American Hospital Association™
Advancing Health in America

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

September 8, 2023

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–1786–P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction Proposed Rule (Vol. 88, No. 145), July 31, 2023.

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2024.

For CY 2024, CMS proposes a market basket update of 3.0% less a productivity adjustment of 0.2 percentage points, resulting in a net update of 2.8%. **The AHA has strong concerns about this inadequate update, especially when taken together with the underwhelming market basket increases from CY 2022 and 2023.** It does not capture either the unprecedented inflationary environment or the other persistent financial headwinds hospitals and health systems are experiencing. It also fails to account for the fact that labor composition and costs have remained extraordinarily high and that as a result, the hospital field has continued to face sustained financial pressures and workforce shortages. **Therefore, we urge CMS to examine ways to**

account for these increased costs to ensure that beneficiaries continue to have access to quality outpatient care. We also urge the agency to reduce the productivity cut for CY 2024 as such a cut does not align with hospital and health systems' public health emergency (PHE) experiences related to actual losses in productivity during the COVID-19 pandemic.

In addition, CMS proposes several changes to the hospital price transparency requirements related to standardization of and changes to CMS' monitoring and enforcement processes, and requests comment on how to better align the various price transparency policies going forward. **The AHA looks forward to working with CMS to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with the Transparency in Coverage and No Surprises Act requirements.**

Finally, the AHA is pleased that CMS recognizes that a more reliable and resilient drug supply is needed so that hospitals can better care for their patients and communities. However, we have several concerns and questions about the agency's proposed policy to make separate payments under the inpatient PPS, and potentially under the OPPS, for the additional costs that hospitals face in establishing and maintaining access to a buffer stock of domestically manufactured essential drugs. While the AHA strongly agrees that it is necessary to support practices that can curtail shortages, we also continue to believe that much more must be done in addressing these concerns.

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 Roslyne Schulman, AHA's director for policy, at rschulman@aha.org.

Sincerely,

/s/

Stacey Hughes
Executive Vice President

American Hospital Association
Detailed Comments on the OPPS and ASC Payment System Proposed Rule for CY 2024

TABLE OF CONTENTS

CY 2024 OPPS PAYMENT UPDATE

For CY 2024, CMS proposes a market basket update of 3.0% less a productivity adjustment of 0.2 percentage points, resulting in a net update of 2.8%. This update, especially when taken together with the underwhelming CY 2022 and 2023 updates, continues to be woefully inadequate. It does not capture what hospitals and health systems need to continue to overcome the many challenges that threaten their ability to care for patients and provide essential services for their communities. **Therefore, we ask that in the final rule, CMS examine ways to account for these increased costs to ensure that beneficiaries continue to have access to quality outpatient care. We also urge the agency to reduce the productivity cut for CY 2024, as such a cut does not align with hospital and health systems' PHE experiences related to actual losses in productivity during the COVID-19 pandemic.**

Financial Context

After battling near historical inflation and the COVID-19 crisis, hospitals and health systems are facing a new existential challenge — sustained and significant increases in the costs required to care for patients and the communities they serve. **We urge CMS to consider the changing health care system dynamics, the unlikelihood of these dynamics returning to "normal" trends and their effects on hospitals. As we detail below, theses shifts in the health care environment are putting enormous strain on hospitals and health systems, which will continue in CY 2024 and beyond.**

Throughout 2022, hospitals battled historic inflation and rising labor and supply costs. These financial pressures have continued into 2023 and will not abate soon. For example, overall hospital expenses increased by 17.5% from 2019 through 2022, yet Medicare reimbursement to hospitals grew at less than half that rate.[1] In fact, over half of hospitals ended 2022 operating at a financial loss.[2] According to an analysis, the first quarter of 2023 saw the highest number of bond defaults among hospitals in over a decade.[3] Hospitals saw a monthly decline in operating margins from 4.3% in June 2023 to *negative* 1.6% in July (the most recent data available),[4] and they are once again facing increased COVID-19 hospitalizations and admissions, with a 20% increase in both of these measures comparing beginning to mid-August.[5] Bad debt and charity care also rose month over month, as Medicaid redeterminations continue to affect hospitals

---

[1] American Hospital Association (April 2023). The Financial Stability of America's Hospitals and Health Systems is at Risk as the Costs of Caring Continue to Rise. www.aha.org/costsofcaring
[2] Kaufman Hall (January 2023). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2023-01/KH_NHFR_2023-01.pdf
[3] Becker's Hospital Review (April 2023). Hospitals See Most 1st-Quarter Defaults Since 2011. https://www.beckershospitalreview.com/finance/hospitals-see-most-1st-quarter-defaults-since-2011.html.
[4] Kaufman Hall (August 2023). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2023-08/KH-NHFR_2023-08.pdf
[5] Centers for Disease Control and Prevention. (August 29, 2023). https://covid.cdc.gov/covid-data-tracker/#hospitalizations-landing

and patients. These indicators once again signal uncertainty to hospital operations and financing in the near future.

Workforce shortages also continue to create outsized pressures on hospitals and health systems.[6] As the demand for hospital care increased, hospitals were increasingly forced to turn to health care staffing agencies to fill necessary gaps, especially for bedside nursing and other critical allied health professionals such as respiratory and imaging technicians. **As a result, contract labor full-time equivalents (FTEs) jumped 139% from 2019 through 2022.[7] Accordingly, hospitals' contract labor expenses increased a staggering 257.9% in 2022 relative to 2019 levels.[8] This, in part, drove up overall hospital labor expenses during the same period by 20.8%. These increases are particularly challenging because labor on average accounts for about half of a hospital's budget.** Our members indicate that while contract labor use has eased somewhat in 2023, they do not see the hospital field reverting to pre-pandemic labor composition or cost structure — changing workforce dynamics will continue to play out in the future.

At the same time, non-labor expenses have also continued to increase due to a historic rise in inflation. Since 2019, non-labor expenses, such as those for drugs, medical supplies and equipment, and purchased services, have increased 16.6% on a per patient basis.[9] For example, hospital supply expenses per patient increased 18.5% from 2019 through 2022, outpacing increases in inflation. Hospitals also rely on a global supply chain for access to these supplies and equipment, and ongoing supply chain disruptions have led to higher manufacturing, packaging and shipping costs, which translate into higher prices for hospitals. In fact, the National Academies recently released a report highlighting the ongoing challenges that supply chain disruptions place on providers needing to access medical supplies and CMS itself has recognized the need for a more robust supply chain for essential medicines carried by hospitals.[10]

Appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital payment update is essential to ensure that Medicare payments for acute care services more accurately reflect the cost of providing hospital care. Indeed, Medicare only pays 84% of hospital costs on average

---

[6] McKinsey & Company (September 2022). The Gathering Storm: The Transformative Impact of Inflation on the Healthcare Sector. https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector

[7] Syntellis (February 2023). Hospital Vitals: Financial and Operational Trends. https://www.syntellis.com/sites/default/files/2023-03/AHA%20Q2_Feb%202023.pdf

[8] Syntellis (February 2023). Hospital Vitals: Financial and Operational Trends. https://www.syntellis.com/sites/default/files/2023-03/AHA%20Q2_Feb%202023.pdf

[9] American Hospital Association (April 2023). The Financial Stability of America's Hospitals and Health Systems is at Risk as the Costs of Caring Continue to Rise. https://www.aha.org/costsofcaring

[10] National Academies Sciences Engineering Medicine (2022). Building Resilience into the Nation's Medical Product Supply Chains. https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains

according to our latest analysis.[11] In 2021, Medicare margins fell to *negative* 8.2% without COVID-19 relief funds,[12] after hitting an all-time low of *negative* 12.3% in 2020. Inadequate payment updates that have not accounted for inflation have caused this underpayment to become even worse since 2021. Specifically, the Medicare Payment Advisory Commission (MedPAC) projects 2023 Medicare margins will fall below *negative* 10%, the *20th straight year* of Medicare paying below costs. These underpayments are simply not sustainable.

Market Basket

As mentioned above, the proposed CY 2024 update of 2.8%, especially when taken together with the underwhelming CY 2022 and 2023 updates, continues to be woefully inadequate for the hospital field that experienced one of the worst financial years in 2022. For CY 2022, CMS finalized a market basket of 2.7%, based on estimates from historical data through March 2021. As we detailed in our comment letter on the CY 2023 OPPS proposed rule, because the market basket was a forecast of what was *expected* to occur, it missed the *unexpected* trends that actually did occur in 2022 with hospitals combatting high inflation and workforce shortages. **Indeed, including data through September 2022 yields a CMS estimate of 5.7% for the change in the actual CY 2022 market basket — a staggering 3.0 percentage points higher than the OPPS payment 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 CY 2021 into CY 2022, which resulted in a large forecast error in the CY 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. Specifically, CMS uses the Employment Cost Index (ECI) to measure changes in labor compensation in the market basket.[13] However, the ECI may no longer accurately capture the changing composition and cost structure of

[11] American Hospital Association (February 2022). Underpayment by Medicare and Medicaid Fact Sheet. https://www.aha.org/system/files/media/file/2022/02/medicare-medicaid-underpayment-fact-sheet-current.pdf

[12] MedPAC. (2023). March 2023 Report to the Congress: Medicare Payment Policy. Chapter 3 – Hospital inpatient and outpatient services. https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

[13] 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."

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. Yet, as mentioned above, this comes at the exact time that hospitals have had to dramatically turn to contract labor to meet patient demand. Contract hours as a percentage of worked hours rose 133% in 2022 compared to 2019[14] and contract FTEs grew in all clinical departments, ranging from surgical, imaging, emergency to nursing. The largest growth was in nursing where contract FTEs grew 180% from 2019 to 2022.

Indeed, CMS itself recognizes that the ECI does not capture these shifts in occupation.[15] In fact, as a response to our comments in the IPPS, CMS stated, "We acknowledge that the ECI measures only reflect price changes and does not capture changes in quantity or mix of labor such as increased utilization of contract staff."[16] This is because the ECI holds the composition of labor fixed between salaried and short-term contract based on a point in time using weights.[17] In fact, from December 2013 through September 2022, the ECI was based on the composition of labor in 2012. This means that in the CY 2022 and CY 2023 market basket payment updates, which used ECI data through March 2022,[18] the price changes in labor compensation were based on the composition of salaried and contract labor from 2012, more than a decade ago. Said another way, *the CY 2022 and 2023 market basket updates used ECI changes that measured the percent increase in the cost of hiring a 2012 labor force*. Clearly, this would not have been an accurate reflection of labor cost growth in CY 2022 or CY 2023 when contract labor use and expense has shifted dramatically.[19]

Indeed, when an alternative labor cost index, the Employer Costs for Employee Compensation (ECEC), is examined, it shows just how much bias is created by ECI's lag in updating the labor composition. The ECEC uses current employment weights, as opposed to fixed employment weights used in the ECI, to reflect the changing composition of today's labor force.[20] Since the fourth quarter of 2019, ECEC-based

---

[14] Syntellis (February 2023). Hospital Vitals: Financial and Operational Trends. https://www.syntellis.com/sites/default/files/2023-03/AHA%20Q2_Feb%202023.pdf

[15] 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."

[16] 88 Fed. Reg. 59032 (August 28, 2023).

[17] U.S. Bureau of Labor Statistics. National Compensation Measures. https://www.bls.gov/opub/hom/ncs/calculation.htm#computing-the-employment-cost-index-eci

[18] 87 Fed. Reg. 49052 (August 10, 2022). CMS uses IGI's second quarter 2022 forecast with historical data through first quarter 2022 to finalize the FY 2023 IPPS market basket.

[19] While we recognize that CMS updates the composition of labor relative to other hospital inputs through its rebasing process, this was last done in FY 2022 using FY 2018 hospital cost reports. CMS rebases the cost categories between wages and salary, employee benefits and contract labor costs and assigns cost weights every four years. However, adjusting the composition, otherwise known as cost weights, in the overall market basket does not address the problem in measuring labor cost growth, known as price proxies, that are due to a stagnant labor composition in the ECI.

[20] U.S. Bureau of Labor Statistics. National Compensation Measures. https://www.bls.gov/opub/hom/ncs/calculation.htm#employer-costs-for-employee-compensation-ecec

wage and salary costs rose 6.7 percentage points more than ECI-based costs (20% vs. 13.3%) with a large proportion of the gap attributable to 2022 Q4 alone. This all suggests that because the ECI does not account for the change in labor composition, it fails to accurately capture the changing dynamic of the current healthcare workforce. Specifically, the ECI fails to capture that labor costs have increased more rapidly due to 1) hospitals using a more expensive mix of labor and 2) that the cost of contract labor is increasing more rapidly than the cost of salaried workers.

In its response to our IPPS comments, CMS stated that because the Medicare cost report data shows contract labor hours only account for 4% of total compensation hours for IPPS hospitals in 2021, the "ECI […] is accurately reflecting the price change associated with the labor used to provide hospital care (as employed workers' hours account for 96% of hospital compensation hours" and therefore continues to be an appropriate measure in the market basket.[21] **We disagree with this assessment.** CMS is citing 2021 data when contract labor use and expense had not yet reached its peak. As we stated previously, between 2019 and 2022, contract labor FTEs jumped 139%.[22] In the same period, contract hours as a percentage of worked hours jumped by 133% and contract labor expense as a percentage of labor expense jumped 179%. To dismiss the small percentage of contract hours present in the 2021 data is shortsighted and misses the large increase in labor costs actually experienced by hospitals in 2022.

These additional shortcomings are yet another reason that we urge CMS to take action to increase the market basket in the final rule to better account for these extraordinary circumstances. Additionally, we ask that CMS expeditiously examine its rebasing and revising methods for the hospital market basket so that it can more accurately reflect the changing labor dynamics. For example, while the ECI has been updated to reflect the composition of labor in 2021,[23] this still means that price changes in the labor compensation category of the market basket going forward measures the *percent difference in the cost of hiring a 2021 labor force*. Again, we do not believe this would be an accurate reflection of labor cost growth going forward.

Productivity

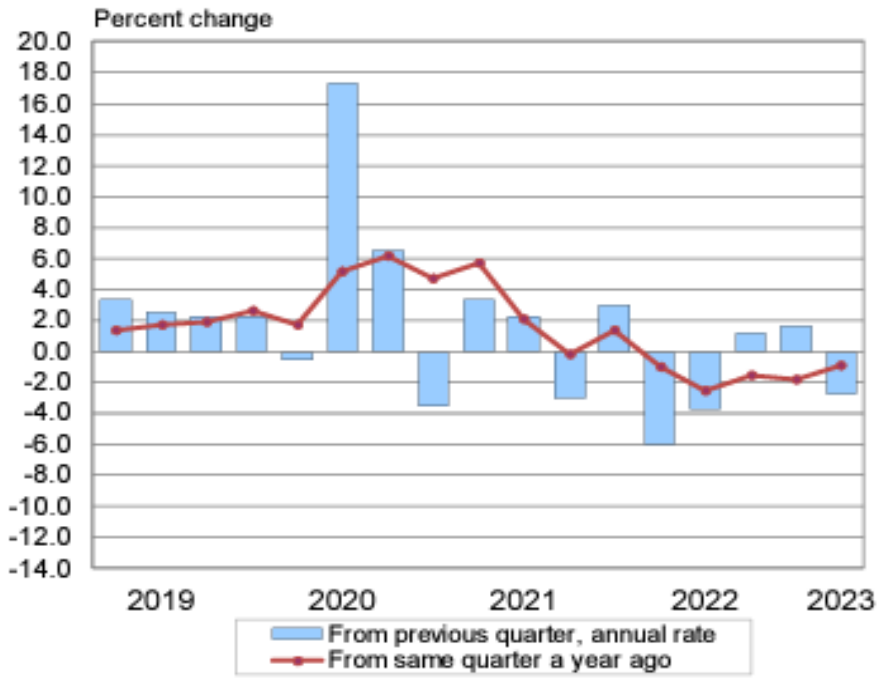
Under the Affordable Care Act (ACA), the OPPS payment update is reduced annually by a productivity factor, which is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP).[24] This measure was intended to ensure payments more accurately reflect the true cost of

[21] 88 Fed. Reg. 59032 (August 28, 2023).
[22] Syntellis (February 2023). Hospital Vitals: Financial and Operational Trends. https://www.syntellis.com/sites/default/files/2023-03/AHA%20Q2_Feb%202023.pdf
[23] In December 2022, the ECI was updated to weights using the composition of labor in 2021. https://www.bls.gov/eci/notices/2022/eci-2021-fixed-weights-and-2018-soc-update.htm
[24] Centers for Medicare & Medicaid Services. (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

providing patient care. For CY 2024, CMS proposes a productivity cut of 0.2 percentage points.

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 eliminate the productivity cut for CY 2024. As we explained in our comments last year, 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. However, in an economy marked by great uncertainty due to workforce shortages and demand and supply shocks, this assumption generates significant departures from economic reality. Indeed, the nonfarm business sector labor productivity decreased 2.7% in the first quarter of 2023 compared to the previous quarter.[25] Compared to the same quarter a year ago, it has decreased 0.9%, the first time since 1948 that the four-quarter change series has remained negative for five consecutive quarters, as shown in the graph below. Although the productivity adjustment uses a 10-year moving average, the consistent decline in this metric is also noteworthy enough that they should be given particular consideration when deciding upon the appropriate productivity adjustment for FY 2024.

Chart 1. Labor productivity, nonfarm business, 2019Q1 – 2023Q1



[25] U.S. Bureau of Labor Statistics. (May 4, 2023). Productivity and Costs, First Quarter 2023, Preliminary. https://www.bls.gov/news.release/pdf/prod2.pdf, https://www.bls.gov/opub/ted/2023/labor-productivity-rose-at-1-1-percent-annual-rate-from-fourth-quarter-2019-to-first-quarter-2023.htm

PAYMENT POLICY FOR OUTPATIENT CLINIC VISITS IN EXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

For CY 2019, citing "unnecessary" increases in the volume of outpatient clinic visits in hospital provider-based departments (PBDs) allegedly due to payment differentials driving the site-of-service decision, CMS finalized a policy to pay for clinic visits furnished in excepted off-campus PBDs at the same rate they are paid in non-excepted off-campus PBDs. For CY 2023, CMS finalized its proposal to exempt rural sole community hospitals from this site-neutral payment policy, however all other hospital outpatient clinic visit services in excepted off-campus PBDs would continue to be paid at 40% of the OPPS payment amount. **By continuing the cut, CMS has undermined clear congressional intent and exceeded its legal authority, despite the U.S. Supreme Court, on June 28, 2021, declining to review the unfavorable ruling by the appeals court that deferred to the government's inaccurate interpretation of the law. We continue to urge the agency to withdraw this policy.**

The AHA refers CMS to our prior and still relevant comments in which we urged the agency to reverse entirely this harmful policy and we provided evidence that:

- contrary to CMS's assessment, outpatient volume and expenditure growth are not unnecessary;
- continued cuts to hospital reimbursements for clinic visits are excessive and harmful, especially at a time of tremendous financial challenges; and
- site-neutral policies are based on flawed assumptions.

PAYMENT FOR INTENSIVE CARDIAC REHABILITATION SERVICES PROVIDED BY A HOSPITAL'S OFF-CAMPUS, NON-EXCEPTED PBD

A provision in the Medicare Improvements for Patients and Providers Act of 2008 requires that, starting in 2010, intensive cardiac rehabilitation (ICR) services provided in physician offices are to be paid at 100% of the OPPS rate. Nevertheless, since 2017, due to the site-neutral payment provisions of Section 603 of BiBA, payments for ICR services furnished in off-campus, non-excepted PBDs of a hospital have been reduced to the physician fee schedule (PFS) equivalent rate of 40% of the OPPS rate.

In this rule, CMS recognizes that a site-neutral payment rate for ICR services is inconsistent with the intent of Section 603, which is to remove the disparity in payment rates for the same services, regardless of whether they were furnished in a physician's office or an off-campus, non-excepted PBD of a hospital. Therefore, CMS proposes to pay for these non-excepted ICR services at 100% of the OPPS rate starting in CY 2024, which is the amount paid for these services under the PFS.

The AHA appreciates that CMS has recognized the need to address this underpayment for off-campus, non-excepted ICR services and supports its proposal to pay for these services at 100% of the OPPS rate moving forward. However, we note that although the agency describes this as an "unintentional reimbursement disparity," it has resulted in the underpayment of hospitals since the site-neutral payment provisions were first implemented in 2017. **As such, we urge CMS to calculate the full amount of underpayment to hospitals and repay each hospital the amount of its underpayment from CY 2017 through CY 2023.**

PAYMENTS FOR 340B DRUGS

The AHA appreciates CMS' decision to continue its current policy to pay 340B hospitals the same rate as non-340B hospitals for separately payable drugs and biologicals purchased under the 340B drug pricing program. However, we urge the agency to abandon its position to require hospitals to report a 340B modifier.

Use of 340B Informational Modifiers

CMS established the use of the "JG" and "TB" modifiers as part of its unlawful policy that cut payments to 340B hospitals. Despite the end of this policy upon the Supreme Court's unanimous ruling, the agency has continued to require hospitals to report separately payable drugs purchased under the 340B program using either the "JG" or "TB" modifiers, depending on the type of 340B hospital. Now the agency is seeking to consolidate these two modifiers into one single "TB" modifier for all 340B hospitals. **While we appreciate that CMS is proposing such a change, the AHA instead urges the agency to abandon the use of the 340B modifier entirely.**

The use and implementation of modifiers adds significant administrative burden — it requires considerable investment in systems and staff time to ensure that the modifiers are appropriately appended to the claims. In this case, even though the agency is attempting to consolidate modifiers, hospitals currently billing the "JG" modifier will need to modify their systems and programs to accommodate this change.

Forcing hospitals to undertake this cost and staff burden directly contravenes CMS' longstanding policy to reduce provider burden, especially when less burdensome alternatives exist. Specifically, CMS states that it needs to have a 340B modifier in place to conform to the Inflation Reduction Act (IRA). However, we disagree. Specifically, the IRA excludes units of drugs that were purchased under the 340B program from being subject to the inflation rebate. To collect the necessary information, the agency could, for example, exclude all units of separately payable outpatient drugs (identified using the claim status indicator "K") that are billed by hospitals that participate in 340B. CMS also has the ability to identify which hospitals are currently participating in 340B, since that list is public and available through the Health Services and Resources

Administration website. Under this alternative, the agency could use a far less burdensome approach, while still adhering to the IRA provision.

340B Remedy Proposed Rule

The AHA has submitted comments on the agency's proposed rule remedying its unlawful policy that cut payments to 340B hospitals between CYs 2018 and 2022. In summary, the AHA strongly supports the agency's proposal to make a one-time lump sum payment to 340B hospitals for the amounts they were underpaid from 2018 to 2022, as well the proposal to pay 340B hospitals what they would have received in beneficiary cost-sharing had the unlawful 340B payment policy not been in effect. **We urge the agency to finalize these aspects of the proposal immediately.**

At the same time, the AHA urges the agency to not finalize its proposal to recoup funds from hospitals as a "budget neutrality adjustment." As explained at great length in our comment letter, the statutes that the Department of Health and Human Services' (HHS) relies on in its proposed rule do not give it the authority to make a "budget neutrality adjustment." Nor do they require budget neutrality as a matter of law. Additionally, the agency's public policy justifications do not support a retrospective adjustment. Thus, contrary to suggestions in the proposed rule, HHS has both the legal obligation and legal flexibility to not seek a claw back of funds that hospitals received as a result of HHS' own mistakes and have long since spent on patient care.

If the agency does finalize a recoupment, the agency must:

- drastically reduce the overall amount to comply with the Supreme Court's recent decision in *Biden v. Nebraska*;
- delay any recoupment until 2026 or later;
- finalize the current aspect of the proposal that would spread the "adjustment" across 16 years, as proposed; and
- recoup funds in a way that does not lead to a Medicare Advantage Organization windfall at the expense of hospitals and health systems.

BEHAVIORAL HEALTH PROVISIONS

CMS proposes multiple provisions related to behavioral health in this rule, many of which are to implement aspects of the Consolidated Appropriations Act (CAA) of 2023. The AHA appreciates CMS' work on these important issues that have long gone under-addressed and welcomes the thoughtful approach to behavioral health care that the agency has employed in this and other recent rules. We look forward to working with CMS to carry out these provisions and hope we can help the Administration further hone its oversight, coverage and payment for behavioral health services in the future.

Intensive Outpatient Programs (IOP)

The CAA established a new Medicare benefit category for IOP services furnished by hospital outpatient departments (HOPDs), community mental health centers (CMHCs), federally qualified health centers (FQHCs) and rural health clinics (RHCs) to begin Jan. 1, 2024. To implement this part of the statute, CMS proposes several provisions, including updates to existing regulations regarding PHPs. **The AHA appreciates CMS' attention to this important advancement in access to behavioral health care provided by ambulatory facilities. It is our interpretation that the agency is appropriately implementing the benefit as directed by the statute; we urge the agency to robustly monitor utilization of IOP services as billed under Medicare Part B to ensure that there are no unintended consequences stemming from the design of the benefit as proposed in this rule.**

That said, we are disappointed that CMS does not discuss how remote services could factor into the newly establish IOP benefit. We understand from the CY 2023 OPPS final rule that remote PHP services were allowed to be delivered under waivers granted as part of the COVID-19 PHE, which ended in April of this year and that patients receiving care through a PHP could receive remote behavioral health services, but they would not be considered part of the PHP. We assume that CMS takes a similar stance in this rule, both for PHP and IOP services. **However, we encourage the agency to consider including at least some or a proportion of PHP or IOP services to be delivered remotely as a way to increase access to these benefits.** CMS proposes that, to be eligible for IOP services under the newly established benefit, patients would have to require a minimum of nine hours per week of therapeutic services as evidenced in their plan of care; requiring the patient to be seen in-person at the HOPD or CMHC for all nine-plus hours (or 20-plus hours, as defined in the PHP benefit) might limit eligibility for coverage. We do not dispute CMS' eligibility criteria and agree that there is certain benefit for patients requiring the level of care provided by a PHP or IOP to be seen at a clinical facility, but we also think there is room for clinicians to determine whether some of those services could be delivered remotely for the benefit of the patient.

Payment Methodology. In implementing a payment methodology for IOP services, CMS proposes to revise the methodology for calculating PHP services and mirror that revised methodology for IOP services. Specifically, it would establish four separate PHP per-diem rates and four separate IOP per-diem rates at the same rates as those proposed for PHP; in addition, the agency proposes to differentiate per-diem payments based on whether the patient received the typical four services in a day versus three or fewer. **We believe it is appropriate to value the services the same regardless of whether they are billed as part of a PHP or an IOP; we also support CMS' revision to define incomplete service days as those when the patient receives three or fewer services due to extenuating circumstances that result in the patient being unable to complete a full day of treatment.** We appreciate CMS' acknowledgment

that an incomplete day of services still requires resources on the part of the HOPD and its staff, and think this is a suitable strategy for addressing those costs.

CMS proposes to establish payment under Part B for IOP services furnished by OTPs for the treatment opioid use disorder (OUD) beginning CY 2024. While the CAA did not specifically include OTPs as providers of IOP services, the Social Security Act does allow the secretary the discretion to add other items and services furnished by an OTP for the treatment of OUD to the list of covered services under the Medicare OTP benefit. Thus, CMS would add a new category of services called OTP intensive outpatient services and incorporate these services in the definition of OUD treatment services that are covered under the Part B OTP benefit. **The AHA supports this proposal and appreciates that CMS is using its authority under the Social Security Act to further expand access to care by including additional settings.** We also agree that it is appropriate to exclude the Food and Drug Administration (FDA)-approved opioid agonist or antagonist medications for the treatment of OUD from this payment, as they are already included in the weekly OTP bundled payment.

Coding and Billing for PHP and IOP Services under the OPPS. To differentiate between IOP and PHP for billing purposes, the National Uniform Billing Committee approved a new condition code 92 to identify intensive outpatient claims. **In response to CMS' request for comment on reporting requirements for PHP and IOP, we support the below proposals as written:**

- to require hospitals and CMHCs to report condition code 92 on claims to indicate that a claim is for intensive outpatient services;
- to continue to require hospitals to report condition code 41 for partial hospitalization claims;
- to require CMHCs to report condition code 41 for partial hospitalization due to CMHCs being permitted to provide both PHP and IOP beginning Jan. 1, 2024.

CMS proposes that the Healthcare Common Procedure Coding System (HCPCS) codes listed in Table 43 of the rule would be payable when furnished by PHPs or IOPs. This list includes the addition of eighteen codes, the removal of one code, and the revision of five code descriptions. **We support the code additions, code removals and code description revisions proposed.** These codes are currently recognized as mental health codes under the OPPS but are not yet recognized for PHP payment. We appreciate that CMS acknowledges that the level of intensity of mental health services a patient requires may vary over time and that a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits would ensure a smooth transition for patients when a change in the intensity or their services is necessary to best meet their needs.

We also support CMS' proposal to add CPT code 90853 (Group psychotherapy) to the list of service codes recognized for PHP and IOP. In addition, CMS believes there could be overlap between 90853 and two existing Level II HCPCS codes for PHP group psychotherapy (G0410 and G0411). As such, it requests comment on whether it would be appropriate to remove G0410 and G0411 from the list of recognized service codes for PHP and IOP and retain only CPT code 90853. **We disagree that removing G0410 and G0411 from the list of recognized PHP and IOP services would be appropriate.** Based on the 2023 CPT Code Book Section Notes for G0410 and G0411, these G codes "are used to identify professional health care procedures and services that would otherwise be coded in CPT but for which there are no CPT codes and refers readers to the CPT book for possible alternate code(s)." While it is possible to have overlap, it is unlikely. These three codes each describe therapy provided in a group; however, there are differences as indicated in the CPT lay descriptions and application of these codes that need to be considered — for example, group therapy provided by differences in approach and who is facilitating the treatment, i.e., "psychiatric treatment providers" vs. "therapist." For this reason, we believe it would be most appropriate to retain all three codes on this list to account for nuances in exactly what services are being provided.

Remote Behavioral Health Services

In the CY 2023 OPPS final rule, CMS established three new HCPCS codes for diagnosis, evaluation, or treatment of a mental health or substance use disorder performed by hospital clinical staff for patients in their homes. In this rule, CMS proposes refinements to those existing codes as well as a new code for group psychotherapy.

Updated Code Descriptors. CMS proposes to remove the word "initial" from the descriptors of the existing HCPCS codes in order to allow for billing with the codes when furnished as a subsequent service. That is, instead of HCPCS code C7901 being described as "Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, *initial* 30-60 minutes" (emphasis added), the code would simply describe 30-60 minutes of care and could be billed again if another 30-60 minutes of care were furnished subsequently. **The AHA supports this change and appreciates that CMS is listening to stakeholders and working to ensure that codes can be billed appropriately.**

New Code for Group Psychotherapy. CMS proposes to create a new, untimed HCPCS C-code describing group therapy that can be reported when a beneficiary receives multiple hours of remote group therapy per day. The agency reasons that this would be less administratively burdensome than reporting and documenting each unit of time using the other three codes. **The AHA supports the creation of this new code.** We believe it will reduce administrative burden and, by explicitly including a code for this

service, will encourage providers to offer remote group therapy, improving access to care.

Delayed In-person Service Requirements. CMS proposes to delay in-person service requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until Jan. 1, 2025. In previous rulemaking, the agency adopted statutory requirements for beneficiaries to receive an in-person service within six months prior to the first and within 12 months after each remote mental health service, with certain exceptions. The requirements were originally set to take effect on the 152nd day after the end of the COVID-19 PHE.

The AHA supports this delay and encourages CMS to work with Congress to permanently remove these requirements. These in-person service requirements are arbitrary and not based upon any clinical guidelines or evidence. While some patients certainly should receive in-person services complementary to their remote interactions, the decision to do so should be made by that patient and their clinician rather than mandated by a regulatory body. While CMS allows for this requirement to be waived if the patient and their physician determine that the risks and burdens outweigh the benefits, providers must include clear justification documented in the beneficiary's medical record including the clinician's professional judgment behind the decision. It is incongruous that providers must provide clinical evidence that the in-person visit is unnecessary while there is no clinical evidence that the in-person visit is necessary in the first place.

PROPOSED OPPS PAYMENT FOR DENTAL SERVICES

The AHA supports CMS's proposal to assign 229 HCPCS codes describing dental services to clinical APCs. Doing so aligns with proposals in the CY 2023 PFS final rule and would result in greater consistency in Medicare payment for these sites of service. It also would help ensure that patients have access to dental services in the hospital outpatient setting.

However, we request clarification from CMS on hospital reporting of HCPCS code G0330, which describes facility services for dental rehabilitation procedures performed on a patient who requires monitored anesthesia and the use of an operating room. That is, may G0330 also be reported when one or more of these 229 dental codes are applicable, and the procedure is performed in an operating room under anesthesia? We note that CMS has discussed adding G0330 to the list of covered ASC procedures and explained that G0330 should be reported in addition to one or more of the applicable dental codes when performed in an operating room under anesthesia. **The AHA requests that CMS provide similar guidance to hospitals for reporting G0330 and one or more of the applicable dental codes when performed in an operating room under anesthesia.**

PROPOSED CHANGES TO THE INPATIENT-ONLY LIST

The inpatient-only (IPO) list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. As usual, CMS, in consultation with stakeholders, has evaluated the IPO list using its longstanding criteria in order to determine whether any services should be added to or removed from the list.

The AHA supports CMS' proposal to add nine new CPT codes to the IPO list. These codes were created by the American Medical Association CPT Editorial Panel for CY 2024 and represent procedures involving thoracolumbar, lumbar and thoracic vertebral body tethering; skull-mounted cranial neurostimulators; and epiaortic and epicardial ultrasound/placement of transducers. **Additionally, we support CMS' proposal to change the status indicator for CPT code 0646T (transcatheter valve implantation/replacement procedures) from status indicator "E1" to "C" and add this code to the IPO list for CY 2024.** This proposed payment status indicator change would reflect a change in payment status from not payable by Medicare on outpatient claims to payable when admitted as an inpatient. We support CMS' clinical review of these services in that the services represented by this code require hospital admission.

While CMS does not propose to delete any CPT codes from the IPO list for CY 2024, the agency does request public comment on whether the services described by the CPT codes listed below, which represent gastric restrictive procedures, should be removed from the IPO list.

- CPT code 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
- CPT code 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less))
- CPT code 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), and
- CPT code 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis).

The AHA believes that the complexities of the patients undergoing these procedures must be considered thoroughly prior to making any determination that these procedures could be safely performed on Medicare beneficiaries in an outpatient setting. We recommend that CMS rely on updated clinical evidence provided by surgeons and other clinical experts as well as the agency's longstanding criteria for final determination of whether it would be appropriate to remove these procedures from the IPO list.

In particular, regarding CPT 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis), we are especially concerned that performing these procedures in an outpatient setting would pose a significant risk of increased morbidity and mortality for the Medicare population. Our clinical experts report that this complex procedure, even when performed in an inpatient setting on a younger and healthier population, with all the tools used to enhance recovery, still requires an approximately three-day hospitalization. In the Medicare population, it would be reasonable to expect a hospitalization of between 3-5 days due to this population's higher rate of medical comorbidities. We believe that it would not be safe or appropriate to permit these procedures to be performed in an outpatient setting and have patients return home the same day. This would place patients at significant risk of deterioration of their conditions and could lead to an increased risk of ileus and anastomotic leak, possibly resulting in sepsis or even death. **Therefore, the AHA urges CMS not to remove CPT 44204 from the IPO list.**

CANCER HOSPITAL ADJUSTMENT

Due to a requirement in the ACA, since CY 2012 CMS has provided additional OPPS payments to each of the 11 "exempt" cancer hospitals so that each cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average "target" PCR for other OPPS hospitals. The 21st Century Cures Act requires that this target PCR be reduced by 1.0 percentage point to account for the exemption these 11 hospitals have from Medicare's site-neutral payment policy.

In the proposed rule, CMS estimated that, on average, the CY 2024 target PCR for other hospitals furnishing services under the OPPS is 0.86. After applying the required 1.0 percentage point reduction, the resulting target PCR would be 0.85. CMS notes that 0.85 is far lower than the target PCR from previous years and expresses concern that the impact of the COVID-19 PHE claims and cost data used to calculate the target PCR may continue to have some limited influence on its target PCR calculations.

Therefore, for CY 2024, CMS proposes to begin with the target PCR of 0.89 finalized for CYs 2020 through 2023 and incrementally reduce it by 1.0 percentage point for each calendar year, beginning with CY 2024, until it equals the PCR of non-cancer hospitals calculated using the most recent data (minus 1.0 percentage point as required by the 21st Century Cures Act). As a result, the proposed target PCR for CY 2024 would be 0.88.

The AHA supports this proposed methodology. We also request that in the final rule, CMS confirm that under this methodology, the repayments to be made to 340B hospitals are appropriately included in the final CY 2024 target PCR calculation. Doing so is necessary to ensure that each cancer hospital's payment adjustment is correctly calculated, as required by the ACA.

OUTPATIENT QUALITY REPORTING PROGRAM (OQR)

CMS proposes several updates to the measure set used in the OQR, including the removal of one measure, the adoption of three measures, and the modification of three more.

Removal of Left Without Being Seen (LWBS) Measure

Beginning with the CY 2024 OQR reporting period, CMS proposes to remove the LWBS measure. The measure assesses the percent of patients who leave the emergency department (ED) without being evaluated by a physician, advanced practice nurse or physician's assistant. Originally adopted for the CY 2013 payment determination, the measure lost consensus-based entity (CBE) endorsement. In addition, CMS found through its routine measure monitoring and evaluation that the measure lacks evidence linking its use to improved patient outcomes. Further, increased LWBS rates may reflect poor access to care rather than inefficient patient flow in the ED. **The AHA supports the removal of this measure from the OQR and appreciates that CMS recognizes the influence of factors beyond the control of HOPDs in this outcome.** We hope that the agency can apply similar logic to other measures still included in the OQR, such as OP-13, Median ED Time from ED Arrival to ED Departure for Discharged ED Patients.

Modification of COVID-19 Vaccination Coverage Among Health Care Personnel (HCP) Measure

Beginning with the FY 2025 OQR, CMS would adopt a modified version of the COVID-19 Vaccination Coverage among HCP currently used in the OQR (and other quality reporting programs). While the current measure assesses the number of HCP who "have received a complete vaccination course against COVID-19," CMS would replace this term with "who are up to date" with their vaccination as recommended by the Centers for Disease Control and Prevention (CDC) at the time of the reporting period.

The AHA strongly supports the vaccination of health care personnel and communities against COVID-19. We also agree with CMS' rationale underlying the proposal to adopt this modified measure, which is that measures used in CMS quality reporting programs should reflect the current science. CMS has already issued final rules for other quality reporting programs, including the IQR, which finalize the adoption of this modified measure, so we assume that the agency will also adopt the measure for the OQR considering that the current measure is reported at the facility level (i.e. it does not differentiate between inpatient and outpatient staff, and thus it would not be feasible to have two different measures across the OQR and IQR).

Despite the inevitability of the adoption of this measure, we reiterate our comments on this measure as proposed in the FY 2024 IPPS Proposed Rule and encourage CMS to learn from the experience of implementing the previous version of this measure.

Specifically, we think CMS should take into account the foreseeable logistical challenges of data collection and reporting of this updated measure. In addition, we continue to urge that CMS get the measure endorsed by a CBE; the CBE endorsement process will enable a full evaluation of a range of issues affecting measure reliability, accuracy and feasibility.

Finally, CMS needs to consider how to implement this measure in a way that is consistent and logical with other sources of information regarding vaccination among health care personnel. The time lag between data collection and the publicly reported rate will result in a mismatch between the true rate of health care personnel who are up to date with their vaccinations and the rate that is displayed on Care Compare; CMS needs to clearly communicate what publicly reported data reflects. We also recommend that CMS develop an additional exclusion for this measure to account for sincerely-held religious beliefs, which was included in the recently sunset Condition of Participation (CoP) requiring vaccination among health care personnel; although the CoP is no longer enforced, the inconsistency across regulatory requirements has proven to be confusing and challenging for providers.

Modification of Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery Measure

CMS proposes to modify this measure that is currently reported voluntarily by HOPDs and ASCs. It assesses the percentage of patients who had cataract surgery and had improvement in visual function within 90 days of the procedure based on results from pre- and post-operative surveys. Currently, CMS does not require the use of a particular survey tool for this measure; however, stakeholders have requested additional guidance from CMS regarding measure specifications and survey instruments considering the continued operational difficulties collecting and reporting the measure. In fact, in AHA's comments on the CY 2023 OPPS proposed rule, we raised the concern that clinicians may use any validated survey as part of this measure; this means that a patient's visual function could be assessed using different surveys in the pre- and post-operative settings, culminating in results that are not entirely comparable.

In response to the latter concern, CMS proposes to limit the allowable survey instruments that an HOPD or ASC may use to inform this measure two three specific tools. While we appreciate that CMS is attempting to address one of the issues with this measure, the change would do little to address that its burden outweighs its utility in improving care for patients undergoing cataract procedures. In the interest of a streamlined measure set focused on the highest priority topics, we think this measure does not merit inclusion.

Modification of Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients Measure

CMS proposes to update this measure, which assesses the percentage of patients aged 50 to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. Specifically, the agency would amend the lower end recommended age to begin screening from 50 to 45, in line with the United States Preventive Services Task Force's 2021 revised recommendations on colorectal cancer screenings. **The AHA supports this change and appreciates that CMS is working to keep measures in use in its quality reporting programs consistent with current science.**

Re-Adoption of HOPD Volume Data on Selected Outpatient Surgical Procedures Measure

The AHA does not support the use of this measure in CMS quality reporting programs. The measure has already been removed from the OQR and ASCQR because it lacks value and evidence of a connection to improved outcomes; it has not been tested for validity or reliability; it was never reviewed let alone endorsed by a CBE because it predates the pre-rulemaking measure review process. We also worry that if adopted into the OQR, it could be used in the calculation of Star Ratings performance or used in other patient safety programs, which would be wholly inappropriate considering the lack of evidence connecting use of the measure to improved patient outcomes.

While CMS acknowledges that "quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes," and that while larger facility surgical volume may be *associated* with better outcomes, these outcomes are likely attributable to other characteristics that are proven to improve care (such as effective care teams and robust surveillance). However, the agency also reasons that a volume measure would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities.

Volume measures are inconsistent with the important and strategic goals of CMS' own Meaningful Measures 2.0 framework, and we are concerned that the agency would consider moving forward with an idea that is so incongruous with the significant work it has undertaken to streamline and focus its quality reporting programs on the most important and useful measures. According to CMS, "Meaningful Measures 2.0 will promote innovation and modernization of all aspects of quality." In the time since the volume measures were removed from the OQR and ASCQR, no new information has emerged about the exact volumes of procedures at which patient outcomes will improve significantly. As a result, any prescribed number of procedures against which a hospital is measured has a significant chance of being arbitrary. Performance comparisons based on those volumes also could mislead, rather than inform, the choice of facilities for patients as this measure "rolls up" volumes by surgical category. For example, "gastrointestinal" procedures cover a wide range of surgeries, so a patient seeing an indicator of good performance in the category might actually receive care from a

provider who has less experience performing a particular procedure under that category.

Much more sophisticated and meaningful measures of quality and safety have emerged, and we believe a modernized approach to measurement should look forward to these new approaches, rather than backwards at measures the agency itself already has concluded do not meaningfully advance quality and safety.

In addition, CMS also notes that its framework "will further shape the entire ecosystem of quality measures that drive value-based care." By definition, value-based care replaces the traditional fee-for-service approach in which providers are paid based on the volume of services they deliver by instead focusing on health outcomes on a larger scale. Thus it is again inconsistent to consider measuring volume to inform a system seeking to improve outcomes.

Finally, it is unclear how such a measure of volume would fit into CMS' streamlined priorities in its 2.0 framework. We support the agency's efforts to use only high-value quality measures that impact key quality domains and align measures across programs; no other CMS quality reporting program utilizes a measure regarding procedure volume.

We urge CMS to continue to support the priorities in its Meaningful Measures framework by focusing on high-value measures and avoid undoing the progress it has made to date by considering reimplementing measures without evidence linking them to improved outcomes.

Adoption of Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

CMS proposes to adopt this measure first on a voluntary basis and then with mandatory reporting beginning with the CY 2027 reporting period. The measure reports the facility-level risk-standardized improvement rate in PROs following elective primary outpatient THA/TKA procedures. The measure was adopted into the IQR in the FY 2023 IPPS final rule and is currently being reported voluntarily with mandatory reporting starting July 1, 2025.

The AHA supports the voluntary reporting of this measure but urges CMS not to mandate its reporting at this time. Patient-reported outcomes measures are a priority under CMS's Meaningful Measures initiative, and this measure addresses procedures for which a PRO is appropriate. In addition, the measure is endorsed by a CBE for use in the inpatient setting, and its adoption across both inpatient and outpatient programs would foster alignment across the hospital continuum. However, testing of the measure for the HOPD and ASC settings has not been completed and the measure has not been endorsed by a CBE for use in those programs; we encourage CMS to wait until these processes have been completed before mandating reporting of the measure to ensure

that the measure operates as intended and gleans information that is useful for providers performing and patients receiving THA and TKA procedures in these settings. In addition, we suggest CMS monitor results from the voluntary periods in the IQR and OQR for feasibility, validity and response rates, particularly in light of certain patient-level characteristics that may influence response rates.

Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults Measure

As noted in our comments on the FY 2024 IPPS proposed rule in which CMS proposes this measure for adoption in the IQR, the AHA does not object to adding this proposed measure to the menu of available eCQMs for the IQR and Promoting Interoperability Program; however, we have questions and concerns about the feasibility of reporting this eCQM as part of the OQR, as HOPDs do not participate individually in the Promoting Interoperability Program and thus do not have options of measures to report. Therefore, if CMS were to move forward with adoption of this measure for the OQR, we urge the agency to implement it in a way that allows for reporting of a single hospital-wide rate rather than distinct inpatient and outpatient measures, like the COVID-19 Vaccination among HCP measure. This would reduce confusion by aligning imaging performed across a single hospital regardless of setting and would ease reporting burden for HOPDs.

Because of this question as well as the sheer complexity of the measure, we strongly urge CMS not to mandate its reporting until hospitals gain further implementation experience.

ASC PAYMENT SYSTEM PROPOSALS

Proposed ASC Payment System Update

For CYs 2019 through 2023, CMS adopted a policy to update the ASC payment system using the hospital market basket update. The agency proposes to extend this policy for an additional two years — through CY 2025 — due to concerns about the impact of the COVID-19 PHE on healthcare utilization. Therefore, for CY 2024, CMS proposes to increase ASC payment rates by 2.8% for ASCs that meet the quality reporting requirements under the ASCQR Program.

Medicare payment should reflect providers' underlying costs and patients served. Hospitals and ASCs obviously have different costs and serve different patients. As such, it is inappropriate to continue to use the hospital market basket to update payments for ASCs. **Thus, the AHA opposes CMS's proposal to extend this policy. We instead recommend that it allow it to expire after CY 2023 as originally intended. We also recommend that CMS work expeditiously with ASC stakeholders to develop and implement a minimally burdensome way to collect**

ASC costs that could then be used to finalize an appropriate update mechanism in the future, if necessary.

We are not alone in our continued concern in this area. Indeed, MedPAC has, since 2010, consistently recommended a similar approach. In fact, in its March 2022 report, it recommended that the secretary "require ambulatory surgical centers to report cost data." It further states, "[b]eginning with the Commission's March 2010 report to the Congress, the Commission has stated in comment letters and in published reports that the CPI–U likely does not reflect the current input costs of ASCs. However, the Commission does not support using the hospital market basket index as an interim method for updating the ASC conversion factor because this index also does not accurately reflect ASCs' costs (Medicare Payment Advisory Commission 2018a) ... We are concerned that neither the CPI–U nor the hospital market basket index reflects ASCs' cost structure … The Commission asserts, however, that all other institutional providers submit at least abbreviated versions of cost reports to CMS, including small entities such as hospices and home health agencies. Moreover, ASCs in Pennsylvania submit revenue and cost data each year to the Pennsylvania Health Care Cost Containment Council, so it is clear that submission of cost data is feasible for ASCs. Nevertheless, CMS has not acted on this issue." MedPAC has suggested several streamlined cost-collection processes that could be used to determine an appropriate input price index for ASCs.

Proposed Changes to ASC Covered-procedures List (CPL)

We appreciate CMS' evaluation of the ASC CPL each year to determine whether any procedures should be added to or removed from the list using general exclusion criteria established under the ASC payment system to evaluate the safety of procedures for performance in an ASC.

For CY 2024, CMS proposes to add 26 dental surgery procedures to the ASC CPL based upon CMS' review of the clinical characteristics of these procedures, as well as consultation with stakeholders and multiple clinical advisors. **We support the addition of these procedures to the ASC CPL for CY 2024.**

Unpackaging of Non-opioid Pain Management Drugs Under the ASC Payment System

Under a policy adopted in 2019, non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are unpackaged and paid separately at ASP plus 6%. The goal of the policy is to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives. In this rule, CMS proposes to pay separately for four drugs, including HCPCS codes C9290 (Exparel), J1097 (Omidria), J1096 (Dextenza) and C9089 (Xaracoll), as non-opioid pain management drugs that function as a supply in a surgical procedure under the ASC payment system.

The AHA appreciates that CMS is engaging stakeholders to investigate novel strategies to address the opioid crisis. We continue to agree that stemming the tide of this epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain. However, packaging payments for non-opioid alternatives not only presents barriers to care in ASCs, but also in HOPDs. **Therefore, we recommend that in CY 2024, CMS similarly unpackage these non-opioid pain management drugs in HOPDs.** Based on feedback from our members, the AHA believes that this strategy has the potential to incentivize use of non-opioid pain management drugs in *all* settings in which outpatient surgery and other outpatient services involving pain management are furnished (such as in the ED). While certainly not a comprehensive solution to the opioid epidemic, unpackaging appropriate non-opioid therapies is a low-cost tactic that could change long-standing practice patterns without major negative consequences.

Moreover, as we discuss below, the AHA continues to support unpackaging other non-opioid treatments including drugs, devices and therapy services that are not currently separately payable in either the ASC or HOPD setting.

COMMENT SOLICITATION ON ACCESS TO NON-OPIOID TREATMENTS FOR PAIN RELIEF UNDER THE OPPS AND ASC PAYMENT SYSTEM

The CAA, 2023 provides for temporary additional payments for non-opioid treatments for pain relief. It provides that for non-opioid treatments for pain relief furnished between CYs 2025 and 2028, the secretary may not package payment into the payment for a covered HOPD or ASC service and must make a separate additional payment for it. The CAA also provides for additional payment and sets a limitation on that amount. Because the additional payments are required to begin on Jan. 1, 2025, CMS states that it will include proposals to implement these provisions in the CY 2025 OPPS/ASC proposed rule.

To prepare for implementing these CAA provisions, CMS is seeking comment on:

- Potential qualifying drugs, biologicals and devices that would meet the definition of a non-opioid treatment for pain relief.
- The best way to obtain, evaluate and assess information from a clinical trial or data published in a peer-reviewed journal which demonstrates the ability of a non-opioid treatment that is a medical device to replace, reduce or avoid intraoperative or postoperative opioid use or the quantity of opioids.

- How the agency should determine the HOPD services with which such devices are furnished for purposes a calculating the payment limitation for each treatment.

The AHA appreciates that CMS is engaging stakeholders in advance of the implementation of this statutory provision. We continue to agree that stemming the tide of this epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain. We are pleased that Congress has determined that packaging payments for non-opioid alternatives not only presents barriers to care in ASCs, but also in HOPDs. Accordingly, we support the provisions in the CAA which would require CMS to unpackage non-opioid pain management treatments in HOPDs in CYs 2025 though 2028.

The AHA specifically supports separate payment for continuous infusion pumps, as our members suggest that this would be a helpful approach to increase the usage of these non-opioid therapies. For example, the "On-Q" pain relief system is a portable pain system that provides non-opioid local anesthetic medication to the site of the pain. Its purpose is the same as Exparel's — to deliver relief at the site of the pain rather than by a systemic pain reliever. It also prevents the side effects that many people experience from oral medications. Other drugs that should be considered for separate payment are intravenous (IV) Ibuprofen and Ofirmev (IV Acetaminophen). Our members also have suggested that CMS consider separate payment for Polar ice devices that use ice and water for post-operative pain relief after knee procedures. In addition, therapeutic massage, THC oil applied topically, acupuncture and dry needling procedures are very effective therapies for relief of both post-operative pain and long-term and chronic pain.

RURAL EMERGENCY HOSPITALS (REH)

Under the CAA, 2021, Congress established a new rural Medicare provider type, the rural emergency hospital (REH), which allows facilities to provide emergency hospital services for Medicare payment without the need to furnish acute care inpatient services. Under statute, REHs are paid 105% of the OPPS rate for covered outpatient services, plus an additional facility payment.

Some tribal and Indian Health Services (IHS) hospitals have expressed interest in converting to an REH. However, they are excluded from the OPPS and are paid for outpatient services furnished to Medicare beneficiaries at a per-visit rate, the all-inclusive rate (AIR). As such, they have expressed reservations in having to transition from the existing AIR payment methodology to the REH payment methodology. Consequently, CMS is proposing that IHS hospitals that convert to REHs be paid for hospital outpatient services under the applicable AIR. That is, the AIR would serve as the payment for services furnished by converted IHS hospitals. Additionally, to the extent that IHS hospitals are currently compensated via the

AIR, rather than another Medicare payment mechanism, for services other than hospital outpatient services that are furnished as part of an outpatient hospital encounter, CMS is proposing that the converted IHS to REH would also be paid the AIR when furnishing these services as part of the outpatient hospital encounter.

The agency is also proposing that the converted IHS hospital receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribally or IHS operated. CMS believes that these proposals would provide tribal and IHS hospitals greater predictability if they choose to convert to REHs, reduce administrative burden, and allow easier conversion back to their prior designation if the REH designation no longer fits the community's needs. **We support these proposals and thank the agency for providing stability and flexibility to tribal and IHS hospitals.**

RURAL EMERGENCY HOSPITAL QUALITY REPORTING PROGRAM (REHQR)

The CAA, 2021 established requirements for a new type of provider, the REH, for payment beginning Jan. 1, 2023. As part of this program, an REH must submit quality measure data. In this rule, CMS proposes to adopt one chart-abstracted and three claims-based measures into the REHQR beginning CY 2024.

Request for Comment: Future Measures for the REHQR

We recognize that CMS faces a statutory requirement to begin implementing measures in the REHQR. However, it remains challenging to offer definitive comments on the proposed measures given the novelty of the REH model. As the ability for hospitals to convert to an REH only began this year, there is still uncertainty regarding what services will be offered most commonly in the setting and what the best opportunities to improve the quality and safety of care are in those facilities. In addition, due to the newness of the model, none of the measures proposed have been tested for feasibility, reliability and validity in the REH setting specifically (although we acknowledge that CMS has analyzed the performance of rural hospitals on these measures). Because of the continued lack of clarity on exactly what REH facilities will be doing, we cannot wholly support the use of any of these measures in the REHQR at this time.

In terms of future measures for the REHQR, we have serious doubts about the feasibility of introducing eCQMs into the REHQR. Small, rural hospitals often lack the resources to implement expensive EHR systems — including the person-power to operate them. We agree that eCQMs, when developed and specified thoughtfully, have the promise to reduce reporting burden by eliminating the need to abstract data from medical charts and multiple other sources. However, several eCQMs that have been reviewed by a CBE or proposed for use in CMS programs already often use fields that

do not always appear universally across all EHRs and may require time-consuming workarounds that negate the automation inherent to eCQMs.

We appreciate CMS' consideration of a tiered approach to measure reporting requirements based on the scope of services provided by the REH. As noted above, the novelty of the model is such that what the scope of services of an REH may be, and we anticipate that that scope will differ based on locality and seasonality. Thus, we support the idea of a tiered or menu-like approach to measure reporting, similar to what is used in the Merit-based Incentive Program (MIPS) where providers report measures that are most relevant to the population of patients they serve.

Adoption of Abdomen Computed Tomography (CT) — Use of Contrast Material Measure

CMS proposes to adopt this claims-based measure that calculates the percentage of CT abdomen and abdominopelvic studies performed with and without contrast — that is, duplicate abdomen CTs — out of all CT abdomen studies performed. CMS reasons that rural hospitals account for a large proportion of duplicate scans, which increase radiation dose to patients and unnecessarily expose them to potential harmful side effects of contrast material itself.

This measure may be appropriate for use in the REHQR and the AHA does not oppose CMS adopting it into the program. According to data from use of this measure in the OQR, rural and small facilities accounted for disproportionally high percentages of outlier facilities, and thus this measure may be an appropriate measure for use in the REHQR even though it lost endorsement for use in the OQR when the developer did not seek re-endorsement. We recommend that the developer test the measure in the REH setting to determine whether there is performance gap and resubmit it for CBE endorsement to ensure that the measure continues to function as intended.

Adoption of Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure

CMS proposes to adopt this chart-abstracted measure that evaluates the median time (in minutes) between arrival to and departure from the ED (ED throughput time). CMS reasons that REH services will likely focus on ED care, and "improving throughput times is important for alleviating overcrowding and reducing wait times."

The AHA does not support the inclusion of this measure in the REHQR. This measure lacks evidence to tie it to improved patient outcomes; it lost CBE endorsement in 2018 as it did not meet the importance to measure and report criterion and lacked evidence that change in wait times influences mortality or other patient outcomes. In addition, the overall change in wait time across multiple years was negligible (approximately four minutes). Further, it is unlikely that variation in wait times are indicators of differences in quality of care rather than patient, provider or market characteristics.

In addition to the measure's lack of clinical relevance, the measure is also burdensome to report. To report the measure, REHs would identify relevant data elements from claims forms, electronic health care data, EHRs, or paper records and submit them to CMS via the HQR System on a quarterly basis. Considering that REHs are scaled down from general acute care hospitals, we assume they will likely have fewer available staff for onerous chart abstraction. In addition, the measure data is stratified into four separate calculations (an overall rate, a rate excluding psychiatric/mental health and transfer patients, a rate specifically for psychiatric/mental health patients, and a rate for transfer patients). We are dubious that REHs will have sufficient volume to calculate statistically reliable rates for all four of these categories.

The disadvantages of this measure are so significant that the measure has been recommended for removal from the OQR by a CBE through the Measure Set Review process, a move we would support. These concerns are more acute for rural providers, like those for whom the measure is under consideration. The rural subcommittee of the Measure Applications Partnership that reviewed this measure in the 2022-2023 cycle voiced additional concerns that their low volumes would be incompatible with this measure's calculation methodology, and that there are many factors (such as weather or local transport modalities) that may lead them to appropriately hold patients in the ED. Because of all of these concerns, this measure would be inappropriate for use in the REHQR.

Adoption of Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure

CMS proposes to adopt this claims-based measure that estimates a facility-level rate of risk-standardized, all-cause unplanned hospital visits within seven days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older. "Hospital visit" includes any ED visit, observation stay or unplanned inpatient admission to any short-term acute care facility. Rates are calculated by comparting predicted (the risk-adjusted number of actual) hospital visits to expected number of visits based on the facility's case mix. The measure calculation is comparable to the version of the measure currently used in the OQR.

This measure may be appropriate for use in the REHQR and the AHA does not oppose CMS adopting it into the program. Because of the novelty of the REH designation, it is still unclear what the scope of services these facilities will provide; thus, it is unclear whether a measure related to colonoscopies will be relevant. If REHs perform a sufficient number of colonoscopies that they will have adequate volumes to calculate performance, this measure would be suitable. As we note in our comments on CMS' request for comment on future measures for the REHQR, we believe it may be appropriate for the agency to implement a tiered or "menu"-type approach to measure reporting based on the scope of services provided by an REH, which would likely be particularly relevant for this measure.

Adoption of Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure

CMS proposes to adopt this claims-based measure that estimates the rate of unplanned hospital visits within seven days after an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). "Hospital visit" is defined similarly to the previous measure, as is the facility-level measure score. "Same-day surgeries" are substantive surgeries and procedures listed on Medicare's list of covered ASC procedures.

This measure may be appropriate for use in the REHQR and the AHA does not oppose CMS proposing it for adoption into the program. Because of the novelty of the REH designation, it is still unclear what the scope of services these facilities will provide; thus, it is unclear whether a measure related to outpatient surgeries will be relevant. If REHs perform a sufficient number of outpatient surgeries that they will have adequate volumes to calculate performance, this measure would be suitable. As we note in our comments on CMS' request for comment on future measures for the REHQR, we believe it may be appropriate for the agency to implement a tiered or "menu"-type approach to measure reporting based on the scope of services provided by an REH, which would likely be particularly relevant for this measure.

UPDATES TO REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

CMS proposes additional changes to the hospital price transparency rule and requests comments on how to better align price transparency policies in the future. **The AHA looks forward to working with CMS to improve the hospital price transparency rule, especially as it relates to better aligning these requirements with the Transparency in Coverage and No Surprises Act requirements.** The AHA continues to support policies that help patients access the information they need when making decisions about their care, including information about their potential costs. Hospitals have long been committed to providing patients access to this information, though earlier solutions required more cumbersome, manual processes with significant technical barriers, such as those related to obtaining cost-sharing information from insurers. Today, the landscape has shifted. Not only are patient price estimator tools commonly available on both hospitals' and insurers' websites, but uninsured and self-pay patients are receiving good faith estimates (GFE) prior to scheduled care, with the industry and CMS hard at work developing the technical standards to implement GFEs and advanced explanation of benefits (AEOBs) for insured patients. In addition, researchers and others have access to large datasets of hospital and insurer rates through both the hospital and insurer machine-readable files.

Alignment across these policies is paramount to ensure the data and estimates available are accurate and meaningful to patients and to minimize duplication of effort and excess cost in the system. We are concerned that both the Administration and Congress are considering changes to the hospital price transparency rule simultaneously. Meanwhile, several states also are creating distinct state-level requirements. While well intentioned, if even a portion of these efforts are adopted, patients, policymakers, researchers and others would face an even more daunting task of deciphering conflicting data from the myriad price transparency sources. In addition, each time changes are made to the requirements, hospitals must invest additional time and resources to come into compliance. **We strongly recommend CMS work with Congress to ensure any legislative changes are made in accordance with any finalized administrative requirements to avoid conflicting requirements as hospitals seek to adhere to both the regulatory and statutory changes.**

Our specific comments on the agency's proposals and requests for comment follow.

Standardization. CMS proposes requiring hospitals to conform to a standardized format for the hospital price transparency machine-readable file requirements. The proposed changes appear to be in part a result of feedback the agency has received from hospitals and other stakeholders on the initial guidance for implementing the machine-readable files. The new format would include additional required fields, such as information on the contracting method used to derive a negotiated rate and an expected allowed amount for non-dollar rates. CMS proposes allowing hospitals two months to transition to the new standardized format following finalization of these requirements. **While the AHA appreciates CMS' willingness to address issues raised by hospitals with the current format, we are concerned about the additional burden the new requirements would place on hospital staff and the short timeline for implementation.**

Hospitals, often in partnership with vendors, developed their machine-readable files based on their understanding of CMS' guidance and to accommodate the different types of contracts insurers and providers have. One common concern hospitals have shared with CMS is how to assign a single rate for a service when the contract with the payer does not include a simple fee schedule but is rather based on multiple factors. In response to this concern, CMS is now proposing that hospitals include far more information in their machine-readable files that would detail both the methodology used to derive a negotiated rate, as well as the amount the hospital expects to be paid based on that methodology. **The additional fields detailing the methodology (e.g., percentage, algorithm) would be incredibly burdensome to produce while meaningless for anyone outside of the hospital and insurer relationship to interpret. Moreover, it would introduce new access issues to the files based on their expanded size.** Instead, we recommend CMS keep the currently required data elements but revise the definition of negotiated rate to allow for dollar amounts beyond a simple fee schedule. That dollar amount could be an established rate when one exists or it could be what CMS is referring to as the *consumer friendly expected allowed*

amount, which is, and may be better described as, the average historic allowed amount. This would address hospitals' concerns about the narrow and restrictive negotiated rate definition without introducing unnecessary burden and size to the machine-readable files.

CMS also is proposing additional modifier and drug data fields that are superfluous and burdensome to produce. CMS proposes that hospitals specify in a new field any relevant modifiers that would change the negotiated rate. Many items and services can be billed with multiple modifiers that impact the calculated payment creating an almost endless number of permutations that would need to be included in the machine-readable file if CMS finalizes this requirement. For drugs, CMS proposes that hospitals indicate the drug unit and type of measurement as separate data elements, which is information already captured in the item description. The inclusion of these new data fields would significantly increase the cost to comply with the new requirements while not providing additional insights to the data users beyond what is already available in other fields. They also would vastly increase the size of the machine-readable files, making them more cumbersome to utilize. **AHA urges CMS not to finalize these data elements in the standardized format.**

Finally, we strongly request that CMS allow hospitals up to 18 months to adopt the new standards following the release of final technical guidance. Hospitals have already dedicated significant resources toward complying with the machine-readable file requirements. Some of our members report spending $15,000-25,000 per hospital on vendors to build the initial machine-readable files, and $10,000-20,000 to maintain the files and update them annually. A different hospital system producing its own file without vendor help reports spending 1,600 hours annually, across 23 individuals, to produce their machine-readable files.

Given the complexity of these files, detailed guidance is going to be required to properly ensure that the new standard format is implemented consistently across hospitals and to avoid excessive updates to the guidance in the future. This will require collaboration between CMS and hospital technical experts and is unlikely to be completed by the time the final requirements are released. The implementation period for the standard files should not begin until this guidance is complete as attempting to meet the requirements before the guidance is released would be inefficient. Once the guidance is released, we recommend allowing hospitals up to 18 months to adopt the new format. Hospitals are only required to update their files annually and often need up to six months to prepare the file for the next year. Therefore, any time less than 18 months could result in duplicating a hospital's effort for the year, resulting in significant added cost and staff time that would be better deployed to other patient care and patient experience endeavors.

Changes to Monitoring and Enforcement Practices. CMS proposes several changes to their monitoring and enforcement practices, including requiring a hospital official to certify the accuracy and completeness of the hospital's machine-readable file. **The AHA**

urges the agency not to finalize this proposal. CMS also is proposing an accuracy and completeness affirmation within the standardized file, which would serve the same purpose but would be completed during the development of the file. A second, duplicative certification after the file has been developed would be administratively burdensome with no additional utility. Therefore, should CMS finalize the affirmation within the standard format, they should not require a separate attestation during the monitoring process.

The AHA also opposes the proposed addition of § 180.70(a)(2)(v) that would require hospitals and health systems to submit certain documentation to CMS. Specifically, the proposed rule suggests that CMS may require hospitals to submit "contracting documentation to validate the standard charges the hospital displays." Courts have long held that certain contracting information — especially negotiated rate data — is commercially sensitive information that is shielded from disclosure by numerous legal protections. *E.g., West Penn Allegheny Health Sys., Inc. v. UPMC,* 2013 WL 12141532 (W.D. Pa. Sept. 16, 2013) (trade secrets protection); *Medical Ctr. at Elizabeth Place, LLC v. Premier Health Partners*, 294 F.R.D. 87 (S.D. Ohio 2013) (discovery protections); 73 Fed. Reg. 30,664-01, 30,675–75 (May 28, 2008) (FOIA Exemption 4). There is no indication in section 2718(e) of the Public Health Services Act (i.e., the statutory text on which the agency relies for this documentation requirement) that Congress authorized CMS to override these well-established legal protections by regulatory fiat. To be clear, the AHA does not oppose CMS requiring submission of other information (e.g., verification of the hospital's licensure status or license number). But requiring hospitals to submit private contractual information crosses a critical legal line and that aspect of the proposed rule should not be finalized.

CMS proposes several other changes to the enforcement process. First, CMS proposes to allow notifications to health system leadership of any compliance activity within their system, as well as notification to the specific hospital's leadership, to better accommodate health systems with a central office responsible for compliance. **The AHA supports this proposal.**

CMS also proposes requiring hospitals to confirm receipt of warning notices to accelerate hospital attention to the issue identified and streamline further communication with CMS. We appreciate CMS' desire to streamline this process and avoid unintentional delays due to communications issues. **To that end, we recommend CMS also copy the primary contact listed on the 855A Enrollment Form.** This individual already expects to be an intermediary between CMS and the hospital and could help to ensure the letter reaches the appropriate individuals within the hospital in a timely manner.

Publication of Compliance Actions and Outcomes. CMS proposes several changes to the public disclosure of information regarding the agency's oversight of hospital compliance with the rule. Specifically, CMS proposes to give itself authority to make public additional information related which hospitals are being reviewed for compliance

(either as part of routine oversight or in response to a public question or complaint), any compliance actions taken against a specific hospital, the status of the compliance action(s) and the outcome of the action(s). While we respect CMS' role as the sole arbiter of compliance and some stakeholders' desire for additional transparency regarding the agency's compliance actions, we are concerned that some of the information that could be released as a result of this proposal could be misconstrued. Specifically, we would expect that some stakeholders may misinterpret CMS' guidance and believe that hospitals under a routine compliance review are noncompliant and use that information to confuse the public and policymakers about the true state of compliance. Similarly, we know there will be situations where CMS may have questions about a hospitals' compliance and engage in follow-up with the hospital only to ultimately conclude that the hospital is indeed compliant. We based this on our understanding that there have been many productive collaborations between hospitals and CMS during review processes to date that have involved education on both sides around what information is and should be displayed in the machine-readable files. **Should CMS finalize this proposal and eventually release this information, we urge the agency to make it clear that hospitals are not deemed non-compliant when under review**. Alternatively, we recommend CMS set up a regular cadence under which they will review hospitals' machine-readable files and publicize that information, making it clear that all hospitals are reviewed on a set schedule and further taking stigma away from the review process.

Price Transparency Alignment. **AHA appreciates CMS' recognition of the several overlapping federal price transparency policies and interest in how changes to the hospital price transparency requirements could help achieve alignment.** Hospitals and health systems are dedicated to improving price transparency for patients. We remain concerned, however, that the numerous and sometimes conflicting requirements at both the state and federal levels create an overwhelming landscape of pricing information that not only is challenging for patients to navigate but also adds excessive costs and workforce burden to the health care system. As we enter the next phase of price transparency regulation implementation, with most of the federal requirements already executed or on the horizon, we strongly recommend CMS focus on streamlining current policies to remove complexity from the patient experience by narrowing the options for patient estimates and other pricing information and ensuring those estimates are as accurate as possible. This will allow the policies to achieve their intended purpose — to help patients understand and compare their expected costs prior to care — while also minimizing duplication and excess burden on the health care system.

Our specific recommendations for aligning the policies are as follows.

- **Streamline the hospital machine-readable file requirements to minimize duplication of effort and the potential for conflicting information, while preserving public access to negotiated rates.** Specifically, we recommend that CMS maintain the requirement that payers post all negotiated rates with

providers while allowing hospitals to focus solely on chargemaster rates and cash prices. In doing so, consumers, third party vendors, researchers and other interested parties would retain access to negotiated rate information while the risk of potentially conflicting information would be reduced. This also would eliminate duplication of effort and therefore reduce unnecessary costs and burden in the health care system.

- **Rely on the No Surprises Act GFE and AEOB requirements to provide patients with the most accurate estimates for their course of care.** We believe that once fully implemented, the No Surprises Act GFE and AEOB policies will have the greatest impact on patients. These estimates will be tailored to the patients' unique characteristics and expected care pathways and, in the case of insured patients, take into account their health care coverage, including where they are in their deductible. In addition, patients will automatically receive these estimates as part of their pre-care paperwork without additional effort on their part.

  We are deeply engaged with CMS and other stakeholders in workgroups to ensure that the insured GFEs and AEOBs will be implemented in a way that will create meaningful estimates in an efficient manner. However, there are still several issues that are slowing down the process, including determining which entity is responsible for collecting and collating estimates from various providers involved in a patient's episode of care. There are two general approaches this process could take: 1) each provider submits its own pre-service estimate to the insurer who collates them and applies its coverage rules to generate the AEOB, consistent with how the explanation of benefit (EOB) process works today or 2) where a single "convening" provider assumes responsibility for collecting estimates from different providers and transmitting the bundle of estimates to the insurer. **To accelerate the process and avoid unnecessary costs and duplication of effort, we recommend CMS clarify that it is the insurers' responsibility to collect and collate all the estimates from the various providers to generate the patient's estimate.**

  The AEOB process is intended to essentially provide patients an EOB in advance of care. AEOBs, like EOBs, are not simply a compilation of claims from unique providers. They are the result of the insurer processing the individual claims and applying its coverage rules, including considering where the individual is within their deductible and maximum out-of-pocket cost limits. These coverage rules — such as whether the insurer bundles some set of services into a single reimbursement or even covers certain items in a given circumstance — are all elements that must be known to generate the AEOB. Insurance companies already have the workflows and technology to not only collect and collate claims from different providers but also to apply their coverage rules and adjustments.

As we previously expressed jointly with the American Medical Association and Medical Group Management Association, requiring a single convening provider for AEOBs would create enormous administrative burdens for providers, utilize a process that diverges from the claims process used to create patient bills, and could potentially lead to delays in care. To ensure that the estimates are most reflective of a patient's final bill and do not create unnecessary burdens on the care delivery process, the AHA urges CMS not to require a single provider to compile preservice estimates before they are sent to the insurer.

- **Finally, we recommend CMS only require GFEs and AEOBs for scheduled services, while relying on the shoppable service/price estimator requirements of the Hospital Price Transparency and Transparency in Coverage rules to provide pre-service information to shopping patients.** GFEs and AEOBs should provide individualized, and therefore highly accurate, pricing information for scheduled services where patient characteristics and the course of care are known. However, generating them is labor and time intensive and their usability is often dependent on clinical information and other personal information that is not known for nonscheduled patients. Therefore, we recommend the agency be thoughtful in applying these requirements where they will provide most value and rely on the more scalable shoppable service/price estimator tool requirements to meet the needs of patients who are evaluating different options (i.e., shopping). In addition, we recommend CMS engage with Congress to preserve hospitals' ability to meet the shoppable service requirement with a price estimator tool. These tools are currently the best mechanism for patients to access price estimates. Changing this policy would move the field in the wrong direction, requiring patients to navigate machine-readable files that can be confusing for them to navigate.

PROPOSED PAYMENT FOR A BUFFER STOCK OF ESSENTIAL MEDICINES

CMS proposes to make separate payments under the IPPS (and potentially, under the OPPS) for the additional costs that hospitals face in establishing and maintaining access to a three-month buffer stock of domestically manufactured essential medicines for cost reporting periods beginning on or after Jan. 1, 2024. **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. However, we have several concerns about the proposed policy, including potential unintended consequences and a substantial reporting burden on hospitals and health systems. In addition, while we agree with the agency that it is necessary to support practices that can curtail shortages of essential medicines and promote resiliency to safeguard and improve the care hospitals provide to beneficiaries, we also continue to believe that much more must be done in addressing these concerns, much of which is beyond CMS' existing authorities.**

Background on CMS' Proposed Policy

Based on a series of executive orders from the Administration, CMS is seeking comments on a separate payment under the IPPS for establishing and maintaining access to a three-month buffer stock of one of 86 essential medicines prioritized in HHS' Administration for Strategic Preparedness and Response (ASPR) report "Essential Medicines Supply Chain and Manufacturing Resilience Assessment." The agency stated that an adjustment under the OPPS could be considered for future years, although, unlike an IPPS payment, it would be budget neutral. It also stated that it may consider expanding such policies in future years to also include critical medical devices.

The agency recognizes that the resources required to establish and maintain access to a buffer stock of domestically manufactured medicines generally will be greater than the resources for a just-in-time stock and for a supply of non-domestically manufactured products. Additionally, the agency recognizes that it is challenging to quantify these additional resource costs based on currently available information, especially given that hospitals can establish and maintain such a stock in a variety of ways including contractual arrangements with distributors or wholesalers.

Therefore, the agency proposes to base the IPPS payment on the IPPS share of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. These would include the costs to hold essential medicines directly at the hospital or arranged contractually with a distributor or wholesaler. *However, they would not include the costs of the essential medicine itself.* The agency proposes that hospitals would separately report to CMS these included costs and Medicare would make a biweekly interim lump-sum payment for its share, to be reconciled at cost report settlement. The agency stated that it would separately seek comment on a potential supplemental cost reporting form that would be used for this purpose.

In addition, CMS is also soliciting feedback on a series of specific questions related to the overall proposal.

Domestic Manufacturing

CMS' proposal would apply to domestically manufactured drugs. Yet, we believe that these products account for only a small proportion of the drug supply in the U.S. A 2019 FDA testimony found that only 28% of manufacturing facilities making active pharmaceutical ingredients to supply to the U.S. market were in the U.S.[26] Thus, we question the utility of restricting the proposed program's payments to only domestically manufactured drugs. **We urge CMS to work with the FDA to develop a more expansive and appropriate definition of domestically manufactured drug**

[26] U.S. Food and Drug Administration (October 2019). Safeguarding Pharmaceutical Supply Chains in a Global Economy. https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019

products. We also urge the agency to consider adding drug products manufactured in Organization for Economic Co-operation and Development (OECD) countries to this proposed policy such that it fulfills the intent of building a more resilient and reliable drug supply chain more meaningfully.

Potential Unintended Consequences

We have concerns over several potential unintended consequence of the proposal. For example, a policy that does not include the costs of the essential medicines themselves could create inequities in access, especially for small independent hospitals which are unable to pay the high up-front cost of the essential medicines themselves to establish a buffer stock. This could create spot shortages, which would defeat the proposal's intent to promote a more reliable and resilient medical supply chain for those providers who may be most in need of creating such a stock. **If CMS finalizes this policy, we urge the agency to consider making up-front payments to small independent providers, small rural providers and other safety net providers to support the acquisition of a buffer stock.**

This proposed policy also poses disadvantages for hospitals and health systems that serve a significant number of non-Medicare fee-for-service (FFS) patients, such as Medicaid and uninsured patients, as it only would apply to FFS Medicare's share of additional holding costs. For example, Medicare FFS utilization varies by state across the country, which could put providers at a disadvantage depending on the state(s) in which they operate. The same holds true for hospitals in states with growing numbers of Medicare Advantage patients.

Furthermore, the agency proposes to make the payment adjustment budget neutral under the OPPS but *not* budget neutral under the IPPS. **If CMS moves forward in future years to adopt this policy under the OPPS, 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.**

Increased Reporting Burden

We are also concerned that this proposed policy would not only increase reporting burden on hospital staff and frontline workers, but also would require information that may be logistically impossible for hospitals to determine. That is, while the costs of essential medicines themselves are not covered under the proposed policy, hospitals would be required to distinguish and determine the source of the essential medicines so as to report to CMS the additional costs of maintaining domestically manufactured products compared to non-domestic ones.

Additionally, hospitals have limited to no information from manufacturers regarding their manufacturing and supply chain process. Indeed, this information is considered proprietary by manufacturers, and there is no way to determine the full provenance of a particular drug. Furthermore, even if hospital did have access to the necessary information, the definition of "domestically manufactured" is unclear. For example, while drug manufacturers may finish and package their essential drugs in the U.S., they may source some or all the active pharmaceutical ingredients (API) and key starting materials overseas. U.S. manufacturers may also have arrangements with foreign contract manufacturers to produce some or all their products. **We encourage CMS to work with the FDA and pharmaceutical manufacturers to ensure providers can efficiently and easily identify the origin of the drugs.**

We also are concerned with CMS' proposal that hospitals and health systems be required to separately report on a new supplemental cost report form the additional cost of holding and maintaining their buffer stock. 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 and domestically versus non-domestically manufactured drugs. Moreover, since this proposal would initially only apply under the IPPS, hospitals also would need to track and segregate the recordkeeping for these buffer supply drugs to ensure that they are not allocated to nor used for the care of patients covered under other payment systems or cared for in other non-inpatient locations.

Moreover, many hospitals simply do not have the space and operational capacity to store buffer stock and therefore would need to contract with upstream distributors or wholesalers. For these hospitals, they would need to obtain separate records from the distributor or wholesaler to distinguish the storage and maintenance of a domestically manufactured stock from their regular contract. It remains unclear whether distributors or wholesalers would be willing to provide such separate recordkeeping for hospitals to accurately report the additional costs of maintaining its buffer stock. **Therefore, we urge CMS to work with manufacturer, distributor and wholesaler stakeholders to determine a less burdensome method of attestation and reporting for these IPPS separate payments.**

Feedback on Additional Questions about the Buffer Supply Proposal

<u>How effective would this potential payment policy be at improving the resiliency of the supply chain for essential medicines and the care delivery system? How could it be improved, either initially or through future rulemaking? Are there suggested alternative pathways for establishing similar separate payments?</u>

The AHA believes that many hospitals would not be able to independently establish a three-month buffer supply of essential medicines because they do not maintain adequate physical facilities to allow for storage and management of such large

amounts of additional pharmaceutical inventory, especially for medicines that have a cold chain storage requirement. Moreover, we believe that holding a three-month inventory of essential medicines at the individual hospital level may not be the most efficient approach to inventory management. For example, in general, hospitals rely on suppliers to make frequent, sometimes daily, deliveries of drugs.

Instead, the AHA supports applying a similar policy upstream of hospitals, with ASPR, in coordination with CMS and FDA, contracting directly with distributors and wholesalers to purchase and hold such a national buffer supply. These companies already use advanced data analytics to manage the purchase and distribution of their products. They are far better equipped than individual hospitals to determine what a three-month supply would represent or, given that most drug shortages last more than three months, whether holding a longer period of buffer supply is appropriate. Furthermore, such an approach would avoid the increased reporting burden on hospitals and the potential unintended consequences related to equity, as discussed above. We recognize that additional congressional authority would be necessary to carry out this alternative pathway.

That said, even if CMS finalizes its policy as proposed, we believe that to ensure that the pharmaceutical supply can keep up with sudden spikes in demand that exceed even a three-month buffer supply, we strongly recommend that the Administration plan to expeditiously utilize its authorities under the Defense Production Act (DPA) to produce additional drugs as needed. While establishing such a three-month buffer supply could build up the supply chain of essential medicines in a way that may help address more common supply shortages, the federal government must be willing to use its DPA authority much more quickly in the event of a sudden spike in demand that exceeds even an established buffer supply of essential medicines, such as in the event of a novel pathogen.

What type of additional hospital resource costs are involved in establishing and maintaining access to domestically manufactured essential medicines compared to non-domestically manufactured ones? Are there alternative approaches that might better recognize the increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines? How might any suggested alternatives be better at improving the resiliency of the supply chain for essential medicines and the care delivery system?

As noted above, it is unlikely that many hospitals would be able to independently establish and maintain access to a three-month supply of essential medicines within their facilities, regardless of whether they were domestically or non-domestically manufactured. But for hospitals that do have the space and funds to do so, these costs would include purchasing more freezers, refrigerators, and racking, leasing additional space, administrative costs related to contracting and record-keeping,

additional security to adequately protect the buffer supply and hiring additional staff to manage the extra inventory to ensure it does not out-date.

That said, hospitals cannot estimate the incremental costs associated with domestic sourcing compared with non-domestic sourcing. As noted above, the provenance of where and how a drug is manufactured is proprietary information and so is unavailable to providers.

However, even if it were not proprietary information, it would still be challenging for a hospital to calculate, as the cost for different generic versions of the same drug is affected by multiple factors and likely varies by purchaser. As noted above, we believe that determining these incremental costs is better suited to drug supply chain organizations upstream of the hospital. In addition, there would be substantial efficiencies in inventory allocation by storing the buffer stock in these locations where it could be shipped as needed and hospitals would not face the risk and potential cost of expired inventory that they do not use in a timely manner. Such a model also creates procurement opportunities for hospitals that help foster a more resilient supply chain for essential drugs and having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase — as opposed to “just-in-time” inventory.

Are these 86 essential medicines prioritized in the ASPR report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* the appropriate initial list of essential medicines for this potential payment policy and how often should HHS consider updating the respective list used for establishing these potential additional payments?

The ASPR initiative that developed the list of 86 essential drugs for acute patient care was based on the expert input of pharmacists and physicians from a cross-section of health care providers and other experts. While a different process might have generated a slightly different list, the existing list is appropriate to use for this proposal.

Indeed, these are the drugs most used and necessary for providing care to hospitalized patients, including required pain medicines, sedatives, paralytic agents, antibiotics and other products that are necessary to operate a hospital. They are crucial for running emergency rooms, operating rooms, intensive care units and other inpatient services. In other words, if these products were not available, a hospital would be unable to continue to provide appropriate care for its patients. In addition, we believe that the proposed two-year update cycle is appropriate.

Should HHS consider expanding the list of essential medicines used in establishing these potential additional payments to include essential medicines used in the treatment of cancer?

As noted above, the ASPR essential medicines list was developed for acute patient care. Given current cancer drug shortages and the likely future shortages of other drugs not included in ASPR's list, we believe that additional drugs could be prioritized from existing lists, such FDA's critical drugs list.[27] Alternatively, given that most cancer chemotherapy is provided in outpatient settings and the agency's current proposal only applies to drugs 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 OPPS.

Is a 3-month supply the appropriate amount of supply for the buffer stock or should an alternative duration be used? What additional considerations, if any, are needed?

We speculate that CMS proposed a three-month supply because this reflects the post-pandemic practice of some larger hospitals and health systems to store an additional three-month inventory of essential supplies, such as personal protective equipment. Taking this perspective into consideration, proposing a three-month supply makes sense. Indeed, we have learned that, in practice, some hospitals already keep three-month inventories of drugs among the 86 essential drugs listed by ASPR. The AHA assumes that these providers will take advantage of CMS's proposed policy, if it is finalized, using their existing reserves.

However, for small independent hospitals, especially rural or other safety net facilities, it may not be practical or feasible to purchase a three-month inventory. This is especially true if their patient volume doesn't justify it, if the essential drugs have short expiration dates, or if the upfront cost of purchasing a three-month supply is out of their reach. Therefore, if CMS finalizes its policy, it may be of benefit for the agency to allow for a range of buffer supply of essential drugs, perhaps between two to six months, and to permit individual hospitals to decide the amount they can reasonably purchase and manage as a buffer supply.

What type of additional hospital resource costs are involved in establishing and maintaining access to a buffer stock of essential medicines? To what degree, and under what circumstances, might hospitals use contractual arrangements? What type of contractual arrangements might be used?

Financially speaking, we believe that for many hospitals, the requirement to purchase the drugs up front would be cost prohibitive. In the absence of the agency including some of these upfront costs within the proposed program, particularly related to the more expensive domestically manufactured drugs, this would be a disincentive to participate. If CMS moves forward with finalizing a buffer stock policy, we encourage the agency to consider covering the additional

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

costs of sourcing and purchasing domestically manufactured essential drugs under this proposed program.

As noted above, logistically speaking, most hospitals would not be able to store and manage a three-month buffer supply for many of these essential drugs. This is due to the lack of adequate space to store an additional three months of inventory, especially for medicines that have a cold chain storage requirement. To do this, hospitals would need to purchase more freezers, refrigerators and racking and would need to determine if leasing additional space is necessary. Additional staff would need to be hired to manage and circulate the extra inventory to ensure it does not out-date. While large health systems may have such capabilities already in place, for example a centralized warehouse and their own group purchasing organization or distribution system, it is unlikely that other hospitals, particularly small and rural hospitals, would be able to accomplish this.

As discussed above, because of this increased burden on hospitals, we believe that, in most cases, hospitals would be unlikely to establish such a buffer inventory within its own facilities and would be far more likely to contract with their distributors or wholesalers to acquire, hold and manage the buffer supply. Having a distributor or wholesaler hold the buffer inventory also has other advantages over individual hospital stockpiles. That is, it would not tie up hospital capital or require the hospital to add storage space or manage inventory and it also eliminates the risk to the hospital for the cost of expired or unused inventory. Further, such an approach could also improve reporting requirements to federal agencies when assessing inventory levels and locations, as there would be fewer reporting sources. Finally, a “shared” buffer inventory allows for efficient allocation in times of scarcity, so that buffer stock is not sitting at hospitals that do not need it.

<u>What immediate impacts on the supply of essential medicines could be expected upon implementation of this potential policy? What steps, if any, would need to be taken to mitigate risks of possible demand-driven shortages as a result of implementation of such a policy?</u>

CMS states that if finalized, it may implement this policy for cost reporting periods starting on Jan. 1, 2024. The AHA is concerned that too rapid of an implementation could result in spot shortages for some of these essential drugs due to sudden increases in demand. We expect this would particularly be the case for those drugs with three or fewer manufacturers, which may already be in or be at risk for shortage. As larger hospitals and health systems are more likely to be able to support a three-month buffer supply of medicines, this could have an inadvertent negative impact on other smaller or rural hospitals, other types of providers and even hospital outpatient departments, which would initially be ineligible to participate in the proposed program.

To address this, if the proposed policy is finalized, we urge CMS to consider phasing in the program over a longer period of time, perhaps on a region-by-region basis so as to provide drug manufacturers, wholesalers and distributors adequate time to increase their production of the 86 essential medicines.

While the availability of essential medicines is always critical, it is especially the case for emergencies. Should there be a separate payment adjustment to more acutely address supply issues that emerge specific to the case of preparedness as a pandemic or other public health emergency emerges?

The AHA believes that CMS should make a separate payment adjustment to address supply chain issues that arise during periods of heightened risk, such as a pandemic or other major PHE. These events can cause sudden and significant increases in demand for certain drugs, which can strain existing supply chains, lead to shortages if not addressed promptly and increase hospital costs, both for sourcing and the price of the drugs necessary to respond. This can result in lost revenue for hospitals and potentially disruptive consequences for individuals and communities.

How should such a policy be considered for essential medicines that are currently in shortage, and thus potentially not appropriate for arranging to have buffer stock? What steps, if any, would need to be taken if an eligible essential medicine enters shortage while such a policy is in place?

As CMS notes in this question, essential medicines that are currently in shortage would not be appropriate for inclusion in this policy until the shortage is resolved. If an essential medicine enters shortage while such a policy is in place, the drug should immediately be removed from the list of drugs eligible for the policy so that no new three-month buffer supplies under this policy would be permitted, until the shortage is resolved. Further, CMS should establish policies to ensure that drug manufacturers, wholesalers and distributors continue to have the ability to place essential medicines in short supply on allocation and to continue to have the ability to direct supplies of these shortage products to those areas where the need is greatest.

DIRECT SUPERVISION OF CARDIAC AND PULMONARY REHABILITATION SERVICES BY INTERACTIVE COMMUNICATIONS TECHNOLOGY

Currently, cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR) and pulmonary rehabilitation services (PR) must be provided under the direct supervision of a physician. Effective Jan. 1, 2024, the Bipartisan Budget Act of 2018 (BBA) authorizes CR, ICR and PR to be furnished under the direct supervision of a

physician assistant, nurse practitioner or clinical nurse specialist. CMS is proposing conforming changes to the regulations.

During the COVID-19 PHE, CMS added CR, ICR and PR to the telehealth list when furnished to non-hospital patients and paid under the PFS. CMS permitted physicians to provide direct supervision of these services remotely via two-way, audio/visual communication technology (but not audio only). These PFS flexibilities were extended by law through Dec. 31, 2024. For consistency with the PFS rules, CMS also extended these flexibilities to the OPPS in prior rulemaking.

CMS now proposes that, for CY 2024, physician assistants, nurse practitioners and clinical nurse specialists may also provide the direct supervision of CR, ICR and PR services remotely via two-way, audio/visual communication technology (but not audio only).

The AHA appreciates and supports CMS' proposals. They will improve access to these important hospital outpatient services for patients and reduce burden on providers as the impact of the pandemic recedes and as CMS unwinds its waivers and flexibilities. Further, permitting direct supervision and remote direct supervision to be furnished by a physician assistant, nurse practitioner or clinical nurse specialist will be particularly valuable in rural and other communities where workforce shortages remain acute and resolving them will take time.

In addition, we urge the agency to consider making this policy permanent, which would improve access to these highly effective, yet underutilized services, in the long term. Indeed, in the CY 2023 PFS proposed rule, CMS identified CR as an underutilized service that may "provide the best possible health outcomes at the lowest possible cost".[28] In fact, the Million Hearts 2027 initiative created by CMS and CDC aimed to prevent one million heart attacks and strokes within five years, in part by increasing CR participation to 70% in eligible patients.[29] However, data show that only 24.4% of Medicare beneficiaries eligible for CR participated and that participation was lower among women (18.9%) compared with men (28.6%) and was lower among Hispanic Americans (13.2%) and non-Hispanic Black Americans (13.6%) compared with non-Hispanic White Americans (25.8%).[30,31] **Making virtual direct supervision a permanent policy would help to close these gaps, including those related to health equity, by providing access to patients who face barriers to participation.**

---

[28] 87 FR 45942, https://www.federalregister.gov/d/2022-14562
[29] CMS. "Million Hearts, Cardiac Rehabilitation." https://millionhearts.hhs.gov/about-million-hearts/optimizing-care/cardiac-rehabilitation.html
[30] "Tracking Cardiac Rehabilitation Participation and Completion Among Medicare Beneficiaries to Inform the Efforts of a National Initiative," ahajournals.org, American Heart Association, 14 January 2020, https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.119.005902
[31] "Racial and Ethnic Disparities in Heart and Cerebrovascular Disease Deaths During the COVID-19 Pandemic in the United States," ahajournals.org, American Heart Association, 18 May 2020, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.054378

PROPOSED CHANGES TO THE IPPS MEDICARE CODE EDITOR

CMS proposes to no longer address the addition or deletion of IPPS Medicare Code Editor (MCE) edits or include the addition or deletion of ICD-10 diagnosis and procedure codes for the applicable MCE edit code lists in the annual IPPS rulemakings. Instead, it proposes to address future changes or updates to the MCE through instruction to the MACs.

MCE proposals are often supported via public comments provided in response to IPPS rulemaking. Additionally, the opportunity for MCE comment has historically been offered through IPPS rulemaking. There are important topics that may warrant additional consideration that hospital coding, clinical and revenue cycle professionals need to ensure awareness of ahead of implementation to allow opportunity for comment as applicable. **Therefore, we strongly recommend CMS not finalize any changes related to the MCE. Instead, we recommend the agency include this proposal in the upcoming FY 2025 IPPS proposed rulemaking.** This will help ensure that the appropriate IPPS audience has ample opportunity to review and provide comment.