American Hospital Association™
Advancing Health in America

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June 5, 2024

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-1808-P, Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes, (Vol. 89, No. 86), May 2, 2024.

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) 2025. We are submitting separate comments on the agency's proposed changes to the long-term care hospital PPS and Transforming Episode Accountability Model.

We support several of the inpatient PPS proposed rule provisions, including certain policies supporting low-volume and Medicare-dependent hospitals. We also appreciate that the agency revised its previous drug buffer stock proposal in response to several matters the AHA raised in last year's request for information (RFI). We also support several aspects of CMS' quality-related proposals, including most of the updates to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey and the removal of five redundant quality measures from the Inpatient Quality Reporting (IQR) program.

At the same time, we continue to have strong concerns about the proposed payment updates. In particular, we are deeply concerned about the inadequacy of the proposed net payment update of 2.6% given the unrelenting financial challenges faced by hospitals and health systems. As such, we strongly urge CMS to utilize its authority to make a one-time retrospective adjustment to account for what the agency missed in the FY 2022 market basket forecast. We also are concerned about the agency's lack of transparency in the underlying calculations for disproportionate share hospital (DSH) payments and disagree with the agency's estimates of the number of uninsured for FY 2025. We urge CMS to consider additional data by researchers and policy stakeholders to reach a more reasonable estimate of the percent of uninsured. Additionally, we are concerned with the agency's graduate medical education (GME) proposals and RFI related to modifications of the "newness" criteria to establish new residency training programs.

Finally, we have concerns about several of the agency's quality-related proposals. We urge CMS not to adopt its two proposed new structural measures and not to increase the number of required electronic clinical quality measures. CMS' proposal to use conditions of participation (CoPs) to compel hospitals to share data with the federal government is both needlessly heavy-handed and inconsistent with the intent of CoPs. Rather than jeopardizing hospitals' Medicare participation status, the AHA urges CMS to take a more collaborative approach and to invest in the infrastructure needed to make the voluntary sharing of important data on infectious diseases less burdensome and more meaningful.

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's director for payment policy, at (202) 626-2963 or swu@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development

American Hospital Association
Detailed Comments on the Inpatient Prospective Payment System Proposed Rule for Fiscal Year 2025

Table of Contents

INPATIENT PPS PAYMENT UPDATE

For FY 2025, CMS proposes a market basket update of 3.0% less a productivity adjustment of 0.4 percentage points, resulting in a net update of 2.6%. This update, especially when taken together with prior inadequate updates, continues and exacerbates Medicare's underpayments to the hospital field. It ignores the fact that hospitals and health systems continue to face high levels of input costs, including the unrelenting challenges — such as the cyberattack on Change Healthcare — with which the field must contend. **As such, we once again urge CMS to use its "special exceptions and adjustments" authority to implement a retrospective adjustment for FY 2025 to account for the difference between the market basket update that was implemented for FY 2022 and the actual market basket for FY 2022. Specifically, the actual market basket for FY 2022 is 5.7% — a full 3.0 percentage points higher than what hospitals received in 2022. Additionally, we also urge CMS to eliminate the productivity cut for FY 2025, as we detail below.**

Financial Context

After battling near historical inflation and significant increases in the costs required to care for patients and communities 24/7, 365 days a year, hospitals and health systems continue to face additional financial challenges — including those brought on by large insurers and their subsidiaries and the difficulties brought on in dealing with the aftermath of the cyberattack on Change Healthcare, which resulted in the most significant attack on the health care system in U.S. history.[1] **We urge CMS to consider the changing health care system dynamics, the unlikelihood of these dynamics returning to "normal" trends and the effects on hospitals. As we detail below, these shifts in the health care environment are putting enormous strain on hospitals and health systems, which will continue in FY 2025 and beyond.**

Fresh off a historically challenging year financially in 2022 in which over half of hospitals closed out the year operating at a loss, many hospitals spent much of 2023 simply struggling to break even.[2] Economy-wide inflation grew by 12.4% from 2021 through 2023 — more than two times faster than Medicare reimbursement for hospital inpatient care, which increased by 5.2% during the same time.[3] From the start of 2022 through June 2023, the number of days cash on hand for hospitals and health systems has declined by 28.3%.[4]

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[1] The AHA adamantly opposed the merger of UnitedHealth Group and Change Healthcare. https://www.aha.org/lettercomment/2021-03-17-aha-urges-doj-investigate-unitedhealth-groups-acquisition-change
[2] American Hospital Association (May 2024). America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities. https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf
[3] Ibid.
[4] Syntellis. Hospital Vitals: Financial and Operational Trends Q1-Q2 2023. https://www.syntellis.com/sites/default/files/2023-11/aha_q2_2023_v2.pdf

An area of persistent cost pressure for hospitals and health systems has been the rapid and sustained growth in labor costs. Specifically, labor costs increased by more than $42.5 billion from 2021 through 2023 to a total of $839 billion.[5] Hospitals and health systems continue to turn to expensive contract labor to fill gaps and maintain access to care, spending approximately $51.1 billion on contracted staff in 2023.[6] Furthermore, hospitals have been forced to contend with record high turnover rates — fueling additional expenses for those looking to recruit new workers. For example, resignations per month among health care workers grew 50% from 2020 through 2023, according to data from McKinsey.[7]

Additionally, 2023 also saw a continuation of a long-standing trend of drug companies both introducing new drugs at record prices and imposing large price increases on existing drugs. In 2023, the median annual list price for a new drug was $300,000, an increase of 35% from the prior year.[8] A recent report by the Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation found that in 2022 and 2023, prices for nearly 2,000 drugs increased faster than the rate of general inflation, with an average price hike of 15.2%.[9] As a result, hospitals spent $115 billion on drug expenses in 2023 alone.[10]

At the same time, hospitals have seen significant growth in completely avoidable and unnecessary administrative costs due to inappropriate practices by large commercial health insurers, including Medicare Advantage (MA) and Medicaid managed care plans. In addition to increasing premiums, which grew twice as fast as hospital prices in 2023, large commercial health insurers have overburdened hospitals with time-consuming and labor-intensive practices like automatic claims denials and onerous prior authorization requirements.[11] A 2021 study by McKinsey estimated that hospitals spent $10 billion annually dealing with insurer prior authorizations.[12] Additionally, a 2023 study by Premier found that hospitals are spending just under $20 billion annually appealing denials — more

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[5] American Hospital Association (May 2024). America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities. https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf

[6] Ibid.

[7] McKinsey & Company. (Sep 2023). How Health Systems and Educators Can Work to Close the Talent Gap. https://www.mckinsey.com/industries/healthcare/our-insights/how-health-systems-and-educators-can-work-to-close-the-talent-gap

[8] Reuters. (Feb 2024). Prices for New US Drugs Rose 35% in 2023, More than the Previous Year. https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/

[9] ASPE. (Oct 2023). Changes in the List Prices of Prescription Drugs, 2017-2023. https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs

[10] American Hospital Association (May 2024). America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities. https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf

[11] KFF Employer Health Benefits Survey. (2023) Health insurance premiums represent premiums for a family of four. Hospital Prices: BLS. Annual average Producer Price index for hospitals.

[12] McKinsey & Company. (2021). Administrative Simplification: How to Save a Quarter-Trillion Dollars in US Healthcare. https://www.mckinsey.com/~/media/mckinsey/industries/healthcare%20systems%20and%20services/our%20insights/administrative%20simplification%20how%20to%20save%20a%20quarter%20trillion%20dollars%20in%20us%20healthcare/administrative-simplification-how-to-save-a-quarter-trillion-dollars-in-us-healthcare.pdf

than half which was wasted on claims that should have been paid out at the time of submission.[13] Indeed, denials issued by commercial MA plans rose sharply, by 55.7%, in 2023.[14] Notably, many of these denials were ultimately overturned as noted above. In fact, a study by the HHS Office of Inspector General (OIG) that found 75% of care denials were subsequently overturned.[15] Making matters worse, MA plans paid hospitals less than 90% of Medicare rates despite costing taxpayers substantially more than traditional Medicare in 2023.[16,17]

Unsurprisingly, these trends have continued and exacerbated Medicare's underpayments to the hospital field. Specifically, recent research findings from key stakeholders confirm what the AHA has stressed repeatedly — that 2022 was the most financially challenging year for the hospital field given input price inflation and workforce shortages. Specifically, the Medicare Payment Advisory Commission (MedPAC) found that all-payer operating and overall Medicare margins both fell to record lows. Indeed, Medicare hospital margins for FY 2022 were *negative* 12.7%. Even MedPAC's own analysis showed that "relatively efficient hospitals" — those hospitals that perform well on quality while keeping unit costs low — were paid less than costs, with Medicare margins of *negative* 3%. MedPAC projects 2024 Medicare margins will fall below *negative* 13%, the *20th straight year* of Medicare paying below costs. The AHA's own analysis showed that Medicare underpayments hit a record high in 2022 — $99.2 billion.[18] **This cannot be sustained. Therefore, we urge CMS to focus on appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital payment update, which is essential to ensure that Medicare payments for acute care services more accurately reflect the cost of providing hospital care.**

Indeed, margins at this level are simply unsustainable, and we are seeing their effects in real time. Rural hospitals continue to close, with nine closing in FY 2023 despite a new Medicare provider type that allows them to convert to a rural emergency hospital (REH).[19] Furthermore, over the last decade, more than 200 rural hospitals have closed obstetric (OB) units. As a result, a recent Office of Government Accountability study

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[13] Premier. (2024). Trend Alert: Private Payers Retain Profits by Refusing or Delaying Legitimate Medical Claims. https://premierinc.com/newsroom/blog/trend-alert-private-payers-retain-profits-by-refusing-or-delaying-legitimate-medical-claims

[14] Syntellis. Hospital Vitals: Financial and Operational Trends Q1-Q2 2023. https://www.syntellis.com/sites/default/files/2023-11/aha_q2_2023_v2.pdf

[15] DHHS OIG. (2023). High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care. https://oig.hhs.gov/oei/reports/OEI-09-19-00350.pdf

[16] MedPAC (2021). MedPAC Report to Congress. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf#page=401

[17] Ensemble Health Partners. (2023). The Real Cost of Medicare Advantage Plan Success. https://www.ensemblehp.com/blog/the-real-cost-of-medicare-advantage-plan-success/

[18] https://www.aha.org/news/headline/2024-01-10-aha-infographic-medicare-underpayments-hospitals-nearly-100-billion-2022

[19] Nineteen rural hospitals have converted to a REH designation in 2023, stemming some of the closures we would have expected to see had the program not been in place.

estimated that half of all rural counties lack access to this essential care.[20] Given the agency's particular focus on maternal health care, these service line closures are particularly troubling.

Coupled with these ongoing headwinds is the recent cyberattack that has been deemed "the most significant attack on the healthcare system in U.S. history."[21] Specifically, the Feb. 21 cyberattack on Change Healthcare, owned by UnitedHealth Group, has disrupted many aspects of the health care ecosystem, including the ability for providers to process claims and receive reimbursement. Essentially, this cyberattack crippled the flow of funding and brought insurance payments to a halt for many providers.[22] While hospitals and health systems have long contended with chronic underpayments by government payors, they are now also contending with the aftermath of inadequate cash flow from commercial payors. For example, the revival of the claims systems is more of a starting point for addressing the issues created by the cyberattack rather than conclusory. Preparing and submitting a backlog of claims will occur simultaneously with preparing and submitting claims for new care provided each day. One hospital executive stated that they "have 25 full-time equivalents dedicated to this."

The disruption and delay in claims submission will inevitably lead to many denials and thus added administrative costs for hospitals and health systems. This is particularly true since most payers did not waive certain administrative requirements impacted by the Change Healthcare outage. Specifically, there are already reports of denials due to providers failing to obtain prior authorization, and we expect also to see denials due to providers not meeting contractual "timely filing" deadlines — of course through no fault of their own. Additionally, hospitals and health systems now face a complicated process of reconciling in their accounting systems payments received without remittances, which include all the information a provider needs to know about the payment. The flow of these remittances was disrupted during the Change Healthcare outage, and as a result, providers could not post payments in their financial accounting systems, nor provide patients with timely billing, without this information.

Hospitals and health systems have already faced considerable costs to mitigate the impact of the Change Healthcare cyberattack, but these costs in terms of both labor and vendor fees will continue to persist for some time after restoration of all systems. In some cases, hospitals and health systems have had to liquidate investments or pursue loans to finance these mitigation and recovery activities, which adds to their costs. Coupled with the added unknown of requirements related to any potential data breaches, hospitals and health systems face an uncertain future with respect to fully returning to pre-attack operations.

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[20] GAO (Oct 2022). Maternal Health: Availability of Hospital-Based Obstetric Care in Rural Areas. https://www.gao.gov/products/gao-23-105515

[21] Washington Post (Mar 2024). Health-care hack spreads pain across hospitals and doctors nationwide. https://www.washingtonpost.com/business/2024/03/03/change-health-care-hack-hospitals/

[22] Wall Street Journal. (Mar 2024). U.S. Health Department Intervenes in Change Healthcare Hack Crisis. https://www.wsj.com/articles/calls-mount-for-government-help-as-change-healthcare-hack-freezes-medical-payments-9545d2e3

Market Basket

For FY 2022, CMS finalized a market basket of 2.7%, based on estimates from historical data through March 2021. As we detailed in our comment letters on the FYs 2023 and 2024 inpatient PPS proposed rules, because the market basket was a forecast of what was *expected* to occur, it missed the *unexpected* trends that did occur in the latter half of 2021 into 2022 with hospitals combatting high inflation and workforce shortages. **Indeed, including data through September 2022 yields a figure of 5.7% for the actual FY 2022 market basket — a staggering 3.0 percentage points higher than the update that was given to hospitals.**

The rationale for using historical data as the basis for a forecast is reasonable in a typical economic environment. However, when hospitals and health systems continue to operate in atypical environments, the market basket updates become inadequate. This is, in large part, because the market basket is a time-lagged estimate that cannot fully account for unexpected changes that occur, such as historic inflation and increased labor and supply costs. This is exactly what had occurred at the end of the calendar year (CY) 2021 into 2022, which resulted in a large forecast error in the FY 2022 market basket update.

In addition to the fact that the market basket, by nature, largely misses unexpected trends, its construction does not fully capture the labor dynamics occurring in the health care field. This is detailed in our FY 2024 inpatient PPS comment letter, where we discuss CMS' use of the Employment Cost Index (ECI) to measure changes in labor compensation in the market basket.[23] However, we believe that the ECI may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs. By design, the ECI cannot capture changes in costs driven by shifts between different categories of labor. Indeed, CMS itself recognizes that the ECI does not capture these shifts in occupation.[24] Yet, as mentioned above, this comes at the exact time that hospitals have had to dramatically turn to contract labor to meet patient demand.

Specifically, since the COVID-19 public health emergency, IHS Global, Inc. (IGI) forecasted growth for the hospital market basket has shown a consistent trend of under-forecasting actual market basket growth. As demonstrated below, there has now been three consecutive years of missed forecasts to hospitals' detriment, beginning in FY 2022. Based on the market basket adjustments alone, this has resulted in underpayments of inpatient PPS of nearly 4.0 percentage points. While AHA is cognizant of the fact that forecasts will always be imperfect, in the past, they have been more balanced. However,

[23] 86 Fed. Reg. 25401 (May 10, 2021). "We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes."
[24] 86 Fed. Reg. 25421 (May 10, 2021). CMS stated that ECI measures "the change in wage rates and employee benefits per hour… [and are superior] because they are not affected by shifts in occupation or industry mix."

with three straight years of significant under-forecasts, AHA is concerned that there is a more systemic issue with IGI's forecasting.

Table 1: Inpatient PPS Market Basket Updates, FY 2022 through FY 2024

Year	FY 2022	FY 2023	FY 2024	Total
Market Basket Update in Final Rule	2.7%	4.1%	3.3%	10.1%
Actual/Updated Market Basket Forecast	5.7%	4.8%	3.5%	14.0%
Difference in Market Basket Update and Actual Increase	**-3.0%**	**-0.7%**	**-0.2%**	**-3.9%**

The missed forecasts have a significant and permanent impact on hospitals. At current levels, cumulative underpayment of near 4.0 percentage points totals more than $4 billion in underpayments annually. Further, and as CMS knows, future updates are based on current payment levels. Therefore, absent action from CMS, these missed forecasts are permanently established in the standard payment rate for inpatient PPS and will continue to compound. In addition, these underpayments also influence other payments, including the growing MA patient population, as well as commercial insurer payment rates.

These shortcomings are yet another reason that we urge CMS to use its "special exceptions and adjustments" authority to correct for the market basket forecast error that occurred in FY 2022 — the 3.0 percentage point difference in what was finalized in FY 2022 at 2.7% and the actual market basket at 5.7%. Additionally, because CMS is scheduled to rebase and revise the hospital market basket for FY 2026, we ask that CMS use this opportunity to examine its methods in incorporating labor shifts and costs for the hospital market basket so that it can more accurately reflect the changing labor dynamic.

Productivity

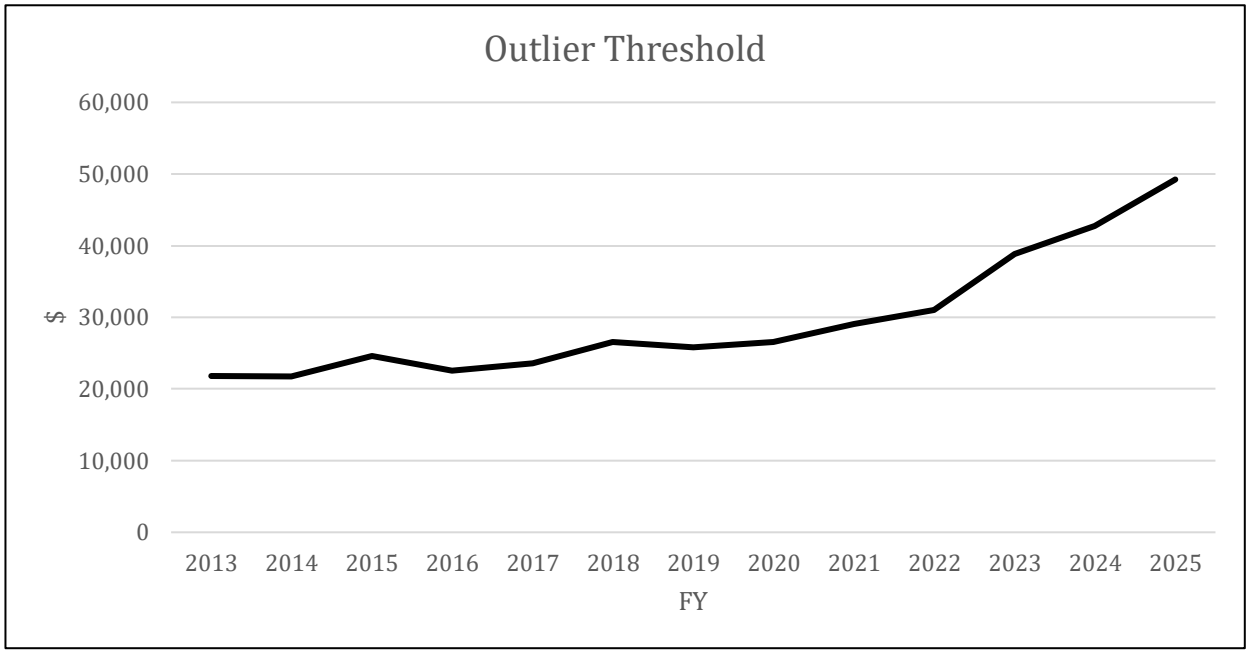
Under the Affordable Care Act (ACA), the inpatient PPS payment update is reduced annually by a productivity factor, which is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP).[25] This measure was intended to ensure payments more accurately reflect the true cost of providing patient care. For FY 2025, CMS proposes a productivity cut of 0.4 percentage points.

[25] CMS. (February 2016). Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf

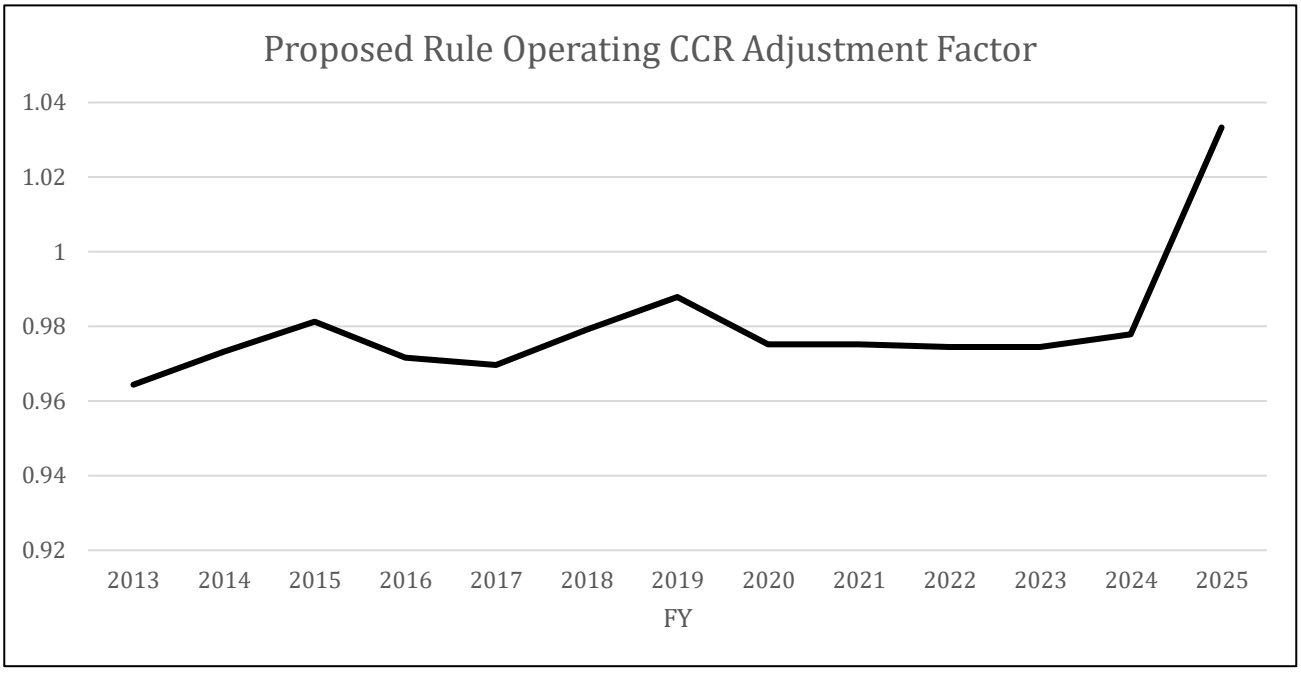
The AHA continues to have deep concerns about the proposed productivity cut, particularly given the extreme pressures in which hospitals and health systems continue to operate. As such, we ask CMS to use its "special exceptions and adjustments" authority to eliminate the productivity cut for FY 2025. As we explained in our comments in 2023 and 2024, the use of the private nonfarm business TFP is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills and changes in production. Thus, this measure effectively assumes the hospital sector can mirror productivity gains across the private nonfarm business sector. However, in an economy marked by great uncertainty due to labor and other productivity shocks, such as those caused by the cyberattack on Change Healthcare, this assumption is significantly flawed.

INPATIENT PPS OUTLIER THRESHOLD

The AHA is concerned about the proposed increase in the high-cost outlier threshold — a 15% increase from the FY 2024 threshold — that would significantly decrease the number of cases that qualify for an outlier payment. The agency states that this increase, from $42,750 in FY 2024 to $49,237 in FY 2025, is necessary to align total FY 2025 outlier payments with its target of 5.1% of total inpatient PPS payments. Not only is this increase substantial, but we are further concerned that it is coming after a decade of increases. Indeed, the chart below details the increase in the outlier threshold over the past decade – a staggering 126% increase from FY 2013 through FY 2025 (as proposed).



We believe much of the increase in FY 2025 is being driven by the fact that CMS has estimated and proposed to use a one-year national operating cost-to-charge ratios (CCR) adjustment factor of 1.03331. This CCR adjustment factor is much higher than it has been in the past, as shown below.



However, this large increase in FY 2025's adjustment factor is largely driven by CCRs that are reflecting the high-cost inflation – namely labor costs – that the field experienced during 2022 and 2023. **As such, we urge CMS to examine its methodology more closely and consider making additional, temporary changes to help mitigate the substantial increases that are occurring in the outlier threshold.** For example, CMS could instead apply the FY 2024 CCR adjustment factor in calculating the FY 2025 outlier threshold, which would mitigate the anomalous increase.

Additionally, the AHA has concerns over Transmittal 12594, published on April 26, 2024, which concerns outlier reconciliation and cost-to-charge ratio updates for the inpatient and LTCH PPS. In this transmittal, CMS changed the threshold and criteria for a facility to qualify for outlier reconciliation. As CMS knows, this will subject many additional facilities to the reconciliation process – a process that is already backlogged and takes several years to complete. This is a substantive change to CMS' payment policy, which is subject to notice and comment rulemaking under the Medicare statute. **Therefore, we urge CMS to withdraw the transmittal.** To the extent CMS wishes to implement this policy, it must be issued through notice and comment rulemaking.

MEDICARE DISPROPORTIONATE SHARE HOSPITAL 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 Calculations

The AHA remains extremely concerned about the agency's lack of transparency about how it and the Office of the Actuary (OACT) are calculating DSH payments. "It would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment. It is not consonant with the purpose of a rulemaking proceeding to promulgate rules on the basis of inadequate data, or on data that, [to a] critical degree, is known only to the agency." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008); *see Independent United States Tanker Owners Committee v. Lewis*, 690 F.2d 908, 925–26 (D.C.Cir.1982) ("[W]here an agency's analytic task begins rather than ends with a set of forecasts, sound practice would seem to dictate disclosure of those forecasts so that interested parties can comment on the conclusions properly to be drawn from them."); *see also United States v. N.S. Food Prods. Corp*., 568 F.2d 240, 252 (2d Cir. 1977) ("To suppress meaningful comment by failure to disclose the basic data relied upon is akin to rejecting comment altogether."). Yet, in this rule, the agency continues to withhold relevant information from the public, thereby depriving the AHA and others of the ability to comment on the basis for the agency's decision. Specifically, without additional information regarding the OACT analysis, stakeholders can neither validate nor evaluate the complex calculations CMS has made in estimating the percent of uninsured and other factors used to determine DSH payments. This failure to disclose relevant information from OACT unmistakably violates the Administrative Procedure Act (APA).

This error is compounded by the fact that available data exists that seemingly contradicts OACT's undisclosed analysis. It, too, raises fundamental legal concerns. After all, "[i]f an agency fails to examine the relevant data—which examination could reveal, *inter alia*, that the figures being used are erroneous—it has failed to comply with the APA." *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015); *see id*. ("[A]n agency cannot *ignore* new and better data."). Consequently, just as its failure to disclose the underlying OACT analysis straightforwardly violates the APA, so too does its failure to account for better contrary data from other sources. *See generally Motor Vehicle Mfrs. Assn. of United States, Inc. v. State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 43 (1983) (an agency's failure to "examine the relevant data" is a factor in determining whether the decision is "arbitrary").

Accordingly, we urge the agency to disclose the OACT information that we outline below in advance of publication of the final rule and permit further comment on it.

Moreover, the agency must disclose such information in its inpatient PPS proposed rule each year in the future.

Factor 1

Factor 1 is the estimate of what total DSH payments would have been under the former statutory formula. In estimating Factor 1, CMS used a variety of data inputs, including discharge numbers, case-mix and other components that impact Medicare DSH. It includes in the rule a table explaining the factors it applied for FYs 2022 through 2025 to estimate Factor 1.[26] 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 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 (such as the 20% add-on for COVID-19 discharges). It also includes a factor for the estimated changes in Medicaid enrollment.

In this year's rule, CMS has revised its estimate of FY 2024 discharges downward yet increased its estimate of "Other." **We thank CMS for increasing the "Other" column from what was finalized in last year's rule for FY 2024. However, the agency *once again* completely fails to detail how this column is actually calculated, which limits the AHA's ability to comment sufficiently on this issue.** For example, stakeholders are unable to determine which of the following inputs, or combination thereof, is driving the change in the "Other" column: Medicaid enrollment, 20% add-on, differences between total inpatient hospital discharges and those discharges paid under the inpatient PPS, or some other adjustment that contribute to Medicare DSH estimates. Without knowing CMS' methodology, we are forced to simply guess why Medicare DSH estimates are changing year to year. **As such, we *once again* urge CMS to transparently detail its calculations rather than obscure them year after year. Specifically, the agency should, for this year and going forward, publish a detailed methodology of its "Other" calculation that specifies how all the components contribute as well as their estimates from year to year.**

In addition, CMS has adjusted its estimates for the number of fee-for-service (FFS) inpatient hospital discharges, decreasing its estimates for FY 2023 and FY 2024. For example, in last year's rule, CMS estimated that the discharge factor for FY 2024 would be 0.982. In this proposed rule, CMS updated its estimate to be 0.977, stating that it is preliminary, and that for FY 2025, its estimate of 0.977 is based on assumption of "recent trends recovering back to the long-term trend and assumption related to how many beneficiaries will be enrolled in Medicare Advantage plans."[27] **The AHA would like to see detailed calculations of the discharge estimates in the inpatient PPS proposed rule each year going forward so that we have sufficient information to evaluate the impact on FFS inpatient hospital payments and provide feedback to the agency on**

[26] 89 Fed. Reg. 36192 (May 2, 2024).
[27] 89 Fed. Reg. 36192 (May 2, 2024).

how growth in MA is affecting the development of FFS rates over time. The growth of MA has had significant impacts on Medicare beneficiaries and providers alike, with many citing the frustrations of prior authorization requirements placed by plans.[28] This calls into the question the sustainability of that growth and its impact on inpatient hospital payments, and in particular, on those hospitals who serve a disproportionate share of lower-income beneficiaries. The AHA welcomes the opportunity to work with CMS in examining the impacts of MA enrollment on FFS inpatient hospital payments.

Factor 2

CMS establishes Factor 2 in the calculation of uncompensated care DSH payments as one minus the percent change in the percent of individuals who are uninsured, determined by comparing the percent of the individuals who were uninsured in 2013 and the percent of individuals who were uninsured in the most recent period for which data is available. In the FY 2024 final rule, CMS used an uninsured rate of 8.3% for FY 2024. In this rule, CMS proposes to use an uninsured rate of 8.7% for FY 2025. **We continue to strongly disagree with these estimates. These are not borne out by the facts. Millions of people are losing Medicaid coverage and becoming uninsured as the Medicaid continuous coverage requirements continue to unwind. As such, we expect to see a *larger increase* in the number of the uninsured in FY 2025.**

To determine uninsured rates, OACT uses projections from the latest National Health Expenditure Accounts (NHEA) historical data, which accounts for expected changes in enrollment across several categories of insurance coverage, including Medicaid. OACT projects enrollment and spending trends for the coming 10-year period; the most recent projections are for 2022 through 2031 and used NHEA historical data through 2021. NHEA projected that in 2024, the uninsured population would increase from 25.7 million in 2023 to 28.6 million in 2024 (an 11% growth rate), rising to 29.8 million in 2025 (an additional 4.2% growth rate). Additionally, NHEA projects that there would be a significant 8.9% drop in Medicaid enrollment in 2024 and continued declines in Medicaid enrollment of 0.7% in 2025.[29] **Taken together, these data lead us to seriously question OACT's certification of an uninsured rate of only 8.7% in FY 2025.** We continue to believe that the uninsured rate would be higher.

Indeed, Medicaid coverage losses, and subsequent uninsured rates, are already substantial as states continue to work through the redetermination process. For example, the Kaiser Family Foundation finds that over a quarter of adults disenrolled from Medicaid are now uninsured.[30] Specifically, only 28% of those who disenrolled from Medicaid were

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[28] https://www.nytimes.com/2024/03/24/opinion/prior-authorization-medical-care.html; https://www.nbcnews.com/health/rejecting-claims-medicare-advantage-rural-hospitals-rcna121012; https://www.npr.org/sections/health-shots/2023/10/17/1205941901/medicare-advantage-rural-hospitals; https://www.beckershospitalreview.com/finance/nearly-half-of-health-systems-are-considering-dropping-ma-plans.html

[29] CMS. National Health Expenditure Projections 2022-2031. https://www.cms.gov/files/document/nhe-projections-forecast-summary.pdf

[30] https://kffhealthnews.org/news/article/quarter-medicaid-disenrolled-uninsured-kff-survey/

able to find coverage elsewhere. Additionally, seven in 10 adults who were disenrolled during the redetermination process became uninsured at least temporarily when they lost Medicaid coverage. Moreover, the number of disenrolled individuals is expected to grow, as states have more months to redetermine enrollees' eligibility. The Urban Institute stated that "as of November 2023, some states had disenrolled more people than [they] had projected for the entire unwinding, suggesting that overall disenrollment could be even greater than anticipated."[31] In fact, the Administration itself, in anticipation of those millions losing Medicaid coverage, extended the temporary special enrollment periods for those who no longer are eligible for Medicaid to transition to Marketplace coverage.[32]

It is difficult to reconcile the agency's own statements on and concern about the declines in Medicaid enrollment with NHEA's analysis, which the agency uses to certify its uninsured rate, when these estimates do not align. In fact, in contrast to NHEA's projections, *CMS itself* in the proposed rule states that Medicaid enrollment is estimated to *decrease* by 13.9% in FY 2024 and 4.3% in FY 2025.[33] This seriously calls into question the underlying data and methods the agency uses to estimate and certify the uninsured rates. **The failure of CMS to publish its methodology severely limits the AHA's ability to comment sufficiently on this issue. The agency has refused to be transparent in its calculations by publishing details of its methodology and how it incorporates NHEA projections, despite stakeholders voicing concerns over this lack of transparency. In a year with continued turbulent coverage losses, we urge CMS to carefully consider its reliance on current data sources and methodologies to estimate the rate of the uninsured. Data and projections that worked when coverage levels were more stable may no longer be adequate during these times of turmoil. We urge CMS to not only publish a detailed methodology on the calculation of Factor 2 and how it uses and incorporates NHEA projections but also to use real-world data from key stakeholders and researchers to arrive at a more appropriate estimate of the uninsured.**

Use of Worksheet S-10 Data

CMS proposes to use three years of audited data to determine uncompensated care payments in FY 2025. Specifically, the agency proposes to use the three-year average of the uncompensated care data from the three most recent FYs for which audited data are available. Therefore, for FY 2025, CMS would average FYs 2019, 2020 and 2021 data to determine the distribution of uncompensated care payments in FY 2025.

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[31] Urban Institute. (May 2024). State Variation in Medicaid and CHIP Unwinding for Children and Adults as of November 2023. https://www.urban.org/research/publication/state-variation-medicaid-and-chip-unwinding-children-and-adults-november-2023

[32] HHS. (Mar 2024). HHS Takes Additional Actions to Help People Stay Covered During Medicaid and CHIP Renewals. https://www.hhs.gov/about/news/2024/03/28/hhs-takes-additional-actions-to-help-people-stay-covered-during-medicaid-and-chip-renewals.html

[33] 89 Fed. Reg. 36192 (May 2, 2024).

The AHA has a longstanding position supporting the use of audited S-10 data to promote accuracy and consistency. We continue to believe that audited data and, by extension, ongoing refinements to the audit process, result in data that are most appropriate for use in Medicare DSH payments. We, therefore, support the use of FYs 2019, 2020 and 2021 S-10 data to determine each Medicare DSH hospital's share of uncompensated care in FY 2025.

Additionally, we appreciate and support CMS' proposal to use a three-year average to determine uncompensated care payments, which would address concerns from stakeholders regarding substantial year-to-year fluctuations in uncompensated care payments. As we have commented previously, utilizing a single year of S-10 data may increase the potential for anomalies and instability in uncompensated care payments — especially when hospitals experience unforeseen circumstances such as a pandemic.

Interim Uncompensated Care Payments

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. For FY 2025, CMS is proposing to use FYs 2021, 2022 and 2023 data to calculate the three-year average. **However, the AHA urges CMS to use alternative data, such as a two-year average instead of three years, to estimate the per-discharge amount of interim uncompensated care payments.** Doing so would better reflect the volume of discharges occurring in FY 2025 as CMS has overestimated discharge volume for the past several years in the proposed rules. In particular, we are concerned that CMS' discharge data from FY 2021, 2022, and 2023 overstates expected discharges and reduces interim uncompensated care payments in FY 2025. The overestimation of discharges depresses interim uncompensated care payments, producing cash flow issues for hospitals, and inadequate interim payments compromise the uncompensated care program's effectiveness in supporting hospital care for uninsured and underinsured patients.

We also support the following DSH proposals:

- Newly Merged Hospitals. CMS proposes to continue its policy to treat hospitals that merge after the development of the final rule like new hospitals. Specifically, the newly merged hospital's (i.e., the surviving hospital's) current FY cost report would be used to determine the hospital's DSH payment. CMS also proposes to continue its policy that interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CMS Certification Number available at the time of the development of the final rule. CMS would then determine the final DSH payment for the newly merged hospital during FY 2025 cost report settlement.
- New Hospitals. CMS proposes to continue its policy for new hospitals. Specifically, for newly established hospitals, 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.

GRADUATE MEDICAL EDUCATION

Medicare direct GME and indirect medical education (IME) funding is critical to educating the physician workforce and sustaining access to care. Yet, the currently insufficient funding levels and limitations 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 several modifications that would affect Medicare GME payments to teaching hospitals.

Distribution of Additional Residency Positions

Section 4112 of the Consolidated Appropriations Act (CAA) of 2023 requires that for FY 2026 an additional 200 Medicare-funded residency positions be distributed. At least 100 of the positions must be for psychiatry or psychiatry subspecialty residency training programs. CMS proposes to use the same method finalized in the FY 2022 inpatient PPS rule to distribute these 200 slots. That is, at least 10% of the aggregate number of total residency positions would be made to each of the four categories of hospitals: 1) hospitals located in rural areas; 2) hospitals operating above their residency caps; 3) hospitals in states with new medical schools; and 4) hospitals that serve health professional shortage areas (HPSAs). The statute limits a qualifying hospital to receiving no more than 10 additional FTEs, and CMS is proposing to first distribute slots such that each qualifying hospital receive up to 1.0 FTE. If any residency slots remain after distributing up to 1.0 FTE to each qualifying hospital, the agency will prioritize the distribution of the remaining slots based on the HPSA score associated with the program for which each hospital is applying. **We refer the agency to our continued concerns regarding the use of the HPSA scores to prioritize certain slots, the determination of hospitals "serving" HPSAs, and the initial limit to 1.0 FTE slot to each hospital when, in reality, a resident occupies one slot for the duration of the training program, which is detailed in our FY 2022 comment letter and a subsequent comment letter on the final rule.**

Additionally, for the 1,000 residents (200 per year) that were distributed under Section 126 of the CAA of 2021, CMS is proposing, for the remainder of the distribution, to prioritize hospitals qualifying under category four, regardless of HPSA score, because it has found that it has not met the statutory requirement to distribute at least 10% of the residents to each of the four categories. **We previously stated that CMS' use of HPSA *scores* during the initial phase of the distribution "[did] not reflect statutory intent [and that] this reliance on HPSAs minimize[d] Congress' other priorities to expand training slots for hospitals in rural areas, training above their cap, and in states with new medical schools" and questioned whether it would meet statutory requirements.[34]**

[34] https://www.aha.org/lettercomment/2022-02-23-aha-comments-cms-hospital-inpatient-prospective-payment-system-final-rule

The agency asserted at the time that this approach would likely result in the statutory minimum of 10% distributions being met for all four of the statutory categories by the end of the five-year distribution process.[35] **Yet this has not borne out and the agency must now prioritize one category over the others for the remaining distribution periods. We had urged the agency in 2022 to prioritize slot distribution based solely on the four categories included in the law and give priority to hospitals that qualify in more than one, with the highest priority given to hospitals qualifying in all four categories.** We continue to urge our original approach and believe that it would be less burdensome and offer a much clearer metric for qualifying hospitals. It also is consistent with the statutory criteria, which do not place any additional emphasis on HPSA service or scores, and still supports teaching hospitals serving underrepresented and historically marginalized populations. We also urge the agency to examine whether previous awardees fall into more than one category and how many awardees may already fall into category four for which the agency has not accounted.

Proposed Modifications to the Criteria for New Residency Programs and RFI

CMS establishes the rules for applying direct GME and IME caps for new medical residency training programs — those established on or after Jan. 1, 1995. The agency previously set the definition of a "new" residency program and adopted supporting criteria regarding whether a residency program can be considered "new" for the purpose of determining if a hospital can receive additional direct GME and/or IME slots for that program. Specifically, to be considered a "new" program, a previously non-teaching hospital would have to ensure that the program meets three primary criteria: 1) the residents are new; 2) the program director is new; and 3) the teaching staff are new.

However, the agency is now proposing more specific policies around the first criterion above. Specifically, it is proposing that to meet the criterion, at least 90% of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. **We have concerns over this proposal. First, we urge CMS to clarify that, if this policy were to be finalized, it would be effective for new residency programs that begin on or after Oct. 1, 2024. The policy should not impact those new residency programs that are currently in their five-year cap building process because these programs did not have such a requirement when they began the process.**

[35] 86 FR 73416. "We thank the commenters for their support. In response to the commenters that disagreed that our proposed approach would result in the minimum statutory distributions being met, we are finalizing our approach, as proposed, to collect information regarding qualification for all four categories in the application to allow us to track progress in meeting all statutory requirements and evaluate the need to modify the distribution methodology in future rulemaking. **However, we continue to believe that our proposed approach will most likely result in the statutory minimum 10 percent distributions being met for all four of the statutory categories by the end of the 5-year distribution process for the 1,000 FTE slots. Therefore, as described in more detail later in this section, we are finalizing our proposal that the residency positions will be distributed to qualifying applicant hospitals using a method that prioritizes allotments based on HPSA scores."**

Additionally, we have concerns over the proposal's impact on those programs that had every intent to meet the threshold of 90% individual trainees being new but through the binding residency matching program, find themselves unable to meet the threshold. This may be particularly true for small or mid-size training programs. For example, there could be programs that had every intent in training at least 90% of postgraduate year one (PGY-1) trainees, but through the binding matching program are unable to fulfill their slots and must pull previously trained PGY-2 trainees. For a small program that may only train 16 residents, this would mean at least 14 of the trainees must be new to meet the threshold. Yet, under CMS' proposal, these programs would be penalized for something completely outside their control. **As such, we urge CMS to allow a program to meet the first criterion by submitting supporting documentation that can demonstrate the program's intent in meeting the 90% threshold.** We also encourage the agency to consider a lower threshold for small and mid-size training programs.

RFI. CMS is also seeking comments regarding potentially "new" programs' selection of a program director and teaching staff and their relative experience, per the second and third criteria listed in the section above. In particular, the agency stated that it wants to avoid new programs essentially taking on all or most of an existing program's experienced faculty, which may lead to closure of that existing program. At the same time, CMS states that it would be reasonable for a new program to wish to hire some staff that already have experience teaching residents and operating a program. As such, the agency believes that there should be some threshold for the relative proportion of non-experienced and experienced staff at a new residency program and is requesting information from commenters what a reasonable threshold might be.

Specifically, CMS is soliciting comments on whether to consider a certain amount of time that would have passed since a program director or faculty member last directed or taught another program in the same specialty. Moreover, the agency is soliciting comments on whether 10 years, or some other amount of time, would be an appropriate period during which a program director or faculty member should not have led or taught in a program in the same specialty.

We are not aware of any other industry or job requirement where experience in the very same field *disqualifies* a person from the job. While we appreciate CMS' desire to avoid the loss of an existing program's experienced program director or faculty, we seriously question the reasonableness of such a policy. It is important to have experienced faculty and program directors to stand up new residency programs, where they have the expertise and knowledge of accreditation requirements and how to properly train the next generation of physicians. **To combat the current physician workforce shortage and ensure that the field continues to train high quality physicians, *experience* is a necessary factor. Therefore, we urge CMS to not finalize any policies regarding an experience threshold for faculty or program directors.**

AREA WAGE INDEX

Permanent Cap on Wage Index Decreases

In last year's rule, CMS finalized a policy to apply a 5% cap on all wage index decreases, regardless of the reason, in a budget neutral manner; it proposes to continue this policy for FY 2025. **The AHA appreciates CMS' recognition that significant year-to-year changes in the wage index can occur due to external factors beyond a hospital's control. While we support this policy that would increase the predictability of inpatient PPS payments, we continue to urge CMS to apply this policy in a non-budget neutral manner.**

Core-based Statistical Areas for the Hospital Wage Index

CMS proposes to apply the most recent labor market areas in the FY 2025 inpatient PPS wage index. The most recent delineations were issued by the Office of Management and Budget (OMB) in July 2023's Bulletin No. 23-01 and include an updated list of Core-based Statistical Areas (CBSAs) that reflect the OMB's new 2020 standards and 2020 Census data. This update will result in a number of significant changes to the existing labor markets. Because CMS will apply the 5% cap on any decrease that hospitals may experience from the prior FY, it is not proposing any transition period and believes that the cap policy would sufficiently mitigate significant financial impacts affected by the proposed OMB updates. **The AHA believes it is vitally important to mitigate the negative effects of the application of the new OMB labor market delineations on hospitals and thanks CMS for applying the 5% cap on wage index decreases.**

Low-wage Hospital Policy

Beginning in FY 2020, CMS finalized a policy to increase wage index values for low-wage hospitals. Specifically, for hospitals with a wage index value below the 25th percentile, the agency increased 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. CMS had indicated that it would adopt this policy for at least four years for low-wage hospitals to use the increased wage index to increase their wages and therefore receive a higher wage index. While this policy had been originally scheduled to expire after FY 2023, CMS has indicated in this rule that it has been unable to disentangle the effects of the COVID-19 pandemic and the low-wage index policy to determine whether the policy has successfully resulted in hospital raising wages to get a higher wage index. Therefore, it is proposing that the low wage index hospital policy and the related budget neutrality adjustment would be effective for at least three more years, beginning in FY 2025.

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 but we maintain that budget neutrality is not a requirement of the statute.

In addition to statutory permissibility, the AHA continues to believe there 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, MedPAC estimates that hospitals' aggregate Medicare margins will be *negative* 13% in 2024. Aggregate Medicare margins in 2022 were a *negative* 12.7% excluding federal relief funds. Unfortunately, these figures are a continuance of a longstanding trend of substantially negative Medicare margins.[36] Taken together, these observations strongly suggest that there is a need to *add* funds into the system, such as by implementing this policy in a non-budget-neutral manner.

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. As such, the AHA urges CMS to implement the low-wage hospital policy in a non-budget neutral manner.

Imputed Rural Floor Calculation

As required by law, CMS proposes to continue the minimum area wage index for hospitals in all-urban states, known as an "imputed rural floor," for FY 2025. 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 to apply this policy in a non-budget-neutral manner. **We support this proposal.**

RURAL HOSPITAL PROVISIONS

Low-volume Adjustment and Medicare-dependent Hospital Program

The CCA of 2024 extended both the low-volume adjustment (LVA) and Medicare-dependent Hospital (MDH) programs through Dec. 31, 2024. Beginning Jan. 1, 2025, the LVA would revert to statutory requirements that were in effect prior to FY 2011. Similarly, beginning Jan. 1, 2025, the MDH program would expire. **The AHA supports Congressional action that would extend the enhanced LVA permanently so that hospitals can continue to qualify for and be paid under the current enhanced method. We also support congressional action to permanently extend the MDH program, with an additional base year that hospitals may choose for calculating**

[36] MedPAC. (2024). March 2024 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch3_MedPAC_Report_To_Congress_SEC.pdf

MDH payments to provide more flexibility for these hospitals to provide care for their patients.

In this rule, CMS is proposing to make conforming changes, including continuing the past process for hospitals to apply for low-volume hospital status and to revert to statutory requirements that would define LVA as one that is located more than 25 road miles from another subsection (d) hospital and has fewer than 800 total discharges. In addition, it proposes the same payment adjustment that was effective from FY 2005 through 2011. Specifically, the agency would apply a 25% LVA to all qualifying hospitals with less than 200 discharges, but hospitals with between 200 and 799 discharges would not receive any adjustment. The agency states that this method is most consistent with the statutory requirement to provide relief to low-volume hospitals where empirical evidence shows higher incremental costs are associated with low numbers of total discharges.

The intent of the LVA program is to support low-volume and isolated hospitals that lack economies of scale and thus have higher standardized costs per stay. **CMS' proposal to only extend the benefits of this program to hospitals with less than 200 discharges would severely undermine the financial stability of rural providers at a time when substantial additional funding, not less, is needed to bolster care in these communities.** For example, while approximately 585 hospitals currently are eligible for the LVA under the enhanced criteria, only 21 hospitals would receive the adjustment under CMS' proposal starting on Jan. 1, 2025. Thus, if CMS' proposal was to go into effect, it would mean that nearly all rural hospitals currently eligible for the adjustment would lose it, cutting nearly $380 million annually in critical funding from rural health care. **We urge CMS to support policies that help rural communities maintain their access to care. As such, it should fully utilize its legal authority to make LVAs to rural hospitals and provide payment adjustment for all those that qualify as having fewer than 800 total discharges.**

In addition, in anticipation of the MDH program expiring, CMS previously revised the sole community hospital (SCH) program to allow MDHs to apply for SCH status. CMS is asking any hospitals uncertain of their status to contact their MACs for verification of their MDH status. **We urge CMS to expeditiously process claims and provide instructions to MACs during program extensions, especially in instances when extensions are made retroactively. Seamless transition of programmatic support is a crucial lifeline for rural providers.**

Hospitals Applying for Rural Referral Center Status

One way in which a hospital can qualify for rural referral 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 use FY 2023 data to calculate case-mix criteria and FY 2022 cost report data to calculate discharge volume. **We support this proposal.**

CHANGES TO MS-DRG CLASSIFICATIONS

Broadly, the AHA supports CMS' proposed changes within the MS-DRG classifications. Given the data, the ICD-10-CM/PCS codes and the information provided, we agree with most proposals. However, we urge CMS to consider the exceptions that are detailed below.

Proposed Changes to the Medicare Code Editor

In the FY 2024 inpatient and long-term care hospital (LTCH) PPS final rule, as noted in the CY 2024 outpatient and ambulatory surgery center (ASC) PPS proposed rule, consistent with the process used for updates to the "Integrated" Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, CMS proposed to address future revisions to the inpatient PPS Medicare Code Editor (MCE) outside of the annual inpatient PPS rulemaking. Specifically, these revisions include any additions or deletions of claims edits and the addition or deletion of ICD-10 diagnosis and procedure codes to the applicable MCE edit code lists.

After consideration of the public comments received in response to the CY 2024 outpatient/ASC PPS final rule, CMS finalized the proposal to remove discussion of the MCE from the annual inpatient PPS rulemaking, beginning with FY 2025 rulemaking, and to address future changes or updates to the MCE through instruction to the MACs.

With the FY 2025 inpatient PPS proposed rule, we acknowledge that CMS made available a draft of the FY 2025 Definitions for Version 42 of the MCE manual to allow the opportunity for public review and comments regarding changes to the MCE that will become effective Oct. 1 of the upcoming fiscal year. In this proposed rule, CMS states that questions, comments, concerns or recommendations regarding the MCE should be submitted to the CMS mailbox at MSDRGClassificationChange@cms.hhs.gov for CMS' review and consideration. While we will submit feedback through that process, we are also providing comment through this comment letter.

The MCE and proposals include essential topics that warrant thorough review and consideration specific to inpatient hospital admissions and operational processes. Specifically, these topics are vital to coding, clinical documentation and revenue cycle professionals to ensure awareness and understanding ahead of implementation and allow the opportunity for comment as applicable. MCE change updates managed outside the inpatient PPS formal rulemaking process create a strong potential for missed opportunities for pertinent public review and comment. These missed opportunities will create the potential for unintended consequences and administrative burdens for hospital teams. A historical review of inpatient PPS comments in response to MCE proposals includes feedback on unacceptable principal diagnoses, age edits, and especially comments that affected the proposal and final implementation of CMS' unspecified code edit implemented in FY 2022. **Therefore, we urge CMS to continue to include inpatient-related MCE proposals as part of the annual rulemaking process.**

Specific to changes to the MCE, the newly created MCE Definitions Manual, effective for FY 2025, is a helpful reference, however, revisions should be explicitly stated as proposed revisions or additions for consideration. **We request that CMS be transparent in thoroughly and clearly outlining the specific MCE proposals related to inpatient admissions as part of the IPPS/LTCH rulemaking content.** For example, the changes to the MCE as stated in version 42 of the MCE Definitions manual are noted in chapter 2 as "a summarization of changes in the edit code lists from the last release of the Medicare Code Editor (MCE) software to the current one". These changes are not listed as proposals within the manual, they are implied as changes that have already been decided and will be effective with the upcoming fiscal year. A specific example being the sex conflict edit which is noted as (Deactivated as of 10/01/2024) in Chapter 2 of the manual. The way in which this is written indicates the change has already been decided with this edit.

Historically, in the FY 2024 IPPS/LTCH proposed rule, we recognize that CMS noted the request then to reconsider the sex conflict edits in connection with concerns related to claims processing for transgender edits. CMS pointed out that the original design of this edit is descriptive of a patient's sex assigned at birth as submitted on the claim. CMS also acknowledged within the FY 2024 IPPS/LTCH proposed rule that the original design of this edit may not be fully reflective of the practice of medicine and patient-doctor interactions. Given that CMS noted that the use of condition code 45 had not been examined in some time, CMS expressed their commitment to looking holistically at the concerns raised by the commenters across care settings to consider how to address future rulemaking and guidance specific to the sex conflict edit. Furthermore, in response to concerns expressed post-publication of the FY 2024 inpatient PPS proposed rule, CMS issued guidance via a Medicare Learning Network Connects (MLN) article on June 8, 2023. This guidance clarified the proper billing and usage of condition code 45 and modifier KX and informed providers of the revised terminology and definition for condition code 45 to "gender incongruence."

We question CMS' intent to deactivate the MCE edit for inpatient admissions as of Oct. 1, 2024. We encourage CMS to revisit and provide details on the outcome of CMS' stated "commitment to look holistically at the concerns raised by the commenters across settings of care to consider how to address for future rulemaking and guidance" before considering deactivating this edit. Additionally, prior to deactivating this edit, we urge CMS to examine the use of condition code 45 since it has not been reviewed in some time. These edits are an additional quality assurance mechanism to ensure appropriate ICD-10-CM/PCS assignment for accurate and timely claims submission. These edits help to prevent added administrative burden associated with unnecessary claims rework and resubmission.

FY 2025 Non-CC Subgroup Criteria Updates

In the FY 2021 inpatient PPS final rule (85 FR 58448), CMS finalized the proposal to expand existing criteria to create a new CC or MCC subgroup within a base MS-DRG. Specifically, CMS finalized expanding the criteria to include the Non-CC subgroup for a three-way severity level split. CMS believed this would better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the Non-CC level MS-DRGs. Since the FY 2022 inpatient PPS final rule, we acknowledge that CMS has continued to delay the adoption of applying this technical criterion to existing MS-DRGs through annual rulemaking finalization.

CMS again proposes to continue to delay the application of the Non-CC subgroup criteria to existing MS-DRGs with a three-way severity level split for FY 2025 as CMS continues to consider the public comments received in response to FY 2024 rulemaking proposals. We agree with CMS' decision to continue delaying the application of the Non-CC subgroup criteria to existing MS-DRGs for FY 2025.

We appreciate that CMS encourages interested parties to review the impacts and other information made available with the alternate test software (V41.A) and other additional files provided in connection with the FY 2024 inpatient PPS proposed rule and provide feedback.

We thank CMS for providing the meaningful data analysis included within the FY 2024 proposed rule. However, the ability to utilize an updated alternate test software and a current batch GROUPER along with additional streamlined data by hospital type is needed. This updated test software and an available batch GROUPER will allow hospitals to analyze the operational and monetary impact of this type of proposed change more thoroughly and over a longer and longer time span.

In response to the request for additional feedback in this FY 2025 inpatient PPS proposed rule to assess the impact of the alternate test software (v41.A), we are reiterating concerns as documented in response to the FY 2024 proposed rule, given that the alternate test software has not been updated to further assess the impacts of the Non-CC subgroup criteria application.

We recommend CMS consider the following.

Again, we appreciate CMS making available the additional files and in-depth analysis associated with the proposed FY 2024 rule. Hospitals must have the opportunity to review information outcomes from the initial alternate software along with continued and new insight gained from an updated alternate test software version. As stated earlier, **we respectively request that CMS provide updated alternate test software so that continued meaningful and longitudinal analysis can be conducted. This continued analysis will allow hospital organizations to better forecast and understand the individual and organizational impact.**

We requested that CMS provide streamlined data analysis by hospital type in FY 2025 rulemaking. Given that data has yet to be provided, we again request this streamlined data analysis for FY 2026 rulemaking. Providing this streamlined data for hospital organizations to review would allow for more specific comments in response to CMS' prior requests for comments related to the experiences of large urban, rural and other hospital types.

We appreciate the additional files and historical information that CMS provided in association with the FY 2024 inpatient PPS proposed rule regarding the Non-CC subgroup criteria to assist with preparation of comment consideration for future rulemaking on this topic. In the FY 2021 inpatient PPS final rule (85 FR 58448), CMS finalized the proposal to expand existing criteria to create a new CC or MCC subgroup within a base MS-DRG but was not transparent within the narrative or files from the proposed rules for FY 2021 through FY 2024 regarding the fluctuation within the MS-DRG proposals year to year. **Thus, we would appreciate CMS' insight regarding the rationale for the dynamic nature of the MS-DRG change applying the Non-CC subgroup criteria. See examples specific to the dynamic nature of changes to follow.**

For example:

- For the FY 2022 inpatient PPS proposed rule, CMS utilized the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file in analyzing the application of the Non-CC subgroup criteria to all MS-DRGs split into three severity levels beginning in FY 2022. Based on CMS' analysis then, the proposal was to delete 96 MS-DRGs and create 58 new MS-DRGs.
- For the FY 2023 inpatient PPS proposed rule, the September 2021 update of the FY 2021 MedPAR file was utilized in the analysis of the application of the Non-CC subgroup criteria to all MS-DRGs split into three severity levels beginning in FY 2023. Based on CMS' analysis at that time, the proposal was to delete 123 MS-DRGs and create 75 new MS-DRGs.
- For the FY 2024 inpatient PPS proposed rule, CMS utilized the September 2022 update of the FY 2022 MedPAR and the December 2022 update of the FY 2022 MedPAR in analyzing the application of the Non-CC subgroup criteria to all MS-DRGs currently split into three severity levels. Based on current CMS analysis, the proposal for FY 2024 included the deletion of 135 MS-DRGs and the creation of 86 new MS-DRGs.
- There were no specific proposals for existing MS-DRG changes that applied the Non-CC subgroup criteria for the FY 2025 proposed rule.

Again, we would appreciate CMS' insight on the above as an opportunity to better understand the rationale for the dynamic nature of the FYs 2022-2024 proposals. As illustrated, not only have the MS-DRG change proposals fluctuated in volume in the FYs 2022-2024 proposals, but the changes among which MS-DRG proposals proposed for deletion and creation have also fluctuated.

Additionally, we want to restate that the proposed Non-CC subgroup methodology, intentionally or unintentionally, eliminates many of the "with CC/MCC" MS-DRGs. For example, as illustrated in Table 6P.10f within the FY 2024 proposed rule for existing MS-DRGs to which the Non-CC criteria has been applied, none of the illustrated changes in that table result in a two-way split with and without CC/MCC. All the MS-DRG two-way splits in the table are with and without MCC only. The direction that this implies is that complication/comorbid conditions increasingly need to be a MCC to impact the complexity and severity of a case. **We are concerned that the impact of CCs is fading without explicit transparency regarding CMS' intent.** We look forward to CMS' response to this concern.

As mentioned in our comments in response to the FY 2023 inpatient PPS proposed rule, we wish to reiterate that the impact of MS-DRG change proposals on smaller community hospitals could be significant as their case mix may be more substantially affected as they likely do not perform as many complex surgeries. For such hospitals, substantial changes in the MS-DRG structure could result in significant financial losses if the MS-DRG redistribution is across all MS-DRGs rather than within related MS-DRG clusters. **We again urge CMS to perform additional analysis for the explanatory power of predicting resource use by hospital types,** i.e., large urban, rural and other hospital types.

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 continued, accurate, thorough and detailed financial analysis, hospitals will be unable to, or be at a disadvantage, renegotiating such MS-DRG-based managed care contracts.

FY 2025 MS-DRG Updates

For this FY 2025 inpatient PPS proposed rule, CMS' MS-DRG analysis was based on ICD-10 claims data from the September 2023 update of the FY 2023 MedPAR file, which contains hospital bills received from Oct. 1, 2022, through Sept. 30, 2023, i.e., these claims data are referred to as the "September 2023 update of the FY 2023 MedPAR file."

MDC 05 – Diseases and Disorders of the Circulatory System – Concomitant Left Atrial Appendage Closure and Cardiac Ablation. CMS received a request to create a new MS-DRG to accommodate better the costs of concomitant left atrial appendage closure (LAAC) and cardiac ablation for atrial fibrillation. CMS acknowledged that it clinically requires more significant resources to perform concomitant LAAC and cardiac ablation procedures based on data analysis. For the FY 2025 inpatient PPS proposed rule, **CMS proposes to create a new base MS-DRG (MS-DRG 317 – Concomitant Left Atrial Appendage Closure and Cardiac Ablation) for cases reporting a LAAC procedure and a cardiac ablation procedure in MDC 05.**

We agree with CMS' analysis that it clinically requires greater resources to perform concomitant LAAC and cardiac ablation procedures and appreciate CMS' willingness to consider changes in MS-DRG assignment for these procedures. **However, we ask that CMS provide insight on the following observations that may influence and drive additional considerations for this MS-DRG proposal.**

CMS' table included in the proposed rule indicates cases with a LAAC and cardiac ablation currently fall into MS-DRG 273 and 274.

MS-DRGs 273 and 274: All Cases and Cases Reporting Concomitant Left Atrial Appendage Closure and Cardiac Ablation				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
273	All cases	7,250	5.4	$35,197
	Cases with a procedure code LAAC and a procedure code for cardiac ablation	80	5.8	$70,447
274	All Cases	47,801	1.4	$29,209
	Cases with a procedure code LAAC and a procedure code for cardiac ablation	781	1.5	$66,277

CMS' analysis of MedPAR data included in the proposed rule indicates the volume of cases that fall into the volume of cases that would be assigned to the new MS-DRG 317.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Concomitant Left Atrial Appendage Closure and Cardiac Ablation	1,723	3.1	$54,629

We ask that CMS provide insight regarding the difference in case volume between these two tables. Specifically, in cases where LAAC and cardiac ablation are performed concomitantly and currently grouped within MS-DRGs 273 and 274 (861 cases) and the volume of cases anticipated to group to the new MS-DRG 317 (1,723 cases), it is unclear from the tables and data associated with this proposed rule where the remaining 862 cases are currently assigned.

In referencing the AOR/BOR report comparing AORv41 with AORv42 MDC 05 MS-DRGs, 18 MS-DRGs have a volume decline. A sample of the larger volumes is captured below for reference. We acknowledge that CMS attributed MS-DRG 273 and 274 to the concomitant LAAC and cardiac ablation. However, there are additional MS-DRGs to which these concomitant procedures are currently attributed. Although the ICD-10 diagnosis and procedure codes that CMS utilized to populate the tables above will expand into other MS-DRGs within MDC 05 (e.g., coronary artery bypass graft MS-DRGs, acknowledging that surgical hierarchy logic occurs during the grouping process).

In the table below, outside of the volumes in MS-DRGs 273 and 274, **we recommend that CMS consider that these concomitant procedures group to some of these other MS-DRGs, depending on the procedures performed, and should be incorporated into the analysis.**

DRG	MS-DRG Description	AOR v41 Cases	AOR v42 Cases	Case Volume Difference
274	PERCUTANEOUS AND OTHER INTRACARDIAC PROCEDURES WITHOUT MCC	51241	50409	-832
229	OTHER CARDIOTHORACIC PROCEDURES WITHOUT MCC	6138	5476	-662
228	OTHER CARDIOTHORACIC PROCEDURES WITH MCC	4657	4483	-174
273	PERCUTANEOUS AND OTHER INTRACARDIAC PROCEDURES WITH MCC	7735	7649	-86
252	OTHER VASCULAR PROCEDURES WITH MCC	19977	19962	-15
243	PERMANENT CARDIAC PACEMAKER IMPLANT WITH CC	19825	19811	-14
244	PERMANENT CARDIAC PACEMAKER IMPLANT WITHOUT CC/MCC	9627	9616	-11
271	OTHER MAJOR CARDIOVASCULAR PROCEDURES WITH CC	12241	12230	-11
242	PERMANENT CARDIAC PACEMAKER IMPLANT WITH MCC	15494	15485	-9
253	OTHER VASCULAR PROCEDURES WITH CC	16394	16386	-8
270	OTHER MAJOR CARDIOVASCULAR PROCEDURES WITH MCC	16516	16508	-8
272	OTHER MAJOR CARDIOVASCULAR PROCEDURES WITHOUT CC/MCC	3909	3901	-8
267	ENDOVASCULAR CARDIAC VALVE REPLACEMENT AND SUPPLEMENT PROCEDURES WITHOUT MCC	39603	39599	-4

MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) – Interbody Spinal Fusion Procedures. In the FY 2024 final rule correction notice (88 FR 77211), CMS noted a manufacturer's request to reassign cases reporting spinal fusion procedures using an aprevo™ customized interbody fusion device from the lower severity MS-DRGs of 455, 458 and 459 to the higher severity MS-DRGs 453, 456 and 460.

We acknowledge that effective Oct. 1, 2021, there were 12 new ICD-10-PCS procedure codes to identify and describe spinal fusion procedures using the aprevo™ customized interbody fusion device. Based on requests for further distinction of these ICD-10-PCS codes, title changes were implemented for these 12 ICD-10-PCS procedure codes used to identify the aprevo™ customized interbody fusion device as reflected in the FY 2024 ICD-10-PCS Code Update files.

Additionally, we recognize that the aprevo™ intervertebral body fusion device technology was approved for new technology add-on payments for FY 2022, and CMS finalized the continuation of the new technology add-on payments for this technology for FY 2023 and FY 2024 for specific indications. And, CMS proposes to discontinue new technology add-on payments for FY 2025 for aprevo™.

In the FY 2024 proposed and final inpatient PPS rules, CMS presented outcomes analysis of claims data from the September 2022 update of the FY 2022 MedPAR file for MS-DRGs 453-460 for cases reporting any one of the 12 original procedure codes describing utilization of an aprevo™ customized interbody spinal fusion device. We acknowledge CMS' agreement that findings from that analysis appeared to indicate that cases reporting a procedure using an aprevo™ customized interbody spinal fusion device reflected a higher consumption of resources. However, due to the concerns indicating coding challenges and potential reliability of the claims data, CMS indicated they would continue to monitor the claims data for consideration in future rulemaking.

For the FY 2025 inpatient PPS proposed rule, CMS analyzed claims data from the September 2023 update of the FY 2023 MedPAR file for MS-DRGs 453-460 for cases reporting any one of the procedure codes describing the use of a spinal fusion procedure using an aprevo™ custom-made anatomically designed interbody fusion device. CMS also

compared this analysis to data provided by the manufacturer. Based on CMS' review and analysis of the spinal fusion cases in these MS-DRGs, CMS' analysis indicates that most of these cases currently group to MS-DRGs 453, 454 and 455. CMS notes that while their analysis does not support the specific manufacturer's requested MS-DRG re-reassignments, new MS-DRGs are warranted to differentiate between multiple-level combined anterior and posterior spinal fusions except cervical, single-level combined anterior and posterior spinal fusions except cervical based on their internal analysis.

We acknowledge that the analysis of the spinal fusion MS-DRGs initiated from a reassignment request that led to the analysis outcomes supporting that approach and multiple versus single level procedures were severity determination factors within these MS-DRGs. Based on this data analysis, CMS proposes to create the following new MS-DRGs:

- MS-DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical).
- MS-DRG 429 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC).
- MS-DRG 430 (Combined Anterior and Posterior Cervical Spinal Fusion without MCC).
- MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC).
- MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC).
- MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC).
- MS-DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC) .
- MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC).

CMS proposes to delete:

- MS-DRG 453 Combined Anterior and Posterior Spinal Fusion with MCC.
- MS-DRG 454 Combined Anterior and Posterior Spinal Fusion with CC.
- MS-DRG 455 Combined Anterior and Posterior Spinal Fusion without CC/MCC.

CMS also proposes to revise the title for existing MS-DRGs 459 and 460 from "Spinal Fusion Except Cervical with MCC and without MCC," respectively to "Single Level Spinal Fusion Except Cervical with MCC and without MCC," respectively.

We acknowledge and support the review of spinal fusion MS-DRGs to consider potential logic revisions. We appreciate and support the distinction that new, revised and expanded spinal fusion MS-DRGs can provide for data analysis, notably in instances where multiple and single-level anatomically different spinal level location procedures are performed during the same operative episode. However, it is essential to address and consider the logic for all spinal fusion MS-DRGs inclusively to maintain the stability of reporting and to ensure a well-rounded capture of the technical complexity and medical severity indications

for these procedures. **Therefore, we request that additional insight and rationale be provided as to the six MS-DRGs that CMS did not incorporate into the analysis and where CMS did not indicate any proposals or where CMS proposes to maintain the current structure related to spinal fusion procedures (MS-DRGs 456, 457, 458, 471, 472 and 473) for FY 2025.**

The data in the table below came from the AOR/BOR v41 and v42 files, and Table 5 provided in the CMS files associated with this proposed rule. It is unclear if the current spinal fusion MS-DRG proposals will better reflect resource consumption based on the relatively minor change in the case mix index between v41 (4.6504) and v42 (4.6545) overall. **While we support CMS' review and consideration of logic changes or potential new MS-DRGs related to spinal fusion procedures, we encourage CMS to consider if the current FY 2025 proposals should be postponed for future rulemaking consideration to ensure that the full complement of all MS-DRGs related to spinal fusion procedures are incorporated into this analysis.**

AOR v41 MS-DRG	AOR v41 case volume	AOR v41 MS-DRG weight	AOR v41 weight total (v41 wt v41 cases)	v41 vs v42 case volume difference	v41 vs v42 wt difference	AOR v42 MS-DRG	AOR v42 volume	AOR v42 MS-DRG weight	AOR v42 weight total (v42 wt v42 cases)
New FY 25				17023	67877.5102	402	17023	3.9874	67877.5102
New FY 25				2833	30329.5314	426	2833	10.7058	30329.5314
New FY 25				13252	95917.9760	427	13252	7.2380	95917.9760
New FY 25				8323	46463.1475	428	8323	5.5825	46463.1475
New FY 25				621	5219.8776	429	621	8.4056	5219.8776
New FY 25				1871	10376.5660	430	1871	5.5460	10376.5660
New FY 25				2200	14818.1000	447	2200	6.7355	14818.1000
New FY 25				15489	64235.9808	448	15489	4.1472	64235.9808
453	4317	8.8614	38254.6638			Delete FY 25	0		
454	21704	6.1163	132748.1752			Delete FY 25	0		
455	17991	4.6056	82859.3496			Delete FY 25	0		
456	1553	8.4294	13090.8582	10	1036.9425	456	1563	9.0389	14127.8007
457	3946	6.0753	23973.1338	25	-399.2923	457	3971	5.9365	23573.8415
458	1310	4.531	5935.6100	8	-160.0022	458	1318	4.3821	5775.6078
459	3355	6.6323	22251.3665	-2185	-16139.6375	459	1170	5.2237	6111.7290
460	30272	3.6579	110731.9488	-15446	-64256.8866	460	14826	3.1347	46475.0622
471	3121	4.919	15352.1990	0	-139.1966	471	3121	4.8744	15213.0024
472	14096	2.9554	41659.3184	0	-429.9280	472	14096	2.9249	41229.3904
473	6424	2.4606	15806.8944	0	-400.8576	472	6424	2.3982	15406.0368
TOTAL	**108089**		**502663.5177**		**487.6426**		**108101**		**503151.1603**
CMI			**4.6505**					**4.6545**	

Regarding CMS' proposed conforming changes to the surgical hierarchy associated with these MS-DRG proposals, we acknowledge that the MS-DRG weight impacts the cost analysis, which in turn affects the hierarchy within the GROUPER. Given that, it is crucial to consider that it is not all multiple level spinal procedures that are having the highest impact on the MS-DRG surgical hierarchy, it is the fact they are combined approach procedures. **MS-DRGs 453, 454, 455, 426, 427, 428, 402, 429 and 430 are the four highest MS-DRG categories listed in the proposed surgical hierarchy MDC 08 table, all of which are the combined approaches**. In the multiple level not combined approach, MS-DRGs 447 and 448 fall below the single level combined and the "any level" for specific diagnosis in MS-DRGs 402, 456, 457 and 458.

While we agree with the surgical hierarchy, we believe there is supporting data that it is not just multiple level spinal procedures that impact the MS-DRG length of stay and charges as the combined approach warrants the highest hierarchy regardless of single or multiple levels. The proposed rule content suggests that the number of levels impact resources and reimbursement. However, the data to differentiate cases where both multiple and single level procedures were performed on the same patient/same operative episode having impact to resources and charges did not appear to be evident in the data analysis provided.

Proposed Surgical Hierarchy: MDC 08	
Delete MS-DRGs 453-455	Combined Anterior and Posterior Spinal Fusion
Proposed New MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRGs 429-430	Combined Anterior and Posterior Cervical Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions
Proposed New MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical
Proposed New Title MS-DRGs 459-460	Single Level Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity
MS-DRGs 471-473	Cervical Spinal Fusion

If CMS moves forward with the proposed spinal fusion MS-DRG additions and revisions, we ask that CMS revisit the proposal to revise the titles for MS-DRGs 459 and 460 due to the impact on reporting specific to the difference in the description of these MS-DRGs and inability to compare accurately moving forward. The titles of these MS-DRGs are proposed to shift from including multiple and single levels to only including single levels. **We ask CMS to consider the creation of two new MS-DRGs instead of revising the titles and to delete MS-DRGs 459 and 460 like the proposed revisions for MS-DRG 453, 454 and 455.**

Comprehensive CC/MCC Analysis

In the FY 2021 proposed inpatient PPS rule, CMS noted its internal workgroup developed a set of guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. CMS noted the intent to use a combination of mathematical analysis of claims data and applying these guiding principles to continue a comprehensive CC/MCC analysis.

In the FY 2025 inpatient PPS proposed rule, CMS proposes to adopt these nine guiding principles as written. In response to this FY 2025 proposal, we are restating or repackaging our original comments specific to these nine guiding principles for CMS' review and feedback for reconsideration in adopting them.

CMS' proposed nine guiding principles:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

Again, we appreciate the opportunity to comment on CMS' proposed nine guiding principles**. Applying these guiding principles represents a consideration for revision to the definition of a CC and could result in significant hospital reimbursement implications.** Specifically, the MS-DRG Definitions Manual, version 41.1 and proposed version 42, provides the following definition: "A substantial complication or comorbidity is defined as a condition that because of its presence with a specific principal diagnosis would cause an increase in length of stay by at least one day in at least 75 percent of the patients."

Some of our concerns with the proposed nine guiding principles include the following.

We acknowledge that CMS provided some illustration in the 2024 inpatient PPS proposed rule. However, there still needs to be more clarity and insight on how the mathematical criteria would be used *with* the proposed guiding principles to determine ICD-10-CM diagnosis code severity levels. It is important to understand if the conditions must meet both mathematical criteria and all, some or one of the guiding principles to be considered severity level designation. For example, CMS does not state how it will handle conditions that would not fit any guiding principles, such as obstetrical diagnoses, congenital conditions or potentially social determinants of health conditions but could meet the mathematical calculation and therefore be considered CC/MCC.

Some guiding principles appear overly strict and go beyond the conventional definition of CC/MCCs; others are too lax and duplicative in their coding requirements for reporting secondary diagnoses.

There is a lack of detailed definitions and criteria for applying the guiding principles. The principles are vague, subjective and open to interpretation without such transparency. For example, the definition of “impedes patient cooperation and/or management of care” is unclear.

Many of the guiding principles seem too strict and could potentially eliminate CCs, leaving only MCCs, thus inadvertently eliminating the current 3-tier severity levels in the MS-DRG system.

The principle requiring a “chronic illness with susceptibility to exacerbations or abrupt decline” cannot be applied across the board, as many ICD-10-CM diagnosis codes do not distinguish exacerbation. Only a handful of ICD-10-CM codes specify “acute on chronic” as part of the code descriptor.

Principles such as “reflects systemic impact” introduce a new requirement that CC/MCCs have not had to meet. Many existing CC/MCCs are limited to a single-body system. Therefore, it remains unclear what the guideline means by “systemic impact.”

The principle “Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay)” overlaps in many respects with Section III of the ICD-10-CM Guidelines for Coding and Reporting regarding what is a reportable secondary diagnosis which states:

- For reporting purposes, the definition for “other diagnoses” is interpreted as additional conditions that affect patient care in terms of requiring:
    - Clinical evaluation; or
    - Therapeutic treatment; or
    - Diagnostic procedures; or
    - Extended length of hospital stay; or
    - Increased nursing care and/or monitoring.

We question how the principle specific to “post-operative condition/complication impacting recovery” would be applied. There are still challenges associated with capturing all post-operative conditions with ICD-10-CM codes as the codes do not always include the terms “post-operative” or “post-procedural” nor are the conditions within a specific ICD-10-CM chapter.

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

We question the validity of the principle related to “recent (last 10 years) change in best practice, or in practice guidelines” and consider that medical conditions’ best practices continue to evolve and change over a 10-year time span. The guiding principles are open

to different interpretations without clear definitions and guidance on applying these principles.

Prior to finalizing the adoption of these nine guiding principles, we request that CMS review and distinctly address the above noted concerns in addition to other public comments that are raised.

Proposed CC Exclusions

Within this FY 2025 inpatient PPS proposed rule, CMS outlines the five reasons for which CMS created the CC exclusions list as established in the May 19, 1987, proposed notice (52 FR 18877) and the Sept. 1, 1987, final notice (52 FR 33154). This list contains certain diagnoses included on the standard CC list that would not be considered valid CCs in combination with a particular diagnosis. These five reasons include:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another.
- Specific and nonspecific (that is, not otherwise specified diagnosis codes for the same condition should not be considered CCs for one another.
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another.
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another.
- Closely related conditions should not be considered CCs for one another.

The CC Exclusion List has continued to be reviewed and revised as applicable and is included as Appendix C in the ICD-10 MS-DRG Definitions Manual, Part 1 and Part 2. Part 1 contains a list of all diagnosis defined as CC or MCC when reported as secondary diagnosis. Part 2 contains a list of diagnosis codes designated as an MCC only for patients that are discharged alive, otherwise, they are assigned as a NonCC.

In conjunction with the April 1, 2024, ICD-10-CM/PCS updates, a new section was added to Appendix C, “Part 3 Secondary Diagnosis CC/MCC Severity Exclusions in Select-MS-DRGs”. This new Part 3 contains a list of diagnosis codes designated as CC or MCC included in the definition of the logic for the listed MS-DRG. When reported as a secondary diagnosis and grouped to one of the listed MS-DRGs as indicated within this Part 3, the diagnosis is excluded from acting as a CC/MCC for severity in MS-DRG assignment. Although not a new concept, we acknowledge that CMS now refers to this concept as “suppression logic” and added the new Part 3 to provide transparency related to this concept.

In CMS’ review of the MS-DRGs containing secondary diagnosis logic in association with

the suppression logic, CMS noted an additional set of MS-DRGs containing secondary diagnosis logic in the definition of the MS-DRG. These include:

- MS-DRG 673 (Other Kidney and Urinary Tract Procedures with MCC).
- MS-DRG 674 Other Kidney and Urinary Tract Procedures with CC).
- MS-DRG 675 (Other Kidney and Urinary Tract Procedures without CC/MCC).

Under version 41.1 ICD-10 MS-DRGs, diagnosis code N18.5 (Chronic kidney disease, stage 5) is designated a CC, and diagnosis code N18.6 (End stage renal disease) is designated an MCC. CMS notes that these diagnosis codes are excluded from acting as a CC or MCC, when reported with principal diagnoses as reflected in Part 1 of Appendix C in the CC exclusion list.

CMS proposes to correct the logic for case assignment to MS-DRGs 673, 674 and 675 by adding suppression logic to exclude diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease) from the logic list entitled “With Secondary Diagnosis” from acting as a CC or an MCC, respectively, when reported as a secondary diagnosis with one of the 13 principal diagnosis codes as listed in Part 1 of Appendix C in the exclusion list. With this proposal, in cases where the diagnosis code N18.5 or N18.6 is reported as a secondary diagnosis with one of the diagnosis codes listed in Part 1 of Appendix C in the exclusion list, the GROUPER will assign MS-DRG 675 (Other Kidney and Urinary Tract Procedures without CC/MCC) in the absence of any other MCC or CC secondary diagnoses reported.

We request that CMS reconsider this proposal as we disagree with the application of the suppression logic within MS-DRGs 673, 674 and 675 when diagnosis N18.5 or N18.6 is assigned as a secondary diagnosis in conjunction with one of the principal diagnosis codes listed in Part 1 of Appendix C in the CC exclusion list. ICD-10-CM codes N18.5 and N18.6 are the highest level of severity for kidney failure with end stage and stage 5 both of which require dialysis and/or kidney transplant. The only principal diagnoses that could meet one of the five principles would be I12.0 (Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease) or I13.11 (Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease or end-stage renal disease) as these two codes actually indicate stage 5 chronic kidney disease or end stage renal disease in the narrative description. We believe that the five conditions established for exclusions were not met for the majority of the diagnoses on the principal diagnosis list and for that reason should not be subject to suppression logic.

NEW TECHNOLOGY ADD-ON PAYMENTS

CMS proposes to increase the new technology add-on payment (NTAP) percentage from 65 to 75 percent for certain gene therapies approved for the treatment of sickle-cell disease (SCD). This would be effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period. CMS notes that if finalized, this

policy would be temporary; these payment amounts would only apply to the gene therapy indicated and used specifically for the treatment of SCD that CMS approves for FY 2025 NTAPs. **The AHA appreciates CMS' proposal to increase the payment percentage form 65 to 75 percent for these technologies and urges CMS to increase the marginal payment rate to at least 80 percent.** Moreover, we have concerns over the rise of these high-cost therapies generally and CMS' ability to appropriately account for their costs when determining payments to hospitals and health systems.

NTAPs are intended to recognize the costs of new medical services and technologies under the hospital inpatient PPS by providing additional payments for eligible cases until CMS has sufficient data for MS-DRG rate setting. These payments are not budget neutral and NTAPs may be provided for two to three years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. After that point, payments for these technologies are incorporated into the existing payment system budget neutral to what the inpatient PPS was without them included. However, many of these therapies' prices are beyond what would have been predicted when the inpatient PPS system was designed. They are therefore adding to the existing and rising challenge of paying for a massive increase in high-cost therapies and technologies in health care. **We are concerned about CMS' ability to appropriately reimburse for new services and technologies in the near future, given the rise of these high-cost emerging therapies and urge CMS to examine the adequacy of its payments to hospitals.**

PROMOTING INTEROPERABILITY PROGRAM FOR HOSPITALS

Broadly, the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) Rule, published on Jan. 9, 2024, finalized the "Base EHR definition" that would be applicable for the certified electronic health record technology (CEHRT) definitions going forward. CMS also finalized the replacement of their references to the "2015 Edition health IT certification criteria" with "ONC health IT certification criteria." AHA appreciates that CMS has aligned the definition of CEHRT with the Office of the National Coordinator for Health Information Technology (ONC) and simplified the update process for CEHRT definitions by requiring them to meet ONC's health IT certification criteria, thus creating a harmonized definition. However, the AHA questions why the FY 2025 rule also suggests changes to the definition of CEHRT in the Medicare Promoting Interoperability Program based, in part, on the definition of Meaningful EHR User in the HHS proposed 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (information blocking rule). This rule is not yet finalized and proposes a confusing disincentive structure with penalties that are excessive, potentially overlapping and unfair. See AHA's comments on that proposed rule. **As such, the AHA strongly recommends that any proposed changes to the Medicare Promoting Interoperability Program (MPI Program), based on the information blocking rule, be delayed at least until FY 2026 or after the information blocking rule is finalized.**

More specifically, CMS is proposing updates to Antimicrobial Use and Resistance (AUR) Surveillance, electronic clinical quality measures (eCQMs), performance-based scoring thresholds, the Security Risk Analysis and SAFER guides measure of the MPI Program for eligible hospitals and critical access hospitals (CAHs), and an RFI describing goals and principles for the MPI Program's Public Health and Clinical Data Reporting objective in the FY 2025 proposed rule.

AUR Surveillance

CMS proposes to split the AUR Surveillance measure into two measures, one for Antimicrobial Use (AU) Surveillance and one for Antimicrobial Resistance (AR) Surveillance, starting from the EHR reporting period in CY 2025; add a new exclusion for eligible hospitals or CAHs that do not have electronic access to the data elements needed for AU or AR Surveillance reporting; change the existing exclusions for the AUR Surveillance measure to apply to the AU Surveillance and AR Surveillance measures, respectively; and consider the AU Surveillance and AR Surveillance measures as two new measures for active engagement starting from the EHR reporting period in CY 2025. **The AHA is not opposed to this proposed change. There are different technical and data requirements for capturing each measure, so separating the measures is logical and, per CMS' estimates, the additional reporting burden associated with this proposed change is less than a minute per year for each eligible hospital and CAH. Additionally, each eligible hospital or CAH will still be able to qualify for an exception for either or both measures, without a loss of total points available. As in prior years, exceptions in this category will result in points being redistributed across the "Public Health and Data Exchange" category and if exceptions are met for all six categories, 25 points will be redistributed to the "Provide Patients Electronic Access to their Health Information" measure.**

eCQMs

The proposed rule adopts two new eCQMs for eligible hospitals and CAHs to select as one of their three self-selected eCQMs, modifies the Global Malnutrition Composite Score eCQM, and changes eCQM data reporting and submission rules. **AHA comments on the proposed changes to eCQMs are in the quality reporting section of this letter.**

Scoring Threshold

Next, CMS proposes increasing the performance-based scoring threshold for eligible hospitals and CAHs reporting to the MPI Program from 60 points to 80 points beginning with the EHR reporting period in CY 2025. **AHA does not support this change, however, as the data CMS cites is cause for some alarm.** In the proposed rule, it's noted that "the CY 2022 Medicare Promoting Interoperability Program's performance results indicates 98.5% of eligible hospitals and CAHs currently successfully meet the threshold of 60 points while 81.5% of eligible hospitals and CAHs currently exceed a score

of 80 points. If this proposal is finalized, the 17% of eligible hospitals and CAHs that meet the current threshold of 60 points but not the proposed threshold of 80 points would be required to better align their health information systems with evolving industry standards and/or increase data exchange to raise their performance score or be subject to a potential downward payment adjustment." Based on this calculation, over 1,000 hospitals would not meet the new scoring threshold and would be adversely impacted by this change. **AHA recommends that the change in scoring is pushed back to CY 2027 to allow ample time for all hospitals to adjust to the reporting requirements.**

Security Risk Analysis, SAFER Guides

Additionally, the Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored in FY 2025; however, the proposed rule states that HHS intends to consider how the MPI Program can promote cybersecurity best practices for eligible hospitals and CAHs in the future. **AHA questions why this measure is necessary, given that it is based directly on HIPAA Security Rule Safeguards and would already be required for HIPAA compliance.**

MPI Program RFI

Finally, aside from the proposed changes in measures, CMS solicits feedback in response to a series of questions related to the interoperability objective and related topic.

Goal #1: Quality, Timeliness and Completeness of Public Health Reporting. What are the risks of including too many measures under the objective? Having too many measures under this objective presents several risks. First, additional measures can increase the program's complexity, making it challenging for hospitals to comprehend and adhere to its requirements. Next, each measure necessitates data collection, reporting and analysis, which can be resource-intensive, particularly for smaller hospitals and CAHs. Also, the focus may shift from key objectives due to the addition of multiple measures, diluting the program's impact and effectiveness. Additionally, the program is seen as overly complex or burdensome, it may deter participation, limiting its reach and impact. Lastly, the quality of collected data could be compromised with too many measures, potentially leading to inaccurate or misleading results.

Goal #2: Flexibility and Adaptability of the Public Health Reporting Enterprise. What, if any, challenges exist around sharing data with PHAs? Data sharing with public health agencies (PHAs) presents several challenges. These include interface-related issues, such as technical problems with data formatting or transmission and system compatibility. Also, many smaller hospitals still lack the capacity for efficient electronic exchange due to insufficient technology, expertise or resources. Additionally, although the use of artificial intelligence (AI) has shown significant promise in organizing and translating unstructured data, the use of different vocabulary standards, specifically in "free text" documentation, can hinder EHR information extraction and exchange even in larger

hospitals and health systems. Finally, inconsistent requirements across various PHAs can create disparities in reporting practices, complicating the process for hospitals, and despite technological advancements, many hospitals still rely on manual processes for data transmission to those agencies, which can be error-prone and time-consuming.

Expansion of non-technical measures in the MPI program. Although this question was not raised by CMS in the MPI Program RFIs, we feel it is warranted to comment on the overall growth of the MPI program. Given the continuous expansion of non-technical measures and guidelines in the interoperability rule, we urge CMS to consider the strategic objectives of the rule and how well that still aligns with the original mission of enabling better patient access to their health information and improving interoperability.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM

The inpatient quality reporting (IQR) program is CMS' pay-for-reporting program in which hospitals must submit measures and meet other administrative requirements to avoid a payment reduction equal to one quarter of the annual market basket update. The IQR program also includes a requirement to report on selected EHR-derived eCQMs using CMS-mandated reporting standards. The IQR eCQM reporting requirements align with the eCQM reporting requirements in the Promoting Interoperability Program.

CMS proposes to add seven new measures to the IQR while removing five other measures. CMS also proposes to increase the total number of eCQMs required for reporting and to begin validating the accuracy of hospital eCQM data. Lastly, CMS proposes changes to the HCAHPS survey questions, resulting in changes in the sub-measures used to calculate performance.

Patient Safety Structural Measure. CMS proposes to add this measure to the IQR for the CY 2025 reporting/FY 2027 payment years. The measure assesses whether hospitals are implementing 25 separate policies and practices across five domains that the agency believes would lead to safer care in hospitals. The measure is attestation-based — that is, hospitals would answer yes or no to whether they implement specific practices. Hospitals would receive a score out of five possible points, and CMS would score each measure domain as "all-or-nothing." That is, for a given domain, if a hospital could not attest "yes" to all the practices within the domain, they would receive zero points.

Patient safety is top priority for hospitals and health systems, and we share CMS' goal of bolstering and accelerating patient safety efforts. Several practices included in the measure have merit and many already are in use across hospitals. However, the AHA is concerned that parts of the proposed measure would be redundant or inconsistent with other CMS regulatory requirements for hospitals and lack evidence tying their use to safer patient outcomes. The sheer number of attestations included in the measure make it take on the appearance of a survey rather than a performance measure, raising questions about its meaningfulness in the context of a hospital measurement program. **For these reasons, we urge CMS not to adopt the measure in its current form. If the agency is**

intent on adopting a structural measure of safety, we urge the agency to consider a streamlined version that does not overlap with existing regulations and that reflects known and significant gaps.

To be clear, while the AHA is skeptical of the proposed patient safety structural measure value, the commitment of our member hospitals and health systems to advancing patient safety is unwavering. Indeed, hospitals and health systems have long known that delivering safe care is a continual process that requires persistent focus, leadership engagement and a relentless process of assessment, measurement, implementation, learning and improvement. This steadfast commitment led to significant improvements in patient safety in the years leading up to the COVID-19 pandemic, including double-digit percentage reductions in healthcare associated infections (HAIs) and other preventable adverse events. This same commitment led to a groundswell of hospital and health system interest in bolstering and accelerating patient safety efforts in the wake of the pandemic's unprecedented disruptions to the field. In November 2023, the AHA launched a member-designed and led Patient Safety Initiative to provide a platform for hospitals and health systems to collaborate on high priority safety practices such as culture of safety, health equity and workforce safety. The AHA welcomes the opportunity for ongoing discussions with CMS about how this effort can complement CMS' ongoing patient safety work and other national efforts.

In the meantime, we are not confident for several reasons that the proposed structural measure will lead to the advancements in patient safety that CMS envisions. **First, several practices in the measure overlap extensively with CMS' CoPs, raising questions about the measure's added value.** Specifically, the practices in the Leadership (Domain 1) and Strategic Planning and Organizational Policy (Domain 2) largely reflect whether hospitals have patient safety included in their strategic plans, allocate resources to patient safety activities and have mechanisms for sharing both the goals and progress with organizational leaders, staff and their boards, and executive level accountability for results. Yet, hospitals already have such requirements as part of the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21(a)-(e). In addition, providing access to patient information (Domain 5, practice #3) is already a requirement of the CMS Promoting Interoperability program.

We also are concerned that several practices lack clear evidence linking their implementation to better outcomes, are written in ways prone to inconsistent interpretations and are inconsistent with other regulation. For example, attestation 1D asks whether hospitals spend at least 20% of their board and "senior governing board meetings" on patient and workforce safety. Yet, CMS does not present evidence linking these two practices to better patient safety outcomes. It also does not specify exactly what is meant by "regular board agenda" or "senior governing board" meetings. Indeed, it is very common for hospitals and health systems to have quality and patient safety subcommittees of their boards that conduct in depth oversight of quality and safety activity and that provide regular reports to the full board. CMS' attestation guide for the measure is silent on the role of such subcommittees. In addition, CMS's QAPI CoP provides hospitals

with the flexibility to articulate what processes its governing boards use to conduct oversight. Yet, this structural measure would seem to contradict the flexibility under CoPs.

Similarly, attestation 1E asks whether hospital governing boards are notified within three business days of "any confirmed serious safety events." CMS does not provide evidence linking this three-day timeframe to better outcomes, and the agency's own draft attestation guide acknowledges that "some incidents may require more immediate reporting per state and local laws." The inclusion of a specific timeframe for sharing safety events with a governing board also contradicts the flexibility afforded to hospital boards under 42 CFR 482.21(e)(3) which gives the governing board the ability to set clear expectations for safety, which would include the appropriate processes and timeframes for sharing safety events.

Even more concerning, attestation 4B appears to be inconsistent with the intent of the Patient Safety and Quality Improvement Act (PSQIA) of 2005. If CMS is intent on adopting this measure, at a minimum, we urge the agency to remove attestation 4B from the measure entirely. Specifically, the attestation asks hospitals whether they report safety events to patient safety organizations (PSOs) that voluntarily report data to the Agency for Healthcare Research and Quality's (AHRQ) network of patient safety databases. Yet, the PSQIA explicitly made both hospital participation in PSOs and the reporting of data from PSOs to AHRQ voluntary. By including this attestation in the measure — and potentially giving hospitals zero points for the entire domain if they do not answer yes — CMS has seemingly developed a *de facto* mandate for hospitals to participate in PSOs and for those PSOs to report data to AHRQ. Simply put, this approach is not only inappropriate but raises questions about CMS' statutory authority to implement the measure.

We also encourage CMS to work with the OMB to clarify whether the patient safety structural measure actually is a measure and not a survey that may require additional OMB processing to field. Indeed, the Paperwork Reduction Act generally requires that surveys sent to more than nine respondents undergo OMB review and have at least a 30-day public comment period on the survey instrument. For example, when CMS has adopted changes to its HCAHPS survey, they have offered a public comment period beyond those afforded as a part of the rulemaking process. Given that this structural measure is comprised of 25 individual attestations answered in yes or no form, it creates the potential appearance of being a survey.

CMS' apparent challenges in identifying evidence-based practices suitable for a safety structural measure underscores why the AHA prefers the use of outcome measures in CMS' quality measurement and value programs rather than structure or process measures. Outcome measures both reflect actual results and give hospitals the flexibility to design interventions that lead to higher levels of achievement, rather than locking them into practices that may not have a strong tie to outcomes.

Nevertheless, the AHA appreciates that there likely are at least a few critical practices that if implemented consistently could help accelerate safety efforts. **Thus, if CMS is intent on developing a structural measure focused on safety, we encourage the agency to develop a more streamlined version of the current measure that does not contradict other regulation and that addresses known gaps.** Indeed, at least part of the shortcoming of this structural measure stems from the fact that it does not appear to have been fully tested in hospitals. Indeed, when the measure was reviewed as part of the Pre-Rulemaking Measure Review process earlier this year, the preliminary analysis from the Consensus-Based Entity noted that entity-level reliability testing was not performed, performance scores were not reported, workflow analysis was not conducted, and empirical evidence of an association with the study population was not provided by the developer. This information would be important to understanding the suitability of the measure for rulemaking, as would information on potential gaps in practices.

Age-Friendly Hospital Structural Measure. CMS proposes to add this measure to the IQR for the CY 2025 reporting/FY 2027 payment years. The measure assesses whether hospitals implement certain policies and practices that CMS believes are linked to better care and outcomes for older adults (i.e., age 65 and over). Like the patient safety structural measure described above, this measure would be attestation-based. Hospitals would answer yes or no to whether they implement specific practices. This proposed measure consolidates two previously separate measures that CMS was considering.

The AHA strongly supports efforts to make health care better for older adults. In fact, the AHA leads the Age-Friendly Health Systems initiative in partnership with the John A. Hartford Foundation and the Institute for Healthcare Improvement. The goal is to rapidly spread a specific framework that ensures that every older adult's care is guided by an essential set of evidence-based practices and is consistent with what matters to the older adult and their family. More than 2,800 health care organizations in the U.S. are now part of this movement. We also appreciate CMS and the measure developers' responsiveness to stakeholder feedback to consolidate its two previously separate age friendly structural measures into a single more streamlined version.

However, the AHA urges CMS to reconsider adopting this measure for the IQR. Like the proposed patient safety structural measure, we are concerned that the attestations in this measure are written in ways that are prone to inconsistent interpretations and implementation across hospitals. For example, several of the questions ask hospitals to confirm whether they "have protocols" for establishing certain processes. While such general statements might make sense in a best practices guide, they are not clear and specific enough for a structural measure whose purpose is to report comparable information about the quality of care in a hospital.

Furthermore, CMS does not present clear evidence showing that the implementation of this structural measure leads to better outcomes for older adults. Indeed, CMS acknowledges this concern, but in response, the agency simply asserts in the proposed rule's preamble that "we have concluded that this measure does support reliable practices

that drive change, transparent reporting and prioritization of resources to implement those best practices." It is also not clear whether the measure has successfully identified practices on which there are gaps in implementation. When the previous versions of this measure were presented through the pre-rulemaking review process, many of the practices were close to topped out, raising questions about whether this is also the case for this revised measure. Simply put, the implementation of a measure on which there is a limited performance gap would be a wasteful use of limited resources. Indeed, these concerns likely contributed to why the pre-rulemaking review process did not reach consensus on the suitability of this measure for the IQR program.

The AHA acknowledges the lack of measures that focus on geriatric surgical care and would be pleased to engage with CMS to develop further ideas for outcome-based measures that help us identify gaps in care for older adults. However, implementing attestation-based measure with potentially small performance gaps and unclear attestations is unlikely to lead to improvement in care for the geriatric population.

HAI Measures for Inpatient Oncology Locations. The IQR has long included several measures assessing the rates of HAIs, including catheter-associated urinary tract infections (CAUTI) and central-line associated blood stream infections (CLABSI). In the proposed rule, CMS notes that oncology patients are at significantly higher risk for developing HAIs during hospitalization. As a result, beginning with the CY 2026 reporting/FY 2028 payment years, CMS proposes to report hospitals' CAUTI and CLABSI standardized infection ratios (SIR) stratified for inpatient oncology locations. In the proposed rule, CMS stresses that these new measures would "supplement, not duplicate, the existing hospital CAUTI and CLABSI measures." That is, CMS would continue to report overall hospital SIRs for CAUTI and CLABSI, while also reporting SIRs specific to the hospital's inpatient oncology units.

The AHA supports this proposal. At the same time, we encourage CMS to conduct analyses prior to publicly reporting the measure to ensure the measure generates equitable comparisons across hospitals. As CMS notes in the rule, not all hospitals will have sufficient volumes to report reliable data on oncology locations or may simply not have oncology units. Furthermore, even across hospitals that have sufficient volume to report on oncology locations for CAUTI and CLABSI, there is variation in the acuity and mix of oncology services provided across hospitals. It will be important for CMS to ensure a level playing field across hospitals in publicly reporting performance.

Hospital Harm – Falls with Injury eCQM. CMS proposes to add this measure to the menu of available IQR eCQMs beginning with the CY 2026 reporting/FY 2028 payment years. The measure assesses the risk-adjusted ratio of hospitalizations with at least one fall with moderate or major injury. The measure includes a risk adjustment model that CMS asserts would ensure hospitals that care for sicker and more complex patients are evaluated fairly. The risk adjustment model accounts for age and certain clinical risk factors for falls, such as weight loss or malnutrition, delirium, dementia and other neurological disorders.

The AHA supports adding this measure to the menu of available eCQMs. However, we urge CMS not to require its reporting until it can examine several critical issues affecting the validity of measure data and the potential for negative unintended consequences. As a general matter, the AHA is pleased that CMS is considering patient safety measures using real clinical data from EHRs instead of claims-based data. If implemented appropriately, patient safety-focused eCQMs can result in timelier and more accurate data because claims often lack enough detail on patient clinical risk factors and history to calculate performance accurately. At the same time, the pre-rulemaking review of this measure raised important concerns that we urge CMS to explore further. For example, there are questions about variations in the capture of data by EHR vendor; as a result, clinicians may be using structured fields differently to input data, and documentation may not be captured in a standardized manner. This could lead to measure performance being more dependent on the sensitivity of the screening technologies and approaches used than on underlying performance.

Furthermore, the importance of preventing falls with injury must be carefully balanced with the benefit of early patient mobilization, which is often critical for recovery. As CMS implements the measure and considers publicly reporting the results, we encourage CMS to monitor results carefully to ensure the measure does not create an inadvertent disincentive for early patient mobilization. For example, CMS could conduct focus groups with a variety of hospitals, including those that perform large numbers of procedures in which early mobilization may be indicated (e.g., some orthopedic and cardiovascular procedures).

Hospital Harm – Postoperative Respiratory Failure eCQM. CMS proposes to add this measure to the menu of eCQMs available for the IQR beginning with the CY 2026 reporting/FY 2028 payment years. The measure calculates the risk-adjusted rate of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure. At a high level, post-operative respiratory failure is defined as unplanned intubation or prolonged mechanical ventilation after an operation.

Similar to the falls with injury eCQM, the AHA supports adding this measure to the menu of available eCQMs but urges CMS not to require its reporting at this time. The concerns described above regarding the variation in the capture of data across EHR vendors also apply to this measure. Furthermore, this proposed measure was tested only in teaching hospitals, raising questions about whether it is feasible to implement for all hospital types. Lastly, CMS also should carefully examine the potential for unintended consequences with the implementation of this measure that were raised by stakeholders during the pre-rulemaking measure review process. For example, some raised concerns that the use of this measure could result in inappropriate use of noninvasive positive pressure ventilation in lieu of mechanical respiration, excessive use of preventive tracheostomy, or avoidance of offering necessary procedures for high-risk patients.

Failure-to-Rescue Measure. CMS proposes to add this claims-based measure to the IQR beginning with the FY 2027 program year. The measure calculates a rate of deaths among certain inpatients following a preventable hospital-acquired complication. The measure would replace PSI-04 (Death Among Surgical Inpatients with Serious Treatable Complications) that CMS has proposed to remove from the IQR. CMS asserts that the Failure-to-Rescue measure improves upon PSI-04 in several ways. For example, CMS believes that the proposed measure focuses on a less heterogeneous patient population than PSI-04, thereby making differences in performance less susceptible to differences in clinical service mix. In addition, the proposed measure excludes patients whose relevant complications preceded (rather than followed) their first inpatient operating room procedure, while broadening the definition of denominator-triggering complications to include other complications that may predispose to death (for example, pyelonephritis, osteomyelitis, acute myocardial infarction, stroke, acute renal failure, heart failure/volume overload). Lastly, the measure would include Medicare Advantage patients.

If CMS is intent on including a failure-to-rescue measure in the IQR, the AHA supports this measure as a replacement for PSI-04 and believes it would be an improvement. However, the AHA continues to urge CMS not to use patient safety measures derived from billing data because they are simply not up to the task of calculating hospital performance accurately. For example, it is unclear whether the revised risk adjustment methodology for the failure-to-rescue measure would appropriately account for between-hospital differences that might escalate the severity of the complication, which would make rescue on behalf of the subsequent hospital more of a challenge. In fact, information from the pre-rulemaking measure review process suggests that this measure has questionable reliability. Furthermore, because this measure would continue to be based on only billing data, it will continue to suffer from the questionable reliability and profound disconnects between performance captured in billing data and clinical reality that have long limited the utility of the patient safety indicator (PSI) measures used in CMS programs.[37,38] That is because billing data simply cannot and do not capture all of the underlying clinical factors that may affect a patient's likelihood for serious safety events, making it fraught to use PSIs for performance comparisons across hospitals. Furthermore, a reliance on billing data means the results of the PSI measure have a significant time lag between when they are captured and when hospitals see the results, making these measures virtually useless for quality improvement efforts.

Measure Removals. **The AHA supports CMS' proposal to remove five measures from the IQR programs due to their redundancy with existing or proposed IQR measures.** For FY 2026, CMS would remove four condition-specific hospital risk-standardized payment measures due to their overlap with the Medicare Spending per Beneficiary measure used in the IQR and HVBP programs. For FY 2027, CMS would remove PSI-04 because of its similarity to the proposed failure-to-rescue measure.

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

[38] Among other studies, see Azad TD et al. Patient Safety Indicator 04 Does Not Consistently Identify Failure to Rescue in the Neurosurgical Population. *Neurosurgery.* 2023 Feb 1;92(2):338-343.

Measure Refinement. **The AHA supports CMS' proposal to expand the measure cohort for its global malnutrition composite score eCQM to include all adults 18 years old and older**. While the AHA noted its concerns about the design and utility of this measure in previous comments, we agree that the components of the measure would be reasonable for all adult inpatients.

eCQM Reporting Requirements. Consistent with the agency's interest in patient safety, CMS proposes to require the reporting of all of its previously adopted hospital harm-related eCQMs. CMS would not require the reporting of the two new hospital harm eCQMs it proposed in this rule. This would result in a stepwise increase to the number of eCQMs that hospitals must report. For the CY 2026 reporting/FY 2028 payment year, hospitals would report nine eCQMs, three of which would be self-selected from the menu of available eCQMs. For the CY 2027 reporting/FY 2029 payment year, hospitals would be required to report 11 eCQMs, three of which would be self-selected. CMS would continue to align the IQR's eCQM reporting requirements with those in the Promoting Interoperability Program.

The AHA shares CMS' focus on advancing patient safety, and as noted above, we agree with CMS' long-term goal of making greater use of EHR-derived measures of patient safety. At the same time, we believe mandating the reporting of all previously adopted hospital harm eCQMs is premature and urge CMS to retain existing reporting requirements until it can address important issues with the existing hospital harm eCQMs.

As CMS had added hospital harm eCQMs to the IQR over the past several years, the AHA has noted both their potential benefits as well as several critical questions that we asked CMS to address about whether the measures are feasible for all hospitals and provide accurate and comparable results across hospitals. For example, on the two glycemic control eCQMs that CMS would require of all hospitals, we noted that the measures were tested in only two hospitals, and that CMS needed to conduct further analyses to determine their feasibility across all hospitals. We also opposed the adoption of the acute kidney injury eCQM because of significant questions about whether the definitions and focus of the measure are appropriate and questioned whether the pressure injury eCQM had a large enough performance gap to warrant inclusion in the IQR. CMS does not appear to have addressed any of these concerns or questions since adopting these measures.

Furthermore, while we understand CMS's desire to incrementally ramp up eCQM reporting requirements in order to advance digital quality measurement, competing demands for limited hospital quality and health IT resources make increasing the number of eCQMs required for reporting a daunting task at this time. As we have consistently stated to CMS, many hospitals have found that their EHR vendors need considerable advance notice to complete upgrades and programming that help them meet CMS's eCQM reporting requirements.

Furthermore, we are concerned that expanded eCQM reporting would be added to an already lengthy list of new quality reporting requirements hospitals have taken on over the past several years. For example, starting later this year, CMS will require hospitals to report data on its hybrid mortality and readmission measures, which will require both health IT and quality resources from hospitals. Additionally, hospitals will be required to report new health-related social needs screening measures this year, and members tell us these measures have drawn significant IT resources to meet the measures' requirements. At a time when the hospital workforce is under tremendous strain, and quality and health IT resources are stretched thin, adding more reporting mandates to hospitals could prove unsustainable.

IQR Validation Changes. Each year, CMS validates the chart-abstracted measures and eCQMs of a sample of up to 400 hospitals. Any hospitals that fail to meet CMS' requirements are considered non-compliant with the IQR and lose one quarter of their annual market basket update. To date, CMS has validated the accuracy of chart abstracted data; for eCQMs, CMS has simply scored hospitals on whether they submit 100% of requested eCQM medical record data. At the same time, CMS has provided hospitals with confidential reports of their eCQM validation agreement rates. In this rule, CMS proposes to implement eCQM validation scoring based on the accuracy of eCQM data beginning with eCQM data from CY 2025, which affects payments in FY 2028. In addition, CMS proposes that the validation scores for chart-abstracted measures and eCQMs would be weighted equally. That is, hospitals would need to achieve validation scores of at least 75% for both chart-abstracted measures and eCQMs to pass validation.

The AHA supports the concept of validating the accuracy of eCQM data. However, we urge CMS to push back the implementation of its new validation scoring approach by one year and consider adopting a more gradual increase to the weight of eCQM validation. CMS correctly asserts that they have provided hospitals with feedback reports on the accuracy of the eCQM data for several years. However, as we have previously noted, hospitals have also expressed concerns about the timeliness and value of the reports, noting that the level of feedback is not as usable and specific as it could be. Given that CMS plans to now tie the accuracy of eCQM data to whether hospitals meet IQR requirements, it is imperative that CMS work with its validation vendor and hospitals to ensure that hospitals have the information they need to submit data accurately and meet validation requirements. We believe one additional year could provide invaluable time to do this work and to ensure the validation process is successful.

In addition, given the steep payment consequences for failing validation and the novelty of the eCQM validation requirements, we recommend that CMS adopt a more gradual increase to the validation weight of eCQM measures. For example, in the first year of validation, CMS could weight eCQM validation as 25% of the total validation score instead of half. This more gradual transition would help achieve CMS' goal of

beginning to tie eCQM validation performance to IQR requirements while allowing hospitals important time to fully acclimate to the new requirement.

HCAHPS CHANGES

CMS proposes to change several of the question included in the HCAHPS patient experience survey for patients discharged on or after Jan. 1, 2025. CMS would add seven new questions, while removing four others. As a result, CMS would modify the composite sub-measures used to calculate overall HCAHPS performance in both the IQR and the HVBP program. Specifically, for the CY 2025 reporting/FY 2027 payment years, CMS would add three new sub-measures — care coordination, restfulness of the hospital environment and information about symptoms — each of which would reflect new or modified survey questions. The care coordination sub-measure would supersede the current care transition sub-measure, which CMS intends to remove from public reporting in January 2026. CMS also proposes to revise the survey questions included in the responsiveness of hospital staff sub-measure.

For the HVBP program, CMS proposes to adopt the updated HCAHPS sub-measures beginning with the FY 2030 program to ensure it can calculate updated baseline and performance period scores. In addition, for FYs 2027-2029, CMS would exclude the care transition and responsiveness of hospital staff sub-measures from scoring to ensure hospitals are scored on only those aspects of the HCAHPS that would remain unchanged from the current survey.

The AHA has long urged CMS to update both the HCAHPS survey administration process and questions used in the HCAHPS survey; we appreciate CMS' progress on both fronts. For example, as long urged by AHA, CMS last year adopted a web-based survey administration option. We believe using web-based surveys in combination with other follow up modes (phone and/or mail) will improve HCAHPS survey response rates. The AHA also appreciates CMS taking a fresh look at the underlying questions in the HCAHPS survey to make them more relevant to patients and families and useful to hospitals in improving the patient experience of care.

The AHA supports most of CMS' proposed updates to the HCAHPS instrument and sub-measures, as well as the staggered implementation timeframes for including the updated sub-measures in the IQR and HVBP program. However, we ask CMS to provide additional information in the final rule about how the items were tested to help us understand whether they measure hospitals accurately.

First, we ask CMS for information about one of the new items proposed for the care coordination sub-measure: "During this hospital stay, how often were doctors, nurses and *other hospital staff* informed and up-to-date about your care" (emphasis added).

While we agree that doctors and nurses should be expected to be familiar with a patient's plan of care, it is less clear to what "other hospital staff" this question may be referring.

Within a hospital environment, not every individual — including those a patient may encounter — will have reason to be fully up to speed on a patients plan of care. For example, environmental services staff are a critical part of maintaining the environment of care but would not be expected (or permitted) to have information about a patient's medical record or treatment. It would be helpful for CMS to provide additional testing information to show whether survey respondents were able to distinguish among the role groups involved in their care and whether they would have access to information about their care.

Second, CMS should provide additional testing information about the following new survey item in the proposed Restfulness of the Hospital Environment sub-measure: "During this hospital stay, how often were you able to get the *rest you needed*?" (emphasis added).

Certainly, rest is a component of a patient's recovery while they are in the hospitals. At the same time, a patient's particular clinical needs may mean that doctors, nurses and other providers may need to visit them frequently to check vitals and perform tests. While caregivers are always sensitive to patients' recovery needs, there sometimes are important clinical reason to interrupt a patient's rest. Furthermore, the wording of the question — that is, the "rest you needed" — appears at first glance to be rather subjective. For this reason, we would be interested in further data from CMS about how patients interpreted the question, whether responses varied by clinical diagnosis and to what extent the risk adjustment approach in the HCAHPS may account for these differences in the score for the overall restfulness sub-measure.

RFI: ADVANCING PATIENT SAFETY AND OUTCOMES ACROSS HOSPITAL PROGRAMS

The proposed rule includes an RFI that asks for feedback on whether CMS should include measures in its value programs that focus on post-discharge interactions with acute care beyond readmissions, such as ED visits and observation stays. CMS notes that the IQR program includes excess days in acute care (EDAC) measures for acute myocardial infarction, heart failure and pneumonia that reflect rates of readmissions, ED visits and observation stays within 30 days of hospital discharge.

The AHA strongly objected to CMS' proposed inclusion of the EDAC measures in the Hospital Readmissions Reduction Program (HRRP) when they were included on the 2023-24 Measures Under Consideration list because of serious questions about whether CMS has the statutory authority to include such measures in the HRRP. We reiterate those concerns here and note that similar statutory considerations likely would preclude CMS from include the EDAC or similar measures in the agency's other value programs.

In the case of the HRRP, our concerns about CMS' authority to implement the EDAC measure stems from the statutory definition of readmissions at 42 USC 1395ww (q)(5)(E): "The term 'readmission' means, in the case of an individual who is discharged from an

applicable hospital, the *admission* of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge" (emphasis added).

We believe this definition is precisely why CMS has used readmission measures reflecting whether patients are readmitted as *inpatients* within 30 days of an *inpatient* discharge since the program's inception on Oct. 1, 2012. It is also why CMS does not use measures that treat either an ED visit or observation stay as index "discharges" from which it could measure inpatient admissions, ED visits or observation stays within a 30-day time period. The HRRP statute simply does not contain the terms "emergency department" or "observation stay."

Furthermore, the definitions of "admissions" to inpatient beds, emergency department visits and observation stays are not used interchangeably in other CMS regulations. In fact, there are multiple examples showing how CMS has separated these definitions for providers and patients alike. For example, CMS' establishment of the "Two Midnight Rule" was specifically designed to distinguish between observation stays (which are considered outpatient visits) and inpatient admissions to the hospital. This distinction is critical because it differentiates how Medicare Part A or B benefits may apply, patient cost sharing amounts, and which CMS billing system hospitals may use. Similarly, emergency department visits in which a patient returns home to the community are not "admissions," and in fact, are not payable under Medicare Part A Hospital Insurance. CMS makes these distinctions clear to patients and families in its own fact sheet titled "Are You a Hospital Inpatient or Outpatient," which includes the following language:

- "You're an inpatient starting when you're formally admitted to a hospital with a doctor's order. The day before you're discharged is your last inpatient day."
- "You're an outpatient if you're getting emergency department services, observation services, outpatient surgery, lab tests, X-rays, or any other hospital services, and the doctor hasn't written an order to admit you to a hospital as an inpatient. In these cases, you're an outpatient even if you spend the night at the hospital."

COP FOR ACUTE RESPIRATORY ILLNESS DATA REPORTING

In 2020, CMS adopted a CoP requiring hospitals and critical access hospitals (CAHs) to submit certain data related to COVID-19 and other acute respiratory illnesses (i.e., influenza) to HHS for the duration of the COVID-19 public health emergency (PHE). In 2022, CMS updated the CoP to require reporting from the conclusion of the PHE through April 30, 2024. However, in this rule, CMS states that it continues to need to monitor the impact of acute respiratory illnesses across the country to inform federal surveillance efforts. The agency also asserts that the reporting of such data is related to and could inform hospital-level infection control and prevention efforts.

As a result, CMS proposes to modify and make permanent its CoP requiring hospitals and CAHs to report certain data on acute respiratory illnesses, including during times outside of a PHE. Beginning on Oct. 1, CMS would require hospitals and CAHs to report data once per week on confirmed infections of COVID-19, influenza and respiratory syntactical virus among hospitalized patients, hospital capacity and limited patient demographic information, including age. The agency also proposes that during declared PHEs — or during an event that is "significantly likely to become a PHE for an infectious disease" — the agency could add additional reporting requirements or increase the frequency of reporting without going through notice and comment rulemaking.

General Comments. Hospitals and health systems understand the potential value of selected data on acute respiratory illnesses to inform public health efforts. **However, as the AHA noted in 2020 and again in 2022, the use of CoPs to compel hospitals to share data with the federal government is both needlessly heavy-handed and inconsistent with the intent of CoPs.** Furthermore, we are troubled by the potentially unlimited scope of data reporting that CMS could require of hospitals during PHEs and ill-defined events the secretary deems "significantly likely" to become a PHE. Rather than jeopardizing hospitals' Medicare participation status through CoPs, **the AHA urges CMS, HHS and the Centers for Disease Control and Prevention (CDC) to invest in the infrastructure needed to make the voluntary sharing of important data on infectious diseases less burdensome and more meaningful.** This investment should go hand-in-hand with a collaborative effort involving multiple stakeholders to chart a sustainable path forward.

CMS' acute respiratory illness data reporting CoP is inconsistent with the core intent of Medicare's CoPs, which is to set health and safety standards for the delivery of health care**.** As CMS has stated, CoPs are "health and safety standards [that] are the foundation for improving quality and protecting the health and safety of beneficiaries." In justifying its proposal, we are concerned that CMS has seemingly conflated the concept of community prevalence with in-hospital processes for patient safety. CMS asserts that these data reporting CoPs fit within its Infection Control CoPs, suggesting that "the prevalence of infections *in the community* affects patient safety within hospitals" (emphasis added). It is true that hospitals use community prevalence information to shape their approach to controlling the spread of infections inside their facilities. **Yet, reporting data on the number of hospitalized patients with particular respiratory illnesses is not the same thing as community prevalence**. In fact, the number of infections inside a hospital would likely severely lag the spread of a disease in the community. The number of hospitalized patients might be an indirect reflection of the *acuity* of acute respiratory illnesses, but indicators such as wastewater surveillance, public health lab testing and other mechanisms likely would be a more meaningful reflection of community prevalence. This makes it a stretch of logic to claim that the data CMS is seeking from hospitals are consistent with the focus of CoPs on the health and safety of hospitalized patients.

Instead, this proposed permanent CoP appears part of a troubling trend of CMS using CoPs to achieve policy goals that do not always have a direct and clear link to

health and safety standards in hospitals. In fact, the rule's preamble alludes to the linkage of this proposed CoP to the Administration's National Biodefense Strategy, one of whose goals is to develop "all-hazards hospital data collection capability." To be clear, we understand fully the potential value of hospitalization data on acute respiratory illnesses to inform broader public health preparedness efforts. However, we do not believe that CoPs are either the appropriate or optimal way to achieve this goal.

The AHA also is concerned by how little of the proposed policy would be subject to the notice and comment rulemaking process. This raises questions about how hospitals and health systems could ensure ongoing compliance and CMS' authority to implement the CoP. Based on the information provided in the proposed rule, the Secretary would grant him or herself the authority to change significant aspects of the rule, like the frequency and format of mandated reporting, seemingly on a whim. Yet, the proposed rule does not articulate specific legal authority or other justification that would support making these types of changes outside of the rulemaking process. The proposed policy also is also inconsistent with the approach CMS uses in its quality measurement programs in which CMS regularly updates reporting requirements through notice and comment rulemaking.

Although the Secretary had the flexibility to adjust the frequency and format of the COVID-19 PHE data reporting required under the CoP in section 482.42(e), that flexibility was due to multiple emergency declarations made by the Secretary and the President. With the termination of those emergency declarations and the end of the COVID-19 PHE, we are very concerned that leaving the "form, manner and timing" up to sub-regulatory processes may be inconsistent with the Administrative Procedures Act and other statutes governing agency actions. Furthermore, we are not aware of any legal standard for a "significantly likely" public health emergency, nor is there any statutory or other authority that would allow the Secretary to change mandatory reporting requirements based on a "significantly likely" public health emergency.

In the short-term, we recommend that CMS and CDC instead adopt a voluntary reporting process to accept acute respiratory illness data from hospitals. The agencies could retain the National Healthcare Safety Network platform for data reporting while adopting the streamlined reporting fields the agency has proposed. This approach would minimize disruptions to hospital processes while also taking away the specter of losing the ability to participate in Medicare if they were to miss a week of reporting.

Indeed, past experience shows that the hospital and health system field would be more than willing to participate robustly in a voluntary effort to share important data with the federal government. Prior to the issuance of the 2020 interim final rule, the federal government itself repeatedly noted that 94% of hospitals were reporting requested data. That is because hospitals and health systems have understood the critical value of providing COVID-19 related data — such as the number of COVID-19 positive patients and number of intensive care unit beds available — and took seriously their role in the data collection and submission process. That is why it was so disappointing to hospitals and

health systems to see their good faith collaboration with the government to provide data to inform the federal response to the COVID-19 pandemic set aside in favor of a regulatory approach that threatens not only their financial viability, but ultimately, access to the care their communities depend upon.

Over the long run, we urge CMS, CDC and other federal agencies to build the infrastructure our nation needs to enable more automated, efficient, timely and lower burden sharing of important public health information between health care providers and federal and state agencies. The foundation of this effort should be a voluntary public-private collaborative effort that involves stakeholders such as hospitals and health systems, post-acute care providers, clinician offices and electronic health record vendors, to name a few. Early work undertaken by the U.S. Digital Service during the COVID-19 pandemic to explore automated approaches to reporting COVID-19-related data could serve as a starting point for further efforts to lower the data collection and reporting burden for acute respiratory illnesses more broadly. This work would enable hospitals and the federal government alike to focus on *using* the data to more effectively respond to acute respiratory illnesses.

Detailed Comments. As noted above, the AHA does not support CMS' proposed CoPs. However, if the agency is intent on implementing a CoP, we offer several recommended changes. **First, we urge CMS to allow hospitals to report a snapshot of data once per week rather than cumulative totals.** Indeed, under the now-expired CoP, CMS and CDC reduced the reporting frequency to once per week in a well-intentioned effort to reduce burden for hospitals. However, the agency still expected hospitals to report relevant data fields from each day of the week. As a result, hospitals found that the reduction of the frequency of reporting did not reduce their administrative burden as much as hoped. As we understand it, CMS' intent with the proposed CoP is to get periodic insights into acute respiratory illnesses in hospitals. We believe this can be achieved by asking hospitals to report data from a single day of the week, which CMS and CDC could then track over time to discern trends.

The AHA appreciates CMS taking steps to streamline the data elements it would require hospitals to report. Yet, the proposed rule lacks enough specificity in some places to understand exactly what data hospitals would be expected to report. If CMS adopts the CoP, we urge the agency to provide more detailed information in the final rule. For example, when CMS indicates it wants to collect "limited patient demographic data," we assume that reporting would look like the process used under the expired CoP in which hospitals reported counts of patient by several broad categories of age (e.g. 18-19, 20-29, 30-39, etc.).

Lastly, we oppose CMS' proposal to allow ramped up reporting requirements and frequency during events "significantly likely" to become a PHE. As noted above, the AHA is concerned that this language would become a vehicle to introduce new reporting requirements — or ramped up reporting frequency — on an arbitrary basis that is not subject to notice and comment rulemaking. Indeed, it is troubling that CMS seeks

comments on what constitutes "substantially likely" rather than proposing concrete criteria in the rule itself. Furthermore, a PHE has a specific meaning in statute and regulation, and the declaration of a PHE conveys significant flexibilities and powers intended to expedite the regulatory process. We are not aware of any law or regulation that creates an effective category of "near PHE," and would be deeply troubled by the precedent of CMS or any other federal agency using such a vague categorization to circumvent the notice and comment rulemaking process. We urge CMS not to finalize this proposal.

Collection of Race, Ethnicity and Social Driver of Health Data. Consistent with the agency's commitment to reducing health inequities, CMS seeks input on whether to require hospitals and CAHs to report race/ethnicity data as part of its patient demographic data reporting requirements. CMS also is interested in whether it should mandate the reporting of data "on additional demographic factors including socioeconomic or disability status that may be associated with disparities in outcome." The agency indicates that it "may decide to finalize a policy of collecting demographic information on race/ethnicity and/or additional factors" based on public comment.

Hospitals and health systems share CMS' goal of advancing health equity. At the same time, as CMS itself acknowledges, federal standards for the collection of race and ethnicity data are undergoing a significant overhaul. On March 28, OMB issued an updated Statistical Policy Directive 15 (SPD-15) that governs how federal agencies collect and use race and ethnicity data in their programs, the first update since 1997. OMB made several groundbreaking changes to the guidance such as consolidating race/ethnicity into a single question, adding a new category for Middle Eastern and North African individuals to identify themselves, and establishing new minimum and detailed categories for each race/ethnicity field. Federal agencies have been given until October 2025 to develop their plans to comply with these new standards and until March 2029 to come into full compliance.

We would anticipate that like other agencies, CMS is undertaking a thoughtful and thorough process to review and standardize its approaches to collecting race and ethnicity data across all of its programs to bring them into compliance with the new guidelines. We are concerned that adopting race and ethnicity data collection as part of this CoP too soon would rush what should be a measured and careful process. We also would be concerned with CMS adopting a set of requirements that could then rapidly change as the rest of the agency's plan comes into place. To be clear, the reporting of these data would constitute a significant change to hospital and health system workflows and would add considerable administrative effort. If CMS were to pursue such reporting, its approach to doing so would need to be stable.

As a practical matter, we also believe there are numerous and complex issues that CMS would need to sort through for the reporting of race, ethnicity or other patient self-reported data demographic or social driver of health data. For example, there are individuals who prefer not to report their race or ethnicity with hospitals and health systems. Some patients also may not wish to share information about their sexual orientation, gender identity or

their living situation. CMS does not articulate in the proposed rule an approach for honoring the choices of patients who may choose not to share these data while also not penalizing hospitals for not reporting "complete" data.

Furthermore, it is not clear what level of data CMS is seeking. For example, is the agency seeking aggregate data on race/ethnicity of patients with confirmed infections? If it is aggregate-level data, CMS would need to consider how to protect patient confidentiality in hospitals where there may be small numbers of a particular race or ethnicity. If CMS is considering the reporting of patient-level data, such reporting would introduce even more questions about how to protect and de-identify patient data, as well as whether the CDC's reporting systems have the capacity to securely accept such data.

SEPARATE INPATIENT PPS PAYMENT FOR ESTABLISHING AND MAINTAINING ACCESS TO ESSENTIAL MEDICINES

Based on a series of executive orders, CMS previously sought comments on the creation of a separate payment under the inpatient PPS for hospitals to establish and maintain access to a three-month buffer stock of one or more of 86 essential medicines prioritized in HHS' Administration for Strategic Preparedness and Response (ASPR) report Essential Medicines Supply Chain and Manufacturing Resilience Assessment. The AHA submitted comments on this proposal.

In this year's inpatient PPS rule, CMS proposes to make separate payments to small independent hospitals under the inpatient PPS for the additional costs that they would face in establishing and maintaining access to a six-month buffer stock of one or more of the essential medicines, referred to in the proposed rule as the "ARMI list" drugs.[39] Such buffer stock could be maintained or held directly at the hospital, arranged contractually for a distributor to hold off-site, or arranged contractually with a wholesaler for a manufacturer to hold the product. The purpose would be to act as a buffer in the event of an unexpected increase in product use or disruption to supply.

The AHA appreciates CMS' recognition that a more reliable and resilient drug supply chain is needed so that hospitals can better care for their patients and communities. We appreciate the agency's efforts to support practices to help curtail shortages of essential medicines and promote resiliency to safeguard and improve the care hospitals provide to beneficiaries. The AHA also appreciates that CMS has revised its previous proposal in response to several matters we raised, as discussed below. **However, we continue to have several concerns about the proposed policy, including a substantial reporting burden on eligible small independent hospitals.**

Hospital Eligibility

[39] ASPR and the Advanced Regenerative Manufacturing Institute's (ARMI's) Next Foundry for American Biotechnology developed this ''ARMI list'' of 86 essential medications.

CMS proposes to limit eligible hospitals as those with not more than 100 beds during the cost reporting period for which the payment adjustment would be made. Furthermore, the agency proposes to define an independent hospital as one that is not part of a chain organization, as defined for purposes of hospital cost reporting. **We appreciate that CMS, in response to AHA and other stakeholder feedback, has reduced the likelihood of demand-driven shortages by narrowing the program's initial eligibility to small independent hospitals. We urge CMS to monitor the uptake of the program by these initially eligible hospitals and consider gradually expanding the program to non-independent and larger hospitals as hospitals acquire and maintain a buffer supply.** In doing so, we recommend that CMS consult with the Food and Drug Administration (FDA) to assess the potential impact of such program expansions on the national availability of these essential medications. **We also urge CMS to include CAHs as eligible.** Many CAHs are the sole provider for their rural communities and are subject to similar drug shortage challenges as small inpatient PPS hospitals.

Additionally, we continue to believe that a policy that does not include the costs of the essential medicines themselves could create inequities in access, especially for these eligible small independent hospitals and CAHs. These hospitals may very well be unable to pay the high upfront costs. **If CMS finalizes this policy, we urge the agency to consider making upfront payments to eligible hospitals to support the acquisition of a buffer stock.**

Proposed List of Essential Medications

The agency proposes that hospitals would have to maintain a six-month buffer stock for one or more of the medicines included in the ARMI list to be eligible for the separate buffer stock payment for that medicine. In the event that one of the hospital's selected medicines, for which it has *already* established and is maintaining a buffer stock, is listed as being "currently in shortage" by the FDA, CMS proposes that the hospital would continue to be eligible for the separate buffer stock payment for that medicine for the duration of the shortage, even if the hospital must draw down its inventory below the required six-month buffer supply for that medicine to meet patient care needs. **The AHA supports this policy. We also appreciate that CMS responded to our concerns about this program potentially exacerbating existing shortages or contributing to hoarding of shortage medicines by proposing that a hospital that *newly* establishes a buffer stock of a medicine while it is in shortage would not be eligible for separate buffer stock payments for that medicine for the duration of the shortage.**

Further, the agency notes that some medicines may remain on the FDA's drug shortage list for many months, and requests comments on the duration that CMS should continue to pay hospitals for maintaining a less than six-month buffer stock of an essential medicine that is in shortage. **To incentivize hospitals to continue to participate in the program, the AHA recommends that the agency continue to pay hospitals, possibly on a pro-rated basis, until their buffer stock is completely depleted and likewise to resume**

payment as the medicine's supply recovers and hospitals can return to the full six-month supply.

CMS also seeks comment on whether certain drugs not on the ARMI list that have recently been in shortage and that may be considered essential, such as oncology drugs, should be eligible for separate payment for the inpatient PPS share of the costs of establishing and maintaining access to a six-month buffer stock. **Given current cancer drug shortages and the likely future shortages of other drugs not included on the ARMI list, we believe that CMS should consider prioritizing additional drugs from other existing lists, such as FDA's critical drugs list.**[40] Doing so would help foster a more resilient supply of lifesaving medicines. Alternatively, given that most cancer chemotherapy is provided in outpatient settings and the agency's proposal only applies to medicines used in inpatient care, CMS may wish to work with ASPR and FDA to create another list of essential drugs for the outpatient setting, including for outpatient cancer care, for a possible future CMS proposal for outpatient-based payments.

The ARMI list includes several Drug Enforcement Administration (DEA) regulated controlled substances, such as surgical anesthesia drugs essential to hospital care. Yet, if eligible hospitals suddenly begin to order larger volumes of such ARMI-list drugs, manufacturers could run into quota problems with the DEA. Such a situation could cause demand-driven shortages of these controlled substances. **As a result, we strongly encourage CMS to immediately begin discussing this proposal with DEA to reduce the likely of demand shock and resulting shortages of these critically important drugs.**

Size of the Buffer Stock

As commenters stated, drug shortages generally persist for many months. Accordingly, CMS believes a buffer stock of at least six months would better support small, independent hospitals in contending with future shortages. CMS is also seeking comments on whether a phase-in approach that, for example, would provide separate payment for establishing and maintaining access to a three-month supply for the first year in which the policy is implemented and a six-month supply for all subsequent years would be appropriate.

The AHA supports such a phase-in approach as it would not only address concerns about the initial infrastructure investments needed to acquire, store and maintain the buffer supply in the program's first year, but also would provide hospitals with a reasonable assurance of a continued supply of the drugs to care for patients in the event of a shortage and be a proof of concept to possibly encourage a more substantial buffer stock in the second and subsequent years of the program.

Separate Payment under Inpatient PPS

[40] https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs

CMS is proposing to establish a separate inpatient PPS payment for the inpatient PPS share of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The agency would use the ratio of inpatient Medicare costs to total hospital costs to measure this share. It states that, on average for the small independent hospitals eligible under this policy, the percentage is approximately 11%.

CMS proposes that hospitals would report these costs to CMS on a forthcoming supplemental cost reporting worksheet. **We continue to be concerned that this proposed policy would increase reporting burden on hospital staff and frontline workers. This is an ongoing problem for all hospitals, but small independent hospitals are the very hospitals that would have the highest upfront costs for staffing and other resource use.** For example, for hospitals that have the capacity and capability to store a buffer stock, they would need to devote critical staff to track, report and maintain these requirements and cost report records for this separate supply. Specifically, they would need to maintain separate records for buffer stock and non-buffer stock. **Therefore, we once again urge CMS to work with manufacturer, distributor and wholesaler stakeholders to determine a less burdensome method of attestation and reporting for these payments.**

Furthermore, the agency had indicated that it would make the payment adjustment budget neutral under the outpatient PPS but *not* budget neutral under the inpatient PPS. **If CMS moves forward in future years to adopt this policy under the outpatient PPS, we urge it to seek congressional authority to make any additional payments non-budget neutral. Redistributing payments from an already underfunded system will not be of benefit to providers or to patients.** Furthermore, we oppose any proposals that would make new conditions of participation (CoPs) in forthcoming notice and comment rulemaking to address hospital processes for pharmaceutical supply, as the agency had indicated that it may do so in the CY 2024 outpatient PPS final rule.

RFI: MATERNITY HEALTH

The AHA appreciates CMS' concern and interest in better understanding maternity care payment rates. Maternal health outcomes are of substantial concern. In addition to overall rates of maternal mortality and morbidity that fall well below norms for developed nations, health disparities result in outcomes that are even more stark for certain populations, especially Black women. The causes are complex and multi-factorial, and they are not immune to broader societal challenges whose effects often present to the health care system, such as community violence, behavioral health and other issues.

Some of the key policy concerns affecting maternal health outcomes include:

- **Inadequate reimbursement.** Over 40% of births are paid for by Medicaid, and Medicaid has historically reimbursed less than the cost of providing care. Payment

rates from public payers have not kept pace with inflation, and the cost of providing care has increased dramatically over the last four years. On average, hospitals experienced negative margins (-18% across all payers) for labor and delivery services in 2023.[41]

- **Staffing challenges.** Many hospitals struggle to recruit and retain physicians, nurses and other appropriately trained caregivers to support labor and delivery services. Staffing challenges may be caused by declining patient volume, limited resources for training and specialty certification, financial pressures, lifestyle preferences and challenges processing visas for foreign-trained clinicians.
- **Rise in patient acuity.** Hospitals and health systems have experienced an increase in patient acuity. For example, between 2019 and 2021, overall patient acuity (as measured by the average length of stay) increased nearly 10%.[42] Hospitals and health systems have experienced rising rates of pregnancies coupled with behavioral health and substance use disorder comorbidities.
- **Declining patient volume.** This affects hospitals' ability to provide certain services. Lower volumes make it challenging for rural hospitals to maintain fixed-operating costs, including malpractice insurance premiums which have historically been higher for obstetricians and gynecologists. Lower volumes also make it difficult to attract and retain clinical staff and provide enough services to maintain expertise and competency. In addition, the demographics of some rural areas may make it difficult to justify full time maternity care.

Considering these challenges, CMS' RFI is timely. Specifically, CMS asks for information about Medicare payment policy's influence on other payers and for information about potential policy solutions to improve maternity care services.

Medicare Payment Rates

Medicare payment rates are generally not perceived to be a driver of practice patterns in maternity care. Medicare has historically paid less than the cost of providing care to Medicare beneficiaries. Hospitals received payments of only 82 cents for every dollar spent by hospitals caring for Medicare patients in 2022. The deficit adds up — 67% of hospitals reported negative Medicare margins in 2022. Moreover, Medicare pays for few births relative to Medicaid and commercial coverage.

Medicare DSH and uncompensated care payments support hospitals that provide care to expectant families. Under the inpatient PPS, many hospitals payments are adjusted to account for the care they provide to expectant families who are uninsured or covered by Medicaid and CHIP. Although not directly linked to maternity care services, these adjustments are critical sources of revenue for hospitals and health systems and are used to support care provided to healthy mothers and babies.

[41] AHA analysis of data from Strata Decision Technology.
[42] https://www.aha.org/system/files/media/file/2022/08/pandemic-driven-deferred-care-has-led-to-increased-patient-acuity-in-americas-hospitals.pdf

Medicaid Payment Rates

Medicaid policy plays a larger role than Medicare in the delivery of maternity care services. Medicaid paid for just over four in 10 births in the U.S. in 2022 (41.3%).[43] There is significant variation around this average, which means that Medicaid pays for the majority of births in many hospitals and health systems. According to AHA annual survey data, Medicaid pays 88 cents for every dollar spent by hospitals providing care for Medicaid patients.

In the proposed rule, CMS seeks information on Medicare's influence and interaction with other payers, and what effect, if any, this has on improvements in maternal care. Medicaid and Medicare payment systems interact in two ways that should be considered.
Some Medicaid FFS programs use components of Medicare inpatient PPS as part of their inpatient payment methodology. Twelve states used MS-DRGs as the basis for inpatient hospital payments in their FFS programs according to a 2018 Medicaid and CHIP Payment and Access Commission (MACPAC) analysis.[44]

Less is known about the payment methodologies and rates paid for inpatient services by Medicaid managed care organizations, although new transparency requirements implemented through the final Medicaid managed care access rule may provide more information once implemented. Hospitals and health systems also report that some Medicaid managed care organizations (MCOs) are slow to adopt changes made to FFS payments. For example, if a Medicaid agency increases the payment rates for labor and delivery services, Medicaid MCOs may delay implementing a rate increase until a new contract year.

As CMS considers how the inpatient PPS interacts with other payers to improve maternity care, CMS should consider the extent to which states' Medicaid payment policies for Medicare cost sharing result in providers receiving only a portion of the full payment for crossover claims. Some of the labor and deliveries Medicare pays for are for individuals who are dually eligible for Medicare and Medicaid. Medicare serves as the primary payer, and as the secondary payer, Medicaid could be liable for Medicare cost-sharing requirements. The majority of states (34) have "lesser of" payment policies in place, which pay the provider the lesser of the Medicare cost sharing or the amount by which, if any, the Medicaid allowed amount exceeds the Medicare rate.[45] According to MACPAC, Congressional Budget Office, and others, these lesser-of policies often result in providers receiving less than the Medicare payment rate.[46,47] As CMS considers the implications of the Medicare inpatient PPS payment rates for labor and delivery services, CMS should

[43] National Center for Health statistics, final natality data. Retrieved May 23, 2024, from www.marchofdimes.org/peristats.
[44] https://www.macpac.gov/publication/macpac-inpatient-hospital-payment-landscapes/
[45] https://www.macpac.gov/publication/state-medicaid-payment-policies-for-medicare-cost-sharing/
[46] https://www.macpac.gov/wp-content/uploads/2014/11/Effect-of-State-Medicaid-Payment-Policies-for-Medicare-Cost-Sharing-on-Access-to-Care-for-Dual-Eligibles.pdf
[47] https://www.cbo.gov/system/files/2023-01/57843-Working-Paper-2023-01.pdf

consider the extent to which providers receive less than the inpatient PPS payment rate due to states Medicaid payment policies for Medicare cost sharing.

Commercial Coverage Payment Rates

Commercial coverage payment policies are generally not perceived to be linked to the Medicare inpatient PPS. Commercial payers may adopt proprietary payment methodologies, and payment rates are generally subject to payer-provider negotiations. Hospitals and health systems report that commercial payers have generally moved away from pay-for-performance incentives that are based on maternal health outcomes.

Policy Options that Could Help Drive Improvements in Maternal Health Outcomes

The AHA and its members support efforts to improve maternal health outcomes. As CMS explores policy approaches to improving maternal health outcomes, the AHA encourages CMS to consider:

- **Increasing reimbursement for obstetric services.** For example, some states have implemented add-on payments for labor and delivery — paid directly to the hospital — by their state Medicaid programs; a federal match could be helpful in maintaining and expanding the use of these payments.
- **Ensure Medicare DSH and uncompensated care payments continue to support expectant families.** Medicare DSH and uncompensated care payment adjustments are critical sources of support for hospitals that provide care to mothers and babies. CMS should ensure that these payments appropriately reflect changes in where people receive care, and that the payment adjustments continue to account for care that hospitals and health systems provide to patients covered by Medicaid or who are uninsured.
- **Reducing regulatory barriers to encourage partnerships and innovative approaches to delivering care.** Partnerships between smaller rural hospitals and larger health systems can allow systems to share staff, connect patients with complex health needs to specialists, and in some cases, transfer high-risk pregnant women to other facilities. However, some partnerships and delivery system changes could be viewed as anti-competitive or risk violating antitrust laws.
- **Encouraging state Medicaid GME programs to support expanding capacity of existing workforce.** States have broad authority to create Medicaid GME programs that meet the needs of their state, including through FFS and Medicaid managed care programs. In some states, primary care or family practitioners have received training in labor and delivery, including performing cesarean sections, to offer care as part of a broader clinical team that includes obstetricians and gynecologists. CMS could assist with guidance and encourage state Medicaid agencies to develop Medicaid GME programs focused on strengthening the maternity care workforce.
- **Supporting the use of telemedicine for maternal care.** Telehealth can provide support throughout the perinatal period as well as to allow for consultations with

specialists and access to care for rural areas that do not have obstetric providers. A study by the Centers for Disease Control and Prevention examined work done by 13 state maternal mortality review committees to identify contributing factors and strategies to prevent future pregnancy-related deaths, which included addressing personnel issues at hospitals by providing telemedicine for facilities with no obstetric provider on-site. In addition, the use of remote patient monitoring, such as with blood pressure cuffs and weekly glucose review, both lowered pregnancy-related stress and improved patient satisfaction with their treatment. While the use of telemedicine for obstetric services has increased over the last few years, not all states may be requiring Medicaid to reimburse for these services.

The AHA looks forward to engaging further with CMS to explore policy approaches to improving maternal health outcomes.

RFI: OBSTETRICAL SERVICES STANDARDS FOR HOSPITALS, CAHS AND REHS

Each year, hospitals and health systems proudly care for millions of expectant mothers and deliver more than 3.5 million babies. As trusted partners for their communities, hospitals work tirelessly to provide safe, high-quality care to every individual who walks through their doors, regardless of age, race, religion or ability to pay.

As the highest volume provider of labor and delivery services — and the only provider of emergency labor and delivery services — the AHA believes that maintaining access to hospital-based care is central to any effort to improve maternal health outcomes. Yet, the ability for hospitals to maintain the access to the care that their communities depend on is under unprecedented strain. Financial pressures, workforce shortages and increasing regulatory requirements are only some of the challenges facing facilities still dealing with the aftermath of the unprecedented COVID-19 pandemic. Rural hospitals and safety net hospitals have been hit particularly hard; more than 135 rural hospitals have been forced to close since 2010, and hundreds more remain at risk. Even when hospitals can stay open, they often must cut services, reduce hours or shutter certain units to stay viable.

In this context, it is imperative that patients, providers, communities, hospitals and regulators work together to improve maternal outcomes. The AHA and its members share CMS' commitment to the provision of safe, high-quality maternal care across the maternal care continuum. Maintaining these high standards while providing access to care to as many women as possible requires a thoughtful and balanced approach that is centered on the needs of patients and that considers the capabilities of providers and communities. Such an approach must also account for existing regulations, as well as federal, state and local laws that ensure oversight of hospital obstetric units.

CoPs are important regulatory tools establishing baseline standards for quality and safety. **However, the AHA believes CoPs are ill-suited to address the complex factors contributing to poor maternal outcomes, most of which occur outside of hospital walls.** Above all else, we are concerned an obstetrical services CoP would inadvertently

limit access to hospital-level care. Rather than adopting obstetrical services CoPs, the AHA and its members would like to partner with CMS to find solutions that better target the full breadth of factors contributing to maternal morbidity and mortality and support safe, high-quality patient-centered care.

Hospitals Play an Important Role in Providing Safe, High-quality Care for Women Across the Maternal Health Continuum

Each year, millions of women go to hospitals to receive safe, high-quality maternal care. Not only do hospitals offer the widest range of medical services and support for women and their newborns, but for many women the hospital is the safest — and only — option for giving birth. As rates of maternal morbidity and mortality continue to rise, accessing safe, high-quality care is becoming increasingly difficult. This trend is especially concerning in rural areas, in states that have not expanded access to Medicaid, and in the South, where women are finding they have fewer and fewer places to go. The AHA shares CMS' concerns regarding the increase in maternal morbidity and mortality. As noted in the RFI, a lack of access to maternal care is contributing to the rise in adverse outcomes for women and their newborns. As trusted members of their communities, hospitals are committed to changing this trajectory.

Hospitals provide critical services for the patients that need them most; they also preserve meaningful choice for women interested in giving birth outside of the hospital setting. In its RFI, CMS asks how the growth of birth centers might impact the establishment of an obstetrical services CoP. In fact, the growing number of women who want to give birth at a birth center, or even at home, underscores the importance of maintaining access to a hospital. A 2020 report from the National Academies of Sciences, Engineering, and Medicine found that birth centers were *safest* when part of an integrated system with agreements in place to provide for quick transfers when a higher level of care is required. However, there are no national requirements like CoPs establishing minimum standards for safety or quality of care at birth centers. State regulations vary, and nearly one fifth of states have no birth center regulations.

Birth centers are not equipped to provide the same comprehensive care offered in the hospital setting. Many will not even consider patients with common risk factors such previous cesarean section, diabetes or high blood pressure. Even among the low-risk patients seen at birth centers, approximately 22% still require transfer to a hospital, with 2% of those situations requiring transfer for emergency care. And while birth centers — which have lower rates of cesarean sections and other medical interventions than hospitals — may be the best choice for some women, they simply are not an option for most. As of 2022, 34 states had five or fewer birth centers, with eight of those states having no birth centers at all. Even when they do have physical access, many women cannot afford to utilize a birth center or engage a qualified provider to provide support for a home birth due to insurance limitations. Hospitals are necessary to ensure no woman is forced to go without safe, timely and appropriate care.

A Balanced Approach to Hospital Regulation Is Critical for Ensuring Patient Health and Safety Without Exacerbating Factors Contributing to Poor Maternal Health Outcomes

Part of the challenge in improving maternal health is that many factors contributing to adverse outcomes occur outside of the hospital, in the periods before and after delivery. Women seeking maternity care are on average older and sicker than previous generations. High rates of chronic illness, smoking, economic insecurity, violent crime, pollution, lack of affordable housing, domestic violence, food insecurity and other factors contributing to poor health are especially prevalent among women living in rural and underserved communities. **Although well intentioned, CoPs for hospital-based obstetrical services will not address the main drivers of maternal morbidity and mortality**. Instead, this approach may further compound the problem for many women by negatively affecting the quality of care and accelerating hospital closures in the areas that need hospitals the most.

The AHA is concerned that distinguishing obstetrical services from other hospital services through regulation could perpetuate silos, counter to the provision of coordinated, comprehensive and integrated care that has been shown to improve maternal health outcomes. Silos have been shown to negatively affect quality of care and lead to duplication of services. CMS itself has highlighted the importance of a holistic, comprehensive approach to care that encompasses the entire maternal health continuum, emphasizing practices like chronic disease management in the periods before, during and after pregnancy. With heart disease, stroke and cardiomyopathy among the top medical conditions contributing to adverse maternal health outcomes, obstetrical services must be further integrated into any hospital, not set apart.

It should also be noted that in areas where patients have greater needs, so too do their hospitals. As the “epicenters” of many communities, hospitals often reflect the patients they serve. In its RFI, CMS acknowledged that rural areas have seen more hospital closures throughout the last decade. In the four-year period from 2015 through 2019, 59% of the community hospitals that closed were rural hospitals. These closures put entire communities at risk by increasing the time and distance to care. Providers are also impacted as closures lead to a reduction in available health care workers, stretching providers and increasing patient loads. The implications are especially important when considering obstetrics has one of the highest burnout rates across medical specialties, with fewer providers further reducing access.

Successfully addressing health disparities means increasing access to safe maternal care, not reducing or restricting it. Maintaining the availability of hospital-based services, especially in rural and underserved communities, is imperative to any effort to improve maternal health outcomes. CMS must balance new demands on hospitals with existing challenges related to rising costs and labor shortages. New requirements must also account for the considerable diversity among hospitals, offering enough flexibility to support innovation, allow for technological advancements and encourage collaboration among disciplines to promote high-quality maternal care.

The AHA and its members firmly believe that CoPs are an essential part of a larger regulatory scheme to ensure safety and quality care in hospitals. However, the AHA believes that CoPs should be evidence-based, aligned with other laws and industry standards, and flexible to support different patient populations and communities. Excessive documentation and other regulatory requirements have been found to increase costs for patients without any corresponding improvement in the quality of care provided. The AHA urges CMS to instead consider working with hospitals to remove regulatory barriers and improve recruitment and retention of health care workers to promote patient safety and care.

Existing CoP and Other Federal, State and Local Requirements Provide for Appropriate Oversight of Obstetrics Units

Hospitals already comply with a myriad of regulations set at the federal, state and local level that address patient health and safety and ensure quality of care. In the RFI, CMS pointed to several CoPs that already apply to obstetrical services, such as standards for medical staff and infection prevention and control requirements. The AHA believes existing CoPs provide adequate protection for patients and fear more requirements that are specific to obstetrical services may lead to overlapping, conflicting or otherwise confusing requirements that negatively impact care.

For example, in the RFI, CMS asks a series of questions about whether it should require CoPs focused on credentialing and privileging of medical staff that deliver obstetrical services. Yet, the existing medical staff CoPs already require that hospitals have processes for determining whether staff have the appropriate qualifications to deliver the care they deliver in the hospital. CMS also asks about requiring obstetrical units, emergency departments, CAHs and REHs to maintain certain types of equipment. However, this may create redundancies with both the surgical services CoP requiring hospitals to maintain specific types of equipment. It also is not clear how such a requirement would align with hospital obligations under EMTALA which requires hospitals to "provide necessary stabilizing treatment for emergency medical conditions and labor within the hospital's capability and capacity."

The AHA also is concerned about the potential redundancy of some of CMS' ideas for an obstetrical care CoP with CMS' quality measurement programs that already are creating a strong incentive for hospitals to improve obstetrical care. In the RFI, CMS asks whether an obstetrical care CoP could be used to require hospitals to adopt evidence-based practices focused on certain drivers of maternal morbidity and mortality, such as hemorrhage and severe hypertension. However, CMS already requires hospitals to report on two quality measures in its Inpatient Quality Reporting (IQR) program that directly or indirectly focus on these issues. CMS' maternal morbidity structural measures ask hospitals whether they participate in perinatal quality collaboratives and adopt evidence-based practices that include those focused on eclampsia and obstetrical hemorrhage. This structural measure also forms the basis of CMS' "Birthing Friendly"

Designation in which hospitals that successfully attest to both parts of the measure have a special indicator placed on CMS' Care Compare website.

In addition, CMS has also adopted an eCQM focused on the rate of severe maternal complications, including both hemorrhage and severe eclampsia. Both the structural measure and the eCQM are relatively new to the IQR program but are intended to encourage hospitals to focus on and improve their performance on these critical topics by requiring them to report data to CMS and share the results on CMS' Care Compare website. For these reasons, adding a CoP whose requirements may not fully align with the quality measure could create unhelpful confusion and redundancy.

Overregulation has led to increased costs and is barrier to increasing access to care, and it is imperative that CMS finds the right balance. Too much regulation may lead to onerous requirements that harm patients navigating the health care system and the providers who care for them, with doctors, nurses and other hospital staff dedicating more and more time to compliance each year. In 2018, the AHA found providers spent the equivalent of $39 billion dollars each year toward complying with regulatory standards — a cost of about $1,200 per patient. An estimated 63% of these compliance efforts were attributed to meeting CoP requirements and billing and coverage verification. The time spent addressing compliance issues meant less time for patient care and increased costs for patients and hospitals.

AHA and its Members Support Efforts to Improve Maternal Health that Effectively Address the Factors Contributing to Adverse Health Outcomes

Recognizing the urgency of the maternal health crisis, AHA and its members support efforts to improve outcomes for all mothers and mothers-to-be. We wish to emphasize that hospitals do not provide safe, effective and high-quality care because of statutes and regulations; rather, hospitals provide excellent care because they care about the people in their communities. The AHA believes that a CoP is more likely to negatively impact maternal health than improve outcomes and does not consider the contributing factors occurring outside of the hospital. Regulators must be careful to ensure any approach to improving maternal health supports the core mission of hospitals, which is to provide the best possible care for their patients.

Before moving forward with new requirements, the AHA urges CMS to examine existing CoPs and statutory and other regulatory mandates to identify gaps in the regulatory framework. As noted above, we urge CMS not to duplicate CoPs efforts that may already be a part of its other regulatory programs, such as its quality measurement and value programs. We also encourage CMS to explore how it could support innovative payment and care delivery models that could lead to better maternal outcomes. For example, the Centering Pregnancy model has demonstrated measurable improvements in patient and provider satisfaction while reducing preterm births, NICU admissions and emergency department use during pregnancy. Further examination of high-value payment models tied to outcomes, along with approaches that promote collaboration among providers and

support a holistic approach to maternity care are better suited to improve maternal outcomes. And improved payment and coverage policies, like increasing reimbursement under Medicaid, are likely to be more successful in improving maternal health than a CoP. CMS might consider establishing guidance for payors that incentivizes the provision of coordinated care across the maternal health continuum. Finally, the AHA recommends CMS explore ways to improve the maternal health workforce pipeline and promote partnerships with organizations that specialize in connecting vulnerable women to critical services, allowing hospitals to focus on what they do best — caring for the members of their communities.