AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code 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

Dear Administrator Brooks-LaSure:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2025 Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare Payment Policies under the Hospital Outpatient Prospective Payment System (OPPS), published in the *Federal Register* on July 22, 2024.

The following are our key recommendations in response to the major proposals in the rule:

- The AMA urges CMS not to finalize the proposed Conditions of Participation (CoPs) for obstetrical services.
- The AMA supports the continued use of the hospital market basket as the annual update mechanism for Ambulatory Surgical Center (ASC) and OPPS payments and seeks further alignment of payment policies.
- The AMA urges CMS to discontinue rescaling the ASC relative weights for perceived budget neutrality to better align payments with service costs.
- The AMA recommends that CMS apply OPPS geographic reclassifications and wage index floor policies to ASCs to harmonize payment systems further.
- The AMA supports separate payment of diagnostic radiopharmaceuticals with a per-day cost greater than $630, addressing access barriers for high-cost, low-volume radiopharmaceuticals.
- The AMA supports the permanent allowance for payment under OPPS and the Medicare Physician Fee Schedule (MPFS) for remote or virtual services and direct supervision.

- The AMA supports CMS' proposal to update and expand Medicare Part B coverage for colorectal cancer (CRC) screening tests, including coverage for Computed Tomography Colonography (CTC) and expanded definitions of complete CRC screening.
- The AMA supports separate payment for non-opioid treatments for pain management in the OPPS and ASC payment systems, aligning with the Consolidated Appropriations Act 2023.
- The AMA supports the removal of two measures from the Hospital Outpatient Quality Reporting (OQR) Program starting in 2025 due to their failure to result in better patient outcomes.
- The AMA urges CMS to delay implementation of certain measures in the Ambulatory Surgical Center Quality Reporting (ASCQR) Program due to their burdensome nature and high costs of implementation.
- The AMA expresses concern over the one-size-fits-all approach to health equity measures in CMS Cross Quality Program proposals, recommending a cautious approach to measurement and consideration of the unique settings of facilities affected.
- The AMA recommends finalizing proposed exceptions to the "four walls" requirement for Medicaid clinic services, expanding access to care for vulnerable populations.

CALENDAR YEAR 2025 OPPS PROPOSED RULE DETAILED COMMENTS OF THE AMERICAN MEDICAL ASSOCIATION

Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals

The AMA shares the Administration's deep concern about the maternal health crisis, which disproportionality affects Black and Native American/Alaska Native pregnant and postpartum individuals. The AMA is committed to being part of the solution and we want to work collaboratively with the Biden-Harris Administration towards that end. On April 11, 2024, the AMA sent Secretary Xavier Becerra a series of recommendations to address the crisis that we hope the Administration will pursue. That said, we have concerns that the new CoPs for hospitals and critical access hospitals (CAHs) for obstetrical services, including new requirements for maternal quality assessment and performance improvement (QAPI); maternal health data reporting; baseline standards for the organization, staffing, and delivery of care within obstetrical units; and staff training on evidence-based best practices on an annual basis will have unintended consequences. CMS has also proposed to revise the emergency services and hospital discharge planning CoPs to ensure adequate obstetric care is provided in these settings.

The AMA agrees that all individuals who receive labor and delivery services should receive care that meets high standards of quality. However, we are deeply concerned that requiring data analysis, reporting, and documentation of the proposed CoPs requirements by all hospitals will significantly increase the cost and burden of providing labor and delivery services. Obstetrical services are historically reimbursed at below cost even before considering these additional requirements. If small hospitals and hospitals in rural areas are unable to shoulder the burden and afford the expense of meeting these CoPs while grappling with inadequate payment and workforce shortages, they could close their labor and delivery units. This could worsen access to labor and delivery services, rather than increase the quality of maternity care. As a result, the proposal could increase maternal mortality and morbidity rates and exacerbate disparities in maternity care outcomes.

Instead of adding burdensome and costly reporting requirements on obstetrical services, the AMA strongly recommends that CMS seek additional funding from Congress to implement evidence-based programs that address the leading causes of maternal mortality, including substance use disorder and

cardiovascular disorders, and reduce inequities facing pregnant, birthing, and postpartum women by enhancing medical-legal partnerships. The AMA strongly supports the Alliance for Innovation on Maternal Health (AIM) Patient Safety bundles, and we agree they can serve as a useful lever to drive best practices and lead to improved outcomes. However, the biggest barrier to implementing these bundles is a lack of resources, particularly in small hospitals. The Agency should also ensure comprehensive Medicaid coverage of virtual maternal health care services, which can alleviate the existing access to care challenges during the pre and postpartum period. We urge greater emphasis on increasing and retaining the number of physicians who deliver babies as they are the only practitioners who provide cesarean sections and are called upon to provide more complex care to higher-risk patients. Finally, CMS should ensure the Transforming Maternal Health model will increase funding for physicians, hospitals, and other providers delivering care in underserved communities and to high-need patients to improve maternal health outcomes, such as by implementing AIM patient safety bundles.

Specific to the proposed CoPs, the AMA recommends that:

- If CMS insists on moving forward with the proposed CoPs, CMS should, at a minimum, delay implementation of these requirements to give hospitals more time to implement the requirements and to allow time for modifications based on feedback from critical interested parties, including the AMA, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American College of Emergency Physicians (ACEP).
- If CMS finalizes these CoPs, rural hospitals and CAHs should be exempt, and the Agency should explore regional partnerships to accomplish the goals of the CoP requirements.
- The CoPs, if implemented, should be phased in over several years.
- The CoPs should ensure that obstetric care is provided by physician-led teams.
- The Administration should provide ample funding to ensure successful implementation of these CoPs, including urging Congress to update Medicare physician payment to account for the increase in costs to deliver maternity and other care.

1. *Implementation of the CoPs should be discontinued or, at a minimum, delayed to give CMS an opportunity to make modifications based on feedback from key interested parties, including physicians and hospitals of all sizes and in all locations, and to allow hospitals sufficient time to meet the CoP requirements.*

The AMA shares CMS' commitment to reducing maternal health disparities and improving maternal and neonatal health outcomes during pregnancy, childbirth, and in the postpartum period and has supported several of the Agency's previous efforts to address this critical issue. Generally, we agree with the overarching goals and topics covered in the proposed CoPs. However, we are extremely concerned that the burden of reporting on these requirements, and particularly the QAPI requirements, will divert resources away from activities that could be better spent addressing maternal mortality. Additionally, we are concerned that the proposed one-size-fits-all approach will have significant unintended consequences, particularly when these criteria are applied to small, rural, and safety net hospitals or in areas where a maternity care desert exists. No one wants to see these CoPs create or exacerbate the challenges that all of us are working so diligently to address.

CMS already requires all hospitals to "develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven [QAPI] program," it requires that the QAPI program "involve all hospital departments and services, including those services furnished under contract or arrangement," and it requires that the

program "focus on indicators related to improved health outcomes and the prevention and reduction of medical errors." There is no evidence that the high levels of maternal mortality and morbidity in the U.S. today are caused by gaps in the way hospitals are analyzing data, nor does CMS provide any evidence that the data analysis requirements it proposes to add to the CoPs are likely to result in significant improvements in maternal outcomes.

Because small rural hospitals deliver a small number of babies each year, there are simply not enough deliveries at these hospitals to enable data analyses to be disaggregated in a statistically valid way. Moreover, small rural hospitals do not employ the "data scientists" that CMS assumes would carry out these analyses, so physicians, nurses, and other staff would have to do this work. Many small rural hospitals are struggling to recruit and retain a sufficient number of clinicians to provide obstetrical services to patients; forcing those staff to spend time carrying out data analyses merely to meet arbitrary requirements established by CMS will not only take time away from patient care but make it more difficult for the hospital to attract and retain the staff needed to provide high-quality care.

In many cases, analyses will show disparities in outcomes, but the biggest causes of those disparities will likely be differences in the resources available to the patients to improve and maintain their health before, during and following their pregnancy, such as insurance coverage, access to transportation, housing quality, etc. These causes are beyond the direct control of the hospitals and the physicians who provide obstetric care, and the resulting disparities in outcomes will not be reduced simply by requiring hospitals to implement "performance improvement projects." If CMS wants to make a meaningful impact on maternal mortality and morbidity, it should provide funding to support evidence-based programs that address the root causes of maternal health problems.

We strongly urge CMS to not move forward with these burdensome and unproven CoPs. We are particularly concerned that they could lead to adverse consequences, including closure of labor and delivery units in under-resourced hospitals and exacerbation of the existing maternal health care access challenges. We have heard from physicians, particularly in rural and underserved communities in states as diverse as Massachusetts and South Dakota, that labor and delivery units in their communities are barely covering costs currently and that it is much more likely that these facilities will close their labor and delivery units rather than adhere to these proposed CoPs. For example, at one hospital in South Dakota that is a lifeline for women in rural parts of the state and women who live on the nearby reservation, there is only one surgeon and one family medicine physician who cover obstetrical services and provide emergency C-sections. Due to the staffing limitations, the hospital hires a locum tenens physician at least one weekend per month for coverage, which is a very expensive requirement to keep their labor and delivery unit open particularly as there may not be any deliveries on some weekends. If these facilities were to close it would mean that patients from their communities would have to travel dozens and, in some cases, hundreds of miles to the next location to receive holistic obstetric care, creating maternal health deserts. This is worrisome for all patients but particularly for marginalized patients who may not have a car or gas money or someone who will agree to transport them in labor.

While a hospital may no longer technically offer these services, it cannot be assumed that women will not seek obstetric care at these facilities resulting in exposure to a risk of further complications or adverse outcomes because the facilities are no longer equipped or staffed to care for these individuals. CMS must avoid any regulation that could potentially exacerbate the very real potential for additional closures of these units as it will only increase the risk of poor outcomes for moms and babies. Therefore, the AMA cannot lend support to the proposed CoP requirements as we are concerned that they will likely worsen the current trends that are resulting in growing maternity care deserts.

If CMS is unwilling to discontinue implementation of the CoPs, CMS should, at a minimum, postpone implementation and seek additional input from key interested parties. This input is a critical step that we believe was not adequately completed as CMS published the proposed CoPs just one month after it received comments responding to a Request for Information about an obstetrical services CoP. Moreover, this additional input should be provided outside of the rulemaking process and should involve a broad set of interested parties including the AMA, ACOG, AAFP, ACEP, other impacted national medical specialty societies, hospital associations and their members, and states. This critical step will ensure that the Agency understands how these CoPs will positively and negatively impact maternity care across the country. For example, CMS may come to realize that these standards should not apply to specific hospitals or may decide that novel approaches such as regional partnerships should be allowed. Furthermore, with additional time and research CMS may give additional weight to the many potential solutions that exist to address these gaps, including leveraging telehealth when in-person visits are not feasible, encouraging partnerships across community organizations and others to facilitate access to care, and continued implementation of the AIM Patient Safety bundles. Therefore, these, and other, nuances must be explored and addressed prior to CMS finalizing any standards.

Furthermore, the AMA agrees with the Association of American Medical Colleges that CMS should delay consideration of requirements related to race and ethnicity data collections until after the U.S. Department of Health and Human Services (HHS) completes its Action Plan on Race and Ethnicity Data for the Office of Management and Budget (OMB) revised standards. These new standards were recently put into effect for all new record keeping and reporting requirements that include race and ethnicity data, and require agencies to submit no later than September 29, 2025, to OMB a publicly available Action Plan on Race and Ethnicity Data describing how the agency intends to bring their collections and publications into compliance with the new standards by March 28, 2029. Due to this, we urge CMS to not require reporting of race and ethnicity under the requirements within a CoP, and instead focus on contributions to a whole HHS approach to devising its Action Plan on Race and Ethnicity Data due in September 2025.

Finally, a delay is essential to give hospitals greater time to come into compliance with the proposed CoPs. Failure to meet CoPs requirements may result in sanctions on hospitals including corrective action plans, monetary sanctions, increased reporting requirements, and even termination from the Medicare program. Due to the punitive nature of Medicare CoPs, hospitals need additional lead time to meet and document that they are meeting the requirements, rather than shutter their labor and delivery services.

2. *Rural hospitals and critical access hospitals should be exempt from the proposed CoPs and CMS should explore regional partnerships to achieve the objectives of the proposed CoPs.*

As noted by CMS, there has been an alarming and significant number of closures of hospital based obstetrical services across the United States. For example, according to a new Center for Healthcare Quality and Payment Reform report, more than half of the rural hospitals in the U.S. no longer offer labor and delivery services, and in 10 states, more than two-thirds of rural hospitals do not have these vital services. The 2022 *Nowhere to Go: Maternity Care Deserts Across the U.S.* report from the March of Dimes identified that areas with limited services provide care to over two million women of childbearing age and 300,000 newborns. These issues are not solely limited to rural areas but also occur in urban areas. A recent analysis by the AMA and the Sinai Urban Health Institute of the variations in access to obstetric care across the Chicago metro area found that those areas with limited maternity care access were primarily where Black residents lived, including closures of labor and delivery units on the South Side. The potential impact that continual closures have on maternal mortality should not be overlooked. For example, a retrospective study of maternal mortality across New Jersey concluded that labor and delivery

closures may have contributed to more deaths in areas with higher numbers of Black residents. These studies, while not comprehensive, provide a very real snapshot of the current state of maternity care in this country, which is nowhere near the goal of ensuring that every woman of childbearing age can easily access obstetrical services and she and her newborn receive the highest and safest quality care. Therefore, in order to mitigate these negative health effects, the proposed CoPs should not apply to rural hospitals or CAHs.

We also urge CMS to consider including novel approaches such as allowing certain hospitals to create regional partnerships as recommended by the Government Accountability Office in a 2022 report. A hospital in a rural area or within a maternity care desert could collaborate with a larger, better resourced hospital that could complete the data analyses, offer training including simulations on topics addressed in the AIM bundles, and enable seamless referrals and transfers of patients. These partnerships would assist all hospitals in further improving the care of mothers and newborns and minimize the risk for many facilities to decide that their only option with these new regulations will be to stop offering obstetrical services.

3. *If CMS moves forward with the CoPs, the implementation should be phased in to provide under resourced facilities greater flexibility to come into compliance.*

The AMA recommends that CMS phase in the requirements to allow hospitals to meet the new requirements over time. For example, CMS could require eligible facilities to meet the proposals on a timeline as detailed in the table below. It should be noted that if finalized, the obstetrical services CoP would be one of the largest and most extensive specialty-specific set of CoPs requirements currently in existence. Many of these requirements, including the QAPI requirements, involve intensive efforts and infrastructure development to meet the minimum standard expected by CMS. Doing this phased in approach broken out by requirement category could help create a glidepath for facilities to utilize in their implementation of the protocols needed to meet these requirements, rather than doing mass implementation in year one and risk unintended closures of labor and delivery units.

Requirement Category	Implementation Year
Emergency Services Readiness	Year 1
Discharge Planning & Transfer Protocols	Year 1
Staff Training	Year 2
Organization, Staffing, and Delivery of Services	Year 3
Quality Assessment and Performance Improvement	Year 4

4. *Obstetric care should be provided by a physician-led care team.*

At § 482.59(a)(1) and § 485.649(a)(1), CMS has proposed that the obstetric patient care units (that is, labor rooms, delivery rooms, including rooms for operative delivery, and post-partum/recovery rooms whether combined or separate) should be supervised by an individual with the necessary education and training. CMS further elaborated that this supervisor could be a registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or a physician. As noted in the proposed rule, we agree that the responsibility for overseeing staff, ensuring patient safety and care, and supporting communication within and across units is very important and, as such, we believe that this task should only be undertaken by a physician-led care team.

We agree that any work to improve obstetric care must include appropriate organization and staffing and adequate training should be provided to those individuals delivering care. However, it is imperative that the care is managed by a physician-led team, including ensuring proper oversight of both obstetric specific care and prohibiting staffing ratios that do not allow for proper physician supervision of non-physician practitioners in the Emergency Department. In alignment with this, the AMA supports all emergency departments being staffed 24-7 by a qualified physician.

Moreover, we oppose the fact that CMS does not require nurse practitioners or nurse midwifes to be employed by, under the supervision of, or associated with, a Doctor of Medicine or Doctor of Osteopathic Medicine unless required by state law, regulations, or facility policy.

Despite claims to the contrary, expanding the scope of practice for nonphysician practitioners does not increase patient access in rural or underserved areas. In reviewing the actual practice locations of primary care physicians compared to nonphysician practitioners, it is clear that physicians and nonphysicians tend to practice in the same areas of a state. This is true even in those states where, for example, nurse practitioners can practice without physician involvement. These findings are confirmed by multiple studies, including state workforce studies. The data is clear—scope expansions have not led to increased access to care in rural and underserved areas.

While all health care professionals play a critical role in providing care to patients and nonphysician practitioners are important members of the care team, their skill sets are not interchangeable with those of fully educated and trained physicians. This is fundamentally evident based on the difference in education and training between the distinct professions.

- Physicians complete four years of medical school plus three to seven years of residency, including 10,000-16,000 hours of clinical training.
- Nurse practitioners, however, complete only two to three years of graduate level education, have no residency requirement, and complete only 500-720 hours of clinical training.
- Physician assistants complete two to two and half years of graduate level education with only 2,000 hours of clinical care and no residency requirement.
- Certified nurse midwives must have a Registered Nurse license and have completed a master's program, which typically lasts two to three years. There is no residency requirement, and no specific hours of clinical experience required for graduation, besides the accrediting body providing suggested guidelines for programs.
- Clinical nurse specialists complete a master's degree but there is no residency requirement and only 500 clinical hours of training are required.

But it is more than the difference in hours and years of training—the depth and breadth of physicians' education is far beyond that of nonphysician practitioners. Equipped to handle any clinical scenario as the most highly trained health care professional, physicians are the appropriate leaders of the health care team. Therefore, to ensure that patients receive the best care possible, obstetric patient care units should operate as part of a physician-led team with the physician providing the necessary supervision.

5. *The Administration should provide ample funding to ensure successful implementation of the proposed CoPs, including urging Congress to update Medicare physician payment to account for the increase in input costs to deliver maternity and other care.*

CMS estimates it will cost approximately $4.27 billion over 10 years to implement the changes to CoPs, which averages $70,671 per year for each hospital affected by these changes. However, we believe this is a significant underestimate as the salary and benefits for one obstetric nurse would exceed this annual estimate. Regardless, physicians and hospitals face significant financial headwinds in implementing these CoPs without additional funding, including inadequate reimbursement for obstetrical services and workforce shortages. Medicaid, which pays for over 40 percent of births in the U.S., historically reimburses less than the cost of providing services to patients and less than what is typically reimbursed by Medicare and private payers. While these proposed requirements technically live under Medicare regulatory rulemaking, this does not change the reality that many hospitals and physicians are receiving woefully inadequate reimbursement for quality maternity care services, especially depending on the proportion of Medicaid births they conduct compared to private payer and Medicare births.

The reimbursement and workforce challenges are magnified in rural hospitals. More than one-third of the rural hospitals that still have labor and delivery services are losing money on patient services overall, putting their ability to continue delivering maternity care at risk. Moreover, the number of providers that are needed to maintain labor and delivery units, such as physicians, nurses, and anesthesiologists, are costly. "As a result, payments per birth that are adequate at a large hospital are not enough to support maternity care at small rural hospitals with far fewer births."

We would be remiss if we did not highlight that Medicare physician payment for maternal services is set to be cut by 2.8 percent in 2025 while the projected input costs for physician services as measured by the Medicare Economic Index (MEI) are projected to increase by 3.6 percent. While Medicare covers a limited number of births in this country, its payment rates are often used as the benchmark for other private and public payers' payment rates, meaning a cut to Medicare will reduce reimbursement from other payers. The AMA urges the Biden-Harris Administration to work with Congress enact a permanent, annual inflation-based update to Medicare physician payments tied to the MEI. This would ensure physician payment for obstetric and other services keeps up with the costs to provide such care.

Moreover, the AMA Current Procedural Terminology (CPT®) Editorial Panel has established a Maternity Care Services Workgroup to assess the current practice of maternity care including antepartum care, labor management, delivery, and postpartum services to bring forth suggested changes to existing maternity care global codes and propose new codes. As such, the AMA supports the separate payment of services not accounted for in the valuation of the maternity global codes and opposes the inappropriate bundling of related services. Therefore, it is imperative that the Administration leverage all of its authorities to provide additional payments in the maternal health space, especially if these CoPs are implemented, to help offset both the losses that labor and delivery units are currently experiencing and the additional $70,000 or more that it will cost each facility to implement these CoPs.

In light of these significant concerns, the AMA urges CMS to discontinue implementation of the proposed CoPs. If CMS insists on proceeding, the AMA believes that CMS should delay implementation of the proposed CoPs and seek input from all relevant stakeholders to develop potential solutions and guidance on how all non-exempt hospitals, regardless of size and location, can successfully meet CoPs on obstetric care. Our concerns and recommendations highlight the issues that could lead to unintended consequences, and therefore, require additional vetting prior to finalization.

6. Emergency Services CoP

Emergency Department (ED) boarding, a symptom of broader health system dysfunction, has become a significant public health concern, leading to delays in treatment and worsened outcomes for all patients, including those in need of intensive care and those in psychiatric crisis. In light of the growing crisis of ED boarding, ACEP has proposed an addition to the Emergency Services CoP that would require hospitals to have a plan or protocol on file for when the number of patients boarding in their ED exceeds manageable capacity. ACEP highlights that the current lack of such protocols exacerbates the strain on EDs, contributing to patient safety risks and operational inefficiencies

CMS acknowledges the need for such action to address boarding when it notes in the proposed rule that it seeks to make changes due to reports it has heard that ED "readiness can be suboptimal, especially for obstetrical, geriatric, and pediatric populations, among others." We believe that adding a protocol on boarding to the proposed modifications to the existing emergency readiness CoP represents a logical and much needed step that CMS can, and should, take now. **The AMA agrees with ACEP's proposed addition and urges CMS to adopt this requirement to help hospitals implement protocols to mitigate harmful effects of ED boarding.**

Updates Affecting ASC Payments

Conversion Factor

Recommendation:

- The AMA supports CMS' continued use of the hospital market basket as the annual update mechanism for ASC payments.

CMS aligned the ASC payment system to the OPPS in 2008 to encourage high-quality, efficient care in the most appropriate outpatient setting and align payment policies to eliminate payment incentives favoring one care setting over another.[1] However, disparate payment policies have led to increasingly disparate reimbursement. We have long urged CMS to adopt the same update factor for both the ASC and OPPS payments, and we appreciate that CMS took the first, necessary step toward better alignment of the payment systems by piloting the use of the hospital market basket for ASCs.

The COVID-19 Public Health Emergency (PHE) arose during the second year of CMS' five-year pilot for aligning the ASC and OPPS update factors which has limited the Agency's ability to fully assess the success of the policy. As such, the AMA appreciates that CMS has proposed to extend the five-year trial for an additional two years. We support the continued alignment of OPPS and ASC update factors and believe that for as long as CMS uses the hospital market basket to update hospital outpatient department (HOPD) reimbursement, the Agency should also use the hospital market basket for updating ASC rates.

[1] CY 2007 OPPS/ASC Proposed Rule (https://www.cms.gov/newsroom/press-releases/cms-revises-payment-structure-ambulatory-surgical-centers-and-proposes-policy-and-payment-changes).

Updating the ASC Relative Payment Weights for CY 2025

Recommendation:

- The AMA urges CMS to discontinue its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective.

Since the OPPS and ASC payment systems were aligned, CMS has taken the relative weights in the OPPS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. CMS' antiquated cost containment mechanisms—trying to maintain budget neutrality in silos for each payment system—penalizes migration to a lower-cost setting because that shift ultimately leads to reductions in reimbursement rates for those providing the care.

While the alignment of update factors was a positive first step, the lack of alignment on other policies leads to ASC reimbursement rates that are often less than 50 percent on average of the HOPD rate for the same procedures. In too many markets, surgeries that could be performed in surgery centers continue to be provided predominantly in hospitals, which we attribute to Medicare's failure to pay competitive rates to ASCs. Lack of alignment for the ASC (secondary) weight scalar threatens outpatient access to care and stifles the ability of these facilities to perform all the Medicare cases that potentially could be absorbed. This lack of migration comes at a high price to the Medicare program and the taxpayers who fund it.

However, since CMS tries to maintain the same level of spending year over year, only accounting for a small update for inflation, any increase in volume would lead to stagnation or a decrease in reimbursement rates. There is no evidence of a growing difference in capital or operating costs in the two settings to support this growing payment differential. By applying a secondary weight scalar to the ASC payment system, the positive impact of the conversion factor alignment is negated, and CMS will not achieve long-term savings.

Under the statute that implemented the current ASC payment system in 2008, CMS was only required to apply this budget neutrality adjustment in the first year of implementation of the new payment system.[2] CMS continued the scalar after the initial year of the new ASC payment system pursuant to its own perceived authority and not pursuant to any identified statutory requirement. As such, CMS has the authority to likewise discontinue the scalar at its discretion under the same rationale. **The AMA urges CMS to encourage additional savings and greater access to surgery centers for Medicare beneficiaries by eliminating the ASC weight scalar.**

The AMA recognizes that the elimination of the ASC weight scalar would represent an initial increase in cost to the Medicare program (a cost that will only increase each year that the scalar exists and continues to depress rates) until volume shifts to the ASC setting and cost savings are achieved. While this would be the right thing to do and save billions of dollars for the Medicare program in the long run, an alternative that CMS should consider is to combine the OPPS and ASC utilization and mixes of services to establish a single weight scalar. In other words, CMS could apply a single budget neutrality calculation to the

[2] See Social Security Act 1833(i)(D)(ii): ***In the year the system described in clause (i) is implemented***, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.

OPPS and ASC payment systems. By incorporating the ASC volume into the OPPS weight scalar calculations, CMS would further the alignment of the payment systems and more accurately scale for outpatient volume across both sites of service.

Wage Index Considerations

Recommendation:

- CMS should apply the OPPS geographic reclassifications and wage index floor policies to ASCs to allow for further alignment between the ASC payment system and OPPS.

A lack of alignment between ASC and HOPD reimbursement methodology is also evident with regards to wage indices. Hospitals can request geographic reclassifications that raise the hospital wage index, depending on the distance between the hospital and the county line of the area to which it seeks reclassification. Unfairly, ASCs cannot seek reclassification.

Hospitals in frontier states receive payment based on a wage index floor at 1.0. A frontier state is defined as a state in which "at least 50 percent of counties located within the State have a reported population density less than six persons per square mile,"[3] (excluding Alaska and Hawaii). South Dakota is one of the frontier states. While the state rural wage index for surgery centers in the state is 0.8073, hospitals in South Dakota receive the "floor" wage index of 1.0. The AMA urges CMS to apply the OPPS wage index policies to ASCs to allow for further alignment between the ASC payment system and OPPS.

Payment for Drugs, Biologicals, and Radiopharmaceuticals

Recommendation:

- The AMA appreciates CMS' thoughtful approach to separate payment of diagnostic radiopharmaceuticals and urges the Agency to continue conversations with physicians and other interested parties about the effects of implementation.

The OPPS currently packages several categories of non-pass-through drugs, biologicals, and radiopharmaceuticals regardless of the cost of the products. CMS refers to these products as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. Payment for the policy packaged products that function as supplies when used in a diagnostic test or procedures is packaged with the payment for the related procedure or service. CMS finalized a policy that packaged radiopharmaceuticals in the CY2008 OPPS final rule. The rationale underlying the packaging policy was that diagnostic radiopharmaceuticals are always intended to be used with nuclear medicine procedures and function as supplies when used in a procedure. CMS continues to underscore the concept of packaging costs into a single aggregate payment as a key feature of a prospective payment system that encourages hospital efficiencies and allows hospitals to manage their resources with optimal flexibility.

Since the inception of the policy, stakeholders have raised concerns about the inadequacy of payment as a result of packaging radiopharmaceuticals and have argued that in some cases the nuclear medicine ambulatory payment classifications (APC) payment rate is lower than the payment rate for the diagnostic radiopharmaceutical itself creating barriers to nuclear medicine services for beneficiaries, particularly

[3] 42 CFR 412.64 (m)(i).

those who rely on safety net hospitals for their care. Similarly, interested parties have argued that certain disease states which depend on the use of radiopharmaceuticals are uniquely disadvantaged and have difficulty recruiting hospitals in clinical studies because of the packaging policy.

In response to these concerns, CMS sought comment on new approaches to payment of diagnostic radiopharmaceuticals in the CY2024 OPPS Proposed rule. In particular, CMS proposed four approaches that could enhance beneficiary access to certain radiopharmaceuticals while maintaining the principles of the OPPS. First, CMS solicited feedback on paying separately for diagnostic radiopharmaceuticals with per-day costs above the OPPS drug packaging threshold of $140 or another threshold that may be greater or less than the drug packaging threshold. CMS also sought feedback on restructuring the nuclear medicine APCs for services that use high-cost radiopharmaceuticals or recommendations regarding a policy that would adopt CPT codes that describe the disease state being diagnosed or diagnostic indication for a particular class of radiopharmaceuticals.

Specifically, CMS explored the feasibility of separate payment for radiopharmaceuticals exceeding a $140 per-day cost threshold and sought input on alternative policy options, including APC restructuring and the development of disease-specific codes, highlighting CMS' recognition of the need to reconsider the current reimbursement framework to better align with the costs and clinical value of these diagnostics and the Agency's intent to refine its approach to ensure that payment policies align more closely with the clinical utility and financial realities of diagnostic radiopharmaceuticals. In the final rule, CMS acknowledged the lack of consensus among medical specialty societies and other interested parties on the most effective approach to reforming its diagnostic radiopharmaceutical payment policy.[4]

For 2025, CMS proposes to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630. Thus, any radiopharmaceutical with a per day cost below that threshold would continue to be policy packaged as it is under the current policy. The AMA acknowledges CMS' proposing packing proposal is intended to address barriers to beneficiary access for high-cost, low-volume radiopharmaceuticals. We appreciate CMS proposes a payment methodology that seeks to focus separate payment policy on "only those diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC."[5] Focusing separate payment on only the radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product will help concentrate the effects of unbundling radiopharmaceuticals to only those products that are most likely to create access issues for beneficiaries and reduce the wider effects on the nuclear medicine APCs.

After collecting input from a wide array of stakeholders and considering several options the Agency proposes to pay separately for radiopharmaceuticals with a per day cost greater than $630. The AMA appreciates CMS' aim of addressing beneficiary access to high-cost low-volume diagnostic radiopharmaceuticals. It is clear the Agency seeks to focus on separate payments for "only those diagnostic radiopharmaceuticals whose costs significantly exceed the approximate amount of payment already attributed to the product in the nuclear medicine APC." The AMA believes this approach will both increase access to those high-cost low-volume services while also mitigating the negative impact on the remaining nuclear medicine procedures to the greatest reasonable degree. We do urge the Agency to carefully monitor the affected nuclear medicine APCs and address any larger than expected alterations to

[4] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, Final Rule, 88 Fed. Reg. 81,540 (Nov. 11, 2023) at page 81,575. Retrieved at https://www.govinfo.gov/content/pkg/FR-2023-11-22/pdf/2023-24293.pdf.
[5] CY2025 OPPS rule

their reimbursement or other unintended consequences of this policy should it be enacted**. The AMA appreciates that CMS responded to concerns raised by the national medical specialty societies and other interested parties and that the proposal balances beneficiary access to high-cost, low-volume diagnostic radiopharmaceuticals while minimizing the negative reimbursement impact on nuclear cardiologists.**

Nonrecurring Changes

Remote and Virtual Services

Recommendation:

- The AMA appreciates that CMS continues aligning policies on remote and virtual services across the OPPS and MPFS and supports the extensions of current policies through 2025, but recommends CMS go further and permanently allow payment under the OPPS and MPFS for remote or virtual services and direct supervision.

Since the COVID-19 PHE, CMS has allowed outpatient therapy, diabetes self-management training (DSMT), and medical nutrition therapy (MNT) to be furnished via a telecommunications system to patients in their homes. CMS' policy has been to align its payment policies for all these services when furnished remotely by hospital staff to patients in their homes with its policies for Medicare telehealth services. To the extent that therapists and those who provide DSMT and MNT continue to be considered distant site practitioners for purposes of Medicare telehealth services, CMS proposes continuing to align its policies for outpatient departments and the physician payment schedule.

CMS also has permitted physicians providing direct supervision of cardiac and pulmonary rehabilitation and of diagnostic services furnished to hospital outpatients to be virtually present for these services through audio/video real-time communications technology since the PHE. Consistent with its proposed policy in the MPFS proposed rule, CMS proposes to extend this policy on virtual direct supervision through the end of 2025. The AMA believes that the current policy has been in place long enough that any serious problems should already have been identified, so, as we also recommend in our comments on the MPFS, it is time to end the uncertainty and make virtual direct supervision permanent. Physician and other workforce shortages are forcing hospitals in many communities to organize and staff services in different ways than in the past, including through remote direct supervision. In addition, some innovative approaches to care, such as hospital-at-home, are only feasible if they can be delivered using remote supervision. It will be more difficult to recruit and retain non-physician staff with the necessary training and experience to safely deliver services under virtual supervision, and to recruit and retain physicians who can effectively provide this supervision, if those staff and physicians are concerned that the policy enabling remote supervision is temporary and could be revoked within a year.

CRC Screening Services

Recommendation:

- The AMA supports CMS' proposal to update and expand Medicare Part B coverage for CRC screening tests.

As discussed in the MPFS proposed rule, CMS proposes to introduce coverage for CTC. CMS also proposes broadening the definition of complete CRC screening to include a follow-on screening colonoscopy after a positive result from a Medicare-covered blood-based biomarker test. The AMA supports CMS' proposal to update and expand Medicare Part B coverage for CRC screening tests by adding coverage for CTC and expanding the definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare-covered blood-based biomarker CRC screening test. The inclusion of CTC and blood-based biomarker tests as part of the CRC screening process provides patients with more effective and less invasive screening options.

Payment for Human Immunodeficiency Virus Pre-Exposure Prophylaxis in Hospital Outpatient Departments

Recommendation:

- The AMA supports CMS' proposal to pay for human immunodeficiency virus (HIV) prevention and pre-exposure prophylaxis (PrEP) provided as hospital outpatient services or by physician practices and appreciates that CMS is not proposing to pay for HIV PrEP counseling under the OPPS as this is a physician-only service.

For the first time since the law allowing coverage of drugs as "additional preventive services" was enacted in 2008, CMS is proposing to pay for a drug in this benefit category which, like other Medicare preventive services, would have no cost-sharing. Specifically, CMS proposes to pay for PrEP for HIV infection prevention once Medicare finalizes its national coverage policy. The proposal in the OPPS rule mirrors that in the MPFS proposed rule.

The AMA strongly advocates for plans to end the HIV epidemic that incorporate a focus on preventing at-risk individuals from acquiring HIV infection, including with PrEP. We support inclusion of PrEP for HIV as an essential preventive health benefit and are committed to educating physicians and the public about its effective use. We support the CMS proposal to use its authority to pay for drugs covered as additional preventive services to pay for this important service.

Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

Recommendation:

- CMS should finalize its proposals to implement separate payment for non-opioid treatments for pain management in the OPPS and ASC payment systems.

In response to Section 4135(a) and (b) of the Consolidated Appropriations Act, 2023 (CAA), titled Access to Non-Opioid Treatments for Pain Relief, which the AMA supported, CMS proposes to make a separate payment for certain qualifying non-opioid treatments, including medications and devices, that would otherwise be packaged with a service or group of services delivered in a hospital outpatient department or ASC. The CAA calls for these separate payments to be implemented for three years, from 2025 through 2027. For a non-opioid drug or biological product to qualify for the separate payment, its Food and Drug Administration label must indicate that it is to "reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors." Likewise, qualifying medical devices must be "used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia."

The CMS proposal explains the limits on the separate payment amounts for qualifying medications and devices required by CAA. It also describes the payment offset, which is the portion of the payment rate for the service or group of services reflecting the non-opioid pain treatment. As 2025 will be the initial year of the new payment policy, CMS proposes a zero-dollar offset, explaining that some of the products are new and their costs may not be reflected yet in the cost of the procedures for which they are used.

Section 4135 of the CAA grew out of a concern that bundling payment for postoperative pain treatments in with other services could lead to use of opioid treatments when effective non-opioid treatments were available because the opioid treatments may be less expensive. Separating out payments for non-opioid treatments while making zero offsets to the underlying service payments should encourage greater use of these treatments, consistent with the intent of the law. The AMA supports finalizing these proposals.

Individuals Currently or Formerly in the Custody of Penal Authorities

Revisions to Medicare Definition of "Custody"

Recommendation:

- The AMA strongly supports the proposal to revise Medicare's custody definition to improve access to care for people with health conditions, including substance use disorders, who are living in the community under supervised release following incarceration.

CMS is proposing to change the definition of custody so that people with Medicare and those eligible for Medicare can access Medicare-covered health care services when they are in a supervised release program following incarceration, such as on probation or in home confinement. Currently, even if these individuals enrolled in Medicare before they were incarcerated, they would be unable to access their Medicare benefits after release because they would still be defined to be in custody. Many incarcerated individuals over age 65 or disabled have substance use disorders; the period following their release is an exceptionally high-risk time for drug-related overdose and death. Modifying the custody definition as proposed will allow people who no longer have access to the medical care that may have been provided to them when they were incarcerated to use their Medicare health insurance benefits during the period that they are in a supervised release program. The AMA has joined the Legal Action Center and more than 100 other organizations in a comment letter calling for CMS to finalize this proposal.

Hospital OQR Program

Recommendation:

- The AMA supports CMS' proposal to remove two measures from the OQR program starting in 2025.

Starting with the 2025 OQR program year/2027 payment year, CMS proposes to remove the magnetic resonance imaging Lumbar Spine for Low Back Pain measure and Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery due to the measures meeting measure removal factor 2 (performance improvement on a measure does not result in better patient outcomes). The AMA supports removal of the measures from the program. We urge CMS to continue to assess the OQR program to

determine whether current or future measures have a clear and demonstrated connection to improved patient outcomes.

ASCQR Program

Recommendation:

- We urge CMS to delay implementation of Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS- CAHPS) survey and *ASC-21: Risk-Standardized Patient Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)* measures. The measures are extremely burdensome and costly to implement, and CMS assumes there is universal adoption of electronic health records (EHRs) within ASCs.

The AMA supports an ASCQR program that fosters facility improvement but continues to urge CMS to reassess the measures in the ASCQR program. The current program lacks a focus on patient safety nor provides the necessary information to patients to select an appropriate site of care. The current program includes several measures that were either not tested at the ASC-level or lack high reliability. Given the lack of appropriate focus, the measures in the program only increase administrative burden without any clear evidence that the measures improve the quality of care at health care facilities or provide benefits to patients.

Beginning in 2025, ASCs will be required to contract with a third-party vendor to administer the Consumer Assessment of Healthcare Providers and Systems OAS-CAHPS survey but are concerned that ASCs will be challenged with meeting the case minimum requirement of 200 completed surveys and the high cost to administer the survey. **We urge CMS to not penalize facilities that cannot meet the case minimum requirement. ASCs are small facilities and CMS' own testing has shown rates lower than 20 percent. In addition, we recommend CMS allow an electronic-only option to better increase response rates like it has proposed in the 2025 Physician Fee Schedule Proposed Rule and now allows in the Hospital Inpatient Quality Reporting program.**

In addition, in the 2024 OPPS/ASC Final Rule, CMS adopted *ASC-21: Risk-Standardized PRO-PM Following Elective Primary TH) and/or TK) in the ASC Setting (THA/TKA PRO-PM)* beginning with voluntary reporting for the CY 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period. This measure includes pre-operative data collected from 0-90 days before the procedure and post-operative data collected between 300-425 days after the procedure. Due to the heavy data collection burden, we recommend CMS delay voluntary reporting of the measure.

As with other measures proposed for the ASCQR program, CMS assumes that ASCs have access to and use EHR technology to assist with compliance. While Office of the National Coordinator for Health Information Technology estimates at least 86 percent of office-based physicians and 96 percent of acute care hospitals are currently using an EHR, it is our understanding from talking with the Ambulatory Surgery Center Association that at best 50 percent of ASCs are using an EHR. We remind CMS that ASCs did not receive any federal funding for EHR adoption in the Health Information Technology for Economic and Clinical Health Act and should not be penalized for slow EHR adoption through burdensome and rigorous quality measure requirements.

Even if an ASC uses an EHR they will be challenged with voluntarily reporting on the measure. The amount of data ASCs would be required to collect and submit for this measure is substantial: a total of 44 to 47 data elements for each THA patient and a total of 46 to 49 data elements for each TKA patient when complete patient-reported outcome data is provided by the patient. Yet, CMS proposes ASCs be required to submit complete and matching preoperative and postoperative PRO data for at least 45 percent of their eligible elective primary THA/TKA procedures to avoid future payment penalties. Therefore, CMS must test the measure in the ASC setting before implementation. In contrast, the OAS CAHPS survey sees much lower response rates, as seen in the OAS CAHPS 2019 mode. The highest return rate was 39 percent for web plus mail follow-up for a much less onerous survey.

With ASC-21, if a patient does not respond to all the items on each of the instruments requiring their input (the preoperative and postoperative HOOS, JR or KOOS, JR, the mental health items from the PROMIS-Global or VR-12, the Health Literacy SILS2, the "Total Painful Joint Count" and the Oswestry Index Question), the patient PRO data submission would be considered incomplete. ASC staff are already worried about survey fatigue with the upcoming OAS CAHPS survey mandate and ASC-21 will require even more information from patients.

A THA/TKA PRO-PM was only recently mandated for inpatient hospitals that have been working toward implementation for years. The proposal to begin voluntary reporting in ASCs in 2025 does not take the beginning of mandatory reporting for OAS CAHPS that same year into account. Given the extensive preparatory work needed for the THA/TKA PRO-PM, voluntary reporting in 2025 is not reasonable and must be delayed.

CMS Cross Quality Program Proposals

Recommendation:

- The AMA is concerned with the one size fits all approach CMS is taking with the structure and implementation of the proposed measures related to health equity and lack of advanced notice to implement. In addition, none of the measures has been tested for use in the Hospital Outpatient, ASC or Rural Emergency facility settings and, as a result, we do not support the measures.

In an effort to align measurement across the hospital OQR, ASCQR, and newly proposed Rural Emergency Hospital Quality Programs (REHQR), CMS proposes several quality measures related to health equity. The AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. As noted by CMS, studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications. However, the AMA is concerned with the one size fits all approach CMS is taking with the structure and implementation of the proposed measures. The AMA urges CMS to consider the risk/benefits of this model and how the measures may burden facilities that are under-resourced. We also urge CMS to consider the amount of quality measures and associated items required to achieve a maximum score and overly ambitious timeline to implement, especially if CMS desires meaningful outcomes. We offer the following measure specific comments proposed for 2025.

Facility Commitment to Health Equity measure

The AMA does not support the measure as it was developed and tested for use in the inpatient setting. Upon review of the measure specifications, it is clear CMS took the measure from the Hospital Inpatient Quality Reporting program and did not modify the measure to appropriately tailor it to the Outpatient, ASC, or Rural Emergency settings. The only noticeable change is CMS changed every reference to "hospital" to "facility." Outside of the inappropriate application of the measure, compliance with the measure is extremely cumbersome and burdensome. To receive credit, a facility will have to attest to five domains and evaluate and determine whether it engages in each of the elements that comprise the domain. Many of the elements require time to implement and access in an EHR. As stated earlier, only 50 percent of ASCs utilize an EHR. For example, Domain B requires the facility to attest that "our facility inputs demographic and/or social determinants of health information collected from patients into structured, interoperable data elements using an EHR technology." Therefore, we urge CMS to reconsider the use of the measure in the facility programs.

Screening for Social Drivers of Health

While the AMA supports the intent of this measure to begin addressing the social drivers of health (SDOH) that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure in the OQR, ASCQR, or REHQR programs is appropriate, especially in the absence of resources or tools that are widely and readily available to facilities. The measure also has not been tested for use in the outpatient setting. Measures must be actionable and facilitate improvements in patient care.

This measure has now been proposed for multiple programs over the last three years and yet no new information on the feasibility, reliability, and validity has been provided, which were some of the conditions placed by the Measures Applications Partnership (MAP) and now Pre-Rulemaking Measure Review. It also remains unclear how CMS plans to address the additional conditions from the MAP around additional details on how potential resources, tools, and best practices map to the individual drivers.

The developer has not provided any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it clear why the developer selected the specific social drivers of health for this measure. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We believe that many of these discrepancies would be resolved if the measure were fully specified and demonstrated to be evidence-based, feasible, reliable, and valid.

Due to the lack of testing and any demonstrated evidence implementation of the measure will result in effective change, we do not support the measure.

Screen Positive Rate for SDOH

While the AMA supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure in the OQR, ASCQR, or REHQR programs, in the absence of any resources or tools that would be widely and readily available to facilities, should be pursued at this time. Measures must be actionable and facilitate improvements in patient care and a measure that only reports the rate of positive screens does not represent the quality of care provided by a facility. While a facility can identify and potentially

assist with addressing social needs, they cannot and should not be held responsible for resolving them. Other strategies such as stratification of populations by race, ethnicity, and social drivers of health should be employed.

The measure also has not been tested at the facility level. CMS indicates in the rule that "pilot studies screening for Health-Related Social Needs Screening have been conducted in the HOPD and ASC settings, with clinicians and staff agreeing that Health Related Social Needs data are important and relevant to collect in these settings to improve patient care and communication as well as to connect patients with social-related services." However, this is not true measurement testing and misleading because one of the two citations is for a "large integrated health system," and does not indicate how outpatient departments are specifically included. The other study "evaluated a pilot of a standardized SDOH screening questionnaire and workflow in an ambulatory clinic within a large integrated health network in Northern California," not an ASC, outpatient department, or rural emergency facility.

While it is helpful that HOPDs, Rural Emergency Hospitals (REHs), and ASCs could confirm the status of any previously reported HRSN in another care setting and inquire about others not previously reported, in lieu of re-screening a patient within the reporting period, CMS assumes the facilities can easily access the data and utilizes an EHR. Even if a facility uses an EHR, facilities will be challenged with obtaining the data due to the lack of interoperability. CMS and the developer have not provided any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it clear why the developer selected the specific social drivers of health for this measure. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the USCDI. We believe that many of these discrepancies would be resolved if the measure were fully specified and demonstrated to be evidence-based, feasible, reliable, and valid.

REHQR Program

Recommendation:

- The AMA believes it is premature for CMS to propose an REHQR Program since Medicare payments specific to REHs only began in 2023.

In the 2025 OPPS proposed rule, CMS proposes to establish an REHQR Program starting in 2025. While the AMA supports ensuring patients receive quality care at any site of service they seek care, we believe it is premature for CMS to propose such a program for the newly established and created rural emergency hospitals. Medicare payments specific to REHs only began January 1, 2023. The purpose of REHs is for hospitals in rural areas that would be forced to close to convert to REHs and remain open. It is unclear whether this program will keep them open and better ensure patients can receive care locally. As a result, it does not make sense to add additional burdens at this point. It also seems like a leap to expect these facilities to be ready to start participating in the REQHR in 2025, when CMS only first proposed the program in this year's proposed rule.

If CMS insists on moving forward with requiring a REHQR program it must delay the start date and take a methodical approach to measurement and consult with providers, physicians, and patients on the best measures to utilize in this emerging care setting. In addition, all measures must be tested at the REH level and demonstrate a high level of reliability, feasibility and validity. CMS must also consider the burden, limited and variable resources many of these facilities have along with sample size requirements.

Medicaid Clinic Services Four Walls Exceptions

Recommendation:

- CMS should finalize its proposal to add three new exceptions to the Medicaid clinic services four walls requirement for Indian Health Service (IHS)/Tribal clinics, behavioral health clinics, and clinics located in rural areas with one small modification to allow states the option to apply the exceptions at the beneficiary level. We encourage CMS to consider additional exceptions for dually eligible beneficiaries, Medicaid beneficiaries living with disabilities, and substance use disorder services.

CMS has proposed to create three new exceptions to the Medicaid four walls requirement, which would allow for Medicaid payment for Medicaid practitioner services benefits, furnished outside of the four walls of the clinic for IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas in addition to the existing exception for treating unhoused persons. The IHS/Tribal clinic exception would be mandatory and the exception for behavioral health clinics and clinics located in rural areas would be optional for states.

The AMA believes all persons should have access to needed care regardless of their economic means and supports improved Medicaid patient access to care. We agree with CMS' reasoning that these proposed exceptions would help to overcome barriers and maintain and improve access for the populations served by IHS/Tribal clinics, behavioral health clinics, and clinics located in rural areas, especially considering the important role Medicaid plays in covering these populations and services. We further agree that these exceptions would advance the administration's goals of improving health care access for tribal, behavioral health, and rural populations and advance health equity overall.

We agree with the Agency's interpretation that these populations have similar needs and face similar barriers to care as unhoused individuals, and therefore, that expanding the exception to these additional populations is both within the administration's authority and within the spirit of the legislation. Furthermore, like many other flexibilities, we believe the grace period offered during the COVID-19 PHE provided a valuable proof of concept that these more flexible coverage policies are effective ways to overcome barriers and expand access to care for vulnerable patient populations.

While the AMA recognizes the importance of expanded access to care, we likewise acknowledge the budget constraints faced by many state Medicaid agencies. Accordingly, the AMA believes the proposal to make the IHS/Tribal clinic exception mandatory while making the behavioral health clinic and rural area optional strikes a reasonable balance.

While we appreciate CMS' concerns about operational complexity when it comes to applying the exceptions at the beneficiary level, we encourage CMS to allow states the option to also apply the exception at the beneficiary level in addition to the clinic level, which would broaden the exception's potential reach and effectiveness at expanding access while giving states discretion regarding how best to operationalize each exception. Because the exception for clinics in rural areas would be optional, we believe a definition of rural should be defined by each state. We believe this additional flexibility may lead more states to utilize this exception.

We appreciate the Agency inviting comment on whether there are additional populations that are likely to meet the outlined criteria for the exception and that have limited alternative access to clinic services. We encourage the Agency to consider additional expansions for dually eligible beneficiaries, Medicaid

beneficiaries living with disabilities, and substance use disorder services, which we feel experience similar hardships accessing services as the populations included in the expanded exceptions. We recommend states should have the option to apply each exception at the beneficiary and/or clinic level (in which case a threshold could be established).

Finally, the AMA would like to acknowledge the importance of CMS including language specifying that services subject to the exceptions would have to be furnished under the direction of a physician. The AMA continues to be a strong proponent of physician-directed care as it helps to ensure quality of care and patient safety, which is especially important in non-clinic settings and when dealing with vulnerable patient populations.

HOPD Prior Authorization Process

Recommendation:

- We appreciate CMS' proposal to shorten the standard prior authorization (PA) processing time for HOPD services from 10 business days to 7 calendar days; however, to align with AMA policy, prevent care delays, and protect patient safety, we urge CMS to reduce the standard and expedited PA processing timeframes to 48 hours and 24 hours, respectively.

The AMA applauds CMS for listening to our physician members, their patients, and many other stakeholders in recognizing the need for important guardrails in PA programs. While PA is touted by health plans as a mechanism to control health care costs and ensure appropriate treatment, PA requirements often delay medically necessary care, putting patients' health and lives at risk. According to the AMA's 2023 survey of 1,000 practicing physicians, an overwhelming majority (94 percent) of physicians report that PA delays treatment, with 24 percent reporting that PA has led to a serious adverse event—such as hospitalization, disability, or even death—for a patient in their care.[6] To prevent patient harms and reduce practice burdens, the AMA strongly advocates for PA reforms that will reduce the overall volume of PA requirements, improve transparency, protect continuity of care, and automate the currently manual process.

We view CMS' proposal to change the current review timeframe for standard (i.e., non-expedited) HOPD PAs from 10 business days to 7 calendar days as directionally appropriate. We also appreciate the transition to measuring timeframes in calendar versus business days, as health care is a 24/7 business that does not close on weekends or holidays. **However, we strongly recommend that CMS shorten PA processing timeframes further to protect patient health and safety. Specifically, we urge CMS to require standard PAs be processed within 48 hours and expedited PAs, which were not changed in this proposed rule, within 24 hours to align with AMA policy and the "Prior Authorization and Utilization Management Reform Principles" (which are formally supported by over one hundred health care organizations and patient groups).**[7] In this proposed rule, CMS opted to maintain the two-business day timeline for expedited requests, which does not conform with the CMS "Interoperability and Prior Authorization" final rule. In addition to causing needless confusion in the industry regarding different PA timelines between different types of government-regulated health plans, we are concerned that the two-business day timeline will continue to jeopardize the health and safety of vulnerable

[6] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[7] Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf.

Medicare beneficiaries. **When care is urgent, two-business days is simply not a safe amount of time to wait to receive approval for coverage.**

As stated in our comments on previous years' OPPS, the AMA strongly advocates against increasing PA requirements in traditional Medicare. Results from the AMA's 2023 physician survey show that PA continues to hurt patients and overwhelm physician practices, with a strong majority (82 percent) of physicians reporting that the volume of medical services requiring PA has increased over the past five years.[8] Expansion of PA requirements in traditional Medicare would compound PA-related administrative burdens, as well as represent a misalignment between CMS and the rest of the health care industry, which prioritized reducing the overall volume of PA requirements in the "2018 Consensus Statement on Improving the Prior Authorization Process."[9] **The AMA strongly advocates against any increase in PA requirements for Medicare HOPD services; processing timeframes for services currently subject to PA should be reduced as outlined above.**

Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

The Consolidated Appropriations Act of 2023 requires states to provide 12 months of continuous eligibility for Medicaid and CHIP enrollees under the age of 19, with limited exceptions, and requires that continuous eligibility "shall" apply to CHIP "in the same manner" as it does to Medicaid, which does not allow for disenrollment for failure to pay premiums. CMS has proposed affirming changes to Medicaid and CHIP regulations, including removing the option to disenroll children from CHIP for failure to pay premiums during the 12-month continuous eligibility period.

The AMA supports improved access to affordable health care services for Medicaid beneficiaries. Accordingly, we strongly support the continuous Medicaid and CHIP eligibility provisions for children under the age of 19, including that enrollment may not be terminated for failure to pay premiums. To further limit churn and strengthen access to and continuity of patient care for Medicaid and CHIP beneficiaries, AMA policy additionally supports consistent 12-month continuous eligibility requirements across Medicaid, CHIP, and exchange plans, streamlined enrollment forms and processes, and Medicaid and CHIP reimbursement at a minimum 100 percent of Medicare allowable rates.

Paying All IHS and Tribally Operated Clinics the IHS Medicare Outpatient All Inclusive Rate

The AMA supports federal efforts to enable the IHS to meet its obligation to bring American Indian health up to the general population level, including increasing funding to develop and expand accessible care services at IHS, Tribal, and Urban Indian Health Programs and associated facilities, continuing to enhance and develop alternative pathways for American Indian and Alaska Native patients to access the full spectrum of health care, and continuing efforts to better understand the limitations of IHS health care, including barriers to access, disparities in treatment outcomes, and areas for improvement.

Accordingly, we strongly support CMS standing up the Tribal Technical Advisory Group and being responsive to its suggestions to strengthen reimbursement for and access to health care services for Native populations, as evidenced by the request for information to pay IHS and Tribally Operated Clinics at the

[8] 2023 AMA Prior Authorization Physician Survey. Available at: https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

[9] Consensus Statement on Improving the Prior Authorization Process. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

IHS Medicare Outpatient All Inclusive Rate. We strongly support these efforts and look forward to additional policy making in this area to strengthen reimbursement for and therefore access to health care services provided to Tribal populations.

All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

The AMA has long been concerned about ensuring that reimbursement policies for Part B drugs provide adequate payment so as to maintain access to high priced drugs for patients who need them. Current payment policies (Average Sales Price (ASP) + six percent) are not always adequate to reimburse physicians for the acquisition costs associated with high-priced part B drugs in certain practice settings. Practices or facilities that cannot avail themselves of high-volume purchase discounts are sometimes forced to pay much higher prices to acquire these drugs. When this happens, ASP + six is not always adequate to fully cover the costs of offering these drugs, potentially leading practices to discontinue use of those drugs in particular practice settings.

The AMA has continued to advocate for drug payment policies that provide adequate reimbursement for physicians in all practice settings. This continues to be true for IHS and other tribal facilities providing care for underserved populations, where adequate reimbursement is critically important. We support CMS' efforts to ensure these facilities are appropriately reimbursed for these high-cost therapeutics so that access issues do not disrupt patient access to necessary care.

We thank you for the opportunity to provide input on this Proposed Rule. If you have any questions regarding this letter, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,

James L. Madara, MD