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Advancing Health in America

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September 9, 2024

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

Re: CMS–1809–P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities (Vol. 89, No. 140), July 22, 2024.

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) 2025.

We support many of the OPPS proposed rule provisions, including unpackaging and paying separately for certain high-cost diagnostic radiopharmaceuticals, unpackaging from the comprehensive ambulatory payment classifications (C-APCs) and paying separately for certain cell and gene therapy products, and establishing new add-on payment for hospitals that use Technetium-99m (Tc-99m) derived from domestically produced Molybdenum-99 (Mo-99). We also appreciate that in response to comments from AHA and its members, the agency is considering reducing the reporting burden of

its policy that helps offset the marginal costs that hospitals face in procuring domestically made surgical N95 respirators.

At the same time, the AHA continues to have strong concerns about the shortcomings in the annual payment update for hospital outpatient departments (HOPDs), in particular the market basket forecast and update. This is especially concerning considering past underwhelming market basket increases, specifically from CYs 2022 through 2024. Indeed, the forecasts on which CMS relies have consistently under-predicted cost growth, and the actual market basket increases are falling well short of inflation. **Therefore, AHA urges CMS to consider whether adjustments are necessary in its approach to annual market basket updates to ensure that beneficiaries continue to have access to high-quality outpatient care. We also urge CMS to eliminate the productivity cut for CY 2025, as detailed below.**

Further, the AHA shares CMS' commitment to improving maternal health outcomes. However, we are concerned that CMS' proposed CoPs fail to address the root causes behind poor maternal outcomes and may further reduce access to safe, high-quality obstetric care. Any potential solution to this crisis must consider the entire maternal health continuum and should prioritize the needs of pregnant and postpartum women. Instead of issuing duplicative and unnecessary regulations, the AHA urges CMS to partner with patients and the hospitals and health systems that serve them to address maternal morbidity and mortality causes. We believe a collaborative approach focused on patients not facilities will lead to meaningful patient outcome improvements while preserving access to safe, high-quality maternal health care.

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/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

American Hospital Association
Detailed Comments on the OPPS and ASC Payment System
Proposed Rule for CY 2025

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CY 2025 OPPS PAYMENT UPDATE

For CY 2025, CMS proposes a market basket update of 3.0% less a productivity adjustment of 0.4 percentage points, resulting in a net update of 2.6%. This update, especially when taken together with prior inadequate updates, continues and exacerbates Medicare's underpayments to the hospital field. It ignores the fact that hospitals and health systems continue to face high input cost levels, including the unrelenting challenges — such as the cyberattack on Change Healthcare — with which the field must contend. **As such, we once again urge CMS to consider whether adjustments are necessary to its approach in annual market basket updates. For example, the actual market basket for CY 2022 was 5.7% — a full 3.0 percentage points higher than what hospitals received in 2022. Additionally, we urge CMS to eliminate the productivity cut for CY 2025, as detailed below.**

Financial Context

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

Fresh off a historically challenging year financially in 2022, in which over half of hospitals closed out the year operating at a loss, many hospitals spent much of 2023 struggling to break even.[2] **Economy-wide inflation grew by 12.4% from 2021 through 2023 — more than two times faster than Medicare rates for hospital outpatient care, which increased by 5.9% during the same time.**[3] From the start of 2022 through June 2023, the number of days cash on hand for hospitals and health systems declined by 28.3%.[4]

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[1] The AHA adamantly opposed the merger of UnitedHealth Group and Change Healthcare. https://www.aha.org/lettercomment/2021-03-17-aha-urges-doj-investigate-unitedhealth-groups-acquisition-change

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

[3] Consumer Price Index for all Urban Consumers (CPI-U), U.S. Bureau of Labor Statistics; OPPS Market Basket data, CMS.

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

An area of persistent cost pressure for hospitals and health systems has been the rapid and sustained growth in labor costs. Specifically, labor costs increased by more than $42.5 billion from 2021 through 2023 to a total of $839 billion.[5] Labor costs have since continued to increase, up 20% year-to-date in 2024 compared to 2021 and up 4% compared to 2023.[6] Furthermore, hospitals have been forced to contend with record-high turnover rates, fueling additional expenses for those looking to recruit new workers. For example, resignations per month among health care workers grew 50% from 2020 through 2023, according to data from McKinsey.[7]

Additionally, the field faces the long-standing trend of drug companies both introducing new drugs at record prices and imposing large price increases on existing drugs. Hospitals and health systems continue to see increased drug expenses, which are up 21% year-to-date in 2024 compared to 2021 and 8% compared to 2023.[8] Moreover, a recent report by the Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE) found that in 2022 and 2023, prices for nearly 2,000 drugs increased faster than the rate of general inflation, with an average price hike of 15.2%.[9] As a result, hospitals spent $115 billion on drug expenses in 2023 alone.[10]

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

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

[6] Kaufman Hall (Aug 2024). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2024-08/KH-NHFR_June-2024-Metrics.pdf

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

[8] Kaufman Hall (Aug 2024). National Hospital Flash Report. https://www.kaufmanhall.com/sites/default/files/2024-08/KH-NHFR_June-2024-Metrics.pdf

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

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

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

annually dealing with insurer prior authorizations.[12] Additionally, a 2023 study by Premier found that hospitals are spending just under $20 billion annually appealing denials — more than half of which was wasted on claims that should have been paid out at the time of submission.[13] Indeed, denials issued by commercial MA plans rose sharply, by 55.7%, in 2023.[14] Notably, many of these denials were ultimately overturned as noted above. In fact, a study by the HHS Office of Inspector General (OIG) found that 75% of care denials were subsequently overturned.[15] Making matters worse, MA plans paid hospitals less than 90% of Medicare rates despite costing taxpayers substantially more than traditional Medicare in 2023.[16,17]

Unsurprisingly, these trends have continued and exacerbated Medicare's underpayments to the hospital field. Specifically, recent research findings from key stakeholders confirm what the AHA repeatedly stressed — that 2022 was the most financially challenging year for the hospital field in recent history. Specifically, the Medicare Payment Advisory Commission (MedPAC) found that all-payer operating and overall Medicare margins fell to record lows. Indeed, Medicare hospital margins for FY 2022 were *negative* 12.7%. Even MedPAC's own analysis showed that "relatively efficient hospitals" — those hospitals that perform well on quality while keeping unit costs low — were paid less than cost, with Medicare margins of *negative* 3%. MedPAC projects 2024 Medicare margins will fall below *negative* 13%, the *20th straight year* of Medicare paying below costs. The AHA's own analysis showed that Medicare underpayments hit a record high in 2022 — $99.2 billion.[18]

Indeed, margins at this level are simply unsustainable, and we are seeing their effects in real time. Rural hospitals continue to close, with eleven closing between 2023 and 2024, despite a new Medicare provider type that allows them to convert to a

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

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

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

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

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

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

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

rural emergency hospital (REH).[19, 20] Furthermore, over the last decade, more than 200 rural hospitals have closed obstetric (OB) units. As a result, a recent Government Accountability Office study estimated that half of all rural counties lack access to this essential care.[21] Given the agency's particular focus on maternal health care, these service line closures are particularly troubling.

Coupled with these ongoing headwinds is the impact of the cyberattack that has been deemed "the most significant attack on the healthcare system in U.S. history."[22] Specifically, the Feb. 21 cyberattack on Change Healthcare, owned by UnitedHealth Group, has disrupted many aspects of the health care ecosystem, including the ability for providers to process claims and receive reimbursement. Essentially, this cyberattack crippled the flow of funding and brought insurance payments to a halt for many providers.[23] While hospitals and health systems have long contended with chronic underpayments by government payors, they are now also contending with the aftermath of inadequate cash flow from commercial payors. For example, the revival of the claims systems is more of a starting point for addressing the issues created by the cyberattack rather than conclusory. Preparing and submitting a backlog of claims occurred simultaneously with preparing and submitting claims for new care provided each day. One hospital executive stated that they had "25 full-time equivalents dedicated to this."

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

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[19] https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/
[20] Nineteen rural hospitals have converted to a REH designation in 2023, stemming some of the closures we would have expected to see had the program not been in place.
[21] GAO (Oct 2022). Maternal Health: Availability of Hospital-Based Obstetric Care in Rural Areas. https://www.gao.gov/products/gao-23-105515
[22] Washington Post (Mar 2024). Health-care hack spreads pain across hospitals and doctors nationwide. https://www.washingtonpost.com/business/2024/03/03/change-health-care-hack-hospitals/
[23] Wall Street Journal. (Mar 2024). U.S. Health Department Intervenes in Change Healthcare Hack Crisis. https://www.wsj.com/articles/calls-mount-for-government-help-as-change-healthcare-hack-freezes-medical-payments-9545d2e3

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

Market Basket

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 letters on the CYs 2023 and 2024 OPPS proposed rules because the market basket was a forecast of what was *expected* to occur, it missed the *unexpected* trends that did occur in the latter half of 2021 into 2022 with hospitals combatting high inflation and workforce shortages. **Indeed, including data through September 2022 yields a figure of 5.7% for the actual CY 2022 market basket — a staggering 3.0 percentage points higher than the update 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 occurred at the end of the CY 2021 into 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. This is detailed in our CY 2024 OPPS comment letter, where we discuss CMS' use of the Employment Cost Index (ECI) to measure changes in labor compensation in the market basket.[24] However, we believe that the ECI may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs. By design, the ECI cannot capture changes in costs driven by shifts between different labor categories. Indeed, CMS itself recognizes that the ECI does not

[24] 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."

capture these shifts in occupation.[25] Yet as mentioned above, this comes at the exact time that hospitals have had to dramatically turn to contract labor to meet patient demand.

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

Table 1: OPPS Market Basket Updates, CY 2022 through CY 2024

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

The missed forecasts have a significant and permanent impact on hospitals. At current levels, cumulative underpayment of nearly 4.0 percentage points totals more than $2.8 billion in underpayments annually. Further, and as CMS knows, future updates are based on current payment levels. Therefore, absent action from CMS, these missed forecasts are permanently established in the standard payment rate for OPPS and will continue to compound. In addition, these underpayments also influence other payments, including the growing MA patient population, as well as commercial insurer payment rates.

These shortcomings are yet another reason that we urge CMS to take action to increase the market basket in the final rule to better account for these circumstances. Additionally, because CMS is scheduled to rebase and revise the hospital market basket for CY 2026, we ask that CMS use this opportunity to examine

[25] 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."

its methods in incorporating labor shifts and costs for the hospital market basket so that it can more accurately reflect the changing labor dynamic.

Productivity

Under the Affordable Care Act (ACA), the 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).[26] This measure was intended to ensure payments more accurately reflect the true cost of providing patient care. For CY 2025, CMS proposes a productivity cut of 0.4 percentage points.

The AHA continues to have deep concerns about the proposed productivity cut, particularly given the extreme pressures under which hospitals and health systems continue to operate. As such, we ask CMS to eliminate the productivity cut for CY 2025. 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. Thus, this measure effectively assumes the hospital sector can mirror productivity gains across the private nonfarm business sector. However, in an economy marked by great uncertainty due to labor and other productivity shocks, such as those caused by the cyberattack on Change Healthcare, this assumption is flawed.

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 continue to be paid at 40% of the OPPS payment amount. **By continuing the clinic visit 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 this harmful policy entirely, and we provided evidence that:

[26] 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

- Contrary to CMS' 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.
- Site-neutral policies are based on flawed assumptions.

PROPOSED PAYMENT CHANGE FOR DIAGNOSTIC RADIOPHARMACEUTICALS

Under CMS' current policy, diagnostic radiopharmaceuticals are "policy packaged" — their costs are packaged with the payment for the related procedure or service. CMS notes that commenters have expressed concern that packaging payment for precision radiopharmaceuticals in the outpatient hospital setting creates barriers to beneficiary access, particularly in safety-net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities. Other commenters have expressed concerns that for newer and more innovative radiopharmaceuticals, the current OPPS packaging policy has generally led to a lack of patient access to technologies after their pass-through status expires, especially if there is a lack of clinical alternatives.

Proposed Per-day Cost Threshold for Separately Payable Diagnostic Radiopharmaceuticals. CMS proposes to pay separately for diagnostic radiopharmaceuticals with per-day costs above $630 — which is two times the volume-weighted average cost amount currently associated with diagnostic radiopharmaceuticals. Alternatively, CMS is also seeking comments about using a cost threshold of 1.75 times the volume-weighted average offset amount, which would set a $550 per-day threshold and be consistent with the threshold in the OPPS outlier policy.

The AHA appreciates CMS' proposal to establish a per-day cost threshold. The current policy of packaging these products puts hospitals into a financial bind because the diagnostic radiopharmaceuticals' costs often significantly exceed the APC payment rates into which they are packaged. Moreover, since there are no clinical alternatives to specialized diagnostic radiopharmaceuticals, there are no alternative treatment options when these products are required. Establishing an appropriate per-day cost threshold for separate payment would improve beneficiary access to precision and innovative new radiopharmaceuticals by mitigating the financial risk hospitals face when they furnish high-cost and complex products. Not only would this benefit patients, but it would also promote continued research and innovation in new radiopharmaceuticals and treatments.

While the AHA agrees with CMS' calculation of the average per-day cost of $314.28 for diagnostic radiopharmaceuticals, we are concerned that multiplying the average per-day cost by two results in a cost threshold that is too high and, as such, would not be

effective. **Instead, we recommend that CMS set the final per-day cost threshold at 1.75 times the mean diagnostic radiopharmaceutical per-day cost, leading to a $550 per-day cost threshold.** This is the same multiplier used in the outlier policy, meaning it is consistent with CMS' high-cost payment policies and therefore is a more appropriate packaging threshold.

Proposed Payment Basis for Separately Payable Diagnostic Radiopharmaceuticals. CMS proposes to pay for separately payable diagnostic radiopharmaceuticals based on their mean unit cost (MUC) data derived from OPPS claims. CMS notes that the average sales price (ASP) is not currently usable for payment purposes because radiopharmaceutical manufacturers are not required to report ASP.

While the AHA understands CMS' rationale for proposing to pay for these radiopharmaceuticals based on their MUC, we urge the agency to work expeditiously with diagnostic radiopharmaceutical manufacturers to support their reporting of ASP, as most other drug manufacturers do, so that separate payment could be based on ASP in future years. We agree with MedPAC's recommendation to Congress in its June 2017 report that the ASP system should be modified to "require all manufacturers of products paid under Part B to submit ASP data and impose penalties for failure to report."[27] Indeed, using ASP information would improve the accuracy of per-day cost calculations and separate payment amounts for diagnostic radiopharmaceuticals. This would be in the best interest of beneficiaries, hospitals and manufacturers of these products.

EXCLUSION OF CELL AND GENE THERAPIES FROM C-APC PACKAGING

CMS generally treats all items and services reported on a C-APC claim as integral, ancillary, supportive, dependent and adjunctive to the primary service and representing components of a comprehensive service. The intent is to make a single prospective payment based on the cost of all individually reported codes that appear on a claim with the primary C-APC service, which CMS believes represents the provision of a primary service and all related services provided to support the delivery of the primary service.

For CY 2025 only, CMS proposes to exclude certain non-pass-through Chimeric Antigen Receptor T-Cell (CAR-T) therapies and gene therapies (i.e., those products with status indicator "K" indicating they are separately payable) from C-APC packaging. The agency explains that there are rare instances where these cell and gene therapies appear on the same claim as a primary C-APC service and therefore have their payment packaged. However, when these therapies are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent or adjunctive to any primary C-APC services.

[27] jun17_ch2.pdf (medpac.gov)

CMS proposes to exclude these listed therapies from C-APC packaging for one year only to gather more information from commenters, including whether to continue this policy or a modified version of this policy beyond one year in future rulemaking. **The AHA supports CMS' proposal not to package these cell and gene therapy products into the C-APCs for CY 2025.**

In addition, CMS discusses the potential in future rulemaking of creating new C-APCs for cell and gene therapies. However, CAR-T involves distinct clinical services to collect and process cells that are performed weeks, and sometimes even months, before dose preparation and administration occurs. Yet, CMS has never before created C-APCs that package services furnished in separate encounters billed on different dates of service. Moreover, in addition to timing issues, the distinct clinical services of cell collection and cell lab processing services vary significantly, including leukapheresis and surgery, cell counts, cell collection and cryopreservation. In addition, cell collection services are often billed with vascular access procedures and many of these procedures pay under C-APCs as well. Finally, the administration of vastly different products with great cost variation would create packaging problems similar to those that led CMS to propose to unpackage high-cost diagnostic radiopharmaceuticals. **Therefore, the AHA urges against CMS developing C-APCs for cell and gene therapy administration.**

CAR-T THERAPY

CAR-T therapy requires hospital services, ordered by treating clinicians, to be provided before and after the drug or biological is prepared by the manufacturer. Specifically, the patient's cells are collected in the hospital via a pheresis procedure ordered and supervised by a clinician. During cell collection, nursing staff monitor the patient. After the collection is complete, other hospital staff, generally from the cell therapy laboratory, prepare and process the cells to be shipped to the manufacturer. Once the manufacturer has prepared the cell therapy product, the product is returned to the hospital. Hospital staff, again usually from the cell therapy laboratory, receive the product and prepare and process it for delivery to the patient.

Providers currently have three options to report these services. These include reporting as part of the drug or biological code (either on an outpatient or inpatient claim) or reporting on the inpatient claim. In addition, if provided in an outpatient setting, hospitals can report on the outpatient claim, but, in this case, no separate payment would be made. Therefore, CMS does not include the hospital costs for collection services in rate-setting. CMS' non-payment for these services is a departure from how the agency recognizes and provides either packaged or separate payment for other similar clinical services rendered by hospital staff. For example, CMS recognizes and pays separately for the facility resources reported via CPT codes associated with collection (e.g. CPT codes 38206, 38230 and 38232) and cell processing (CPT codes 38207 through 38215) for hematopoietic cell transplants.

Despite repeated stakeholder requests that separate payment is warranted for CAR-T-related collection services, including recommendations from CMS' Advisory Panel on Hospital Outpatient Payment, CMS has not changed the status indicator "B" assignment to either "S" for separate payment or "Q1" for conditional payment.[28,29,30] While it appears that the agency believes that the hospital's payment for the CAR-T *product* includes payment for cell *collection* and cell *processing*, this is not correct. The work to collect and prepare the cells is separate and completed by the hospital — manufacturers do not provide these services, nor do they take responsibility for the cells until they receive them. Indeed, CMS' current stance barring separate payment for these services places unnecessary financial pressure on hospitals, is inconsistent with how it pays for other services and could negatively impact patient access to these services.

There are three new CPT codes for CAR-T therapy cell collection and cell processing (which replace existing codes) that will become effective starting Jan. 1, 2025, including:

- CPT code 3X018 (CAR-T therapy; harvesting of blood-derived T lymphocytes for development of genetically modified autologous CAR-T cells, per day).
- CPT code 3X019 (CAR-T therapy; preparation of blood-derived T lymphocytes for transportation (e.g., cryopreservation, storage).
- CPT code 3X020 (CAR-T therapy; receipt and preparation of CAR-T cells for administration).

The AHA recommends that CMS assign status indicator "S" to these new cell collection and processing CPT codes and assign these codes to the most clinically appropriate APC(s). As noted, hospitals incur a cost for these services and should receive appropriate payment under the OPPS. Further, cell collection and cell processing services should be able to be reported using standard claims reporting practices. This would streamline reporting, reduce billing confusion for these services and allow providers to report them in real time on outpatient claims, without facing a rejection. Further, this would reduce the administrative burden on hospitals as they could follow their usual claims submission processes. This approach also would allow CMS to collect data on the costs for these services which could be used in future rate-setting.

[28] Not paid under OPPS. May be paid by intermediaries, when submitted on a different bill type, for example, 75x (CORF). An alternated code recognized by OPPS when submitted on an outpatient hospital Part B bill type (12X and 13x) may be available.
[29] Paid under OPPS; separate APC payment.
[30] Paid under OPPS; Addendum B displays APC assignments when services are separately payable. Packaged APC payment if billed on the same date of service as an HCPCS assigned status indicator "S," "T," or "V". In all other circumstances, payment is made through a separate APC payment.

ADD-ON PAYMENT FOR RADIOPHARMACEUTICAL TECHNETIUM-99M

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99m (Tc-99m), the radioisotope used in most such diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). Historically, most of the Mo-99 used in the U.S. was produced in legacy reactors outside the U.S. using highly enriched uranium (HEU). As the use of HEU poses a national security threat, the U.S. wanted to eliminate reliance on these reactors and promoted the conversion of all medical radioisotope production to non-HEU sources. However, it was expected that this supply source change would increase costs in the payment system that would not be fully accounted for in the historical claims data until all Tc-99m was produced from non-HEU sources. Therefore, beginning in CY 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost of radioisotopes produced by non-HEU sources. CMS proposes to continue this add-on policy for CY 2025. **The AHA supports CMS' proposed policy to continue making an add-on payment for CY 2025.**

CMS is also concerned that once U.S. companies initiate or resume Mo-99 production, the difference in pricing models likely will create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 likely would pay higher prices than those purchasing Tc-99m derived from imported Mo-99. Therefore, CMS proposes to address this payment inequity by establishing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99. **The AHA supports CMS' proposal to establish a new add-on payment, starting in CY 2026, to encourage hospitals to use Tc-99m derived from domestically produced Mo-99**.

INVOICE DRUG PRICING PROPOSAL FOR CY 2026

CMS notes that in recent years there has been an increasing number of drug and biological Healthcare Common Procedure Coding System (HCPCS) codes for which ASP, wholesale acquisition cost, average wholesale price, and MUC information are unavailable. These are often HCPCS codes for new drugs or biologicals approved for marketing, but for which the manufacturer does not have sales data. As a result, CMS has been unable to assign a payable status indicator to these drugs or biologicals. Therefore, to provide payment rates for these drugs and biologicals, CMS proposes to adopt an invoice pricing policy. Invoice pricing uses temporary drug or biological cost information to generate a representative payment rate and CMS believes that it supports the utilization of new drug or biological HCPCS codes. Due to the operational changes needed to implement this policy, the agency proposes to implement this policy in CY 2026.

CMS proposes that its Medicare Administrative Contractors (MACs) would calculate a payment amount based on provider invoices. **However, the AHA is concerned about using invoice pricing to establish the OPPS payment rate for these new drugs and biologicals.** Requiring providers to track and report a specific invoice amount for a drug, the price of which could change frequently, would be overly burdensome, and in many cases, infeasible. This is particularly true with the significantly growing number of drugs without ASP or other cost data. The fact that CMS would require rebates, chargebacks or post-sale concessions to be netted out to get to the invoice cost would be especially burdensome. Some of this data may not be available for months for new drugs and biologicals, and we are uncertain how this would fit into the timeline that CMS envisions for MACs to obtain this data. Such burdens could result in providers not seeking reimbursement, thereby rendering the proposed solution ineffective.

In addition, we are concerned that this proposal would require providers participating in the 340B Drug Pricing Program to disclose to CMS their 340B acquisition costs for these drugs. This policy should not be used as a means for obtaining proprietary data. **Therefore, should the agency move forward with this proposal despite our objections, we urge it to not require any sharing of proprietary 340B acquisition cost data.**

Manufacturers should instead be required to report additional pricing information to enable CMS to create an ASP, thereby eliminating or substantially reducing the need for providers to report. As noted above, AHA supports MedPAC's recommendation that all manufacturers of products paid under Part B be required to submit ASP data, with penalties for failure to report. **Accordingly, the AHA recommends that CMS consider alternative reimbursement methods for these drugs using manufacturer-collected information.**

REQUEST FOR INFORMATION ON CARDIAC COMPUTERIZED TOMOGRAPHY SERVICE

Payment for cardiac computerized tomography (CT) services has declined annually since 2017. Commenters notified CMS of a specific claims edit that may have inappropriately affected the revenue codes reported with the cardiac CT codes in prior years' claims data which likely led to this decline. CMS confirmed the existence of the outdated revenue code edit and removed it in early December 2023, but this was too late to appreciably affect the 2023 utilization data used to set 2025 OPPS rates. This revenue code edit has resulted in a lower-than-appropriate payment rate for cardiac CT services because it was based on the imaging cost-to-charge ratio (CCR) rather than the cardiology CCR.

As such, CMS conducted a study of cardiac CT CPT codes to determine the extent the revenue code edit may have affected payment for these codes. It found that if 50% or more of HOPDs had billed these services with the cardiology revenue code (048X) and

cardiology cost center (03140), instead of the imaging ones, it would have resulted in a revised APC assignment and payment increase — from $182 to $386. As such, in the proposed rule, CMS requests comments on how hospitals perform and bill for these services and notes that, based on the comments received, it will decide whether to revise the payment methodology for 2025 using a simulated payment based on the study it conducted.

The AHA appreciates the opportunity to comment on the billing concerns for cardiac CT services, specifically, the existence of this inappropriate edit and ways to correct this problem in CY 2025 and future years. Not only does this edit result in an inappropriately low geometric mean cost, and therefore payment, for these services, but it prevents hospitals from accurately following CMS' guidance in Chapter 4 of the Medicare Claims Processing Manual to "report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report." **Therefore, the AHA urges CMS to revise the payment methodology for 2025 using a simulated geometric mean cost based on the study it conducted.**

However, we are concerned that the issues caused by this erroneous edit may persist. This is because it was not only the MACs that had the outdated edit but claims clearinghouses and other payer edits. Moreover, this issue may have been exacerbated by the impact of the Change Healthcare ransomware attack, which resulted in many providers being required to rebuild their edits from scratch this year. There are likely still some providers rebuilding their historical edits now that they are finally receiving reimbursement for their services. **As such, we are concerned that CMS likely will not see the appropriate revenue codes in the claims data even in CY 2024.**

We urge CMS to provide additional explanation and education on this issue given the agency's requirements for uniform charging and proper revenue code selection consistent with cost reporting. Specifically, some hospitals report that they have tried to change the revenue code for these tests to cardiology and radiology revenue codes that better reflect where their operational costs of specially trained staff are recorded but are unable to do so because of these ongoing and inappropriate clearinghouse and payer edits. Still, other hospitals are not convinced of CMS' guidance to select different revenue codes because "CT" is in the CPT code test description. For this reason, they are concerned that it could become a compliance issue to change the revenue code used.

In addition, we ask CMS to use its authority under the OPPS and as the enforcement entity for the Health Insurance Portability and Accountability Act (HIPAA), to educate providers and other HIPAA-covered entities, including health plans and clearinghouses, to not restrict revenue code assignment when CPT codes do not include explicit instructions about the use of particular revenue codes. Should these instances continue occurring, CMS will not have the most accurate information to review and assess rate-setting.

Finally, as requested by CMS, the AHA offers the following summary of responses from hospitals and health systems to the questions posed in the proposed rule.

1. *Where are cardiac CT services performed in a hospital? Are cardiac CT services performed in a dedicated cardiology department, radiology department, or some other hospital outpatient department?*

   Few hospital systems perform cardiac CT services in only one single department. They are usually the result of combining the resources of multiple departments that share cardiac and radiologic work. The CT equipment may or may not be in the CT department, but the staff that perform the tests may come from another department, such as cardiology. Irrespective of the revenue code utilized, the cost to the hospitals or health system remains high, given that facilities must compensate for advanced scanners, specialized resources and highly trained personnel, in addition to extra work that comes with a coronary CT angiography, regardless of the reader's specialty of radiology or cardiology.

   In addition, cardiac CT services often utilize and share equipment from other departments in the hospital, including to monitor heart rate, blood pressure, electrocardiogram and telemetry and nursing staff to administer medications such as beta blockers and nitroglycerin. This sharing of resources occurs with other cardiac services as well.

2. *What factors determine the revenue code assignment for cardiac CT services (i.e., the department in which the service is performed, the type of service that is performed, or some other factor)?*

   Despite CMS removing the problematic revenue code edit in December 2023, other payer and clearinghouse edits continue to dictate using the revenue code 0350, a CT radiology revenue code. Many of our member hospitals and health systems are not able to use the cardiology revenue code 0480 to better reflect appropriate department costs for the tests. Given that this barrier remains, CMS is unlikely to identify any noticeable change in 2024 claims. The complexity of the cardiac CT study remains the same, regardless of the revenue code being utilized, requiring the same pre-medication, pre-and-post patient evaluation, a nurse to administer medication, vital monitoring, and advanced beyond routine CT tests.

3. *What revenue codes are HOPDs reporting for these services in CY 2024? Are HOPDs using the cardiology revenue code on claims for cardiac CT services now that they are no longer restricted from using this revenue code?*

   As noted above, changes in claims practices are unlikely to surface quickly. Currently, many hospitals are still not able to submit claims using the cardiology

revenue code because they are prevented from doing so by a claims clearinghouse and/or other payer edits.

CANCER HOSPITAL ADJUSTMENT

Historically, 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 points to account for Medicare's site-neutral payment policy exemption for these 11 hospitals.

Considering the pandemic, CMS maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. In CY 2024, CMS finalized a policy to reduce the target PCR by 1.0 percentage points each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For CY 2024, it finalized a target PCR of 0.88.

For CY 2025, CMS proposes a target PCR of 0.87 to determine the CY 2025 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.87 for each cancer hospital. **The AHA supports the proposed CY 2025 PCR target.**

PROPOSED PAYMENT FOR INTENSIVE OUTPATIENT AND PARTIAL HOSPITALIZATION PROGRAMS

In the CY 2024 OPPS final rule, CMS established payment methodologies that established four separate Intensive Outpatient Program (IOP) and Partial Hospitalization Program (PHP) APC per-diem rates. In this rule, CMS proposes payment updates for IOP and PHP based on the previously finalized methodologies. **The AHA continues to support these methodologies to calculate APCs for IOP and PHP services. We hope the agency can glean early lessons from the first year of these benefits in further honing payment for behavioral health services.** As with the CY 2024 OPPS rule, we continue to be disappointed that CMS did not discuss how remote services could factor into the newly established IOP benefit. We again encourage the agency to consider allowing at least some or a proportion of IOP or PHP services to be delivered remotely to increase access to these benefits.

REMOTE OUTPATIENT THERAPY, DIABETES SELF-MANAGEMENT TRAINING AND MEDICAL NUTRITION THERAPY

We urge CMS to work with Congress to extend waivers in support of virtual therapy services, preferably permanently. During the COVID-19 Public Health Emergency (PHE), CMS established the Hospital Without Walls policy, which enabled hospitals to reclassify patients' homes as temporary extension sites during the state of emergency. This also enabled billing of virtual services furnished by hospital outpatient departments. For CY 2024, CMS allowed institutional providers to continue to provide remote outpatient physical therapy, occupational therapy, speech-language pathology, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) in patients' homes via telehealth. This was predicated on statutory waivers, including eligibility for physical therapists, occupational therapists and speech-language pathologists to serve as distant site providers and eligibility of the patient's home as a designated originating site for telehealth services. These statutory waivers were extended as part of the Consolidated Appropriations Act (CAA) of 2023, however, without congressional action these are scheduled to expire at the end of 2024.

Without extending these flexibilities, we risk a telehealth "cliff" that will negatively impact access to care across communities. Many organizations continue to depend on remote therapy services for geographically dispersed patients, patients without reliable transportation, patients with lengthy drive times and those with mobility issues. For example, some organizations have cited the critical role that virtual swallowing therapy has had for patients with head and neck cancer and Parkinson's patients who may have challenges with mobility and transportation. This has prevented hospital admissions for aspiration pneumonia.

Also, recent studies from Harvard Medical School and Spaulding Rehabilitation Hospital found high levels of patient satisfaction across age, gender, and the specialties of physical therapy, occupational therapy and speech-language pathology.[31] Survey respondents also reported benefits such as receiving tailored feedback from providers on equipment that was set up in their home, more easily coordinating caregiver training for patient transitions back to their homes since caregivers could be at the patient's home with the patient, and reduced drive times and added convenience.

PERIODIC IN-PERSON VISITS FOR MENTAL HEALTH VISITS FURNISHED BY HOSPITAL STAFF TO BENEFICIARIES IN THEIR HOMES

The CAA, 2021 required in-person visits six months prior to administration of remote mental health services and annually thereafter. In-person visit requirements for tele-behavioral health services were waived during the COVID-19 PHE, and waivers were extended through 2024. However, these statutory waivers are scheduled to expire on Dec. 31, 2024 without additional congressional action.

[31] Outpatient Physical, Occupational, and Speech Therapy Synchronous Telemedicine: A Survey Study of Patient Satisfaction with Virtual Visits During the COVID-19 Pandemic - PMC (nih.gov)

We strongly urge CMS to work with Congress to extend in-person visits for behavioral health waivers permanently. Behavioral health is one specialty area that has seen sustained utilization of telehealth services. Specifically, prior to the pandemic, telehealth visits accounted for less than 1% of behavioral health visits. However, during the pandemic, they peaked at about 40% of all behavioral health visits and have often remained above 30%.[32] Issues like increased demand for behavioral health services and shortages of behavioral health providers have contributed to this trend and underscore the continued need for virtual access. In addition, more than 30% of the U.S. adult population reported symptoms of anxiety and depression during the pandemic (compared to 11% prior), and provider shortages in areas like psychiatry are only expected to grow.[33]

The requirement for in-person visits may, in fact, adversely impact access, quality and cost for behavioral health services. This is particularly true considering most patients utilizing behavioral telehealth during the pandemic were in rural areas (55%).[34] In fact, over 158 million people live in mental health provider shortage areas as defined by the Health Resources & Services. Administration (HRSA).[35] These patients cannot readily see an in-person provider given the shortages in their geographic area.

From a quality perspective, ASPE has highlighted that part of what makes behavioral health a great use case for telehealth is the fact that in-person and physical exams may not be required as frequently.[36] Finally, from a cost perspective, an analysis by Epic of over 4.3 million behavioral telehealth visits found that only 15% needed an in-person visit within three months.[37] Data from the pandemic suggest that behavioral telehealth visits were generally substitutes for in-person care. Therefore, while some patients may benefit from a periodic in-person evaluation, it should be left to clinical judgment, rather than an arbitrary general requirement. Indeed, adding a requirement for an in-person visit at specific cadences may unintentionally lead to the scheduling of additional appointments that otherwise are not clinically necessary.

HOPD PAYMENT FOR TELEMEDICINE EVALUATION AND MANAGEMENT SERVICES

[32] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/
[33] https://www.kff.org/statedata/mental-health-and-substance-use-state-fact-sheets/
[34] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/
[35] https://data.hrsa.gov/topics/health-workforce/shortage-areas
[36] https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf
[37] https://epicresearch.org/articles/telehealth-visits-unlikely-to-require-in-person-follow-up-within-90-days

The CY 2025 OPPS asked for feedback on virtual evaluation and management (E/M) services and the applicability of G0463 since CPT E/M services are not recognized under OPPS. During the PHE, HOPDs used the G0463 code to bill for E/M services provided where the patient was registered as a hospital outpatient in their home. However, because the Hospital Without Walls policy has expired, the provision of HOPD remote services has been limited. It also means that these services are only available when both the patient and provider are physically located in the same HOPD. **We urge CMS to explore opportunities to expand virtual services provided by HOPDs to beneficiaries in their homes.** One lesson learned from the pandemic has been that the benefits of digital health are not limited to a single site of care or geography. **As such we specifically encourage CMS to allow for the provision of certain virtual HOPD services, including G0463, when the provider and patient are not in the same location.**

VIRTUAL SUPERVISION OF CARDIAC REHABILITATION, INTENSIVE CARDIAC REHABILITATION, PULMONARY REHABILITATION SERVICES, AND DIAGNOSTIC SERVICES FURNISHED TO HOSPITAL OUTPATIENTS

In CY 2024, CMS extended virtual supervision flexibilities for cardiac rehabilitation services (CR), intensive cardiac rehabilitation services (ICR) and pulmonary rehabilitation services (PR) in accordance with CAA 2023. Specifically, CMS allowed direct supervision to be furnished via two-way, audio/visual communication technology for CR, ICR and PR. CMS proposes to extend virtual supervision flexibilities for OPPS through December 31, 2025.

The AHA strongly supports the proposed extension of virtual presence to satisfy direct supervision requirements by interactive telecommunications technology. This critical flexibility has supported improved access to care for patients in underserved areas.

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 evaluated the IPO list using its longstanding criteria to determine whether any services should be added to or removed from the list.

The AHA supports CMS' proposal to add three new CPT codes (0894T, 0895T and 0896T) to the IPO for CY 2025. These codes describe the cannulation and connection of liver allografts. We agree with CMS' clinical review that these services require hospital admission and are inappropriate for payment under the OPPS.

PROPOSED QUALITY REPORTING PROGRAMS

Hospital Commitment to Health Equity Measure. America's hospitals are committed to reducing disparities in health outcomes and promoting diversity, equity and inclusion within their own organizations. We agree that advancing health equity is important across the care continuum, including those services delivered in ambulatory care settings. Beginning with the CY 2027 payment determination, based on data reported in CY 2026 which would reflect performance in CY 2025, CMS proposes to adopt a structural measure that assesses whether an HOPD, ASC or Rural Emergency Hospital (REH) demonstrates certain equity-focused organizational competencies. Facilities would be asked to attest to several statements across five domains. The same measure was adopted in the inpatient quality reporting (IQR) program last year and will be required for reporting for the first time this year.

While this measure is too new to truly be able to evaluate its potential impact on quality of care, it has potential for future use in CMS programs because it fills a critical gap. When the measure was proposed for adoption in the IQR, AHA was pleased to support the proposal and offered several suggestions for changes that would make the measure more meaningful, actionable and transparent. While we reiterate that America's hospitals, including ambulatory care facilities, are steadfastly committed to advancing health equity within their organizations and their communities, **we have concerns about some of the specifications of the measure as well as the implementation of this measure in the Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR), in particular.** CMS declined to make the changes to the measure that we suggested in our comments (summarized below), which limits the overall utility of the measure. In addition, we believe that reporting separate measure calculations for the OQR (and for health systems that operate ASCs, the ASCQR) and IQR would be redundant. Thus, if CMS moves forward with its proposal to adopt this measure for the OQR and ASCQR, **we recommend that the agency allow hospitals to report the measure as representing the entirety of the organization rather than requiring separate reporting for the inpatient and HOPD parts of the organization.** CMS has applied this approach to health care personnel vaccination reporting measures in IQR and OQR, and we believe it would work similarly well for this measure.

CMS proposes implementing the Hospital/Facility Commitment to Health Equity measure in the same way as the measure has been adopted for the IQR and Inpatient Psychiatric Facility Quality Reporting Program. As such, the proposal in this rule exhibits the same disadvantages as those in previous rulemaking. For example, one major concern relates to how performance would be calculated. According to the

measure's proposed specifications, performance would be reported as a percentage of questions out of five to which the hospital responded affirmatively to all sub-parts of the question. Suggesting that a hospital or facility is "40% committed to health equity" would be unhelpful — and potentially misleading — to patients, providers, administrators and the community. We therefore recommend that CMS reconsider how to convey to the public what hospitals and health systems are doing to demonstrate their commitment to this essential issue.

In addition, we continue to believe that CMS should revise the "all-or-nothing" approach to scoring of this measure across the quality reporting programs in which it appears. Instead, CMS should award one point for each individual attestation. We believe this approach would make the measure more transparent and useable to reporting facilities and the public, as the proposed performance calculation approach "rolls up" answers to multiple questions within individual domains.

Finally, it is not necessary or consistent with hospital policies regarding organizational integration to require separate reporting of this measure for the inpatient and outpatient settings. The structural Hospital Commitment to Health Equity measure concerns the organizational competencies of the hospital rather than individual patient interactions in a particular setting. The inpatient setting and outpatient settings within a hospital operate under the same overarching structures for strategic priorities, leadership, data collection and reporting, and quality improvement; the Board, strategic plan and QAPI programs are the same for inpatient services as for outpatient.

In fact, CMS requires such integration as a Condition of Participation in the Medicare program: 42 CFR 482.54(a) states that "outpatient services must be appropriately organized and integrated with inpatient services," and the interpretive guidance for outpatient services notes that "[t]he Medicare Hospital Conditions of Participation apply to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the Condition of Participation in 42 CFR §482 in all on-campus and off-campus outpatient service locations," as well as that "[t]he hospital's outpatient services must be integrated into its hospital-wide Quality Assurance and Performance Improvement program." The attestations to the statements in the IQR version of this measure would be identical to those in the OQR version. If anything, requiring separate reporting between outpatient and inpatient settings may inadvertently discourage integration. To reduce the reporting burden and confusion among patients and providers seeking information on a hospital's commitment to health equity, we recommend that CMS allow a hospital to report the measure on behalf of its entire organization.

Screening for SDOH Measure. Beginning with voluntary reporting in CY 2026 of data collected in CY 2025 and required reporting in CY 2027 of data collected in CY 2026 data (to inform the FY 2028 payment determination), CMS proposes to adopt this structural measure that evaluates whether HOPDs, ASCs and REHs are screening patients for certain health-related social needs (HRSNs). CMS explains that these facilities could use a self-selected screening tool to collect these data. The measure

was adopted for the IQR in the FY 2023 Inpatient Prospective Payment System (IPPS) final rule with voluntary reporting during CY 2023 and mandatory reporting beginning in CY 2024.

While the AHA believes that this measure addresses a critical gap in care — the connection between outpatient services and drivers of health-related social needs — we urge CMS to consider how this measure will glean the most useful information. We understand CMS' argument against a single screening measure for the OQR/ASCQR and IQR, considering there may not be total overlap in inpatient and outpatient populations. However, outpatient care occurs in more settings than just an office, which presents unique complexities in reporting this measure.

In the proposed rule, CMS states that, in alignment with the IQR program, ambulatory facilities could confirm the current status of any previously reported HRSNs in another care setting and inquire about others not previously reported in lieu of re-screening a patient within the reporting period; in addition, if the information has been captured in the EHR in another outpatient setting or the inpatient setting during the same reporting period, the ambulatory facility could use that information for purposes of reporting the measure in lieu of screening the patient. **The AHA supports this proposal and requests clarification on whether practitioners performing patient screenings in the inpatient setting could use information captured from ambulatory settings during the same reporting period to inform screening rather than re-screening patients.**

Further, we urge CMS to clarify the outpatient population in the denominator of this measure for use in the OQR. In the proposed rule, CMS defines the denominator as "patients receiving services" from an HOPD. Not all outpatient interactions involve an office visit where screening would be appropriate; for example, a patient may receive imaging or lab services from an HOPD or visit an ASC for a diagnostic procedure as directed by a primary care physician with whom the patient has an existing relationship. We question whether those interactions would be adequate for performing screening for health-related social needs; we understand that measure adoption would not *require* screening for patients, but we worry that including those services that constitute less than an office visit may dilute the effectiveness of the screening. For example, an administrative professional at a lab may offer a form to a patient dropping off a sample; however, that patient may not feel comfortable sharing detailed personal information with the administrative professional (as opposed to their personal physician), and thus may complete the screening form in a perfunctory manner or opt out of screening altogether. This patient would be considered screened for purposes of the measure, but useful information would not be gleaned from the screening. To achieve the underlying goals of this measure — to identify health-related social needs in hopes of connecting patients to services beyond their clinical care — we encourage CMS to consider narrowing the focus of this measure to patients receiving office visits.

Screen Positive Rate for Social Drivers of Health Measure. Beginning with voluntary reporting in CY 2025 of data collected in CY 2024 and required reporting in CY 2026 of data collected in CY 2025 data (to inform the FY 2027 payment determination), CMS proposes to adopt this measure that assesses the percent of patients admitted receiving services from an HOPD, ASC or REH who were screened for the HRSNs listed above who screen positive for one or more. Facilities would report five separate rates (one for each HRSN). According to CMS, the measure is intended to provide transparency in the delivery of care and actionable information to ambulatory facilities on the level of unmet HRSNs among patients served, "and not for comparison … between healthcare facilities." The measure was adopted for the IQR in the FY 2023 inpatient PPS final rule.

We agree that screening for HRSNs is an important part of the work our members are taking on to advance health equity; however, we have logistical and conceptual concerns with using screening measures in the quality reporting programs for HOPDs, ASCs and REHs. **Similar to our position on this measure for inpatient hospitals, we support voluntary reporting of this measure but urge CMS not to set a date certain for mandatory reporting at this time.** In addition to the same issues listed above, we offer additional considerations.

As part of the Pre-Rulemaking Measure Review process, the Hospital Recommendation Group did not reach a consensus to recommend this measure for use in the OQR, REHQR or ASCQR. The committee expressed concerns about ambiguity in data interpretation, and the related expectations of health care facilities to reach a certain rate of positive attestations of HRSNs. Further, the measure has not undergone endorsement review by a Consensus-based Entity (CBE); we recognize that CMS is not required to adopt into its programs only measures endorsed by a CBE, but the endorsement review process helps determine the validity, reliability and usefulness of a measure. In its proposal, CMS states that the urgency of addressing health equity is such that the agency wants to implement this measure as soon as possible. We agree that it is urgent to address health equity, but we believe it is important to do so effectively and meaningfully. It is unclear the extent to which this measure achieves this goal.

CMS acknowledges that the "score" on this measure could be interpreted differently. In fact, the AHA would argue this measure is a reflection of the community a hospital serves more than hospital quality or safety performance. In fact, it is unclear where the measure is a truly "directional" indicator. For example, some would consider a lower score — suggesting a smaller percentage of adults demonstrate HRSNs — to indicate better performance by the facility. Yet, a lower score also could mean that the hospital is located in an area with high average income, better public transportation and more accessible nutrition. We would be concerned about CMS using this particular measure to judge hospital performance because it could mean that hospitals serving the most financially challenged neighborhoods will be falsely judged to be of lesser quality because they have higher scores. Conversely, if one assumed a higher screen positive rate indicated better performance, that, too, would be problematic because some

hospitals may serve communities with fewer identified health-related social needs. For this reason, we encourage CMS to consider not using the screen positive rate in contexts in which hospitals are comparatively ranked, such as Star Ratings.

CMS does not provide data showing a clear causal relationship between quality of care and the proportion of patients with higher social risk scores on this measure. While patient outcomes are often poorer for patients with health-related social needs, nothing in this measure's description makes the connection between a positive screen for a social driver of health and actual utilization — or even availability — of services to address patients' social needs. The details are important; and without them, we fear this critical information will be unusable to improve outcomes.

We reiterate that identifying social drivers of health is vital and that hospitals, health systems and society as a whole should engage in addressing inequities in health outcomes and the underlying social pressures that exacerbate these disparities. However, we are not confident that using this measure as currently specified will help make progress on this goal.

Patient Understanding of Key Information Patient Reported Outcome Performance Measure (PRO-PM). CMS proposes to adopt this patient-reported outcome measure beginning with voluntary reporting in CY 2026 and mandatory reporting in CY 2027. The measure reports the average score of a patient's ratings on a three-domain, nine-item post-operative survey regarding the clarity of clinical information given before, during, and after an outpatient surgery or procedure.

The AHA does not support the adoption of this measure; if CMS moves forward with its proposals, we encourage the agency to maintain voluntary reporting for the foreseeable future. Considering the recent addition of the patient-reported outcomes following elective primary total hip and/or total knee arthroplasty (THA/TKA) as well as additional Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS) questions recently adopted in the FY 2025 inpatient PPS final rule and the newly mandatory (as of Jan. 1, 2024) Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, the AHA is concerned by the increasing burden on patients of the ever-growing list of provider survey questions they are being asked to answer. To be sure, hospitals and health systems deeply value the patient perspective on their care and use data from patient experience and Patient-Reported Outcome Performance Measures (PRO-PM) across their efforts to make care safer, higher quality and more equitable. PRO-PMs are a newer measure type that carries the important potential to capture whether patients are regaining function and activities that matter in their daily lives.

At the same time, such measures also require patients to provide a significant amount of information — often, the same information multiple times. With the recent already adopted inpatient and outpatient surveys, not to mention individual CAHPS surveys from individual clinicians involved in an outpatient procedure, we worry that CMS' plans

to rely upon patients for an increasing amount of data production could affect survey response rates across the board. It also could lead to confusion among patients about what aspect of their care they are being asked to assess. This is especially true of this PRO-PM, which could potentially overlap with the PRO-PM for THA/TKA.

CMS argues in its proposal that the administration timeline of PRO-PM proposed in this rule "mitigates overlap" with OAS CAHPS and PRO-PM for THA/TKA — the Patient Understand of Key Information PRO-PM survey would be administered between two and seven days post-procedure, whereas the OAS CAHPS is administered on the first-day post-procedure with follow-up of non-respondents at 14 days and the survey for PRO-PM for THA/TKA is administered up to 90 days before the procedure and 300-425 days following. It is true the surveys would not be administered on the exact same day; we do not believe this "mitigates" overlap at all, as the same patient could still receive survey after survey after survey in the span of three days of a surgical procedure.

In addition to the logistical challenges presented by yet another patient survey, this particular measure suffers from conceptual disadvantages. The name of the measure, Patient Understanding of Key Information, and CMS' purported purpose of considering the measure, to evaluate the clarity of clinical information, are inconsistent. A patient's understanding of information presented to them certainly relies partly upon the completeness and articulation of the information; however, there are other factors including general literacy and health literacy, not to mention the literacy of any proxy or caregiver who may complete the survey on the patient's behalf, that would influence the patient's evaluation. In other words, this measure does not evaluate the quality of information provided to the patient, but rather the patient's ability to comprehend it; PRO-PMs are inherently subjective, but this particular topic is assessed objectively elsewhere. Indeed, the study that CMS cites in its proposal background that identifies disparities in end-of-visit summaries between those provided in the inpatient and outpatient settings bases its conclusions on *documentation review* rather than patient responses. Similarly, the Transfer of Health Information to the Patient measure used in post-acute care quality reporting programs assesses the *content and timeliness* of medication profiles provided to the patient, family and/or caregiver at discharge.

The subjective nature of the response categories (Very, somewhat, and not) may pose challenges for providers to interpret as well. The survey does not provide details on how the information could be clarified or what information was missing. Hospitals already work closely with their Patient and Family Advisory Councils to meaningfully improve their patient communications, and this measure is unlikely to provide additional insight into that process. In summary, the AHA does not believe the burden of administering yet another patient survey is worth the shallow information gleaned from it.

Proposed Removal of Measure. Beginning with the CY 2025 reporting period, CMS proposes to remove the MRI Lumbar Spine for Low Back Pain and Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk surgery. These measures have lost CBE endorsement; in addition, there is limited opportunity for improvement

across the field and no association between the use of the measures and improved patient outcomes. **The AHA supports removing these measures and appreciates that the agency is seeking to hone the OQR.** We recommend that CMS continue to evaluate measures for removal, starting with others in the OQR that have lost endorsement by a CBE, including:

- OP-18: Median Time for Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients
- OP-22: Left Without Being Seen

Proposed Public Reporting of Median Time from ED Arrival to ED Departure for Discharged ED Patients — Psychiatric/Mental Health Patients Stratum. CMS proposes publicly reporting on *Care Compare* data for the stratum of this measure of ED throughput time that represents patients seeking care in the ED for psychiatric or mental health concerns. The measure is calculated, and data is publicly available for download, but not currently displayed along with the reporting measure rate (which excludes psychiatric or mental health and transfer patients). CMS argues that the discrepancy in throughput times across strata suggests additional room for improvement for patients seeking care in the ED for behavioral health concerns.

The AHA does not support the proposal to include the psychiatric/mental health patients' stratum in the Care Compare display for this measure; in fact, we suggest that CMS consider removing this measure from the OQR. When reviewed by the Cost and Efficiency Standing Committee during the spring 2018 Consensus Development Process, the measure did not meet the criteria for importance (which incorporates information on the strength of evidence supporting the measure's use in quality reporting programs and quality improvement as well as evidence of a performance gap) and thus was not recommended for re-endorsement. Among several concerns with this measure, the most striking was the lack of evidence that a change in wait times influences mortality or other patient outcomes. When it was suggested by the Standing Committee that certain population types — such as those seeking mental health services — should be separated, the developer clarified that these patients are addressed in a separate rate, and the data regarding this population is not publicly reported.

From its inception, CMS and its contractors were well aware of the unique factors driving ED throughput times for patients seeking care for mental health issues, including those well outside of the control of the hospital such as the availability of community resources, and thus have always separated this patient population from the overall rate to provide a more accurate evaluation of ED processes. In this proposed rule, CMS notes that it is the agency's understanding that "many hospitals face such concerns," and that the public reporting of these data of Care Compare "could help patients and their caregivers identify which facilities are performing better than others despite potential challenges, and drive quality improvement efforts." **The AHA believes that publicly reporting this information along with the overall rate would be confusing**

and counterproductive and would be unlikely to influence the decisions of people making decisions during a mental health crisis. Due to the siloed nature of psychiatric medicine, mental health emergencies are inherently different from other physical health emergencies; that is why there is a separate crisis number, 988, to call in instances of mental health crises. The ED is not generally the recommended location for a person in crisis, so including this information in a throughput measure is misleading and oversimplifies a complex care network. In other words, by publicly displaying this stratum, CMS would suggest that the measure is more an indicator of quality than it actually is.

In addition, the data on ED throughput times is already publicly available via download, and hospitals receive their stratified performance in their feedback reports. Thus, the information is already available for use in quality improvement; publicly reporting it on Care Compare would be of no additional benefit. The AHA supports data transparency; however, simply displaying a rate representing a population fraught with challenges to accessing appropriate treatment only serves to underscore an already inadequate measure.

Request for Information: Specialty-focused Reporting for ASCs. CMS acknowledges that the ASCQR measure set includes measures that may not apply to all ASCs considering that some ASCs only perform certain specialty clinical procedures. The agency seeks comment on two potential frameworks wherein all ASCs would report the same group of common measures and then either be required to report measures for which they meet a certain volume threshold or be allowed to choose from a menu of relevant measures based on their case mix.

The AHA appreciates that CMS is considering ways to hone the quality reporting programs to make them more relevant. However, based on the ASCQR's current measure set, it is unlikely that either suggested approach would yield more customized information. The non-claims-based specialty-specific measures in the set are limited and of low quality, such as ASC-11: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery; CBE endorsement for this measure was removed, and it is voluntarily reported for the foreseeable future due to inherent disadvantages in its design. If CMS were to populate the ASCQR with more specialty-specific measures that were reported on an as-needed basis, the program overall would be inconsistent with other CMS quality reporting programs (like the OQR and IQR) and more akin to a qualified clinical data registry (QCDR). Since QCDRs already collect and report specialty data to CMS for quality reporting programs, the changes to the ASCQR would make it redundant.

Therefore, while the AHA values CMS' attempt to make the ASCQR more relevant to individual facilities, we believe that the strategies suggested in this proposed rule would do little to reduce the burden for multi-specialty ASCs who would be subject to several measures regardless and would result in even less useful information for specialized ASCs than is currently collected in the program.

Proposed Extension of Voluntary Reporting of the Hybrid Hospital-Wide All-Cause Readmission and Mortality Measures in the IQR. In previous rulemaking, CMS adopted two measures for the IQR that use multiple data sources for measure calculation — namely, claims data, core clinical data elements (CCDEs) and linking variables derived from EHRs for risk adjustment. Reporting for these measures is currently voluntary, but beginning Oct. 1, 2024, hospitals would be required to submit linking variables on 95% of hospital discharges and CCDEs on 90% of hospital discharges or be subject to a one-quarter reduction to their annual payment update.

Based on performance during the most recent voluntary reporting period, CMS found that about three-quarters of hospitals that chose to report these measures (which represent about one-third of all inpatient PPS hospitals) would not have met the reporting threshold; in addition, the agency has received feedback from hospitals as well as inquiries to its helpdesk regarding various issues with reporting the data. In response, CMS proposes extending the voluntary reporting period for an additional year.

The AHA also has heard significant concern from hospitals regarding the challenges of administering the patient-matching methodology necessary to submit CCDEs and linking variables. Additionally, members have concerns that the feedback reports received from CMS do not contain sufficient information to validate the accuracy of the vital signs, labs and linking variables that they have submitted. **For these reasons, the AHA supports the delay of mandatory reporting of this measure. Specifically, we suggest that CMS consider a delay of more than one year considering the substantial procedural issues in complying with the measures' requirements. We also urge CMS to use a process outside of the notice and comment rulemaking period to confirm that hospitals not meeting reporting thresholds will not be penalized in their FY 2027 payment determination.** The final CY 2025 OPPS rule, which would contain the final decision regarding this delay, will not be published until after the Oct. 1 reporting period deadline for the hybrid measures. Our members greatly appreciate CMS proposing relief, but would welcome explicit assurance from CMS before Oct. 1, 2024, that they will not be deemed out of compliance with the IQR if they do not submit data on that date.

The AHA also suggests that CMS proactively consider how the issues with the patient matching methodology in these hybrid measures may arise in other measures. Specifically, the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Performance Measure, which was finalized in the FY/CY 2023 IPPS/OPPS Final Rules uses similar patient matching methodology and thus is likely to suffer from the same challenges. Mandatory OQR reporting for pre-procedure data also begins in October this year, while IQR reporting began in April. **We recommend CMS determine whether providers are experiencing similar issues for this measure before performance data influences payment determinations.**

Request for Information: Potential Modifications to the Overall Star Rating Methodology to Emphasize Safety of Care. To calculate a hospital's Overall Star Rating, CMS uses hospital performance on measures in five categories: Safety, Mortality, Readmissions, Patient Experience, and Timely & Effective Care. Based on analysis of the July 2023 calculation of Overall Star Ratings, CMS found that while there was generally a strong relationship between hospital performance on measures in the Safety group and the hospital's Overall Star Rating (i.e. hospitals that had good scores on the measures related to patient safety tended to have higher star ratings, and vice versa), a small number of hospitals (19 out of 3,076 hospitals that met the criteria to receive a star rating) received five stars despite being in the lowest quartile of performance on measures in the Safety measure group; 94 more hospitals also received five stars despite being in the bottom quartile of performers in Safety measures but did not have volume to calculate the minimum three measures in that group for it to count toward their Overall Star Rating. CMS interprets this information to mean that a hospital can be rated highly while delivering unsafe patient care.

To address this issue, the agency requests feedback on potential strategies that would more heavily emphasize the scores on the measures in the Safety group as they contribute to the Overall Star Rating. These strategies include increasing the weight of the Safety group score toward the Overall Star Rating so that the other four categories would contribute less toward the score; adopting a policy where CMS would apply a post hoc adjustment to the Overall Star Rating of a hospital by subtracting one star from the rating of any hospital that scores in the lowest quartile of performance on at least three measures in the Safety group (which would affect those 19 hospitals noted above); and adopting a cap on the number of stars so that a hospital would not be able to receive more than four stars if it scored in the lowest quartile of performance on at least three measures in the Safety group.

Patient safety is a top priority for hospitals and health systems. The AHA agrees with the basic notion that it is important to consider the safety of care provided at a hospital when choosing where to receive services. However, the star ratings changes proposed by CMS likely would further undermine the already tenuous concept of applying a single score to represent the quality of hospital care. As CMS has acknowledged in past work, the Overall Star Rating is not itself a comprehensive reflection of quality, but rather a reflection of hospital performance on the measures that the agency has chosen to include in the program. Further, the Overall Star Rating is not solely focused on Safety — indeed, the rating is informed by dozens of measures addressing other topics and issues that vary in importance to individual patients and providers. Because of these characteristics, the Overall Star Rating is not universally helpful or applicable. That is why CMS' own Care Compare website recommends that people searching for care "consider a variety of factors when choosing a hospital, like physician guidance about your care plan." While the desire to emphasize patient safety is reasonable, doing so by altering the mathematical processes that result in the rating rather than the underlying process for evaluating the safety of care ascribes more agency to the Overall Star

Rating than it has. In other words, the Overall Star Rating does not alone determine the optimal hospital, so changing the math so that the rating is more informed by a certain group does not alone make certain higher-scoring hospitals safer.

In addition to the conceptual shortfalls of the suggested approaches, we have several logistical concerns. In short, the existing methodological disadvantages of the Overall Star Rating program would be exacerbated by modifying just the Safety group. The measures included in the Safety group change over time as CMS adopts and removes measures from the IQR and OQR programs; in addition, performance in the Safety group does not reflect the same measures for each hospital. For example, Hospital A's Safety score may be based on its performance on measures related to CLABSI, CAUTI and C. Diff, while Hospital B's Safety score may be based on its performance on measures related to TKA complications and surgical site infections regarding colon surgery or hysterectomy. Thus, arbitrarily increasing the weight of the Safety group confounds the lack of comparability between these hospitals and decreases the usefulness of the ratings in informing a patient seeking a hospital for colon surgery.

This result would be particularly concerning for facilities that care for higher patient volumes, as they would have sufficient volumes to calculate performance in more measures in the Safety group. Put differently, such facilities could have a higher "exposure risk" stemming not from differences in quality of care, but instead from simply being scored on more measures. Comparing their performance directly to smaller facilities would be fraught because many smaller hospitals do not have sufficient volumes to calculate a statistically reliable score on some or all health care-associated infections (HAI) measures.

Finally, the AHA believes a major overhaul to the Overall Star Rating methodology to address an issue involving less than 1% of hospitals eligible to receive a rating likely is unwarranted. Further, the change to the methodology would more likely affect hospitals receiving two and three stars than those receiving four and five stars, as there are more hospitals in the middle of the distribution of scores; if the existing methodology is functioning as intended, the performance of those hospitals should already be reflected in their star rating and thus modifying the methodology could arbitrarily shift distribution.

The AHA appreciates that CMS is contemplating ways to improve the Overall Star Ratings methodology, and we are supportive of several of the changes the agency has incorporated over the past few years to make the ratings easier to understand. We would be interested in any further analysis CMS has on its modifications under consideration and the potential effects of the changes on different types of hospitals (e.g. large, freestanding, academic medical centers, etc.) or reporting groups. However, we would not support the approaches to emphasize the measures in the Safety of Care group as outlined in this proposed rule.

ASC PAYMENT SYSTEM PROPOSALS

Proposed ASC Payment System Update

For CYs 2019 through 2024, CMS adopted a policy to update the ASC payment system using the hospital market basket update. The agency proposes to extend this policy through CY 2025 due to concerns about the impact of the COVID-19 PHE on health care utilization. Therefore, for CY 2025, CMS would increase ASC payment rates by 2.6% for ASCs that meet the quality reporting requirements under the ASCQR Program.

The AHA remains opposed to this policy and CMS' proposal to extend it through CY 2025. 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 use the hospital market basket to update payments for ASCs. **We instead 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**.

We are not alone in our continued concern in this area. Indeed, MedPAC has, since 2010, recommended that CMS collect ASC costs. In fact, in its March 2024 report, it states, "The Commission reiterates its March 2022 recommendation that the Secretary require ambulatory surgical centers to report cost data." It further states, "Cost data would enable policymakers to establish payment rates that accurately reflect ASC costs. Currently, ASC payment rates are not based on ASC cost data but instead are largely derived from the OPPS payment rates, which are based on HOPD charges adjusted to cost."[38] 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

We appreciate CMS' evaluation of the ASC Covered-procedures List (CPL) each year to determine whether any procedures should be added to or removed from the list. For CY 2025, CMS proposes to add 20 medical and dental procedures to the ASC CPL and ancillary services lists based on these criteria. **The AHA agrees with and supports CMS' proposal to add these procedures to the ASC CPL.** We appreciate CMS' continued focus on maximizing patient access to care by carefully reviewing and considering additions to this ASC CPL list, especially as medical practice and technology evolve.

[38] https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch10_MedPAC_Report_To_Congress_SEC.pdf

REQUEST FOR COMMENT ON PAYMENT ADJUSTMENTS UNDER THE INPATIENT PPS AND OPPS FOR DOMESTIC PERSONAL PROTECTIVE EQUIPMENT

The CY 2023 OPPS final rule implemented payment adjustments under the OPPS and inpatient PPS to support a resilient and reliable supply of surgical N95 respirators. Currently, available payment adjustments are designed to offset the marginal costs that hospitals face in procuring domestically made National Institute for Occupational Safety and Health (NIOSH)-approved and Food and Drug Administration (FDA)-certified surgical N95 respirators. CMS has noted that even though payment adjustments began on Jan. 1, 2023, its use has been limited.

In the CY 2025 proposed rule, CMS seeks feedback on a variety of modifications and product expansions related to this policy intended to increase uptake and better support the medical supply chain. **We thank CMS for soliciting additional feedback on this separate payment; our additional recommendations follow.**

First, the AHA supports CMS' proposal to modify its existing adjustment methodology to provide a national standard unit cost difference between domestic and non-domestic NIOSH-approved surgical N95 respirators rather than continuing to require hospitals to report this individually. Currently, hospitals must separately report on their cost report the aggregate cost and total quantity of domestic and non-domestic respirators, enabling the calculation of a hospital-specific unit cost differential. We agree with MedPAC's assessment that creating a national standard unit cost difference would reduce the administrative burden on hospitals of tracking their expenditures on such products. This view is consistent with concerns AHA expressed in its CY 2023 OPPS comment letter. Further, in response to CMS's inquiry as to how it should calculate a national standard unit cost differential, we suggest that CMS utilize a reliable benchmarking service, such as ECRI or Vizient. **Finally, we also continue to urge CMS to make this payment adjustment in a non-budget-neutral manner under the OPPS, as it does under the inpatient PPS.**

Second, the AHA urges CMS to develop a publicly available list of fully domestically produced products eligible for the payment adjustment as this would make it easier for hospitals to identify and locate products eligible for the payment adjustment. In developing such a list, we encourage CMS to collaborate with other federal agencies and departments with experience in vetting personal protective equipment (PPE) suppliers, including the Agency for Strategic Preparedness and Response, which manages the Strategic National Stockpile, and the Department of Defense. However, hospitals should not be limited to solely choosing products on this CMS-developed list but should have the flexibility to receive the payment adjustment for otherwise verified domestically produced equipment.

Additionally, if CMS develops such a vetted list, we urge it to modify the current requirement that receiving the payment adjustment must be contingent on the hospital obtaining a written statement from the manufacturer attesting to the product being wholly domestically made. Instead, CMS should establish a less burdensome verification step that should only be applied to fully domestically produced N95 surgical respirators not included on CMS's vetted list. In previous comments, the AHA has noted that it is difficult for hospitals to obtain such manufacturers' attestations, and conditioning the payment adjustment on this provision is a disincentive for participation in this program.

CMS also asks whether hospitals need additional support to purchase domestically made surgical N95 respirators, and if so, how much support is needed and in what form. **In addition to what we have mentioned above, hospitals would also need a clear understanding of the supplier's production capacity and redundancies, along with expected lead times for supplying new customers.** Understanding these factors is crucial for any health care facility thinking about incorporating new types of PPE into their operations. Of particular importance is a clear understanding of whether a domestic manufacturer of PPE, particularly a smaller supplier, would be able to scale up production to meet demand, if necessary. As we learned during the pandemic, even large PPE manufacturers did not have the industrial capacity to adequately meet demand. Moreover, understanding manufacturer lead time for supplying new customers is also critical for hospitals due to respirator fit-testing requirements. That is, a newly introduced brand of surgical N95 respirators may only be used after each employee has been individually fit-tested with the product to ensure a tight seal. This process is time-consuming and, to ensure that respiratory protection is available when it is needed requires an understanding of lead times in this context.

Third, we support CMS expanding the program to apply the payment adjustment to surgical and non-surgical N95 respirators. Hospitals rely on a variety of PPE to safeguard their workforce, and it would be less burdensome and more cost-effective to procure and receive the payment adjustment for both surgical and non-surgical N95s. Further, as the program goal is to bolster domestic production of PPE, including both types of N95s would likely be more attractive to suppliers considering expanding their domestic footprint. Finally, we believe that the increased demand for both types of domestically made N95 respirators will likely strengthen the supply chain leading to a more consistent product flow in the event of an emergency.

Fourth, the AHA supports CMS expanding this program to include a similar payment adjustment for domestically made nitrile gloves, gowns, syringes and needles. These are all essential medical supplies largely manufactured, in part or wholly, in other nations and have experienced serious shortages in recent years. We believe, as noted above, that expanding to these other supplies would make the program more attractive to manufacturers considering expanding their domestic footprint. In addition, including additional domestically-made essential medical supplies in the program would improve hospital participation in the program as this would be an

opportunity for them to offset increased costs for additional high-volume, domestically-made supplies. Finally, increased demand for these domestically-made essential medical supplies will likely strengthen the supply chain leading to a more consistent flow of product in the event of an emergency.

However, the AHA stresses that if the program is expanded to these other essential medical supplies, all the recommendations we made above about domestically made N-95 respirators also apply to these products. This includes CMS developing a national standard unit cost difference, a CMS-vetted publicly available list of these wholly domestically-made products and their suppliers that would qualify for this program, and information about the manufacturers' capacities, redundancies, and lead times for supplying new customers.

PROPOSED NON-OPIOID POLICIES FOR PAIN RELIEF UNDER THE OPPS AND ASC PAYMENT SYSTEM

The CAA, 2023 requires CMS to unpackage and provide separate payments for three years, beginning Jan. 1, 2025, for non-opioid treatments for pain relief. Specifically, it provides that certain non-opioid treatments for pain relief furnished in CY 2025 through CY 2027 may not be packaged into payment for a covered outpatient department service or group of services and instead require that the agency make a separate payment.

Therefore, for CY 2025, CMS proposes to pay separately for six drugs and biological products with an FDA-approved indication to reduce post-operative pain or produce post-surgical or regional analgesia, as well as one medical device for which the agency has received literature references and determined that it meets the statutory criteria for an applicable medical device eligible for separate payment. In addition, CMS proposes to exclude these non-opioid treatments for pain relief identified as satisfying the CAA 2023 criteria from the C-APC policy.

The AHA supports CMS' proposals and agrees that stemming the tide of the opioid epidemic must involve changes to how services are reimbursed so that financial incentives promote a full range of approaches to treating pain. Moreover, we are pleased that Congress has determined that packaging payments for non-opioid alternatives not only present care barriers in ASCs but also in HOPDs.

PROPOSED CONDITIONS OF PARTICIPATION FOR OBSTETRICAL SERVICES IN HOSPITALS AND CRITICAL ACCESS HOSPITALS

The AHA and its members overwhelmingly support efforts to improve maternal health outcomes in the United States. We agree with CMS that maternal morbidity and

mortality is a complex problem requiring urgent attention. With more than 98% of women opting to deliver at hospitals, the AHA and its members are deeply invested in identifying and improving upon ways to provide safe, high-quality care to millions of women.

Year after year, hospitals and health systems demonstrate their commitment to reducing maternal morbidity and mortality through the care they provide each and every day. By incorporating nationally recognized best practices, participating in statewide quality collaboratives, and partnering with research institutions and government agencies to study new ways to deliver high-quality care, hospitals are constantly working to provide pregnant, laboring, and postpartum women with the best possible care.

We also agree that more work needs to be done. More than 5.6 million women live in counties with limited or no access to maternity care services, and another 32 million women are at greater risk for poor health outcomes due to limited access to safe maternity care. We noted in our response to CMS' RFI that in many areas, particularly rural areas, areas in the South, and non-expansion states, there are simply fewer and fewer places for women to receive maternity care. Research indicates these issues are not limited to labor and delivery; a lack of access to prenatal and postpartum care affects the entire pregnancy continuum and has directly contributed to poor maternal outcomes.

As the highest-volume provider of labor and delivery services, hospitals are eager to engage with partners to improve maternal outcomes. Yet, maternal morbidity and mortality is a multifaceted problem that spans the entire maternal health continuum. Any viable solution will require thoughtful, evidence-based interventions that support women across that continuum. The need for evidence-based approaches that include, but are not limited to, hospital-based obstetric care can be found in any number of peer-reviewed studies, including those cited by CMS in its proposed rule. Notably, many of these studies have found that more than half of all maternal deaths are not from obstetric causes; in fact, more than 50% of pregnancy-related deaths occur in the 12 months after giving birth. Cardiovascular disease and mental health issues — specifically opioid overdose and suicide — are among the leading causes of death. Roughly half of all maternal deaths occur at home, underscoring the importance of early and ongoing interventions and highlighting the need for community-based services that support women before, during and after pregnancy.

In other words, our nation's maternal health challenges do not cleanly start, or end, with hospital-based obstetric care. The broad-based nature of the issue limits the effectiveness of hospital CoPs, which by their very nature are focused on care during hospitalization. Furthermore, while well-intentioned, several parts of CMS' proposed CoPs are redundant with existing regulations, lack clarity and would impose potentially unworkable one-size-fits-all requirements. The AHA is concerned that the proposed

CoPs could, as currently written, inadvertently reduce access to vital obstetrical services.

For these reasons, the AHA urges CMS to reconsider the use of CoPs and instead work with hospitals to develop coalitions of partners that span the maternal health continuum and lead to meaningful improvements in maternal health. The AHA first comments on the content of the proposed CoPs and then offers our recommendations on how CMS could help advance a more collaborative and sustainable approach to improving maternal outcomes.

Response to Proposed CoPs. As noted above, the AHA does not believe new CoPs are the right approach for advancing maternal outcomes. **However, if CMS is intent on pursing such CoPs, we urge CMS to take several steps to make the CoPs more workable, flexible, and clear. First, CMS should identify whether there are gaps in existing regulations that support the imposition of additional requirements and eliminate redundancy in its proposed regulations.**

Hospitals are highly regulated. They are required to comply with a dizzying number of Federal, state, and local laws and regulations. Frequent oversight from accrediting organizations, state surveyors, and others further guarantees compliance. As we noted in our response to the RFI, overregulation is a serious challenge for providers and does not contribute to better patient care. Indeed, overregulation has been shown to increase costs and often serves as a barrier to increasing access to care. Too much regulation creates onerous requirements that do little to support patients navigating the health care system or the providers who care for them. A 2018 study conducted by the AHA found providers spent the equivalent of $39 billion dollars each year towards complying with regulatory standards –- a cost of about $1,200 per patient. Sixty-three percent of these compliance efforts were attributed to meeting CoP requirements and billing and coverage verification. With doctors, nurses, and other hospital staff reporting that more and more time is spent on compliance rather than direct patient care each year, it is imperative that CMS finds the right balance.

As a general matter, before finalizing additional regulatory requirements, **we urge CMS to comprehensively examine existing regulations and identify if there are areas where gaps exist, and new regulations would add value**. In addition to Federal requirements, CMS should consider state and local regulations, and rules imposed by third parties such as accreditors and insurers. Conducting such a survey would not prevent CMS from imposing new regulatory requirements where needed. Instead, this approach would avoid duplicative and unnecessary regulations that could lead to more closures and negatively impact patient care.

In the proposed rule, CMS acknowledges that at least some of its newly proposed standards are already required under existing CoPs. For example, CMS has proposed obstetric services maintain “a roster of practitioners specifying the privileges of each practitioner.” CMS concedes that maintenance of such a roster is already a hospital

requirement specified in §482.22(c) of title 42, Code of Federal Regulations. The agency says this new standard will create "additional specificity for an obstetrics service," but it fails to explain how such a requirement promotes patient safety or improves the quality of care provided. Similarly, CMS proposes to require hospitals to adopt policies for within and between hospital transfers at 42 CFR §482.43(c), which could overlap and even conflict with existing transfer and stabilization policies required under EMTALA. **We urge CMS to reconsider the necessity of these requirements in the final rule.**

The AHA also urges CMS to consider the impact of one-size-fits-all requirements on a diverse group of providers. Hospitals have different needs based on their size, location, patient population, and access to resources, among other factors. Because CoPs are meant to serve as a floor, not a ceiling, for care, CoPs should be written in ways that account for these differences. For example, CMS has proposed to require particular types of equipment in each labor and delivery suite at 42 CFR §482.59(b) and 42 CFR §485.641(b)(1). Yet some hospitals may not have the volumes to use all their labor and delivery suites every day. The requirement could lead to significant amounts of equipment being unused for significant periods, thereby adding complexity and cost to compliance that would not result in better outcomes. A more reasonable approach would permit hospitals to provide equipment in accordance with the scope, volume and complexity of services they offer, which would enable them to account for individual differences described above. This is of particular importance when, as noted in our response to the RFI, the hospitals at risk of closing their labor and delivery services are generally located in the areas where the need is greatest. The added time and expense to keep up with these new regulations or risk losing participation in the Medicare program is more likely to push vulnerable obstetric practices to close, increasing the risk to the most at-risk patients.

The AHA also asks that any new CoPs focus on maternal care, in furtherance of CMS' stated goal. Because of the direct impact on patient care, any proposed solution should be narrowly tailored to address the problem it intends to solve. Overly broad regulation that extends beyond maternal health, such as the proposed updates to emergency services and discharge planning CoPs, is unnecessary, unhelpful, and beyond CMS' stated intent. Specifically, CMS has proposed changes to the emergency services CoPs for hospitals and CAHs at 42 CFR §482.55(c)(1) and 42 CFR §485.618(e)(1) that require hospitals to have "protocols…for the care of patients with emergency conditions, including but not limited to patients with obstetrical emergencies, complications and immediate post-delivery care." The AHA appreciates CMS' focus on ensuring that hospitals respond to obstetrical emergencies. Yet, the proposed regulation appears to span nearly all kinds of emergency conditions beyond obstetrical emergencies, making the regulation potentially redundant with the remainder of the emergency services CoPs and with hospital requirements under EMTALA. Similarly, the aforementioned transfer requirements at 42 CFR §482.43(c) do not appear to be focused on only obstetrical or maternity care. The proposed rule preamble does not articulate a clear evidentiary basis for adopting this CoP, or its link to

maternal outcomes. The additional regulatory burden they create, however, could serve to accelerate the pace of hospital closures without benefitting pregnant, laboring, and postpartum women.

Lastly, the AHA urges CMS to work collaboratively with hospitals and other stakeholders to increase the clarity of any maternal care-related CoPs it adopts. As written, hospitals are confused as to the value the new regulations will add and exactly what is needed to ensure compliance. Seemingly self-evident terms included in the proposed regulations such as "protocol," "practice," "staff," "training" and "equipment" can all be interpreted in variable ways. To be clear — we appreciate that CMS has generally not been prescriptive in the proposed regulation about specific processes hospitals use to comply. At the same time, hospitals would appreciate greater clarity from CMS about examples of ways in which they could demonstrate compliance. Hospitals have also expressed concerns about whether CMS' regulations would contradict state-level requirements, including states that have adopted formal statewide systems for managing maternal levels of care. They want to ensure that their efforts to collaborate with their state agencies and fellow providers do not run afoul of any regulations CMS adopts.

For this reason, were CMS to finalize these regulations, we strongly urge CMS to use a collaborative process for developing any interpretive guidance for the regulation. For example, CMS could make its interpretive guidance available for public comment. CMS should also consider patient preferences and be realistic about the time it takes to stand up new programs. The agency should ensure new requirements align with the hospital's role and are realistic with respect to the circumstances and outcomes that hospitals can control.

Towards a More Collaborative Approach. **The AHA and its members want to work with CMS to improve maternal health outcomes.** In conversation after conversation, each of our members has reiterated their commitment to providing the safest, highest quality maternity care possible. Hospitals ask that before imposing new and overly burdensome requirements, CMS work with them to identify innovative solutions and employ proven strategies that will lead to success. They emphasize the need to ensure that proposed solutions will actually address the problem. And they ask that before implementation, all parties weigh the effects of each proposal on patients, their communities, and the hospitals that serve them. The AHA and its members support evidence-based strategies that have demonstrated success and meaningfully improved maternal health outcomes, and we hope CMS will partner with us to solve the maternal health crisis.

A collaborative approach that promotes safe, high-quality care before, during, and after giving birth is in line with recommendations from HHS, academic institutions and

nationally recognized experts in the field.[39,40,41] Our members report that increased funding, greater collaboration, and strong partnerships with agencies like CMS would enable them to provide the best, most innovative care possible. Such an approach places each woman, rather than any single facility or practitioner, at the center of care. It recognizes the unprecedented challenges providers face and minimizes the chance of decreasing access to maternity care. Most importantly, it is the approach that is most likely to succeed.

INDIAN HEALTH SERVICE AND TRIBAL HOSPITALS

Currently, Indian Health Service (IHS) and tribal outpatient departments are excluded from the Medicare OPPS and paid the Medicare outpatient hospital all-inclusive rate (AIR). However, IHS and tribal hospitals have increasingly provided higher-cost drugs along with more complex and expensive services, such as cancer-related services, which greatly exceed the $667 payment (in CY 2024) an IHS or tribal facility receives through the AIR.

Therefore, CMS believes that the AIR may no longer be adequate to cover these hospitals' costs of providing these complex services. As such, it is proposing paying an add-on for certain high-cost drugs for people with Medicare who receive care at IHS or tribal hospitals. Specifically, CMS proposes that starting Jan. 1, 2025, it would separately pay IHS and tribal hospitals for high-cost drugs furnished in HOPDs. It proposes to define high-cost drugs as drugs covered under Medicare Part B and whose per-day cost exceeds two times the lower 48 AIR (e.g. $1,334 in CY 2024). Additionally, the agency proposes that the amount of the add-on payment would be the ASP for the drug. **We support these proposals.**

COVERAGE CHANGES FOR COLORECTAL CANCER SCREENING SERVICES

For CY 2025, CMS proposes to update and expand coverage for colorectal cancer (CRC) screening. Specifically, it proposes removing coverage for the barium enema procedure, adding coverage for computed tomography colonography (CTC) and expanding the existing definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare-covered blood-based biomarker CRC screening test.

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[39] HHS Initiative to Improve Maternal Health, https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.
[40] Stuebe, Allison M., *How Academic Centers Can Accelerate Partnerships and Progress in Maternal Health*, https://academic.oup.com/book/55963/chapter/439447325.
[41] HHS Initiative to Improve Maternal Health, https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.

The AHA supports CMS' proposal for updating and expanding coverage for CRC. We agree with the recommendations made by other knowledgeable stakeholders who in recent years noted that it is appropriate to remove Medicare coverage for the barium enema test since the test no longer meets modern clinical standards and is no longer recommended in clinical guidelines. Further, we agree with the U.S. Preventive Services Task Force (USPSTF) recommendation that CTC, which is a more effective test for CRC screening, should be the replacement to the barium enema test. Finally, we support CMS's determination that there are several advantages to choosing a non-invasive CRC screening test as a first step. These include the relative ease of administration and reducing the experience of burdensome preparation and invasive procedures.

PAYMENT FOR HUMAN IMMUNODEFICIENCY VIRUS PRE-EXPOSURE PROPHYLAXIS IN HOPDS

In 2023, CMS published a proposed national coverage determination (NCD) for pre-exposure prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) infection prevention for covering PrEP under Medicare Part B.[42] This would include coverage for the HIV PrEP drugs, drug administration, HIV and hepatitis B screening, and individual counseling performed by either physicians or certain other health care practitioners. If finalized as proposed, all components would be covered as an additional preventive service without Part B cost sharing. In this rule, CMS lists seven applicable HCPCS codes and the description of each, which, if covered in the final NCD, it proposes to pay for under the OPPS beginning in 2025.

The AHA supports CMS' proposal to pay for HIV PrEP drugs and related services as additional preventive services under Medicare Part B. However, we are concerned about how this policy would impact the ability of hospitals' in-house pharmacies that currently provide PrEP services under Medicare Part D to continue to do so. This is because pharmacists are not eligible to enroll as Medicare Part B providers under Provider Enrollment, Chain, and Ownership System (PECOS). Therefore, we are concerned that if CMS' proposal is finalized without the agency making other conforming programmatic changes in Medicare, such as permitting hospital pharmacists to enroll as Medicare providers, this could lead to a shift in payment for PrEP from Medicare Part D to Part B in a manner that could inadvertently limit access to these services for Medicare Part D beneficiaries**. The AHA recommends that while CMS is evaluating this policy, it ensures that it considers and removes any potential barriers that could hinder access to HIV PrEP services for beneficiaries.**

[42] NCA - Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N) - Proposed Decision Memo (cms.gov).

Moreover, we strongly disagree with CMS' proposal to pay for HIV PrEP at a site-neutral rate – that is, to pay hospitals at the PFS rate. We strongly dispute CMS' assertion that the resource costs for the HIV PrEP services would be similar in the HOPD and physician office. Site-neutral payment policies endanger hospitals' ability to continue to provide 24/7 access to emergency care and standby capacity for disaster response. Hospitals have a higher cost structure than freestanding physician offices due, in part, to the costs of standby capability and capacity that they bear. **Therefore, the AHA recommends that CMS calculate the payment for HIV PrEP services furnished in an HOPD in the same manner as it does for other OPPS services, and not at the PFS rate.**

PROPOSED CHANGES TO THE REVIEW TIMEFRAMES FOR THE HOPD PRIOR AUTHORIZATION PROCESS

CMS proposes updating the response timeframes for prior authorizations under the OPPS, indicating a desire to promote consistency with the Interoperability and Prior Authorization Final Rule.[43] Specifically, CMS recommends updating review timeframes for standard, non-urgent prior authorizations, while requesting feedback regarding its policies for urgent care authorizations.

Standard Prior Authorizations. **The AHA supports CMS' proposal to shorten the permissible amount of time for the agency to respond to a non-urgent prior authorization request from 10 business days to seven calendar days.** Prior authorization can be a significant obstacle to the timely delivery of care. In a 2023 survey, the AMA found that 94% of physicians reported delays in necessary care due to prior authorization and that such delays often had a detrimental impact on patient health outcomes.[44] Although CMS does not impose prior authorization requirements at the same troubling breadth as many commercial and managed care plans, Medicare requires prior authorization for a subset of services. By shortening the decision timeframe and promoting consistency with the procedures of plans covered under the Interoperability and Prior Authorization Rule, CMS will enable better care planning, reduce administrative waste, and prevent delays in patient access to these services.

Expedited Prior Authorizations. CMS expresses reservations about changing its existing requirement that MACs respond to expedited prior authorizations in no more than two business days, as such a change could increase the time plans take to process such a request. **The AHA agrees that CMS should not adopt a policy that may extend**

[43] CMS currently requires PA for: blepharoplasty, rhinoplasty, botulinum toxin injections, panniculectomy, vein ablation, cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions.
[44] https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

prior authorization delays, as this would be inconsistent with reform efforts to ensure timely access to care.

However, we remain concerned about instances in which a prior authorization request might occur during or immediately preceding a holiday or weekend, as two business days could extend to four or more calendar days. **To address this issue, we recommend that CMS adopt a policy requiring MACs to respond to prior authorizations for urgent care within the shorter of 72 hours or two business days.** This would prevent the new policy from extending delays, improving timing for all applicable prior authorizations. Furthermore, we remain concerned that waiting 72 hours for an urgent prior authorization still may detrimentally impact necessary patient care, and we recommend that CMS and other plans strive to respond more rapidly to promote timely patient care.

CLOSING THE COVERAGE GAP

Meaningful health care coverage is critical to living a productive, secure and healthy life. Health insurance coverage facilitates access to care and is associated with lower death rates, better health outcomes and improved productivity. **AHA supports policy approaches to close the coverage gap, especially for vulnerable populations who are already enrolled in coverage.**

In this rule, CMS proposes three changes to Medicare and Medicaid regulations that are intended to strengthen public coverage and improve access to care for people who are enrolled in these programs by:

- Narrowing the definition of “custody” for the no legal obligation to pay exclusion.
- Codifying provisions of the CAA, 2023, which requires 12 months of continuous eligibility in Medicaid and Children’s Health Insurance Program (CHIP) for children under age 19, with limited exceptions.
- Increasing exceptions to the four walls exclusion in Medicaid clinic services.

The AHA supports each of these proposals.

Medicare currently is prohibited from paying for care for which its beneficiaries have no legal obligation to pay. This policy has been interpreted to include justice-involved individuals who are in custody with the expectation that the criminal justice system has responsibility for these costs. Historically, CMS has defined “custody” broadly to include many classes of individuals presumed to have no legal obligation to pay for care. However, this policy has left some Medicare beneficiaries without coverage for medically necessary care and, as a result, CMS proposes to narrow the definition of “custody” to exclude certain situations. For example, the revised definition would exclude certain classes of individuals who have been lawfully released from

confinement. These changes are important to support access to care, minimize friction in provider-patient relationships, reduce the administrative cost and burden on providers of determining a patient's custody status, and reduce uncompensated care. **Therefore, the AHA supports CMS' efforts to close the coverage gap by narrowing the definition of custody and allowing Medicare to pay for care provided to Medicare-enrolled individuals.**

In the CAA, 2023, CMS required states to provide 12 months of mandatory continuous eligibility in Medicaid and CHIP for children under age 19, with limited exceptions. CMS proposes to eliminate several exceptions, including one that allows states to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums. Health insurance coverage for children is critically important for healthy development, and research continues to find that investments in children's health insurance coverage are associated with future benefits for the workforce, tax revenue and other long-term fiscal effects. **The AHA supports CMS' efforts to close the coverage gap for children who are eligible and enrolled in Medicaid and CHIP by codifying the continuous eligibility provisions of the CAA, 2023.**

Current regulations prohibit Medicaid from paying for clinic services provided outside the four walls of a clinic, except when provided to unhoused individuals. CMS proposes to add three additional exceptions: a mandatory exception for Indian Health Service/Tribal clinics and optional exceptions for behavioral health clinics and clinics located in rural areas. These changes would improve access to services for eligible individuals in certain settings. Moreover, these exclusions could prove to be important tools to address the behavioral health crisis for certain providers and states. For example, expanding access to care outside the four walls of a Medicaid clinic could help reduce patient acuity and increase provider capacity. **The AHA supports CMS' efforts to expand access by adding exceptions to the four walls requirements for Medicaid clinic services.**