addition to statutory permissibility, the AHA continues to believe there also is strong policy rationale for making the low-wage hospital policy non-budget neutral. As we have previously stated, Medicare consistently reimburses inpatient PPS hospitals less than the cost of care. For example, the Medicare Payment Advisory Commission (MedPAC) found that hospitals' aggregate Medicare margin was -8.7% in 2019, continuing the longstanding trend of substantially negative Medicare margins.[16] MedPAC also cautions that any changes in the Medicare margin will largely depend on the duration and severity of the ongoing pandemic. Taken together, these observations strongly suggest that there is a need to *add* funds into the system—not to take them away from hospitals that are already operating in a below-cost reimbursement environment and in a PHE.

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

Area Wage Index Transition Policy. Last year, as a result of adopting updates from the Office of Management and Budget's (OMB's) core-based statistical area modifications, CMS finalized a policy to cap any decrease in a hospital's final FY 2021 wage index compared to its final FY 2020 wage index at 5%. This was set to expire at the end of FY 2021. As a result of the COVID-19 PHE, CMS is now considering the appropriateness of applying a transition policy to the FY 2022 wage index for hospitals that would be negatively impacted by the adoption of those previous OMB modifications. **The AHA appreciates CMS' recognition of the impact on hospitals affected by OMB's modifications, especially during the PHE. However, all hospitals, not only those impacted by OMB's modifications, have been severely impacted by the PHE. Indeed, America's hospitals continue to serve at the front lines caring for patients and fighting the pandemic. Therefore, we urge CMS to apply a non-budget neutral transition policy—one that holds hospitals harmless to wage index reductions—to all hospitals, not only those impacted by OMB's modifications.**

Indeed, the AHA believes that such a policy should be made permanent, in a non-budget-neutral manner. As previously stated, hospitals have repeatedly expressed concerns that the wage index is greatly flawed in many respects. Instituting a hold harmless policy is one step in improving current flaws that exist within the wage index.

---

[16] MedPAC. (2021). March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_ch3_sec.pdf?sfvrsn=0.

Furthermore, the financial stability of hospitals continues to be impacted by the COVID-19 pandemic, threatening their ability to continue to provide essential services to their patients and communities. The AHA estimates that hospitals have already suffered an estimated $323.1 billion from March 2020 to December 2020.[17] Hospitals still face uncertainty about patient volume, revenue and expenses, which raises questions about how quickly and to what extent will hospitals recover financially. While federal and state funding have helped hospitals stay afloat, new analysis suggest that hospitals could face an estimated $53 - $122 billion total revenue loss during 2021.[18] This outlook is especially bleak for rural hospitals, who could be hit especially hard by the lingering effects of COVID-19 and see no improvement in operating margins during 2021.[19]

AWI Exclusions. In the rule, CMS states that in reviewing Worksheet S-3 data it identified aberrant data from 86 hospitals. The agency excluded these data from the wage index calculations, but noted that it intends to include corrected data from some providers in the final wage index for FY 2022.

The AHA supports CMS' 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. The agency does not provide any rationale why data from the hospitals that were removed are aberrant and stakeholders are left to make educated guesses as to why CMS has deemed the wage data aberrant, limiting their ability to fully comment on the exclusion of individual hospitals. CMS does not provide any criteria, standards, thresholds or trim methodologies that substantiate aberrant data, and consequently, exclusions of hospitals from the wage index. The agency simply states "we performed an extensive review of the wage data, mostly through the use of edit designed to identify aberrant data."[20]

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.

---

[17] AHA (2020). Hospitals and Health Systems Continue to Face Unprecedented Financial Challenges due to COVID-19. https://www.aha.org/issue-brief/2020-06-30-new-aha-report-finds-losses-deepen-hospitals-and-health-systems-due-covid-19.
[18] Kaufman Hall (2021). COVID-19 in 2021: The Potential Effect on Hospital Revenues. https://www.kaufmanhall.com/sites/default/files/2021-02/kh_2021-covid-impact-report.pdf.
[19] Kaufman Hall (2021). COVID-19 in 2021: Pressure Continues on Hospital Margins. https://www.kaufmanhall.com/sites/default/files/2021-03/kaufmanhall_2021marginsreport.pdf
[20] 86 Fed. Reg. 25398 (May 10, 2021).

Rural Floor Calculation. Per statute, the area wage index value of any urban hospital may not be less than the area wage index applicable to hospitals located in rural areas in the same state – this is known as the "rural floor" policy. As finalized in FY 2020, CMS would continue to exclude the wage data of urban hospitals that reclassify to rural areas when calculating the wage index for the rural floor. **We support this proposal.**

Imputed Floor Calculation. As required by the American Rescue Plan Act, CMS proposes to permanently reinstate a minimum area wage index for hospitals in all-urban states, known as an "imputed rural floor" for FY 2022. This policy applies to states that have no rural hospitals or no rural areas to set a rural floor wage index for those states. Also as required by law, CMS proposes apply this policy in a non-budget-neutral manner. **We support this proposal.**

Reclassification from Urban to Rural. In order for a hospital to be treated as rural in the wage index and budget-neutrality calculations for the coming FY, CMS currently stipulates that an application for rural reclassification must be approved no later than 60 days after the public display date of the inpatient PPS proposed rule. This is known as the "lock-in date." CMS proposes to change this timing so that requests to cancel rural reclassification cannot be submitted to the CMS regional office earlier than one calendar year after the reclassification effective date. CMS also proposes that hospitals approved for rural reclassification would have its data included in the calculation for the rural wage index for at least one FY before rural reclassification status can be canceled. **We support this proposal. That said, the wage index policy is complicated and ever-evolving. As additional circumstances and instances present themselves, there may be a need to revisit this policy.**

NEW COVID-19 TREATMENTS ADD-ON PAYMENTS (NCTAP)

In light of the COVD-19 PHE, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) for COVID-19 cases that meet certain criteria occurring on or after Nov. 2, 2020 until the end of the PHE. CMS proposes to extend NCTAP for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends. In addition, CMS also proposes to extend NCTAP for eligible products that are not approved for NTAPs through the end of the fiscal year in which the PHE ends and to discontinue NCTAP for discharges on or after Oct. 1, 2021 for a product that is approved for NTAPs beginning in FY 2022. **We support the extension of these payments through the end of the fiscal year in which the PHE ends and urge CMS to maintain flexibility to be able to continue these payments beyond the proposed timeframe if necessary.**

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.

CMS identifies clinical trial CAR T cases in order to exclude them from CAR T weight setting and adjusts the CAR T MS-DRG payment by a multiplier calculated by dividing the costs associated with clinical trials by costs associated with non-clinical trial cases. This is to account for the fact that resources used for clinical trial cases do not include the costs of the therapy. Using FY 2019 data, CMS proposes a payment adjustment of 0.17 when calculating payment for clinical trial cases and expanded access cases assigned to MS-DRG 018 for FY 2022. Recently, a fast-growing number of CAR T clinical trials have actively explored and expanded their potential application scenarios, increasing the number of diseases currently being studied. For example, clinicians are beginning to explore new ways to treat multiple myeloma in clinical trial CAR T-cell therapies.[21] Understanding the full extent of resources used across different diseases and cases are still unknown and may fluctuate greatly. Indeed, the number of clinical trial cases continue to increase substantially year to year. For example, the number of CAR T clinical trials cases has risen from approximately 170 cases to 230 cases from FY 2019 to FY 2020 – an increase of 35% in just one year.[22] Thus, it is uniquely important to use the latest data available to ensure an accurate reflection of the resources used in these new and evolving clinical trial cases. **As such, we urge CMS to use FY 2020 data to calculate the multiplier that is used to adjust for CAR T clinical trial cases.**

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

In the rule, CMS proposes to allow ACOs participating in the glide path of the MSSP BASIC track the opportunity to forgo automatic advancement and maintain their participation for Performance Year (PY) 2022 at their PY 2021 level. CMS offered this same opportunity in PY 2021, thus allowing ACOs to freeze their participation for PY 2021 at their PY 2020 level. Under this proposal, ACOs that elected the option last year would be permitted to freeze their participation a second time, thus remaining at their PY 2020 participation level for PY 2022. Any ACO that elects to remain at its current participation level for PY 2022 would be automatically advanced to the BASIC track level in which it would have participated during PY 2023 if it had not frozen its advancement (unless the ACO chooses to advance more quickly).

We support this proposal and appreciate CMS' recognition of the ongoing impact of the COVID-19 pandemic on ACOs. However, we are concerned about the proposal to

[21] National Cancer Institute (2019). New Clinical Trial Tests CART T-cell Therapy for Multiple Myeloma. https://ccr.cancer.gov/news/article/new-clinical-trial-tests-car-t-cell-therapy-for-multiple-myeloma.
[22] Based on analysis of FY 2022 Proposed Rule Data Files and FY 2022 Proposed Alternative Considered Files.

automatically advance ACOs to the level at which they would have otherwise participated in PY 2023, especially for ACOs going from upside-only to up- and downside participation. If an ACO participating at Level A in PY 2020 chooses twice to freeze its participation level, it would participate at Level A in PYs 2020 through 2022 and then be advanced to Level D in PY 2023. This is a dramatic escalation in risk for ACOs in any year, but especially in the years following a global pandemic. It also defeats the original purpose of the BASIC track's glide path, which was to support ACOs in gradually taking on risk. We understand that the glide path was designed to last five-and-a-half years over six performance periods and that CMS is disinclined to extend it, but we urge the agency to reconsider given the circumstance of the pandemic. **Specifically, we recommend CMS allow ACOs to advance along the glide path as originally planned – advancing one level every year until reaching Level E.** While this would extend BASIC track participation for some ACOs, it would simultaneously protect their ability to increasingly take on risk and avoid forcing ACOs to exit the program simply because of the jump in risk they could encounter by taking advantage of CMS' proposed policy.

COUNTING DAYS ASSOCIATED WITH SECTION 1115 DEMONSTRATION PROJECTS IN THE MEDICAID FRACTION

The AHA opposes CMS' proposal to further limit the inclusion of patient days for patients who are made eligible for Medicaid through a Section 1115 expansion program for purposes of the Medicare DSH calculation. States, under the authority of Social Security Act Section 1115(a), can request, from the Secretary of Health and Human Services (HHS), approval to waive certain statutory Medicaid requirements for state demonstration projects that will help promote the objectives of the Medicaid program. These state demonstration projects, widely known as Medicaid 1115 Waiver programs, enable more individuals to receive Medicaid benefits without satisfying all statutory Medicaid requirements. Because a component of the Medicare DSH patient percentage includes Medicaid patient days known as the "Medicaid Fraction," questions have been raised over the years as to whether individuals provided medical services through a Medicaid 1115 waiver could be included in the "Medicaid Fraction" of the Medicare DSH patient percentage. Congress answered those questions in 2005 through a provision of the Deficit Reduction Act:

> "In determining [the Medicaid fraction,] the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under [Medicaid], the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

A plain reading of this statutory phrase "…include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration

project approved under title XI," suggests that Congress intended that patients receiving benefits under a Medicaid 1115 Waiver program would be counted in the "Medicaid Fraction." This reading is supported by the opinions from several federal courts.[23] In the U.S. Court of Appeals for the Fifth Circuit decision on *Forrest General Hospital v. Azar*, the appellate judges clearly ruled in favor of the plaintiff hospital's inclusion of patient days from the state's Medicaid 1115 Waiver program in the determination of the hospital's "Medicaid Fraction." This opinion states, "The governing provisions unambiguously require HHS to include such patient days. By excluding instead of including, HHS committed a fraction infraction—and flouted the law's plain language."[24]

Yet CMS seems to be flouting the plain language of the law as well as the judgement of these federal courts when it proposes, to further limit the inclusion of patient days for patients who are made eligible for Medicaid through a Section 1115 expansion program for purposes of determining the Medicaid Fraction. Specifically, CMS proposes to include those days in the DSH calculation only if the patient directly receives inpatient hospital insurance coverage on that day under a waiver authorized under Section 1115.

The agency further describes that this proposed change would exclude from the Medicaid Fraction patient days where the hospital: 1) receives payment from the uncompensated care pool under a state Medicaid 1115 waiver program; and 2) counts days for patients that receive premium assistance to purchase health insurance (paid for by Medicaid) under a state Medicaid 1115 Waiver program. CMS asserts that it is necessary to change the regulatory language because the courts did not understand the agency's intent in choosing to exclude these patients days. CMS specifically states

> "….that was not our intent when we adopted the current language of the regulation, and we continue to believe that it is not appropriate to include patient days associated with these types of expansion programs in the Medicare DSH calculation because the benefits offered under these section 1115 demonstrations are not similar to traditional Medicaid benefits and may be provided to individuals with much higher incomes."[25]

Yet the Judge Ginsberg of the U.S. District Court of the District of Columbia in the *Bethesda* decision looks beyond the Medicare DSH regulations to discern the meaning of a patient provided inpatient hospital services through an 1115 Medicaid waiver program. Judge Ginsberg writes, "It was "obvious to the [c]ourt that uninsured and underinsured patients received inpatient hospital services" through the Low Income Pool, because (1) the Secretary authorized federal matching funds to reimburse hospitals for these services,

---

[23] HealthAlliance Hosps., Inc. v. Azar, 346 F. Supp. 3d 43 (D.D.C. 2018); Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019); Bethesda Health, Inc. v. Azar, 980 F.3d 121 (D.C. Cir. 2020).
[24] Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019).
[25] 86 Fed. Reg. 25459 (May 10, 2021).

and (2) the hospitals rigorously documented the services provided using funds from the Pool. Bethesda, 389 F. Supp. 3d at 45.[26]

It would appear that CMS is picking and choosing interpretations of the statute to suit a current policy objective. Nowhere does the statute require the Secretary to limit countable days for the "Medicaid Fraction" to "inpatient hospital insurance coverage" that are similar to the traditional Medicaid benefits. CMS with this regulatory proposal is ultimately redefining what an approved 1115 waiver program really is.

Furthermore, the agency is choosing to make this policy without considering its impact on hospitals. CMS states that it cannot estimate the impact because it does not have information on 1115 waiver days by hospital.[27] In addition, the agency is overlooking another consequence of its actions and that is on 340B hospitals whose eligibility is dependent on meeting the various Medicaid DSH patient percentages prescribe in federal law. The 340B hospitals in these states 1115 Waiver states would pay the added penalty of potentially losing their access to drug discounts that allow these very hospitals to stretch the funding they have available to meet the needs of their patients in vulnerable communities.[28] The loss of access to drug discounts provided by the 340B program will only put added pressure on these hospital as they continue to struggle during the COVID-19 PHE. CMS should not move forward with this proposed change.

MEDICARE BAD DEBT

Under existing Medicare and Medicaid law and regulations, state Medicaid programs are required to pay providers for Medicare cost-sharing on behalf of dually-eligible Medicare enrollees who also are enrolled in Medicaid. State Medicaid programs are permitted to limit payment for Medicare cost-sharing and providers may recover a portion of unpaid cost-sharing amounts as Medicare "bad debt." Before providers can claim these bad debt, the provider must bill the state (or the Medicaid managed care organization) and obtain from the state documentation of completed claims processing and the state's cost-sharing liability. However, some states have not recognized certain provider types under their Medicaid programs. Therefore, CMS proposes to require, for the purposes of determining Medicare cost-sharing obligations, that state Medicaid programs accept enrollment of all Medicare-enrolled providers and suppliers if they meet all federal Medicaid enrollment requirement. **We support this proposal, which would facilitate the processing of providers' Medicare bad debt claims in the case that they are not eligible to enroll in the state Medicaid program.**

[26] Bethesda Health, Inc. v. Azar, 980 F.3d 121 (D.C. Cir. 2020).
[27] 86 Fed. Reg. 25755 (May 10, 2021).
[28] H. Rep. 102-384 (II), 102d Cong., at 12 (1992).

RURAL HOSPITAL PROVISIONS

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

Hospitals Applying for Rural Referral Center (RRC) Status. One way in which a hospital can qualify for RRC status is based on a combination of discharge volume and case-mix criteria, in comparison to other providers in the hospital's region. CMS proposes to, in light of the COVID-19 PHE, use FY 2019 data to calculate case-mix criteria and FY 2018 cost report data to calculate discharge volume. **We support this proposal.**

Rural Community Hospital Demonstration Program. The Consolidated Appropriations Act of 2021 extended the Rural Community Hospital Demonstration for an additional five years. To implement this change, CMS proposes to provide an additional five-year period under the cost-based reimbursement method for hospitals that were participating as of Dec. 30, 2019. For hospitals with a scheduled end date during 2021, 2022 and 2023, CMS propose that they would be eligible to elect to participate for an additional five-year period after its end date. In addition, CMS proposes to permit hospitals that withdrew from the demonstration in February 2020 to elect to participate for an additional five-year period. **We support this proposal and urge CMS to use the first year of the additional five-year period as the rebase year for its cost-based reimbursement method.**

Critical Access Hospitals (CAHs). The Frontier Community Health Integration Project (FCHIP) demonstration allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. Specifically, CMS waived certain Medicare rules for CAHs participating in the demonstration to allow for alternative reasonable cost-based payment methods in the areas of telehealth services, ambulance services and skilled nursing facility and nursing facility beds expansion. The Consolidated Appropriations Act of 2021 extends the demonstration project by five years beginning July 1, 2021. Based on analysis of complete data for the initial demonstration period, CMS concluded that the demonstration satisfied the budget neutrality requirement. Therefore, CMS is not proposing to apply a budget neutrality payment offset to payments in FY 2022. **We support this proposal.**

CHANGES TO MS-DRG CLASSIFICATIONS

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

Changes to MS-DRG Classifications

FY 2022 MS-DRG Updates. CMS uses the criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major

complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted. In the FY 2021 final rule, CMS expanded the criteria to include the Non-CC subgroup for a three-way severity level split. CMS believes that this will better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the Non-CC level MS-DRGs.

CMS' analysis applying the Non-CC subgroup criteria to all current MS-DRGs split into three severity levels found that it would delete 96 MS-DRGs (32 MS-DRGs x 3 severity levels = 96) and create 58 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative rates and thus the payment rates.

We appreciate CMS' recognition of the burden hospitals continue to bear because of the PHE, and we agree with CMS' proposal to delay the application of the Non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split. Additionally, for FY 2022, we agree with maintaining the current structure of the 32 MS-DRGs that currently have a three-way severity level split that would have been subject to the Non-CC subgroup criteria. Due to the lack of data transparency and operational issues listed below, we urge CMS to delay the change beyond the proposed FY 2023 cycle to FY 2025 at the earliest.

We respectfully recommend CMS consider the following timeline:

- First, publish the data on the proposed weights and volume of cases affected in the FY 2022 final rule or the FY 2023 proposed rule, if it's not possible to include in the FY 2022 final rule.
- Allow hospitals a year to analyze the implications of the change to their own patient population and case mix and provide the opportunity for public comment on specific changes.
- Typically CMS has required two years of good data to reassign MS-DRGs for new codes, we believe CMS should also consider a couple of years of good data be available for analysis. CMS should consider a run out period through the end of FY 2023 for the MedPAR file to use for a FY 2025 rule.
- Allow at least a one year grace period for hospitals to fully roll out; as the changes proposed, along with the proposed changes to "unspecified" diagnosis codes, amount to having to roll out a new MS-DRG Grouper, similar to the transition from DRGs to MS-DRGs.

Data Transparency Issues

- Hospitals have not had the opportunity or possibility to closely analyze the operational or financial impact of the proposed change due to the lack of data transparency. Neither the FY 2021 final rule, nor the FY 2022 proposed rule provided the specific data required for such an analysis. For example, the data did not include anticipated redistribution of cases, volumes by MS-DRG, nor proposed relative weights that would support the proposal to reduce the 96 MS-DRGs.

Without this crucial information, hospitals cannot analyze the potential payment rates and how they will affect their case mix, their annual budgets, specific bottom lines and future projections.

- It is unclear what time frame CMS will use for the data comparison, particularly in light of the pandemic's impact on the MedPAR data. Specifically, volumes for MS-DRGs unrelated to COVID-19 have been atypical since hospitals and patients have postponed or canceled elective surgeries.

Operational and Financial Impact Issues

- The impact on community hospitals could be significant as their case mix may be more significantly affected because they do not perform as many of the more complex surgeries. For such hospitals, significant changes in the MS-DRG structure could result in large financial losses if the MS-DRG redistribution is across all MS-DRGs rather than within related MS-DRG clusters. We urge CMS to perform additional analysis for the explanatory power of predicting resource use. The change in the case-mix index could potentially adversely affect the ability of some hospitals to participate in academic programs or attract medical residents.
- Hospitals have faced a significant financial loss during the PHE. If the MS-DRG redistribution results in additional financial cuts at the specific hospital levels, community hospitals and rural hospitals will be at risk which can have dire effects on access to care in communities where health care services have already been stressed.
- Hospitals will need to educate their physicians, clinical documentation specialists and professional coders on the nuances related to the change in "unspecified" codes and the potential need for additional training on documentation and potential additional physician queries for more detailed documentation.
- As an additional unintended consequence, commercial payers and MA programs may rely on the MS-DRG groupings to calculate payment or negotiate annual contracts. Without the ability to perform a detailed financial analysis, hospitals will be at a disadvantage when renegotiating such MS-DRG-based managed care contracts.

- **Pre-MDC: Chimeric Antigen Receptor (CAR) T-Cell Therapy**. CMS is proposing to classify 16 new ICD-10-PCS procedure codes that describe the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies that will be effective with discharges on and after Oct. 1, 2021 as non-O.R. procedures affecting Pre-MDC MS-DRG 018. CMS is also proposing to revise the title for Pre-MDC MS-DRG 018 from "Chimeric Antigen Receptor (CAR) T-cell Immunotherapy" to "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies that would also be assigned to this MS-DRG in addition to CAR T-cell therapies.

As more CAR T-cell type therapies become available through the FDA approval process, we respectfully request that CMS continue to assess the appropriateness of these therapies being grouped with MS-DRG 18 Chimeric Antigen Receptor (CAR) T-Cell Therapy. In a rapidly evolving field we note that CMS has created some product-specific New Technology ICD-10-PCS procedure codes, as well as broader codes for future technologies distinguishing autologous vs. allogeneic engineered CAR T-cell immunotherapies which are indicated for the treatment of different disease processes. As data availability increases and technology advances in this area, we request that consideration be made for the development of new MS-DRGs to further distinguish the differences in the clinical characteristics and resource consumption that may exist among these populations.

- **Major Diagnostic Category (MDC) 3 (Diseases and Disorders of Ear, Nose and Throat): Other Ear, Nose, Mouth and Throat O.R. Procedures**. CMS received a request to reconsider the MS-DRG assignments for a list of 82 procedure codes from Table 6P.1d currently assigned to MS-DRGs 143, 144 and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC and without CC/MCC, respectively) when reported in conjunction with a principal diagnosis code from MDC 03. CMS provided further analysis and proposes to maintain the current structure for MS-DRGs 143, 144 and 145. **We respectfully recommend that CMS take a closer look at the codes in MS-DRGs 143-145, or provide a rationale for several procedure codes that do not appear to be related to principal diagnoses in MDC 3.** While we understand that some of the procedures may be related to the evaluation or treatment of metastasis originating from conditions in MDC 3, it is unclear what clinical scenarios would result in the following procedure codes being assigned with a diagnosis in MDC 3:
    - 02JA4ZZ Inspection of heart, percutaneous endoscopic approach
    - 02JY4ZZ Inspection of great vessel, percutaneous endoscopic approach
    - 06HY0DZ Insertion of intraluminal device into lower vein, open approach
    - 06HY3DZ Insertion of intraluminal device into lower vein, percutaneous approach
    - 06HY4DZ Insertion of intraluminal device into lower vein, percutaneous endoscopic approach

  We acknowledge that “other” surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. We note that codes 02JA4ZZ, Inspection of heart, percutaneous endoscopic approach and 02JY4ZZ, Inspection of great vessel, percutaneous endoscopic approach, are in the “other” surgical category for MDCs 3, 4, 5, 16 and 17, but not across all MDCs.

- **MDC 4 (Diseases and Disorders of Respiratory System): Major Chest Procedures.** CMS is proposing to reassign 17 procedure codes shown in Table 6P.2b of this proposed rule describing laser interstitial thermal therapy (LITT) of body parts that do

not describe areas within the respiratory system, from MS-DRGs 163, 164 and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively) in MDC 4, and 166, 167 and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively) to their clinically appropriate MDC and MS-DRGs. It would not be clinically appropriate to maintain the codes in the logic because the body parts described by the codes are not consistent with the organ system, etiology or clinical specialty of the MDC to which the procedure code is currently assigned.

We agree with the proposed reassignment of the LITT procedure codes with the exception of code D0Y6KZZ, Laser interstitial thermal therapy of spinal cord. **We request CMS instead consider reassignment of code D0Y6KZZ to MS-DRGs 28-30 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators and without CC/CC respectively) rather than MS-DRGs 40-42 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC and without CC/MCC, respectively) as being more clinically and anatomically homogenous. MS-DRGs 40-42 include procedures on the spinal cord.**

- **MDC 5 (Diseases and Disorders of the Circulatory System): Short-term External Heart Assist Device**. CMS is proposing to reassign three procedure codes that describe the intraoperative insertion of a short-term external heart assist device as follows:

From	To
MS-DRG 215 (Other Heart Assist System Implant)	• MS-DRGs 216, 217 and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively) and • MS-DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC and without CC/MCC, respectively)

CMS clinical advisors agreed that cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS-DRG 215. CMS believes this reassignment would be more clinically homogenous, coherent and better reflect hospital resources while addressing concerns related to the relative weight of MS-DRG 215 at the same time.

We agree that the claims data analysis supports cases with intra-operative insertion of short-term external heart assist devices are generally less resource intensive and should be moved from MS-DRG 215. Based on CMS' analysis, the majority of the cases (87%) are moving to MS-DRGs 216-218 and the remainder moving to MS-DRGs 219-221. **We request reconsideration of MS-DRGs 219-221 in light of the fact that the volume of**

change with the current and proposed grouper is small within those MS-DRGs (427 accounts) as well as a review of the weights for MS-DRG 219-221 to ensure they reflect the external heart assist device.

Several members expressed concern about the impact this change would have related to the increased use of the external heart assist devices and resources required to insert the device, including the cost of the device. The device is commonly used during valvuloplasty and coronary angioplasty procedures performed on patients requiring a high level of care. Patients requiring intraoperative short-term external heart assist devices tend to be more severely ill and more likely to need a hybrid operating room than ordinary coronary angioplasty procedures for stent insertions. We also believe there may be hospital-specific differences with some facilities performing the diagnostic cardiac catheterizations as outpatient services prior to the inpatient admission for the other cardiothoracic procedures.

Additionally, we respectfully request CMS consider re-valuation once the MedPAR data is normalized from the pandemic. Once normalized, we request CMS assess claims data to consider structure revisions for these MS-DRGs (e.g., intra-operative only vs. maintain device instead of heart catheterization, etc.). 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 note that MS-DRG 215 has had significant revisions for the last four fiscal years resulting in a significant decline in recent years.

Operating Room (O.R.) and Non-O.R. Issues. In the FY 2020 IPPS/LTCH PPS proposed rule, CMS 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, 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, the agency planned 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 O.R. procedure.

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. In consideration of the public health emergency, CMS believed it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for a planned comprehensive, systematic review of the ICD-10-PCS procedure codes. Additional time also is necessary as CMS continues to develop its process and methodology. Therefore, CMS will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

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 of the ICD-10-PCS procedure codes considered for change. **We caution CMS that the data for FY 2020 and portions of FY 2021 related to procedures will not be representative of typical procedures performed by facilities in light of the COVID-19 pandemic impact which resulted in many hospitals and patients postponing or cancelling elective surgeries.**

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

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

For FY 2022 CMS is addressing requests they received to change the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures, or change the designation from O.R. procedure to non-O.R. procedure.

- **O.R. Procedures to Non-O.R. Procedures: Open Drainage of Subcutaneous Tissue and Fascia.** Under this proposal, CMS proposes to change the status of 22 ICD-10-PCS codes from O.R. designation so that they will no longer impact MS-DRG assignment. Per CMS clinical advisors, these procedures do not require the resources of an O.R. and they consume resources comparable to related ICD-10-PCS procedure codes that currently are designated as Non-O.R. procedures. All of these procedure codes describe an “open approach” drainage of the subcutaneous tissue and fascia specific to anatomical sites, including but not limited to, chest, (Drainage of chest subcutaneous tissue and fascia, open approach); abdomen (Drainage of abdomen subcutaneous tissue and fascia, open approach); and perineum (Drainage of perineum subcutaneous tissue and fascia, open approach, pelvic sites). **We strongly encourage CMS to retain the O.R. Procedure Designation for Open Drainage of Subcutaneous Tissue and Fascia procedures.** We have heard from members that these are typically O.R. procedures, especially when the patient is not able to tolerate the procedure at

bedside, or for community hospitals that do not have hybrid O.Rs or special procedure rooms.

- **Non-O.R. Procedures to O.R. Procedures: Endoscopic Fragmentation and Extirpation of Matter of Urinary Tract.** Although listed under the "Non-O.R. to O.R." section of this proposed rule, the resulting proposal is to maintain two of the ICD-10-PCS codes that describe endoscopic extirpation from a urinary body part as non-O.R. procedures (0TCB8ZZ, 0TCC8ZZ). Additionally, the CMS clinical advisors are proposing to move six ICD-10-PCS codes from O.R. to non-O.R. procedures that are similar and "not surgical in nature" that also describe endoscopic extirpation from a urinary body part. These six codes include 0TC08ZZ, 0TC18ZZ, 0TC38ZZ, 0TC48ZZ, 0TC68ZZ and 0TC78ZZ). **We strongly encourage CMS to reconsider these eight procedures codes and maintain the current O.R. designation for the six codes and revise the two codes from Non-O.R. to O.R. procedure codes.** The extirpation of matter of these urinary tract locations such as ureter, kidney, etc. would require the use of an O.R. as they would not be performed at bedside.

Comprehensive CC/MCC Analysis

In the FY 2018 IPPS final rule, CMS provided public notice of their plans to conduct a comprehensive review of the CC and MCC lists for FY 2019. For FY 2020, CMS proposed but did not finalize a change in the severity level designation for 1,492 ICD-10-CM diagnosis codes.

For FY 2021, CMS finalized nine guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. CMS plans to use a combination of mathematical analysis of claims data and the application of these guiding principles, to continue a comprehensive CC/MCC analysis and present the findings in future rulemaking.

For FY 2022, as another interval step in the comprehensive review of the severity designations of ICD-10-CM diagnosis codes, CMS is soliciting comments on adopting a change to 3,490 "unspecified" diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a Non-CC for FY 2022. Table 6P.2a of this proposed rule includes the list of ICD-10-CM unspecified diagnosis codes with data for impact on resource use. If approved, the change would affect the severity level assignment for 4.8% of the ICD-10-CM diagnosis codes. The net result of these potential changes to the Version 39 ICD-10 MS-DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD-10-CM classification, would be a decrease of 507 (3,278 – 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 – 11,696) codes designated as a CC, and an increase of 3,490 (58,154 – 54,664) codes designated as a Non-CC.

We urge CMS to delay the downgrading of the severity designation of "unspecified" codes to non-CC to allow for further analysis, education of providers, updating of systems, potential updating of the *ICD-10-CM Official Guidelines for Coding and Reporting*, and training of coding professionals for the reasons noted below. Some members have already noted that the change will result in a significant financial loss and will need time to implement mitigation plans. We therefore request that the implementation be delayed and phased over a two year period.

- While the AHA continues to support complete and accurate documentation to support clinical coding, the concept of laterality (right side or left side) would not affect the resources required to treat patients with the exception of bilateral conditions. We further note that laterality is *not* one of CMS' long- standing criteria for determining the severity level of a condition. We request that CMS provide insight pertaining to how the laterality of the condition impacts the severity of the diagnosis, especially with internal locations not visible to the eye. The condition/diagnosis itself is still being addressed and treated as applicable.
- If the principal diagnosis is unrelated to the secondary "unspecified" diagnosis, there should not be a requirement to perform medically unnecessary tests or procure prior medical records from other facilities to determine laterality.
- The Medicare population encompasses an elderly population who usually see multiple providers, have chronic conditions and may exhibit a decline in mental alertness. It may not be feasible to expect the documentation to reflect laterality for chronic conditions such as neoplasms, and patients with dementia may not be able to provide accurate histories.
- *ICD-10-CM Official Guidelines for Coding and Reporting* Section I.B. 14 states "Code assignment is based on the documentation by the patient's provider (i.e., physician or other qualified healthcare practitioner legally accountable for establishing the patient's diagnosis)." If the provider (as defined by the guidelines) documentation does not specify the side affected, hospitals would be required to conduct administratively burdensome physician queries in order to capture the more specific code to qualify for a CC or MCC.
- In AHA's role as one of the ICD-10 Cooperating Parties responsible for the development of the Official Coding Guidelines, we are collaborating on the potential revision of the guidelines to allow coding of the more specific laterality based on documentation from other clinicians involved in the care of the patient, such as nurses. If approved, the change would be effective FY 2022, which would require further education of professional coders.
- While many hospitals have robust clinical documentation improvement programs, some may not have explicitly focused on documentation of laterality as it did not affect the severity level of the condition.
- **We request CMS reconsider the inclusion of neoplasms in the list of "unspecified" sites or limit it to neoplasms that are externally visible.** While the neoplasm may still be under active treatment, the specific side of the neoplasm may

not be documented if the patient is admitted for a different, unrelated condition such as trauma or infections.

Proposed Changes to the Medicare Code Editor (MCE)—Unspecified Codes. As discussed in section II.D.12.c. of the preamble of this proposed rule, CMS is requesting public comments on a potential change to the severity level designations for "unspecified" ICD-10-CM diagnosis codes to be adopted for FY 2022. In connection with that request, CMS is also requesting public comments on the potential creation of a new MCE code edit involving these "unspecified" codes for FY 2022. Specifically, this MCE code edit could trigger when an "unspecified" diagnosis code currently designated as either a CC or MCC, that includes other codes available in that code subcategory that further specify the anatomic site, is entered. This edit could signal to the provider that a more specific code is available to report.

We support the creation of a new edit for "unspecified codes" for laterality with the exception of the neoplasm codes. This edit should be phased in with some, but not all of the "unspecified" codes at one time. This approach will also help provide training for coding professionals and inform clinical documentation programs on the proposed change of severity level for unspecified codes.

Proposed Changes to Surgical Hierarchies. The surgical hierarchy is a decision rule within the GROUPER, which orders surgical classes from most resource intensive to least resource intensive. This rule is used to assign a single DRG when an inpatient stay entails multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different DRG within the MDC to which the principal diagnosis is assigned. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the DRG associated with the most resource intensive surgical class.

CMS proposes to revise the surgical hierarchy for the MS-DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) as shown below:

Proposed Surgical Hierarchy MDC 05	
215	Other heart assist system implant
216-221	Cardiac valve and other major cardiothoracic procedures
231-236	Coronary bypass
222-227	Cardiac defibrillator implant
266-267	Endovascular cardiac valve replacement and supplement procedures
268-269	Aortic and heart assist procedures except pulsation balloon
228-229	Other cardiothoracic procedures
319-320	Other endovascular cardiac valve procedures

We would like to call attention to the wide range within the (CABG) Coronary Bypass MS-DRGs 231-236 which is a unique MS-DRG grouping for bypass procedures in conjunction with other procedures specifically with percutaneous coronary angioplasty (MS-DRGs 231-232), cardiac catheterization (MS-DRGs 233-234) and without cardiac catheterization (MS-DRGs 235-236). The majority of the cases fall in the "without cardiac catheterization" range for CABG MS-DRGs which would be MS-DRGs 235-236, as illustrated in CMS table 7A. Therefore, it is probable that if CABG was considered before the defibrillator, this would not account for the higher cost of the defibrillators. **After reviewing the CMS data, we agree with all of the resequencing proposed by CMS with the exception of MS-DRGs 231-236. We request that CMS reconsider that Cardiac Defibrillator MS-DRGs 222-227 be higher than CABG MS-DRGs 231-236.**

Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems. At the March 9-10, 2021 ICD-10 Coordination and Maintenance Committee meeting CMS announced its consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current Oct. 1 annual update for ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. This April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process.

CMS believes this earlier recognition of diagnoses, conditions and illnesses as well as procedures, services and treatments in the claims data would be beneficial for purposes of reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions and data interoperability. Any new ICD-10 code updates finalized for implementation on the following April 1 would be announced in November of the prior year, which would provide a four-month timeframe for the public to receive notice about the diagnosis and/or procedure code updates with respect to the codes, code descriptions, code designations (severity level for diagnosis codes or O.R. status for procedure code) and code assignment under the ICD-10 MS-DRGs. CMS further noted that if an April 1 update were to be adopted, it could be through a phased approach, such that initially, the number and nature of the code updates would be fewer and less comprehensive as compared to the existing Oct. 1 update.

If this new April 1 implementation date is adopted, CMS would assign the codes approved for the April 1 update to an MS-DRG(s) using its established process for GROUPER assignments for new diagnosis and procedure codes. Specifically, CMS would review the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, CMS would consider other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition.

The health care field has embraced the recent updates to diagnosis and procedure codes outside of the normal Oct. 1 update because of the need to quickly adapt to the emergent need to identify COVID-19 and related therapies to deal with this devastating disease. **While the COVID-19 coding changes demonstrated that it is possible to have more frequent coding updates if they are limited in number and there is a pressing need, there were significant adjustments and work needed to incorporate the modifications as code changes result in significant operational issues for hospitals.**

We include below our comments and recommendations regarding CMS' consideration of an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the current Oct. 1 annual update for ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes. Some of these recommendations were previously included in our letter to the ICD-10 Coordination and Maintenance Committee Chairs.

- April 1 updates should be limited. While CMS has indicated that the implementation of April 1 updates would be a phased approach with fewer codes and be less comprehensive as compared to the existing Oct. 1 update, we believe **any April 1 updates, if approved, should routinely be limited, and not just for the first year. New codes without a pressing need should not be included in the April 1 updates.**
- We are concerned that introducing new codes in April would result in two versions of MS-DRG groupers during a single fiscal year. Even if the new codes do not affect MS-DRG assignment, new codes need to be recognized by the grouper software.

We are deeply concerned that the introduction of new codes in April without the ability to comment on whether the procedure should be considered O.R. or non-O.R. or the severity level of a diagnosis, would result in at least six months of incorrect reimbursement. While we understand that CMS intends to use its traditional method of evaluating new codes, we remind CMS of the unintended misclassification of Extracorporeal Membrane Oxygenation (ECMO) codes for FY 2019. New ECMO codes were introduced at the March 2018 Coordination and Maintenance Committee meeting. Because the procedure codes were not yet approved, there were no proposed MDC, MS-DRG, or O.R (surgical) and non-O.R. (medical) designations for these new procedure codes included for comment in the FY 2019 IPPS proposed rule. As a result, all ECMO procedures were moved from MS-DRG 03 with a relative weight of 18.2974, to several different MS-DRGs with weights ranging from 1.3454 to 6.2953 without the opportunity for public comment. Fortunately, ECMO is a low-volume procedure performed in a limited number of hospitals. Nevertheless, this MS-DRG group change resulted in significant underpayment for hospitals providing this life-saving procedure as the reimbursement for each case resulted in the loss of as much as $90,000 per case.

- The data analytics for this disease process remains complex in terms of mapping for time periods; as well as extensive quality review with the need for constant education for accurate reporting and understanding of data shifts.

- It is important to remember that changing to a twice a year rollout of new codes would affect every payer and every system vendor that utilizes ICD-10-CM/PCS codes. Not every payer or system vendor can move as quickly as CMS to incorporate changes to the coding system. In fact, some commercial payers took longer to recognize the ICD-10-PCS codes released in August 2020 for COVID-19 treatments, causing a backlog in payment processing.
- Any code change/update requires lead time to plan, incorporate into multiple computer systems (including billing systems, patient accounting systems and coding tools), test, develop potential updates to coding guidelines and to educate coding professionals and providers. Incorporating new codes into coding and billing systems is only one component of a complex chain of activities required for code changes. Additional activities include renegotiating managed care contracts which may only allow annual revisions. While some contracts may be at the MS-DRG level, many are at the ICD-10 code level, especially for surgical procedures.
- Training for coding professionals on new ICD-10-CM/PCS code changes would result in loss of productivity twice a year because some hospitals require from four to eight hours to educate them on the changes.
- New codes can have significant impacts on hospital's MS-DRG reimbursement and budgets prepared a year in advance, as well as on the quality reporting performed by hospitals. As such, data shifts with different codes in each six months of the fiscal year need to be considered for impact to MedPAR Data and quality indicators for MS-DRG logic revisions and updates for code designations.
- Challenges with payers and systems exist in the current environment as not all payers use the current version of grouper or codes within their versions of groupers and/or contracts. Some systems may be at capacity for the number of versions that can be facilitated.

PROMOTING INTEROPERABILITY PROGRAM

General Comments. In our comments on the FY 2021 IPPS proposed rule, the AHA urged CMS to take a holistic view and approach to the future of the Promoting Interoperability Program in light of the ongoing PHE and range of regulatory requirements that rely on information technology (IT) infrastructure and support. Hospitals and CAHs urgently and appropriately redirected resources to support technology and data needs specific to the COVID-19 emergency including COVID response, vaccine distribution, data reporting, and telehealth. While the PHE remains in effect, much of this work continues, while, at the same time, many hospitals are attempting to advance outstanding IT projects delayed during the height of the pandemic. **In this period of recovery and rebuilding, we urge CMS to utilize a measured approach to finalizing changes to the Promoting Interoperability Program for CY 2022.**

Reporting Period. The AHA consistently has advocated for an electronic health record (EHR) reporting period of any continuous 90-day period and appreciate that CMS proposes to continue this policy, previously finalized for CY 2022, for CY 2023. However,

we do not support CMS' proposal to increase the reporting period to a minimum of any continuous 180-day period for CY 2024. A reporting period of any 90 days during the calendar year historically has recognized that EHRs are not static – software upgrades, system downtime and other factors must be accounted for. As past experience demonstrates, vendor capacity to implement upgrades across the entirety of their customer base can cause delays. In some cases, this requires hospitals and CAHs to select a reporting period later in the year to allow for sufficient time for testing which is necessary to identify and resolve problems with the software and provide essential training to end users. These activities are critical to ensuring patient safety is not compromised.

Electronic Prescribing Objective: Query of PDMP Measure. Prescription drug monitoring program (PDMP) integration with certified EHRs continues to pose a number of challenges for eligible hospitals and CAHs. **The AHA supports CMS' proposal to retain the query of PDMP measure under the electronic prescribing objective as optional and increase the bonus points from five to 10**. We further support mitigating burden on providers by continuing to require only a "yes/no" attestation vs. a numerator/denominator for this measure. This appropriately recognizes that technical capabilities vary across EHRs, PDMPs do not exist in every state, and, where they do exist, can be impacted by state laws prohibiting integration and storage of PDMP data.

Key federal and private sector efforts are currently underway aimed at improving technical approaches to EHR-PDMP integration and implementing key PDMP-related provisions of the SUPPORT for Patients and Communities Act (P.L. 115-271). We believe additional time for this work to mature and continued assessment of the PDMP landscape across states is needed prior to CMS proposing to modify the current structure of this measure.

Health Information Exchange (HIE) Objective. CMS proposes to add a new HIE Bi-Directional Exchange measure for CY 2022. **The AHA supports the addition of this optional HIE measure as an alternative to the two existing HIE measures – Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Incorporating Health Information.** We further support that this measure would be reported via attestation and are encouraged to see CMS' acknowledgement that this measure could align with the Office of the National Coordinator (ONC) for Health Information Technology's efforts on the Trusted Exchange Framework and Common Agreement (TEFCA).

Provider to Patient Exchange Objective. CMS proposes to modify the Provide Patients Electronic Access to their Health Information measure to require eligible hospitals and CAHs to ensure that patient health information remains available indefinitely and using any application of the patient's choice that is configured to meet the technical specifications of the application programming interface (API) in the certified EHR. This would include all patient health information from encounters on or after Jan. 1, 2016.

The AHA strongly supports patients having access to their health information. Today, nearly every hospital in the U.S. provides patients with the ability to view their information online, highlighting the field's commitment to empowering patients to be active partners in their health and health care through access to information. **We are concerned, however, that CMS' proposed changes to the measure do not accurately reflect the realities of the EHR technology environment within hospitals.** This is particularly true with respect to the proposed requirement that the information remain available indefinitely with a lookback to Jan. 1, 2016.

We appreciate that CMS is requesting comment on alternate encounter start dates. **The AHA supports an alternate encounter start date, as suggested by CMS, starting on or after Jan. 1, 2019 which we believe more accurately accounts for the inherent challenges with aligning data to current standards from previous years.**
We further request that CMS define exceptions for any historic encounter period that appropriately consider circumstances under which the hospital or CAH may not retain full access to historical data. In that vein, we request that CMS align this requirement, and an associated exception, with the availability of the electronic health information (EHI) export functionality IT vendors are required to roll out by December 31, 2023 per the Cures Act Final Rule. CMS also should further define what is meant by "indefinite" availability.

With respect to third-party applications, we urge prioritization of patient privacy protections and cybersecurity considerations as their use becomes more prevalent in health care. These applications both present opportunities to allow patients to access their health information in new and innovative ways but also present significant risks as data increasingly flows outside of the HIPAA-protected EHR environment.

Public Health and Clinical Data Exchange Objective. The ongoing PHE highlights the critical importance of the ability to collect, exchange and analyze public health data. Hospitals and CAHs have increasingly implemented public health reporting capabilities over the past several years. Yet, our nation's public health agencies' (PHA) IT systems are, in many cases, antiquated and often unable to receive or incorporate data electronically. Similar to the state of PDMPs, PHA data systems vary widely by state and jurisdiction.

Hospitals and CAHs are eager to engage in standards-based exchange of public health data with PHAs. We support CMS' proposal to allocate five bonus points to hospitals and CAHs that attest to either the Public Health Registry Reporting or the Clinical Data Registry Reporting measures. In contrast, we believe requiring the remaining four measures is infeasible for CY 2022 and does not accurately reflect current PHA data systems capabilities and the corresponding reporting landscape for hospitals and CAHs.

We are encouraged that Congress recognized the need for investment in public health data systems and provided significant funding for modernization efforts in multiple COVID

relief bills. While this work is underway, and at a nascent stage, expansion of this objective should be considered in the context of the current state of PHA data infrastructure.

For CY 2022, the AHA recommends that CMS use a flexible, staged approach to scoring the four measures it proposes to require. This could include requiring two of the four measures for a total of 5 points and allowing hospitals and CAHs to earn an additional 5 points for the remaining two measures. We anticipate that as modernization efforts advance, hospitals and CAHs will be better positioned to meet a higher standard for this objective. This balanced approach will both recognize current IT limitations of PHAs as well as continue to incentivize hospitals and CAHs to engage in increased reporting as feasible.

Protect Patient Health Information Objective. The Promoting Interoperability Program was established to incentivize eligible hospitals and CAHs to "adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology." While we agree that implementing safety practices for planned or unplanned EHR downtime is important, we believe the addition of a Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) measure is out of scope for this program. Further, the SAFER Guides have not gone through a comprehensive review and update process since 2016, calling into question whether their content remains relevant.

Additionally, requiring this type of annual assessment of all nine guides would place burden on hospitals and CAHs, particularly those with limited resources. CMS should work with ONC to engage in an update of the guides, informed by stakeholder input, and undertake an education and awareness campaign to disseminate information to the field, including information tailored to small and medium-sized health care organizations. **Given these considerations, the AHA does not support CMS' proposal to require hospitals and CAHs to attest to having completed an annual assessment of the nine SAFER Guides.**

Prevention of Information Blocking Attestation Requirement. **The AHA supports CMS' proposal to remove attestation statements 2 and 3 from the prevention of information blocking attestation requirement.** We agree that the similarities between practices described in statements 2 and 3, and the practices that could constitute information blocking under ONC's information blocking regulations, could create confusion for participating hospitals and CAHs. We further believe that streamlining this attestation to require only statement 1 more accurately reflects the original statutory provision in the Medicare Access and CHIP Reauthorization Act (MACRA).

Scoring Methodology. CMS proposes both several changes to measures for CY 2022 as well as to increase the minimum threshold score from 50 to 60 points. CMS justifies this increase by citing 2019 performance results showing that 3,776 of 3,828 participating eligible hospitals and CAHs met the 50-point threshold. **As stated above, we urge CMS to take a measured approach to implementing program changes in CY 2022 and,**

therefore, do not support CMS' proposal to increase the minimum threshold score to 60 points at this time.

Hospitals and CAHs are constantly evolving their IT footprint to improve patient care and advance health outcomes for individuals and communities. Further, the Promoting Interoperability Program is only one of a number of regulatory programs that require IT development, upgrades, testing and end-user training. Among these are the Cures Act Final Rule information blocking provisions and the CMS Condition of Participation requiring hospitals to send admission, discharge and transfer notifications that recently went into effect and require significant new IT resources.

If CMS considers proposing to increase the minimum threshold score for a future program year, it should utilize a staged approach that balances any increase with the full scope of program changes being proposed. Additionally, CMS should consider the role of bonus points in achieving the minimum threshold score that are often associated with measures less feasible for small hospitals and CAHs to report.

Clinical Quality Measurement. CMS proposes to make several changes related to eCQM reporting that align with the Hospital IQR Program. The AHA has a number of comments on these proposals that are described in detail in the IQR section of our letter.

QUALITY AND VALUE-BASED PROGRAMS

Measure Suppression Policy for the COVID-19 PHE

The AHA supports CMS' proposed measure suppression policy for its hospital quality measurement and value programs and appreciates the agency's objective to apply a consistent approach across all provider quality measurement programs. Using the proposed policy, CMS could "suppress" (i.e., not use) measure data it believes have been affected by COVID-19 PHE in calculating hospital performance, and would use multiple factors to make this determination. We agree strongly with the agency's stated goal of ensuring that hospitals are not rewarded or penalized for their quality performance based on non-representative quality data. We appreciate the agency engaging with hospitals to gauge the impact of COVID-19 on individual measures and programs, and using a data-driven approach to inform its proposals.

The AHA also thanks CMS for the other steps it has taken to account for the unprecedented impact of COVID-19 on hospital quality measurement and value programs. In March 2020, CMS used its extraordinary circumstance exception (ECE) policies to make submitting quarter 1 and quarter 2 2020 data optional. CMS further clarified in its August 2020 interim final rule that it would not use data from Q1 and Q2 2020 in either program performance calculations or public reporting. These steps provided hospitals with critically

needed administrative burden relief and ensured hospitals' performance on quality measurement programs would not be based on non-representative data.

While the proposed policy is specific to the COVID-19 PHE, we encourage CMS to develop a measure suppression policy that could be used in future PHEs as a complement to the agency's ECE policies. CMS' ECE policies were designed to work on a largely prospective basis by allowing hospitals to ask for reporting exemptions within 90 days of an extraordinary circumstance, and allowing CMS to grant regional and national exceptions during and shortly after emergencies. Yet, the COVID-19 pandemic has demonstrated that the full impact of PHEs can be hard to ascertain fully until the agency has more data to assess its impacts to hospital performance. Indeed, several of the analyses CMS included in the proposed rule to support its proposed suppressions include data from Q3 2020, which is outside of the timeframe of the ECE exception CMS implemented in March 2020.

Hospital Value-based Purchasing (HVBP) Program
The ACA mandated that CMS implement the HVBP program, which ties a portion of hospital payment to selected measures of the quality, safety and cost of hospital care. CMS funds the program by reducing base operating diagnosis-related group payment amounts to participating hospitals by 2.0% to create a pool of funds to pay back to hospitals based on their measure performance. Hospitals may earn back some, all or more than the 2.0% withhold based on their measure performance. By statute, the program must be budget neutral – that is, the entire pool of dollars must be paid back to hospitals, and CMS may not hold back any portion of it to achieve savings to the Medicare program. CMS proposes several significant changes to the HVBP program for FYs 2022 and 2023 to account for the impact of the COVID-19 PHE.

FY 2022 Measure Suppressions and Neutral-payment Adjustments. **The AHA supports CMS' proposals to suppress most of the HVBP program's measures for FY 2022, and to apply neutral payment adjustments to all hospitals for FY 2022.** We agree that hospital performance on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare spending per beneficiary (MSPB) and healthcare-associated infection (HAI) measures are likely non-representative because of the pandemic.

Furthermore, we believe it is both appropriate and well within CMS' statutory discretion to apply neutral HVBP payment adjustments for FY 2022. Indeed, it would have been problematic to apply any positive or negative HVBP payment adjustments because CMS would only have sufficient data for one HVBP performance domain. Furthermore, the HVBP program's budget neutral design means that the program does not result in costs or savings to the Medicare program.

At the same time, we urge CMS to continue analyzing data from both 2020 and 2021 to determine whether further suppressions—and even neutral HVBP payment

adjustments—may be necessary in future fiscal years. For the most part, the measure performance periods for the FY 2022 HVBP included data from 2020. Yet, the pandemic has continued into 2021, and many parts of the country saw their largest surges of COVID-19 cases and hospitalizations during quarters 1 and 2. As a result, the baseline and performance periods that include 2020 and 2021 data likely will be affected by the COVID-19 PHE. We would be pleased to continue working with the agency to help it assess the continued impact of COVID-19 on its measures and program.

HVBP Mortality Measure Proposals. **The AHA supports CMS' proposal to suppress the pneumonia mortality measure for FY 2023.** Prior to the pandemic, CMS established the FY 2023 mortality measure performance period as July1, 2018 – June 30, 2021, a timeframe that includes the COVID-19 PHE. The agency's analysis showing that a substantial proportion of patients with pneumonia had COVID-19 as a secondary diagnoses comports with anecdotal evidence from hospitals. This overlap means COVID-19 would confound measure performance and make it non-representative.

The AHA also supports—with some caveats—CMS' proposal to exclude patients with COVID-19 from the HVBP's other five mortality measures. Specifically, CMS would use ICD-10 CM codes to remove patients with COVID-19 as a secondary diagnosis from each measure's denominator. On balance, this appears to be a reasonable attempt to mitigate the impact of COVID-19 on measure performance, and is a good starting point.

However, it is possible CMS' proposed approach may result in the incomplete exclusion of COVID-19 patients; we encourage CMS to examine the feasibility of additional exclusions. As we understand it, CMS' proposed approach relies on positive COVID-19 diagnoses being coded as a secondary diagnosis at the time of hospital discharge. Yet this approach may leave out those patients whose COVID-19 infections occur *after* hospital discharge, but *within* the 30-day time window of the measure. For example, a patient could be discharged from the hospital and become infected either in the community, or at a nursing home. Regardless of when it happens during the measure's time window, a positive COVID-19 diagnosis would affect a patient's mortality risk. That is why we ask the agency to examine whether it can capture post-hospital discharge COVID-19 diagnoses in the measure exclusion criteria.

In addition, we caution that the impact to mortality measure performance may not stem solely from a patient having a COVID-19 diagnosis. The virus had a wide-ranging impact to the full spectrum of health care operations, both inside and outside of the hospital. These measures assess mortality within 30 days of a hospital admission; but the pandemic significantly affected the post-discharge care processes and resources that are typically available to patients when they leave the hospital. For example, public transportation resources that might have helped patients get to follow-up care were often not available, or operating under severe capacity constraints. As CMS notes in various parts of the rule, there was significant variation in the intensity, duration and geography of COVID-19 surges throughout the pandemic. It will be important for CMS to analyze measure performance

and dialog with hospitals to understand to what extent performance was impacted and why.

Removal of Patient Safety Indicator (PSI 90). **The AHA strongly supports CMS' proposal to remove PSI 90 from the HVBP program beginning in FY 2023.** For nearly a decade, the AHA has recommended that CMS phase out its use of the deeply flawed PSI 90 across its programs. Furthermore, CMS' previous policy of using the PSI measure in both the HVBP and the Hospital-Acquired Condition (HAC) Reduction Program meant that hospitals could receive directionally different scores in each program, thereby impeding their efforts to track and improve performance. The proposed removal of PSI 90 from HVBP is a good first step to reducing unnecessary duplication of efforts and administrative burden.

Revised Baseline Periods for FY 2024. **The AHA supports CMS' proposal to alter the FY 2024 baseline periods for some HVBP measures in order to account for the COVID-19 PHE**. Specifically, for the HCAHPS, HAI and MSPB measures, CMS would use CY 2019 as the baseline period instead of CY 2020. This would allow CMS to use data unaffected by the COVID-19 pandemic, while permitting CMS to use a full year of data to compare to the CY 2022 performance period.

Hospital Readmissions Reduction Program (HRRP)
The HRRP imposes penalties of up to 3% of base inpatient PPS payments for having "excess" readmissions rates for selected conditions when compared to expected rates. CMS uses six Medicare claims-based readmission measures to assess performance in the program. As required by the 21st Century Cures Act, CMS implemented a sociodemographic adjustment approach beginning with the FY 2019 HRRP in which CMS places hospitals into one of five peer groups based on the proportion of patients dually eligible for Medicare and Medicaid that they treat. In this rule, CMS proposes several changes to account for the impact of the COVID-19 PHE.

FY 2023 Pneumonia Measure Suppression. **The AHA supports CMS' proposal to suppress the pneumonia readmissions measures in calculating FY 2023 HRRP performance.** As with the HVBP's pneumonia mortality measure described in the previous section, we agree with CMS' analysis that the "clinical proximity" of pneumonia to COVID-19 is significant enough that including the measure in calculating HRRP performance could distort hospital performance.

Also, we urge CMS to continue analyzing data from both 2020 and 2021 to determine whether additional HRRP suppressions may be necessary in future fiscal years. As we noted in the HVBP section of this letter, the pandemic has continued into 2021, and many parts of the country saw their largest surges of COVID-19 cases and hospitalizations during quarters 1 and 2. As illustrated in the table below, data from during the COVID-19 PHE will affect multiple fiscal years of the HRRP program, making it important CMS continue to track this issue for as long as the PHE is in effect.

HRRP Performance Periods, FYs 2022 – 2026

Fiscal Year (FY)	HRRP Performance Period*
FY 2022	July1, 2017 - Dec. 31, 2019
FY 2023	July1, 2018 – Dec. 31, 2019 AND July1, 2020 – June 30, 2021
FY 2024	July1, 2019 – Dec. 31, 2019 AND July1, 2020 – June 30, 2022
FY 2025	July1, 2020 – June 30, 2023
FY 2026	July1, 2021 – June 30, 2024

**Assumes the continued application of the August 2020 interim final rule, which removed Q1 and Q2 2020 data from performance calculations.*

Readmission Measure Exclusions for COVID-19 Patients. Similar to the HVBP program, CMS proposes to update the measure specifications for the other five HRRP measures to exclude patients who have COVID as a secondary diagnosis. **The AHA supports this proposal, but urges CMS to view these exclusions as a first step.** Indeed, the impact to readmission measure performance may stem from more than a COVID-19 diagnosis. See the HVBP section of this letter for additional details.

Performance Periods and Payment Adjustments. CMS' August 2020 interim final rule resulted in an FY 2022 HRRP performance period of July 1, 2017 through Dec. 31, 2019. In this rule, CMS proposes to align the MedPAR data it uses to determine aggregate payment amounts and payment adjustments with the modified performance periods. **The AHA supports this proposal.**

Hospital-acquired Condition (HAC) Reduction Program

The HAC Reduction Program imposes a 1% reduction on all Medicare inpatient payments for hospitals in the top (lowest-performing) quartile of certain risk-adjusted national HAC rates. The HAC Reduction Program's basic scoring methodology and measure set are unchanged.

However, CMS proposes to suppress performance data from Q3 and Q4 2020 in calculating HAC Reduction Program performance for FYs 2022 and 2023. When combined with the August 2020 interim final rule in which CMS announced it would not use Q1 and Q2 2020 data to calculate performance, the performance periods for the HAI and PSI measures are significantly truncated. Hospitals would have their FY 2022 performance determined using 12 months of HAI data and 18 months of PSI 90 data, instead of the customary 24 months. For FY 2023, both HAI and PSI performance would be based on 12 months of data. CMS asserts these truncated performance periods would retain sufficient reliability for the program's measures, while excluding the timeframes most affected by the COVID-19 pandemic.

The AHA agrees that it is appropriate to suppress data from Q3 and Q4 2020 in calculating HAC Reduction Program performance. While we support CMS' proposed policies for the HAI measures, we are less confident that the proposed approach is optimal for the PSI 90 measure. We urge CMS to conduct two further analyses before it adopts its proposal.

First, we urge CMS to re-examine the potential impact to the PSI 90 measure's reliability by truncating the performance periods to as little as 12 months. The AHA has long been concerned about the low levels of reliability of some of PSI 90's component measures with even 24 months of data, and a CMS-commissioned analysis[29] shows that reliability only degrades with shorter reporting periods. For example, CMS' study showed that PSI 06's median reliability was 0.30 with 12 months of data, and 0.39 with 18 months of data. PSI 14's median reliability was an extraordinarily low 0.04 with 12 months of data, improving to only 0.07 with 18 months of data. This falls short of the "moderate" reliability standard of 0.40 CMS used in justifying the adoption of several other measures in prior rulemaking, and well short of the generally accepted standard of "good" reliability (which is generally 0.70 or greater). For hospitals and the public alike to have confidence that the assessment of HAC performance is meaningful, the underlying measure data must be reliable.

Second, we encourage CMS to consider excluding COVID-19 patients from PSI measure calculations, in similar fashion to what the agency has proposed for its readmissions and mortality measures. We acknowledge that simply excluding COVID-19 patients is an imperfect approach to accounting for the wide-ranging impacts of the pandemic, but it could help improve the accuracy of PSI 90 results.

The AHA understands that CMS' options for mitigating the impact of the pandemic on the HAC Reduction Program are constrained by the underlying statute. Rationally, we believe that the program should be suspended for FY 2022 and FY 2023 because the data captured during the pandemic do not represent typical performance of the hospitals and because some of the measures are well outside the range of acceptable statistical reliability when using the truncated performance periods. We do understand, however, that CMS believes it is obligated to implement a HAC Reduction Program that results in savings to the Medicare program by penalizing up to 25% of eligible hospitals. To do so, it needs to use quality measures, and continuing to use both the HAI and PSI measures may be the most appropriate short-term action. As a practical matter, there is likely not sufficient time to identify alternative measures, have them reviewed by the Measure Applications Partnership (MAP), and promulgated in rulemaking. It also is possible that truncating the FY 2022 and 2023 performance periods for the PSI measures is CMS' best available option, even if it is not optimal. We believe the steps described above could increase the field's confidence in CMS' suppression policies.

---

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

At the same time, the pandemic has once again underscored the significant problems with the PSI 90 measure. We urge CMS to develop a plan to sunset the PSI 90 measure from the HAC program and any hospital reporting or pay-for-performance program. In addition to the reliability concerns described above, the AHA has longstanding conceptual concerns about PSI 90. PSIs use hospital claims data to identify patients that have potentially experienced a safety event. However, claims data cannot and do not fully reflect the details of a patient's history, course of care and clinical risk factors. As a result, the rates derived from the measures are highly inexact. PSI data may assist hospitals in identifying patients whose particular cases merit deeper investigation with the benefit of the full medical record. Nevertheless, the measures are poorly suited to drawing meaningful conclusions about hospital performance on safety issues. In other words, PSI 90 may help hospitals determine what "haystack" to look in for potential safety issues. However, the ability of the measure to identify consistently and accurately the "needle" (i.e., the safety event) is far too limited for use in public reporting and pay-for-performance applications.

Lastly, as we noted for both the HVBP and HRRP, the pandemic continues into 2021, and many parts of the country saw their largest surges of COVID-19 cases and hospitalizations during quarters 1 and 2. CMS should continue to assess the HAC Reduction Program's measure data and consider implementing additional measure suppressions in future fiscal years if the data warrant it.

Hospital Inpatient Quality Reporting (IQR) Program
Hospitals are required to report measure data 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 to add five new IQR program measures, while removing five existing measures.

Proposed COVID-19 Vaccination among Health Care Personnel (HCP) Measure. This proposed measure would calculate the percentage of HCP eligible to work in the facility for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all facility personnel—including licensed independent practitioners affiliated with but not directly employed by the facility, students, trainees and volunteers—are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's National Healthcare Safety Network (NHSN) Healthcare Personnel Safety Component submission framework.

The AHA strongly supports COVID-19 vaccinations of both HCPs and the communities they serve. We have worked closely with our members and the federal government to

encourage vaccination within all of our members' facilities to help protect both patients and our health care workforce from this crippling disease. Hospitals and health systems have made remarkable progress in vaccinating large proportions of their teams in a short timeframe, and are working hard to close any remaining gaps. Notwithstanding the remarkable scientific achievement of having three available and highly effective COVID-19 vaccines, we are barely six months into deploying them. The underlying scientific evidence about how to implement the vaccines continues to evolve, and there remain important unanswered questions that would affect both the design and feasibility of any HCP vaccination measure. For example, how long do the vaccines confer immunity? How frequently might booster shots be required? Should one receive the same type of booster shot as the original shot? Will vaccine supply remain sufficient across the nation to ensure all HCP can receive it?

None of these questions detracts from the importance of encouraging COVID-19 vaccinations. However, the answers to all of these questions are of foundational importance to building a meaningful, accurate and fair performance measure whose results would be shared publicly. The AHA is concerned that a premature mandate to report this measure would lead to unpredictable shifts in reporting requirements that would prove disruptive to hospitals, and result in data that are unhelpful to policymakers, the public and health care providers.

Due to the unique nature of the COVID-19 pandemic and the limited experience the nation has with the vaccine products currently available, we do not recommend implementing this measure for adoption and mandatory reporting this year, as its use could have negative unintended consequences and might not be the most useful tool to promote vaccination. Instead, the AHA recommends that CMS either delay adoption and mandatory reporting of the measure for at least one year (i.e., until Oct. 1, 2022), or adopt the measure for voluntary reporting for at least the first year to allow time for the issues described below to be addressed. Any voluntarily reported data should not be publicly reported.

In its rationale and explanation of the measure's design, CMS relies heavily on the specifications and experience with the Influenza Vaccination among Healthcare Personnel measure (NQF #0431). However, the circumstances around use of the COVID-19 vaccine are not entirely comparable to those of the influenza vaccine, as COVID-19 and its vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market—from Moderna, Pfizer and Johnson & Johnson—are currently only available under the Food and Drug Administration's (FDA) emergency use authorization. While we are confident in the safety and efficacy of these products and at least one is likely to receive full FDA approval imminently, we find it to be inappropriate to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Additionally, the measure only excludes patients who do not get the vaccine due to medical contraindications. According to the Equal Employment Opportunity Commission, employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice or observance prevents them from receiving the vaccination; this policy seems to conflict with the specifications of the proposed measure.

Another important distinction between the measure proposed in this rule and the influenza measure already in use is that the COVID-19 vaccination measure has not gone through the rigorous testing and National Quality Forum (NQF) endorsement review process to which other measures adopted in CMS quality reporting programs are subject. The measure was presented to the MAP as a concept, not as a measure ready for implementation. In fact, CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that was not "fully fleshed out" in anticipation of CMS attempting to incorporate it into rule-writing in 2022 at the earliest.

While the measure is designed nearly identically to the flu vaccine measure in terms of its calculation and reporting structures, many questions about the specifics of the COVID-19 measure remain (questions that might be answered during the testing and NQF endorsement processes). For example, what are the long-term plans for use of this measure in terms of its reporting period? The flu vaccine measure assesses vaccinations during "flu season," which is defined as October through March; will there be a similar "COVID-19 season," and how will reporting interact with that of the flu measure? Is this measure in alignment with other COVID-19 vaccination measures under consideration, such as the Merit-based Incentive Payment System measure that was reviewed by the MAP which assessed patients who received at least one dose (as opposed to a complete course)?

Considering the magnitude of changes in the circumstances regarding COVID-19 vaccinations in 2021 alone, additional questions concerning the logistics of this measure may arise. The availability of doses played a major role in vaccination status earlier this year. For example, safety violations at a single plant resulted in millions of unusable doses of the Johnson & Johnson vaccine; variation in distribution strategies, communication between pharmacies and clinics and site-to-site transfer of unused doses led to confusion, waste and vaccination delays. If the supply chain were disrupted again, health care facilities could be unable to ensure the vaccination status of their employees through no fault of their own. The nation has not yet completed the first wave of complete vaccinations—as of this writing, less than 50% of Americans were fully vaccinated—and thus we have not yet begun to address needs or logistics for "booster" shots. **Because of the rapidly changing circumstances in which the COVID-19 vaccines are being deployed, we believe it is unwise to permanently adopt this measure into federal quality reporting programs at this time.**

Also, CMS should consider the potential unintended consequences in using this measure. The reporting burden associated with this measure may be high depending on how it

interacts with other COVID-19 data reporting requirements. Certain health care settings, such as skilled nursing facilities and inpatient psychiatric facilities, do not use NHSN to report data for quality reporting programs, so the introduction of this measure would require adjustments in workflow for which CMS would need to provide significant technical support. In addition, use of this measure may cause providers to amend other employee-facing policies, which take time to implement.

Moreover, publicly reporting performance on this measure might compel facilities to ensure that their employees are vaccinated. Clearly, an employee vaccination mandate could be beneficial to measure performance. Yet, the decision about whether to implement a mandate is complex, and in some cases, the decision may be beyond the control of health care facilities. For example, multiple states have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also prohibit mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate the vaccine could be at a systematic performance disadvantage on the measure.

The COVID-19 pandemic is not the last public health emergency this nation will face, but our national COVID-19 response will have long-lasting effects on policy. The AHA is concerned about the precedent of adopting a measure assessing COVID-19 vaccination of HCP under these circumstances, and thus recommends that CMS reconsider adopting the measure during this rulemaking cycle**.**

Again, the AHA recommends CMS either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting only—without publicly reporting performance—for one year, or at least the first quarter of the measure's use (beginning Oct. 1 of this year) to allow for time to answer the questions raised above regarding feasibility, validity and the incidence of any unintended consequences.

Proposed Maternal Morbidity Structural Measure. Beginning with the FY 2023 IQR program, CMS proposes that hospitals attest to whether they participate in statewide or national quality improvement programs related to reducing maternal morbidity, and have implemented certain safety practices related to reducing maternal morbidity. CMS asserts the measure would address a national quality priority, encourage hospitals to participate in perinatal quality improvement programs and reduce maternal morbidity.

The AHA strongly agrees that reducing maternal morbidity is a national priority. Through our Better Health for Mothers and Babies initiative, we have shared a plethora of tools, resources and educational offerings with our members to assist in their work of improving maternal health. Many hospitals already are participating in state and national-level collaborative efforts aimed at reducing maternal morbidity and find considerable value in leveraging such efforts to identify and implement the practices that are most beneficial to the patients and communities they serve and learning from peer institutions.

While the AHA does not object to the implementation of the proposed maternal morbidity measure, we question its long-term value to hospitals, the public and CMS. We believe that hospitals could make more progress—and that CMS and the public would be better informed of this progress—if CMS were to instead pursue measures that more directly assess the quality of maternal care. The proposed measure reflects participation in activities of clear benefit to hospitals and patients, but it is not really a performance measure. Hospitals cannot use this measure for benchmarking purposes because all it tells them is whether their peers are participating in improvement projects. Furthermore, because many hospitals already are participating in perinatal quality improvement programs and are implementing safety practices, we suspect the overwhelming majority of hospitals will report an answer of "yes." The measure also does not provide actual performance data on maternal morbidity to patients and families trying to make a better-informed decision about where to receive their maternal care.

We understand that developing process and outcomes of maternal care is a complex undertaking. It will require time, stakeholder participation, measure testing and NQF endorsement to ensure any measures are accurate, reliable and feasible to implement. However, given the importance of addressing maternal morbidity, it is vital for such work to begin.

Thus, the AHA urges CMS to view the adoption of this measure as a "bridge" while it undertakes the critical work of developing more robust maternal morbidity measures. In implementing the proposed measure, CMS also should provide additional guidance around which types of state and national-level quality improvement programs meet the measure's definition**.** The measure specification descriptions provided on CMS' website are vague, and CMS should work to expand the list of example collaboratives that might qualify.

Hybrid Hospital-wide All-cause Mortality Measure. CMS proposes an all-cause, risk-standardized measure assessing mortality with 30 days of hospital admission for most conditions or procedures. The proposed measure is a "hybrid" measure in which hospitals submit certain "core clinical data elements" from EHRs to supplement the Medicare claims data used to calculate the measure. The reporting of the measure would be voluntary for the FY 2025 IQR program, with a reporting period of July 1, 2022 – June. 30, 2023. However, it would become required beginning with the FY 2026 IQR program, with a reporting period of July 1, 2023 – June 30, 2024. CMS adopted a similar hybrid hospital-wide readmissions measure in the FY 2020 inpatient PPS final rule.

The AHA agrees that hybrid measures hold considerable promise for the future. However, the AHA urges CMS to keep the reporting of the hybrid mortality 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.

Yet, we are concerned that the experience with reporting such a measure 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. CMS adopted a hybrid readmissions measure for required reporting in the FY 2020 inpatient PPS final rule, but the required reporting of the readmissions measure will not begin until the FY 2026 IQR program. The readmission measure has been available for voluntary reporting, but the most recent data we have suggests that 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. Similar concerns about the dearth of implementation experience also apply to the hybrid mortality measure. In reviewing the NQF submission for the hybrid mortality measure, it appears the mortality measure was tested in only 22 hospitals. While we would not expect for the measure to be tested in all hospitals before NQF endorsement, it is far from clear that the measure is ready for use on a broad scale. At a minimum, we would urge CMS not to mandate the reporting of the proposed hybrid mortality measure until it has experience with the reporting of the hybrid readmissions measure.

Furthermore, the AHA remains concerned that the current QualityNet system may not 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 mortality measure, it must ensure its infrastructure is ready to accept such data. This is especially true since CMS adopted a proposal in last year's inpatient PPS final rule to expand the required reporting of eCQM data to a full year beginning in 2023. We urge CMS to ensure its submission portal has the adequate capabilities to receive test and production QRDA-I files and send submission summary and performance reports.

The AHA also has several conceptual concerns about the design of a hospital-wide mortality measure. First, CMS hospital quality programs already include condition-specific mortality measures. The proposed measure would overlap with these measures, making the measure data potentially redundant. Second, we are concerned that this measure's design will lead to inaccurate, misleading and unfair performance comparisons. Each hospital's mix of available services and patient acuity—which greatly influence mortality rates—is different. For example, a 100-bed community hospital is unlikely to offer the specialized tertiary and quaternary services of an academic medical center. Moreover, the patients treated in an academic medical center or other large referral center will likely have greater clinical complexity. Yet, by including all conditions, this measure assumes one can perform an "apples to apples" comparison of these types of hospitals and render a generalized judgment of which ones provide better care.

While risk adjustment can help, we know of no risk adjustment methodology that is up to the task of adjusting for the many varied clinical and sociodemographic differences that may put a patient at a higher risk of death. Thus, this measure might actually serve to obscure any meaningful differences in performance. In fact, a November 2017 technical report on a claims-only version of this measure showed limited performance variation. Of

the 4,793 hospitals included in the analysis, only 102 (2.1%) show up in the better than average category, and only six hospitals in the worse than average category (0.1%), leaving over 97% of hospitals as not statistically different from one another.

Proposed Glycemic Control eCQMs. **The AHA supports adding the two proposed glycemic control eCQMs to the menu of available eCQMs from which hospitals can choose to fulfill eCQM reporting requirements. However, we urge CMS not to require all hospitals to report these measures at this time.** The measures reflect the rates of severe hypoglycemia and hyperglycemia. The AHA agrees that poor glycemic control can pose patient safety risks, especially hypoglycemic events. However, we are concerned about the limited environment in which this eCQM was tested. According to the information provided to the MAP at the time of its review in 2019, this measure was tested in two sites comprising six total hospitals across two states; both sites were teaching hospitals in urban settings. While the sites used two of the most common EHR systems, they are not representative of the diversity in hospitals across the country. This raises questions of how feasible reporting of this measure may be in different types of facilities. We urge CMS to use the experience hospitals that choose to report these eCQMs to understand whether the measure works as intended.

Proposed Measure Removals. CMS proposes to remove a total of five IQR program measures because the measures have costs that exceed their benefits, or because they overlap with the new measures proposed for the program. **The AHA supports these proposals.**

eCQM Reporting Standard. CMS previously finalized regulations permitting hospitals to report the IQR's eCQMs using either the 2015 Edition of certified EHR technology, or the 2015 Edition Cures update. The 2015 edition Cures update was finalized in the ONC's 21st Century Cures final rule in 2020. In this rule, CMS proposes that, beginning with the FY 2025 IQR (CY 2023 reporting), hospitals would be required to report eCQMs using EHR technology certified to the 2015 Edition Cures Update. **While the AHA supports this proposal, we recommend that CMS monitor vendor and hospital progress in transitioning to this standard to ensure this timeframe is feasible.**

Request For Information—Closing the Health Equity Gap in CMS Hospital Quality Programs

The AHA applauds CMS' commitment to advancing health equity, and we are pleased the agency seeks input on a range of potential policy actions intended to accelerate the nation's progress on this vital topic. Hospitals and health systems are working hard to identify and address health disparities and to close remaining gaps in quality performance across patient populations. Our ultimate goal is the same as CMS': to ensure that all patients feel valued and recognized, and that the care they receive does not vary due to race, ethnicity, gender, sexual orientation or other demographic or social risk characteristics.

General Considerations. Most of the policy ideas shared in the RFI focus on the collection, analysis and use of health equity-related data within the context of CMS' existing framework of quality measurement and value programs. We certainly understand this focus, given both the visibility and importance of CMS' quality measurement programs, and the vital need to have reliable, accurate and actionable data to both identify disparities and track progress over time. As CMS continues to work with the health care field to advance equity and considers advancing its use of equity data, our members have asked that CMS:

- *Work to foster alignment and standardization of approaches to collecting, analyzing and exchanging demographic and social risk data.* This includes a consistent approach across CMS itself, and across other federal agencies and programs. Given the breadth of health equity issues, and the wide range of stakeholders affected by it, CMS can help ensure that all stakeholders use consistent definitions and standards. Furthermore, such standards should be thoroughly field tested before broader implementation.

- *Ensure that equity data use and collection efforts are aligned with CMS' broader goals and strategy related to health equity.* In other words, the collection, use and analysis of data should not be done in isolation and should be linked to achieving specific goals in CMS' strategy.

- *Identify and share more broadly data to which CMS itself may have access.* For example, to the extent CMS is collecting demographic and social risk data during the time of Medicare enrollment, the agency should explore ways of determining whether this information could be linked to quality data. These steps could help provide additional data for CMS' efforts to identify disparities in performance and outcomes.

- *Be judicious in requests for new data and ensure any efforts to collect equity data achieve an appropriate balance of value to advancing health equity and administrative burden*. As CMS notes in the proposed rule, "the development of consistent and sustainable programs to collect data on social determinants of health can be considerable undertakings." Indeed, data reporting often involves investments in systems and personnel, and redesigns of workflows to ensure data can be captured. However, certain types of data (e.g., living situation, sexual orientation and gender identify) also may sensitive for patients to disclose. We encourage CMS to engage patients and providers extensively as it explores additional data collection.

Facility Equity Score. CMS recently developed—but not yet implemented—an equity summary score for MA plans, which aggregates results from multiple quality measures and then assesses to what extent disparities in performance may exist among beneficiaries along the lines of race and dual-eligible status. CMS is interested in building a similar

score for hospitals that would supplement the measure data already reported on the *Care Compare* website. The agency asserts that this summary score could provide easy-to-interpret information regarding disparities measured within individual facilities and across facilities nationally.

The AHA understands the conceptual appeal of an overarching "facility equity score." However, such a score would not be a helpful step in advancing health equity at this time; thus, we recommend that CMS prioritize other mechanisms for advancing health equity.

The AHA is concerned that a facility equity score may inadvertently lead to a reductionist approach to assessing provider efforts related to health equity. The facility equity score would assess for disparities only along the lines of race and ethnicity and dual-eligible status. Certainly, knowing whether disparities exist along those dimensions is important. At the same time, recent work around health equity also has highlighted the concept of "intersectionality;" that is, disparities often are driven by a confluence of multiple characteristics rather than just one or two. The drivers that matter the most to particular patients, communities and hospitals are likely to vary, and be interconnected. For example, other factors such as education, housing and access to healthy foods also can contribute to health disparities. As a result, judging a hospital's success or failure in addressing disparities through just the dimensions included in the facility equity score could result in an incomplete assessment.

Furthermore, we question whether a summary equity score would be actionable by hospitals, or meaningful to the public. As we understand it, the score blends together the performance for racial and ethnic subgroups along with those for beneficiaries who are eligible for both Medicare and Medicaid. Yet, a hospital wanting to improve their performance would be challenged to use a single summary score to identify the specific quality measures and dimension of equity that drives their performance. Even more concerning is the prospect of hospitals or the public drawing either false comfort or false alarm from such "rolled up" results. For example, a high overall score may inadvertently obscure lower performance on particular quality measures, or among particular segments of a hospital's patient population.

Lastly, we are not sure that a composite score of only hospital-level process of care and outcome measures would give hospitals the information they need to help make a bigger impact on health equity in their communities. The difference in health outcomes and disparities in health are the results of longer term processes that begin well before a hospitalization and extend until far after a patient is discharged from the hospital. Addressing them will require a common engagement of providers, public health experts, patients and families across the care continuum. Certainly, the stratification of individual hospital process of care measures by race/ethnicity or dual-eligible status can help hospitals ensure that the care provided to patients in these different groups is not different based on these characteristics. However, many of the most critical factors influence overall

health during a person's whole life, not merely the few days they are a patient in our hospital. To truly understand and address disparities in health, we need to examine critical indicators of health experiences over time, alongside both hospital and longer range health outcomes, and then engaged with public health experts, other providers, community leaders and others to begin to address these issues.

Measure Stratification and Indirect Estimation. **Instead of a summary facility equity score, we encourage CMS to prioritize further stratification of individual quality measures by race and ethnicity and dual eligibility.** We would support providing hospitals with additional confidential reports, and believe this approach would result in data that are more actionable by providers and less susceptible to the methodological challenges of a roll up summary score highlighted above.

As we understand it, one of the methods CMS is considering for creating these stratified reports is indirect estimation. Given the gaps in available demographic data for Medicare beneficiaries, CMS is considering using data from existing sources like the U.S. Census and Medicare administrative data (e.g., first and last names, and the racial and ethnic composition of the patient's neighborhood) to "impute" (i.e., infer) the demographic composition of hospitals' patient populations. **While the AHA appreciates that CMS is trying to make the highest use of the data it has, we are concerned about the potential for indirect estimation to lead to measurement bias, and thus encourage the agency not to prioritize the use of this methodology.** As CMS notes, the "gold standard" for race, ethnicity and other demographic data is patient self-reported information. Furthermore, the quality of the indirect estimation model would be only as good as the data that go into it. To the extent CMS draws on data from the census, we expect the data could lag the actual demographic composition of a hospital's patient population by several years. This would limit the usefulness of analyses based on indirect estimation. At a minimum, we urge CMS not to use indirect estimation in any public-facing analysis of hospital equity performance.

Health Equity Structural Measures in the IQR. CMS also is considering implementing a structural measure in the IQR that would ask hospitals whether they are implementing certain practices the agency believes reflect a hospital's commitment to health equity. In general, the AHA does not favor structural measures in public reporting programs because they are not as direct a reflection of actual performance as either process or outcome measures.

However, if CMS is intent on including a health equity measure in the IQR program, a structural measure may be an appropriate starting point. As described above, the particular drivers and dimensions of health equity that matter the most to particular hospitals and communities may vary, which would make it challenging to develop specific process or outcome measures related to health equity that would apply to all hospitals. Presumably, a structural measure would not be tied to either specific health equity data elements or to specific quality measures. Rather, it would instead focus

on broader practices. To the extent CMS wishes to pursue this idea further, we strongly urge the agency to work closely with hospitals and other stakeholders to identify the practices most closely related to improving health equity and most universally applicable to all hospitals.

Request For Information—Digital Quality Measurement

The proposed rule includes a request for comment on CMS' plans to advance the use of digital quality measures (dQMs) and expand the agency's use of Fast Healthcare Interoperability (FHIR) standards and Application Programming Interfaces (APIs) for both current eCQMs and future quality measures. CMS states that its goal is "to move fully to digital quality measurement" by 2025 and to enhance the interoperability of quality measure data.

The AHA agrees that a digital and interoperable quality measurement enterprise is a laudable long-term goal that could have positive and far-reaching impacts to quality of care and the provider experience. The AHA also sees significant potential in expanding the use of FHIR, as this standard is easier to implement and more fluid than many other available frameworks. At the same time, transitioning to only dQMs in CMS quality measurement programs will prove a staggeringly complex task. In this rule, CMS offers a working definition of dQMs, a long list of laudable attributes for dQMs and correctly identified the need to work with multiple stakeholders. While all of these things are helpful and necessary, they are not by themselves enough to ensure a successful transition to dQMs. This also is why it is difficult for AHA to judge whether CMS' stated goal of transitioning to fully digital quality measures by 2025 is achievable, though given the complexity of the task, we are skeptical.

For these reasons, we urge CMS to propose a clearer overarching plan and goals for its proposed transition to dQMs. CMS should specify what steps it expects for hospitals and other stakeholders to take, the sequencing and timing of those steps, and identify any interdependent steps and policies across CMS, ONC and any other relevant federal agencies. We also believe that any new standards or processes that emerge from this plan would need to be adequately vetted and field-tested before they are made into regulatory requirements. The AHA and our members would be pleased to engage CMS in such a planning process.

Below we offer comments on several specific issues included in the RFI and provide additional recommendations to the agency.

Digital Quality Measure Definition. CMS' proposed definition of dQMs is very broad and lists a range of data sources, including administrative systems, clinical assessment data, case management systems, EHRs, instruments (e.g., wearable medical devices), patient portals, health information exchanges (HIEs), registries and "other sources." Hospitals do not manage some of these sources themselves; yet, their performance on a dQM could be

linked to such data. We are concerned that the accuracy and reliability of dQMs could be compromised by poor data quality from outside sources. For these reasons, CMS, ONC and other stakeholders may need to consider the development of source system verification and/or certification criteria.

dQMs as Self-Contained Tools. In the RFI, CMS offers a lengthy list of attributes and functionalities that dQMs could have. This ranges from simple tasks like the ability to generate measure score reports, to considerably more complex tasks like being "compatible with any data source" and "having the ability to adopt to emerging advanced analytic approaches like natural language processing." The AHA encourages CMS to work across stakeholders to determine whether these attributes can be sequenced and scaled. We are skeptical that all of the attributes on CMS' proposed list would be achievable for even a single dQM by 2025. But, certain attributes may be achievable by that point.

Public-Private Sector Collaboration. The AHA is pleased that CMS is considering the development of a "common portfolio" of dQMs that could be used across federal program and agencies, and with private sector quality measurement programs. Hospitals have long aspired to an approach to quality measurement that enables them to report data only once, and have it used for multiple purposes. Unfortunately, hospitals continue to face discordant reporting requirements among federal, state and private sector quality reporting and value programs. Even when the measure topics are the same, often there are differences in measure design across programs that result in the need for duplicative data collection, excess costs and confusion. As CMS advances a plan for dQMs, we encourage the agency to prioritize the development of dQMs that are usable across the public and private sector.