AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT

james.madara@ama-assn.org

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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–1808–P: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

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 Fiscal Year 2025 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System (LTCH PPS), published in the Federal Register on May 5, 2024 (89 Fed. Reg. 35934).

- The AMA recognizes the efforts of CMS in advancing health care technology through the Promoting Interoperability Program. However, we express concerns regarding the proposed changes to the certified electronic health record technology (CEHRT) definitions. While alignment with the Office of the National Coordinator for Health Information Technology standards is beneficial, the suggestion of altering CEHRT definitions in the upcoming fiscal year may lead to significant compliance challenges and potential penalties for physicians. We recommend that CMS delay these changes until after the finalization of the related Disincentives Rule, ensuring that physicians are not unfairly penalized and have adequate time to adapt to new requirements.
- The AMA supports the inclusion of new quality measures that enhance patient care and safety. However, we caution in the rapid implementation of these measures without robust evidence linking them to improved patient outcomes and recommend a phased approach that allows for comprehensive evaluation and adjustment based on real-world data. This method ensures that the measures enhance rather than complicate the care process, avoiding unnecessary increases in administrative burdens.
- The AMA advocates for an overhaul of current patient safety measures and recommends that CMS prioritize the development and integration of measures that directly contribute to the reduction of patient safety incidents and the improvement of clinical outcomes. This includes

leveraging advanced analytics and real-time data monitoring to better understand and mitigate risks in patient care.

- The AMA commends CMS' focus on improving maternity care, an important area where disparities in health outcomes remain a significant concern. We support the expansion of resources and the removal of barriers to the training and retention of obstetric care physicians, especially in rural and underserved areas. We also recommend that CMS consider increasing support for programs that integrate comprehensive approaches to maternity care and highlight the importance of social determinants of health (SODH) in maternal and infant outcomes.
- The AMA supports the allocation of Graduate Medical Education (GME) slots to be strategically targeted to address the most pressing needs within the health care system, including the shortage of mental health professionals. We urge CMS to adopt a distribution framework that considers the specific needs of communities and the capacity of institutions to provide high-quality education and training to residents.

Additionally, the AMA will be submitting a separate comment letter on the Transforming Episode Accountability Model Proposed Rule that includes our recommendations. Please find below our detailed comments in response to these proposals.

I. Promoting Interoperability Program

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

Scoring Threshold

CMS proposes increasing the performance-based scoring threshold for eligible hospitals and Critical Access Hospitals (CAHs) reporting to PI from 60 points to 80 points beginning with the EHR reporting period in CY 2025. **The AMA does not support this change, however, as the data CMS cites is cause for some alarm.** In the proposed rule, it is noted that "the CY 2022 Medicare Promoting Interoperability Program's performance results indicates 98.5 percent of eligible hospitals and CAHs currently successfully meet the threshold of 60 points while 81.5 percent of eligible hospitals and CAHs currently exceed a score of 80 points. If this proposal is finalized, the 17 percent of eligible hospitals and CAHs that meet the current threshold of 60 points but not the proposed threshold of 80 points would be required to align their health information systems with evolving industry standards and/or increase data exchange to raise their performance score or be subject to a potential downward payment adjustment." Based on

this calculation, over 1000 hospitals would not meet the new scoring threshold and would be adversely impacted by this change. It is important to remind CMS that many hospital and CAH EHRs updates and information capabilities are contingent on their EHR developer's software timeline and ability to make updates. It is a long-held fact that EHR developers take between 18-24 months to update, test, and deploy new software and capabilities. **The AMA recommends that the change in scoring is pushed back to CY 2027 to allow ample time for all hospitals to adjust to the reporting requirements based on their EHR developers update timeline and capabilities.**

Security Risk Analysis, Safety Assurance Factors for EHR Resilience (SAFER) Guides

The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) are required but will not be scored in FY 2025; however, the proposed rule states that HHS intends to consider how PI can promote cybersecurity best practices for eligible hospitals and CAHs in the future. **The AMA questions why this measure is necessary, given that this measure is based directly on HIPAA Security Rule Safeguards and would already be required for HIPAA compliance. We are concerned that CMS views PI as a "catchall" program and believes it is necessary to "dump" all of its health IT polices in the program regardless of their impact, clinician burden, or usefulness in achieving goals.** Further, we expect overlap with reporting timelines and the release of updated guides. Already, there has been millions of dollars and thousands of hours spent over the last couple of years attesting. Updating the guides and making reporting for all nine guides mandatory will negate the work and accomplishments during the most recent attestation year. **The AMA recommends that CMS stick with voluntary reporting of the current SAFER guides until the updated SAFER guides have been developed, available, and tested in health systems of various sizes.**

II. Inpatient Quality Reporting (IQR) Program

Fiscal Year 2025/ 2027 Payment Determination

In the 2025 IPPS Proposed Rule, CMS proposes seven new measures for the Inpatient Quality Reporting (IQR) program. Starting in Fiscal Year 2025/ 2027 payment determination, CMS proposes the following measures for adoption. We offer the following measure specific comments:

Patient Safety Structural Measure

While the AMA supports the ongoing focus of improving patient safety, including targeting a hospital's leadership and the entity's overall structure and practices, we do not believe that the development of a structural measure, particularly one that primarily looks for the presence of patient safety-focused documents, in the absence of any demonstrated linkage to improvement in patient outcomes or clear evidence to support should be pursued. For example, what evidence is there to require a board to spend twenty percent of their time discussing quality and safety? In addition, allowing three business days to report a serious safety event to an entity's governing board appears to be an excessive delay in reporting; we would expect a serious safety event to be elevated to the board much sooner.

CMS continues to put forward these structural measures that require only "yes/no" attestation that specific requirements are met, with the baseless inaccurate assumption that this approach does not increase administrative burden and that there are gaps to be addressed. We believe that there are many activities already integrated into a hospital's structures and processes, including actively engaging patients and families in activities such as a Patient and Family Advisory Council, reporting to a Patient Safety

Organization, participating in large-scale learning networks, and tracking progress on safety metrics against external benchmarks. Several of the practices (mainly in Domain 1 and 2) also overlap with Conditions of Participation and required participation in a Patient Safety Organization (PSO) runs counter to the statutory intent because PSO participation and the reporting of data from PSOs to Agency for Healthcare Research and Quality are both intended to be entirely voluntary.

While reporting on this measure may appear to initially increase overall performance, it remains unclear the extent to which attesting to these domains is directly linked to increased quality and safety of care delivered within a hospital. We encourage CMS to shift its focus from developing this type of measure, and to instead target those measures, initiatives, and activities that prioritize the collection and reporting of additional relevant safety data and to promote interventions that address safety. Therefore, we do not support inclusion of this measure in the Hospital IQR Program.

At a minimum, the measure must be trimmed down to include only practices supported by strong evidence that are linked to better outcomes, as well as inclusion of requirements that physician and medical staff must be part of a health care organization's operational and strategic planning to safeguard the interest of patients, the community, the health care organization, and the medical staff and its members.

Age Friendly Hospital Measure

The AMA supports the inclusion of the *Age Friendly Hospital Measure* in the CMS Hospital Inpatient Quality Reporting Program. The Age Friendly Hospital Measure considers the full program of care needed for geriatric patients in the hospital. The measure was developed in partnership with the American College of Surgeons (ACS), the Institute for Healthcare Improvement (IHI), and the American College of Emergency Physicians (ACEP), to help build a better, safer environment for older adults and to support patients and caregivers when seeking where to find good care. The measure encourages hospital systems to reconceptualize the way they approach care for older patients with multiple medical, psychological, and social needs at highest risk for adverse events. It also puts an emphasis on the importance of defining patient (and caregiver) goals not only from the immediate treatment decision, but also for long-term health and aligning care with what the patient values.

The Age Friendly Hospital Measure is an updated measure that combines two measures previously reviewed by the National Quality Forum's Measures Application Partnership (MAP) in 2022: the Geriatrics Hospital Measure (MUC 2022-112) and the Geriatrics Surgical Measure (MUC 2022-032). Both measures received broad support; however, the MAP Hospital Workgroups recommended that the two measures be combined into a single measure to reduce burden. Based on this feedback, ACS submitted the updated Age Friendly Hospital Measure for review under the 2023-2024 Pre-Rulemaking Measure Review process where 73.68 percent of voting Committee members supported recommendation of the measure for the Hospital IQR program.[1]

The concept behind the programmatic measure is based on several decades of history implementing programs that demonstrably improve patient care provided by the clinical team along with the facility. The Age Friendly Hospital Measure incorporates elements of IHI's Age-Friendly Health Systems program known as the 4Ms (What Matters, Medications, Mentation, Mobility), standards from the

[1] Partnership for Quality Measurement. *Pre-Rulemaking Measure Review Measures Under Consideration: 2023 Recommendations Report*. 2024. Accessed May 23, 2024. https://p4qm.org/sites/default/files/2024-02/PRMR-2023-MUC-Recommendations-Report-Final-.pdf.

Geriatric Emergency Department Accreditation (GEDA) framework developed by ACEP, and ACS Geriatric Surgical Verification (GSV) standards.

Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure.

The AMA does not support inclusion of this measure in the Hospital IQR program given our concerns with the scientific acceptability of this measure. Specifically, testing demonstrated that reliability is 0.231 using the measure's case minimum of 25 patients and it required roughly 600 patients to achieve a high level of reliability (0.70 at a minimum). These results were also questioned during the recent consensus-based entity (CBE) endorsement review and the committee placed conditions on endorsement asking that the low reliability results be addressed. Information around the rationale on why social risk factors were also not included in the risk model was not sufficient to justify their omission. The AMA does not support inclusion of this measure in the Hospital IQR Program until the reliability of the measure scores is improved and the condition on endorsement is removed.

2026 reporting period/FY 2028 Payment Determination

Beginning with the 2026 reporting period/FY 2028 payment determination CMS proposes several measures for adoption. We offer the following measure specific comment:

The Hospital Harm-Falls with Injury Electronic Clinical Quality Measure

The AMA questions whether the information provided because of this measure is truly useful for accountability and informing patients of the quality of care provided by hospitals. Specifically, our concern relates to the relatively limited amount of variation discovered during testing of the measure with variation across the 12 hospitals ranging from 0.00 percent to 0.258 percent. We do not believe measures that currently only identify such small differences in performance allow users to distinguish meaningful differences in performance.

CMS Proposed Measure Removal

- Proposed Removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) Measure Beginning with FY 2027 Payment Determination.

The AMA supports removal of this measure from the program. We continue to have concerns with the reliability and validity of the measures and CMS has yet to demonstrate improvements on the issue.

In addition, the AMA supports removal of the following four-episode measures. The costs of each episode are captured in the hospital Medicare Spending Per Beneficiary (MSPB) measure, so the episode measures are duplicative of MSPB.

- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction measure, beginning with the July 1, 2021 – June 30, 2024 reporting period;
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure measure, beginning with the July 1, 2021 – June 30, 2024 reporting period;
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia measure, beginning with the July 1, 2021–June 30, 2024 reporting period; and

- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty measure, beginning with the April 1, 2021–March 31, 2024 reporting period.

III. Request for Information: Advancing Patient Safety and Outcomes Across the Hospital Quality Programs

CMS is seeking feedback on ways to build upon current measures in CMS quality reporting programs that account for unplanned patient hospital visits to incentivize hospitals to improve discharge processes, such as by introducing existing quality reporting measures into Value-Based Purchasing (VBP) programs or by adopting new measures that better represent the range of patient outcomes post discharge. There are currently three Excess Days in Acute Care measures in the Hospital IQR Program that estimate days spent in acute care within 30 days post discharge from an inpatient hospitalization ((i) Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction, (ii) EDAC after Hospitalization for Heart Failure, and (iii) EDAC after Hospitalization for Pneumonia). The Hospital Visits After Hospital Outpatient Surgery measure has been adopted in the Hospital Outpatient Quality Reporting and Rural Emergency Hospital Quality Reporting Programs. The agency does not believe that these measures comprehensively capture unplanned patient returns to inpatient or outpatient care after discharge, and notes that since the existing measures are in quality reporting, and not VBP programs, performance on measures is not enforced through payment incentives.

The AMA agrees that any unplanned return to an acute care setting should not be viewed as a desirable outcome of patient care and hospitals and others should continue their efforts to reduce these occurrences. However, we also believe that hospitals should not be penalized across multiple quality programs for overlapping outcomes. For example, because the EDAC measures include unplanned readmissions, they serve as good examples on how double counting of patients and outcomes could occur across programs. Since unplanned readmissions are already captured through the Hospital Readmissions Reduction Program, it would not be appropriate to consider them for another program such as the Hospital Value-Based Purchasing Program. As a result, we encourage CMS to avoid duplicative measures across programs. Rather, CMS should identify evidence-based, reliable, and valid measures that are not duplicative to those currently in programs that include payment incentives or penalties and submit them for consideration for quality programs as applicable.

Hospital Readmission Reduction Program (HRRP)

While there are no proposals or updates in the 2025 IPPS proposed rule for the HRRP, we continue to urge CMS to make improvements to the program and monitor the impact the program is having on hospitals that disproportionately treat patients with social risk factors. We recognize CMS has made some recent improvements to HRRP through inclusion of stratification of quality data by dual eligibility, race and ethnicity and disability. However, CMS must make significant efforts to advance the data that are used to identify health care inequities. For example, quality measures should account for risk factors such as lack of access to food, housing, and/or transportation that affect patients' ability to adhere to treatment plans. Continued reliance on existing data that have known deficiencies is not acceptable, and we must advance to more accurate and relevant data.

We discourage CMS from strictly relying on dual-eligibility (DE) status when stratifying readmission measures. While the 2016 Assistant Secretary for Planning and Evaluation (ASPE) report to Congress[2] on social risk factors and their impact on measures in CMS value-based purchasing programs may have identified dual eligibility as a strong predictor for disparities, a recent study found that due to the differences in the DE population stratifying by DE-only within the confidential hospital Disparities Report is misleading and further exacerbates inequities, which is counter to the goals of quality and its related incentives to close or minimize health care inequities.[3] The potential addition of race and ethnicity data using the indirect estimation approach, while potentially informative for quality improvement purposes, should not be used for any other purpose.

We urge CMS to focus on longer-term strategies that will truly drive improvements as opposed to spending time on resources to implement "quick fixes" and utilize proxies. The methodologies chosen to stratify and present data for purposes of improvement are multifaceted and it is a complex topic. Therefore, it requires more research to develop an evidence-based approach to account for social risk-factors and reduce inequities.

In addition, **we recommend that CMS consider exploring the following concepts through an open and transparent measure development process that involves extensive opportunity to provide input:**

- Stratify by race, ethnicity, language, disability, age, gender, and other demographic factors and determinants of health (e.g., insurance type) for root cause analysis;
- Reduction of inequities through positive incentives;
- Access to interpreters;
- How well are social and structural determinants of health data collected and addressed; and
- Access to care or patient experiences during health care interactions.

The development of new quality measures that more effectively address health equity should be prioritized. For instance, the Hospital-wide, All-cause Readmission measure is duplicative of the current set of condition-specific measures. During previous reviews of the evidence provided by CMS on the measure, no research was presented that demonstrated that hospitals can directly or indirectly impact readmissions within 30 days across the broad patient populations treated. This lack of evidence paired with the continued omission of social risk factors in the risk adjustment model leads us to have significant concerns regarding the use of this measure that holds hospitals responsible for all-cause, 30-day readmissions. The traditional approach of risk adjusting at the patient level may not be appropriate for measures where the measurement period includes care that is outside of the control of the hospital and a 30-day post-acute phase where the availability of community supports, and other resources will directly impact a patient's care. We believe that there may be community-level variables that affect the risk of readmission during the 30 days following a hospital admission but are not currently addressed. Measures that extend beyond the hospital stay or outside the locus of control of the measured entity should continue to have sociodemographic status adjustment addressed and analyzed at different levels (e.g., patient, hospital, and community). In addition, CMS should work with the developer to continue to explore new variables that are directly related to the community in which a patient resides, particularly given the

[2] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs. Washington, DC: 2016.

[3] Alberti, Philip., Baker, Matt., Dual Eligible Patients Are Not The Same- How social risk may impact quality measurement's ability to reduce inequities.

ASPE report. As a result, we believe that our concerns fall under CMS rules for removing a measure from a program, specifically Factor 2—measure does not align with current clinical guidelines or practice. Therefore, **the AMA recommends that CMS revisit inclusion of the Hospital-Wide All-Cause Readmission measure in the HRRP**.

Proposed Changes to the MS-DRG Diagnosis Codes- SDOH – Inadequate Housing/Housing Instability

In the 2025 IPPS proposed rule, CMS proposes to change the severity level designation for the seven inadequate housing/housing instability from non-complication or comorbidity (Non-CC) to complication or comorbidity (CC) due to the resources necessary to addresses patients with social determinants health issues related to housing instability. CMS highlights that evidence suggests that housing instability is associated with higher prevalence of many health conditions including overweight/obesity, hypertension, diabetes, and cardiovascular disease. The AMA supports CMS' acknowledgement of the increase in resources needed to treat patients with social risk factors and changing the severity level, but CMS must ensure the change is administratively feasible through the existing claims processing process.

IV. Request for Information: Maternity Care

We applaud the Administration for its commitment to reducing maternal health disparities and improving maternal health outcomes during pregnancy, childbirth, and in the postpartum period. Moreover, we commend the Administration for its work on the White House Blueprint and the Action Plan, which are holistic assessments that highlight specific federal actions and outline long-term goals for improving maternal health. The AMA is especially glad to see that the Administration has noted that the maternal health crisis is at the intersection of multiple complex issues including health equity, adequate access to health care, socioeconomic factors, and more–making the maternal health crisis an issue that will require large systemic changes to be successfully addressed. In order to help improve maternal health the AMA offers the following information and recommendations.

What policy options could help drive improvements in maternal health outcomes?

The AMA strongly supports the Alliance for Innovation on Maternal Health (AIM) patient safety bundles, and we are encouraged that they are included in both the White House Blueprint and the new Transforming Maternal Health program. However, it is important for states and the federal government to recognize that the biggest barrier to implementing these bundles is a lack of resources and that additional funding, beyond what has already been invested, is needed to adequately implement the AIM bundles, especially in smaller institutions and institutions that do not have vast resources. **Therefore, the AMA strongly recommends that the Administration provide the financial resources necessary for implementation of the Core AIM bundles and seek input from physicians providing obstetrical services about the barriers to implementing the AIM patient safety bundles.** The AMA would welcome the opportunity to facilitate discussions between the Administration, the states, and physicians to help achieve this outcome.

Address Physician Workforce Needs in Maternity Care

A greater emphasis is needed on increasing and retaining the number of physicians in the maternal and infant care space to decrease maternal care deserts and improve health outcomes. To help with the retention of physicians who provide maternal care, the Administration should:

The Physician Residency Cap and Training

- Work to help remove the cap on physician residency slots. If this is not possible, the Administration should work to increase the cap on physician residency slots and ensure that the cap is not stagnant, but rather, is increased as needed. Moreover, the cap-building period for new residency programs should be increased.
- Expand maternal care education and training, especially to those physicians who are likely to have to administer care to pregnant or postpartum individuals but are not Obstetrics & Gynecology (OBGYN) or maternal-fetal medicine specialists.

Teaching Health Center Graduate Medical Education

- Increase funding for Teaching Health Center Graduate Medical Education (THCGME) Programs. Since 2010, this program has helped 21 OBGYNs complete their residency and enter the workforce. Though this is an excellent start, additional funding, and support for this program, and in particular OBGYNs in the THCGME Program, is needed.

National Health Service Corps

- Increase funding for the National Health Service Corps (NHSC) and ensure that a higher percentage of physicians are accepted to the NHSC Loan Repayment Programs and Scholarship Programs.
- Ensure that further information about the Maternity Care Target Area (MCTA) addition to the NHSC is provided to the public and grant more funding for the MCTA addition so that an adequate number of maternity care physicians can be placed in Health Professional Shortage Areas (HPSAs) through the NHSC.

Indian Health Service

- The Indian Health Service (IHS) should establish an Office of Academic Affiliations responsible for coordinating partnerships with the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, accredited medical schools, and residency programs accredited by the Accreditation Council for Graduate Medical Education. Furthermore, to support these partnerships, funding streams should be developed to promote rotations and learning opportunities at IHS, Tribal, and Urban Indian Health Programs.
- The IHS Loan Repayment Program should be strengthened. The payments received through the program are taxable. To align this loan repayment program with other similar programs, the loan repayments received should be tax-free.
- Compensation for IHS physicians should be increased to a level competitive with other federal agencies and additional funding should be provided to the IHS Loan Repayment Program to increase the number of physicians who can be supported, especially in the maternal care space.
- Additional funding should be provided for the IHS Maternal Child Health (MCH) program. The IHS MCH should ensure that the funds it receives are used to increase access to OBGYNs and maternal-fetal medicine specialists for American Indian/Alaska Native (AI/AN) pregnant individuals.
- The CDC should increase its engagement in the following ongoing initiatives (this list is not exhaustive): develop awards to fund support for Maternal Mortality Review Committees for AI Tribes, expand materials on the Hear Her Campaign website for AI Tribes, and continue support for the Healthy Native Babies Project to assist local programs in addressing safe infant sleep in AI/AN communities.

Residency

Additional specific training tracks for maternal and infant care should be created and expanded. Rural track programs (RTP) already exist and are designed to encourage the training of residents in rural areas. Specifically, Maternal Health and Obstetrics Pathway within the Rural Residency Planning and Development Program is available for both OBGYN rural residency programs and family medicine rural residency programs that have enhanced obstetrical training.

While the Maternal Health and Obstetrics Pathway is an important first step, it needs to be expanded so that additional maternal health pathways can be created. For example, additional training tracks should be created that allow for both rural and urban training for OBGYNs, maternal-fetal medicine specialists, family physicians, and other physicians who will likely have to provide maternal care. These training programs could be modeled off existing programs that are already accredited by the Accreditation Council for Graduate Medical Education, such as the family medicine RTP programs, which exist in the "1-2 format"—meaning the resident's first year is at a core family medicine program and the second and third years are at another site. Since there are already provisions of law and regulations that allow urban hospitals to create multiple RTPs and receive adjustments to their caps for newly established RTPs, it would be possible to create an educational format that allows for residents to train in urban and rural settings in maternal care, thereby, enabling physicians who will ultimately practice in rural areas to do rotations in hospitals with a high volume of deliveries, so they can receive ongoing training and experience with cesarean sections and pregnancy-related complications. The AMA believes that **more funding should be provided for the Maternal Health and Obstetrics Pathway and programs with similar goals should be created. Moreover, additional funding for rural clinics and hospitals should be provided to enable them to offer rotations for medical students and residents in rural obstetric care.**

How can CMS support hospitals in improving maternal health outcomes?

Infrastructure for Remote Patient Care

Although there are a number of positive uses for telemedicine in obstetrics, implementation of such technologies has been minimal. This is in part due to limiting factors such as high startup costs, limited internet access in rural areas, and inconsistent reimbursement requirements across different state Medicaid programs and commercial insurance plans.[4] Furthermore, physician practices and other facilities may lack the requisite hardware, software, and internet connection to provide reliable and high-quality remote care.[5] Therefore, in order to guarantee that remote maternal care can be offered, it is vital to first ensure that the infrastructure for remote care services is in place.

Internet access has been called a "super determinant" of health and yet approximately 19 million people in the United States do not have reliable broadband service. [6] Accordingly, it is imperative that there are reliable broadband connections at both the site of the provider and the patient to ensure that consistent, reliable, maternal care can be provided virtually. Thus, the Administration should build out, and make permanent, initiatives like the Connected Care Pilot Program which provides funding for "eligible costs

[4] https://www.kff.org/womens-health-policy/issue-brief/telemedicine-and-pregnancy-care/.
[5] https://journals.lww.com/greenjournal/Fulltext/2020/02000/Implementing_Telehealth_in_Practice.44.aspx.
[6] https://www.samhsa.gov/blog/digital-access-super-determinant-health#:~:text=Internet%20access%20has%20become%20an%20essential%20component%20of,obesity%2C%20cancer%2C%20and%20drug%20mortality%2Fopioid%20prescription%20rates.%205.

of broadband connectivity, network equipment, and information services..."[7] Moreover, it is exceptionally important that these initiatives focus on rural areas that tend to have the worst broadband access.[8] Consequently, programs like the Rural Health Care Program and the Rural Telehealth Initiative Task Force should be provided with additional support, potentially through the Internet for All Initiative, so that broadband access can be provided to these communities as quickly as possible.[9]

Coverage of Telehealth

As almost half of births in the U.S. are financed by Medicaid, expanded access to telehealth technologies in pregnancy will largely depend on state and federal decisions regarding telemedicine coverage. To support access to perinatal care via telehealth, the AMA has strongly supported extending Medicaid eligibility for pregnant women to 12 months after birth and appreciates the Administration's efforts to support state actions to implement this coverage.

While maternity care is covered without cost-sharing by private plans and the Medicaid expansion program under the Affordable Care Act (ACA) there are no federal requirements for coverage or reimbursement of telehealth care provided during or after pregnancy. Rather, each state regulates and sets reimbursement policies, which may vary significantly across states and between public and private plans.[10] However, due to the increased reliance on telemedicine over the past few years, Medicaid programs have begun to permanently expand coverage of telemedicine as a modality to provide health care services. For example, all 50 states plus Washington, DC now provide reimbursement for some form of telehealth in Medicaid fee-for-service.[11] Additionally, 37 Medicaid programs now provide reimbursement for remote patient monitoring, and 43 states plus Washington, DC have instituted private payer laws that address telehealth reimbursement.[12] However, maternal and postpartum virtual care is not always included in these policies.

The AMA believes that telehealth and remote patient monitoring are a critical part of the future of effective, efficient, and equitable delivery of health care in the United States and advocates for comprehensive Medicaid coverage of virtual maternal health care services.

Monitoring of Hypertension During Pregnancy and Postpartum

Over the last decade, the AMA has developed and disseminated an evidence-based quality improvement program, AMA MAP™ hypertension (HTN), that has demonstrated improvement in blood pressure (BP)

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[7] https://www.fcc.gov/wireline-competition/telecommunications-access-policy-division/connected-care-pilot-program.
[8] https://www.fcc.gov/reports-research/maps/connect2health/map.html#ll=31.5,-96.4&z=4&t=insights&hmt=opioid&inb=in_bb_in_adoption&slb=0,84&inc=none&dmf=none&ino=in_alldrugs_age_adj_mortality_rate&slo=20.1,126.3&zlt=county.
[9] https://www.fcc.gov/connecting-americans-health-care.
[10] https://www.kff.org/womens-health-policy/issue-brief/telemedicine-and-pregnancy-care/.
[11] https://www.cchpca.org/2023/10/Fall2023_ExecutiveSummaryfinal.pdf.
[12] https://www.cchpca.org/2023/10/Fall2023_SummaryChartfinal.pdf.

control for adult patients with hypertension in primary care settings.[13,14] In addition the AMA has collaborated with other interested groups to increase access to tools, resources and services to improve the clinical management of hypertension, including clinical services and home devices for self-measured blood pressure (SMBP), specifically increasing Medicaid coverage.[15] SMBP is an evidence-based strategy for BP control that is incorporated into AMA MAP HTN and other AMA solutions.

The AMA is convening clinical subject matter experts to identify effective strategies and best practices to improve care of patients with HDP. Expected deliverables include clinical resources, issue briefs/commentaries, and peer-reviewed publications for national dissemination. The AMA collaborates regularly with organizations and leaders in maternal health who are national experts on Hypertensive Disorders of Pregnancy (HDP) to build upon the AMA work to develop an SMBP postpartum strategy.

Improving Care for Patients with Hypertensive Disorders of Pregnancy

HDP are one of the leading causes of pregnancy-related deaths that occur in the first 6 weeks postpartum.[16] The rate of patients entering pregnancy with chronic HTN and the overall rate of HDP have risen considerably in recent years.[17] The use of SMBP has been shown to increase compliance with American College of Obstetricians and Gynecologists (ACOG) recommendations for BP monitoring, increase patient satisfaction, and decrease readmissions for HDP.[18,19] SMBP has also shown promise in reducing inequities in the monitoring and treatment of BP in postpartum patients.[20] Multiple barriers prevent the widespread adoption and use of SMBP for which there are potential solutions. These include:

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[13] Egan BM, Sutherland SE, Rakotz M, et al. Improving Hypertension Control in Primary Care With the Measure Accurately, Act Rapidly, and Partner With Patients Protocol. *Hypertension*. 2018;72(6):1320-1327. doi:https://doi.org/10.1161/hypertensionaha.118.11558.

[14] AMA announces success with helping patients control high blood pressure. American Medical Association. Published January 11, 2023. Accessed March 15, 2024. https://www.ama-assn.org/press-center/press-releases/ama-announces-success-helping-patients-control-high-blood-pressure.

[15] SMBP coverage insights: Medicaid. (n.d.). https://www.ama-assn.org/system/files/smbp-coverage-medicaid-april-2023.pdf.

[16] Martin SS, Aday AW, Almarzooq ZI, et al. 2024 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association. *Circulation*. 2024;149(8). doi:https://doi.org/10.1161/cir.0000000000001209.

[17] Petersen EE, Davis NL, Goodman D, et al. Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017. MMWR Morbidity and Mortality Weekly Report. 2019;68(18). doi:https://doi.org/10.15585/mmwr.mm6818e1.

[18] Kumar NR, Hirshberg A, Srinivas SK. Best Practices for Managing Postpartum Hypertension. Current Obstetrics and Gynecology Reports. 2022;11(3):159-168. doi:https://doi.org/10.1007/s13669-022-00343-6.

[19] Hoppe KK, Thomas N, Zernick M, et al. Telehealth with remote blood pressure monitoring compared with standard care for postpartum hypertension. *American Journal of Obstetrics and Gynecology*. Published online May 2020. doi:https://doi.org/10.1016/j.ajog.2020.05.027.

[20] Hirshberg A, Sammel MD, Srinivas SK. Text message remote monitoring reduced racial disparities in postpartum blood pressure ascertainment. *American Journal of Obstetrics and Gynecology*. 2019;221(3):283-285. doi:https://doi.org/10.1016/j.ajog.2019.05.011.

Coverage and Access

Medicaid covers 42 percent of all births in the U.S.[21] Coverage varies by states including whether the inclusion of an extra appropriately size cuff, often needed to ensure clinical accuracy, is offered. This variation and others are barriers to scaling SMBP. Even when coverage exists, there are still access issues. Some states prohibit shipping a covered device directly to a patient or require the patient to go to a specific DME supplier rather than a more convenient location. For SMBP coverage to be clinically impactful, it necessitates that patients have coverage and access to devices that are appropriately sized and clinically validated.

Therefore, the AMA recommends policies that support increased coverage and access to SMBP devices clinically validated for pregnancy with appropriate cuff sizing options.

Clinical Infrastructure

SMBP requires investments in clinical personnel and technology integration into clinical practice. **Therefore, the AMA recommends policies that support improved interoperability of apps/platforms to support the transfer of BP measurement data from patients to clinical teams. We also support increased payment for physician-led team-based care to increase patient access to programs that improve care for patients with HDP.**

Clinical Quality Improvement

Clinical teams require access to data to drive and measure quality improvement programs as well as research efforts. Dedicated funding to scale promising interventions nationally and measure the impact on outcomes is also needed to identify the most effective solutions and strategies.

Therefore, the AMA recommends policies that support increased availability of standardized clinical and billing data for use in quality improvement. We also support increased funding for clinical, dissemination, and implementation research on HTN and cardiovascular disease during pregnancy and postpartum to identify and measure effective interventions to improve quality of care and health outcomes.

Additional factors that may impact the use of SMBP are the availability of maternity care, the status of policies related to caregiving (for example, parental leave) and the status of health insurance coverage availability (for example, Medicaid expansion).

Request for Information: Obstetrical Services Standards for Hospitals, CAHs, and REHs: Potential solutions that could reduce the rates of maternal mortality and reduce disparities in maternal mortality and morbidity, which can be implemented through the hospital conditions of participation (CoPs).

As highlighted in the NPRM there has been an alarming and significant number of closures of hospital-based obstetrical (OB) 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

[21] Maternal & Infant Health Care Quality. Medicaid. (n.d.). https://www.medicaid.gov/medicaid/quality-of-care/quality-improvement-initiatives/maternal-infant-health-care-quality/index.html.

these vital services.[22] The AMA is extremely concerned about this lack of access to OB care and its impact on our patients. Given the worsening climate of OB care access, the AMA is concerned that an obstetrical services CoP could have the unintended consequence of resulting in additional closures of labor and delivery units and, therefore, cannot lend support to requirements that could exacerbate the current trends that are resulting in growing maternity care deserts.

In our response to the 2023 IPPS proposed rule, the AMA noted that "there may be value in the creation of CoPs specifically for labor and delivery and recommends CMS explore options to establish such conditions for participating hospitals with relevant stakeholders." Notably, however, our comments urged focus on adoption of behavioral health screening, integration of behavioral health into care workflows, adoption of virtual interprofessional consultations, expansion of Project ECHO (Extension for Community Healthcare Outcomes) to empower OBGYN care teams to collaborate with psychiatrists and other behavioral health professionals to provide treatment, and use of standardized instruments to measure care. Our comments were not intended to support sweeping obstetrical related health and safety standards, including CoPs. In fact, for the reasons outlined above, we believe it would be a mistake to propose a broad CoP only a few weeks after soliciting input from the relevant specialty societies and interested parties. **Consequently, the AMA urges CMS not to move forward with proposing CoPs related to labor and delivery in the 2025 Outpatient Prospective Payment System proposed rule as indicated in this RFI.** Rather, CMS should meet directly with the AMA, ACOG and other impacted national medical specialty societies outside of the rulemaking process to ensure the agency understands how CoPs would impact maternity care across the country.

Staff Training

Simulation Training

"In order to ensure prevention when possible and optimal outcomes when this is not possible, it is critically important that members of the health care team are educated and are readily able to recognize, diagnose, treat, and manage medical emergencies in pregnancy."[23] We therefore believe it is imperative that physicians have regular and reliable access to simulation-based training. "Simulation offers a way for learners to gain fluency with skills without risk to patients, and gain experience recognizing and responding to uncommon, high-risk, situations that might not otherwise occur over the course of their training. When employed properly, simulation-based training allows the opportunity to learn new skills, engage in deliberate evidence-based practice, and receive focused and real-time feedback."[24] Moreover, simulations can increase physician competency, help programs meet ACGME Residency Review Committee (RRC) requirements, and can be altered to meet the varying needs of both rural and urban health care facilities.[25]

Within obstetrics, it has been shown that simulations can improve the "composite maternal morbidity rate, decrease the number of massive transfusions and improve management, with a decreased length of stay" in the hospital.[26] This is because "[r]eal-time simulation provides training for low-probability but high-

[22] https://ruralhospitals.chqpr.org/downloads/Rural_Maternity_Care_Crisis.pdf.
[23] https://saferbirth.org/wp-content/uploads/FINAL_AIM_ObstetricInSituDrill-ProgramManual-2.pdf.
[24] https://psnet.ahrq.gov/primer/simulation-training#:~:text=Simulation%20offers%20a%20way%20for,the%20course%20of%20their%20training.
[25] https://www.ruralhealthinfo.org/topics/workforce-education-and-training#simulation.
[26] https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17640.

risk events often associated with maternal deaths."[27] It is therefore important to provide simulation training for physicians and their teams who care for pregnant, birthing, and postpartum individuals. For instance, one area where simulation can significantly impact maternal care is implementation of physician-led team-based "training simulations [that] facilitate interprofessional communication and teamwork in obstetrical emergencies. For example, scheduled multidisciplinary postpartum hemorrhage simulations at Parkland Health in Dallas, Texas, were associated with faster times for medication and blood transfusion administration as well as a decreased estimated blood loss after delivery."[28] Therefore, to help build up the education of OBGYN residents and physicians, ACOG "formed a Working Group of state-of-the-art simulation centers, with the goal of developing and validating a variety of Obstetrics and Gynecologic simulation-based curricula."[29]

The ACOG Simulations Working Group[30] has already created multiple simulation resources including obstetric surgical skills, emergencies in clinical obstetrics, uterine atony, and cerclage.[31] Moreover, the Alliance for Innovation on Maternal Health (AIM) has created simulations and drills for patient safety.[32] Additionally, to make simulation training the best it can be, case examples from the community that the physicians serve in should be used in the simulation training so that the physicians can better understand and be integrated into the care.

We recognize that the cost of implementing simulations is always a concern, especially for smaller practices, practices in underserved areas, and rural practices. However, it is vital that **funding be provided for consistent, up to date, holistic simulations that can improve maternal health. Moreover, these simulations should be available for every physician who engages in maternal care including OBGYNs, maternal-fetal medicine specialists, family physicians, and emergency medicine physicians.**

Ensuring that More Physicians Know How to Provide Maternal Care

It is important to ensure that we have enough OBGYNs and maternal-fetal medicine physicians. However, patients may seek obstetric care in a number of non-obstetric settings "including EMS/911, hospital-based emergency departments, standalone emergency rooms, or urgent care facilities."[33] Therefore, it is important to ensure that the larger physician workforce, especially those physicians who are often required to provide prenatal and postpartum care, are trained and prepared to provide this medical care. For example, "[w]omen often see their primary care physicians for common acute conditions during pregnancy, even if they are not the primary maternity care clinician."[34] Moreover, "[f]amily medicine physicians have a prominent role in delivery of women's health services, particularly in rural areas…. Given their broad skill set, family medicine physicians are especially well-suited to provide prenatal care and to attend births in sparsely populated settings because they can attend to the totality of the family's needs."[35] Furthermore, Emergency Department use in pregnancy is common.[36]

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[27] https://www.contemporaryobgyn.net/view/how-can-we-prevent-pregnancy-related-deaths-.
[28] https://www.contemporaryobgyn.net/view/how-can-we-prevent-pregnancy-related-deaths-.
[29] https://www.acog.org/education-and-events/simulations/about.
[30] https://www.acog.org/education-and-events/simulations/about/curriculum.
[31] https://www.acog.org/education-and-events/education-search#q=simulations%20working%20group.
[32] https://saferbirth.org/aim-resources/aim-cornerstones/simulations/.
[33] https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.
[34] https://www.aafp.org/pubs/afp/issues/2018/1101/p595.html.
[35] https://fdslive.oup.com/www.oup.com/academic/pdf/openaccess/9780197662984.pdf.
[36] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5290191/.

"The proportion of pregnancy-associated emergency department visits among reproductive-age women is increasing, as are inpatient admissions from the emergency department for pregnancy-associated diagnoses."[37] Therefore, **it is important to expand maternal care education and training especially to non-obstetrics providers, including family medicine and emergency medicine physicians, to ensure they can diagnose, manage, and treat pregnant and postpartum patients.**

To help aid in the education and training of non-obstetrics providers, fellowship programs recognized by the Board of Certification in Family Medicine Obstetrics, have been designed to train family medicine physicians, often practicing in rural or otherwise medically underserved settings, to provide basic obstetrics care including antepartum, delivery, and postpartum care.[38] Additionally, in the past 10 years, emergency obstetrics training programs have been developed to provide emergency medicine physicians with the skills necessary to recognize and manage obstetric emergencies, including uncomplicated and complicated vaginal deliveries, eclampsia, and postpartum hemorrhage.[39]

Furthermore, to help physicians who do not have obstetrical training address obstetric emergencies, ACOG developed resources concerning the appropriate administration of care for pregnant, birthing, and postpartum patients. These resources include materials to help physicians identify and manage pregnancy-related emergencies in non-obstetric settings such as emergency departments, emergency medical services (EMS), and urgent care. Some examples of these resources are the Cardiovascular Disease in Pregnancy and Postpartum Algorithm, an Acute Hypertension in Pregnancy and Postpartum Algorithm, an Eclampsia Algorithm and more.[40,41]

In maternity care deserts where pregnant and postpartum patients may not have access to OBGYNs, it is important to equip all physicians with the skills necessary to recognize and treat obstetric emergencies. As such, **the resources developed by ACOG, and resources that are similar to these, should be widely disseminated and additional resources of this kind should be created to help increase non-obstetricians' knowledge surrounding maternity care.**

Teleconsultation

In many rural and underserved areas that lack regular and reliable access to physician specialists and subspecialists, such as maternal-fetal medicine physicians and fetal cardiologists, primary care physicians routinely manage pregnancy care. These primary care providers need access to specialist consultations to help address complex clinical challenges that may arise over the course of pregnancy or delivery. One way to support multidisciplinary peer collaboration is through a telehealth hub-and-spoke model in which one large "hub" hospital provides additional support and training for smaller "spoke" facilities.[42] This model, introduced through Project ECHO, enables physicians in rural areas to connect with specialists in facilities with capacity to provide higher levels of maternal care via telehealth. Evaluations of these programs show that remote consults are generally feasible, acceptable to patients, and can save patients time and money on travel. Telemedicine may also increase access to specialty care for patients who may otherwise forgo this care due to lack of availability in their communities. Having specialists accessible via telemedicine may also encourage local providers to maintain care of their high-risk patients and safely

[37] https://pubmed.ncbi.nlm.nih.gov/37790954/.
[38] https://www.abpsus.org/family-medicine-obstetrics-fellowship-programs/.
[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6440410/.
[40] https://www.acog.org/programs/obstetric-emergencies-in-nonobstetric-settings.
[41] https://saferbirth.org/wp-content/uploads/FINAL_AIM_OERRK.pdf.
[42] https://www.ruralhealthinfo.org/toolkits/telehealth/2/care-delivery/specialty-care.

facilitate more deliveries in nearby hospitals.[43] These models should continue to be supported to enable patients to access higher levels and more specialized care without having to leave their communities.

Should such additional staff training include separate training on methods for providing respectful care for pregnant, birthing, and postpartum patients in an effort to improve maternal health outcomes? Should staff also be trained on implicit bias, trauma-informed care, or other specific training topics aimed at addressing bias and reducing disparities in maternity care?

Narratives from the experiences of Black women indicate a rupture of trust between Black women and the health care system that must be repaired.[44] As Black Mamas Matter Alliance, Inc. asserts, "Care partnership—where Black female patients plan for their care alongside their provider—is the only way forward."[45] Similarly, AIM safety bundles, and others, recommend that educating clinicians and staff about racial and ethnic disparities in maternal outcomes, and emphasizing the importance of shared decision making, cultural competency and humility, implicit bias, and enhanced communication skills are important steps to rebuild trust and eliminate disparities in maternal health care.[46]

The AMA agrees and provides educational resources for physicians with focuses on pregnancy[47] maternal mortality and morbidity[48] and more. In addition, the AMA Ed Hub™ Health Equity Education Center continues to publish continuing medical education (CME) and other educational activities aimed at addressing the root causes of inequities, including racism and other structural determinants of health.[49] These educational activities will equip physicians and other learners with core health equity concepts needed to support them as they continue to take action and confront health injustice.

Should additional staff training include separate training on the screening, assessment, treatment, and referral for maternal depression and related behavioral health disorders by staff?

The AMA, along with the American Academy of Pediatrics, the American College of Physicians, the American Osteopathic Association, the American Psychiatric Association, the American Academy of Family Physicians, the American Academy of Child & Adolescent Psychiatry, and ACOG, recently created a Behavioral Health Integration (BHI) Compendium as a tool for physicians and their practices to learn about, implement, and ultimately sustain BHI in order to achieve the goal of enabling timely access to optimal, equitable whole-person care. The Compendium includes an important and informative chapter (Assembling and Aligning the Team) on the appropriate roles and responsibilities of the physician and other key members of the care team when providing behavioral health treatment.[50] We have also recently hosted a webinar on behavioral health screening which includes an important discussion about what this should look like in the OB setting.[51] Additionally, our BHI Workflow Guide has important information

[43] https://www.kff.org/womens-health-policy/issue-brief/telemedicine-and-pregnancy-care/.
[44] https://docs.house.gov/meetings/WM/WM00/20190516/109496/HHRG-116-WM00-Wstate-HarrisP-20190516.pdf.
[45] https://blackmamasmatter.org/wp-content/uploads/2018/04/BMMA_BlackPaper_April-2018.pdf.
[46] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/.
[47] https://edhub.ama-assn.org/collections/5864/pregnancy?hd=edhub&f_SiteID=&fl_Categories=Pregnancy&page=2.
[48] https://edhub.ama-assn.org/searchresults?hd=edhub&q=maternal&f_SiteID=&&SearchSourceType=1&exPrm_qqq={DEFAULT_BOOST_FUNCTION}%22maternal%22&exPrm_hl.q=maternal&fl_IsDataSupplement=false.
[49] https://edhub.ama-assn.org/health-equity-ed-center.
[50] https://www.ama-assn.org/system/files/bhi-compendium.pdf.
[51] https://www.ama-assn.org/about/events/behavioral-health-screening-part-ongoing-care.

about best practices for implementing effective behavioral health care.[52] Based on the AMA's experience developing these resources in collaboration with several of the nation's leading physician organizations, we wish to emphasize that training is not enough. It is imperative that any corresponding administrative requirements for physicians are not burdensome, and that appropriate coverage and payment is provided for all the related services in this space including screening and treatment.

Care for Pregnant and Postpartum People with Substance Use Disorder (SUD)

Among pregnant and postpartum persons, drug overdose mortality increased approximately 81 percent from 2017 to 2020, mirroring trends observed among persons of reproductive age overall.[53] Pre-adolescent females and women who died from a drug overdose during pregnancy, compared to those who died from obstetric causes, were more likely to be aged 10 to 34, be non-college graduates, be unmarried, and die in "non-home, non-health care settings."[54]From 2018 to 2021, the mortality ratio more than tripled among pregnant and postpartum women aged 35 to 44 years.[55]

There are many evidence-based programs and other efforts underway in the states to extend Medicaid and CHIP coverage to pregnant people. **The AMA urges the Administration to highlight those efforts and encourage states to build on evidence-based practices to improve care, reduce inequities and support pregnant people, their newborns, and families. This includes support for removing harmful policies that stigmatize and punish pregnant and postpartum individuals who receive medications for opioid use disorder (MOUD).** MOUD is recognized as part of the standard of care for treating pregnant individuals with an opioid use disorder (OUD). Too many pregnant people, however, fear prosecution for taking MOUD as well as threats to being able to keep their newborn if taking MOUD through a pregnancy or postpartum period.[56] The AMA appreciates the efforts of CDC, SAMHSA, ONDCP, NIDA and other agencies that highlight the benefits of MOUD during pregnancy, and the AMA would be pleased to work with CMS to further emphasize the medical and public health benefits.

Correctional facilities and judicially supervised diversion programs should provide all justice-involved people, including pregnant and postpartum individuals, with access to FDA-approved MOUD and universal screening for SUD. Rates of SUD and OUD among incarcerated individuals are disproportionately high; the DOJ estimates that more than half of those incarcerated in state prisons and jails meet the criteria for an SUD, compared to one in 20 people in the general population.[57] Despite DOJ guidance that denial of MOUD in jails and prisons violates the Americans with Disabilities Act, and federal court decisions protecting the right to receive MOUD in carceral settings, jails and prisons still provide far less access to MOUD than do community providers.[58] It is contrary to all medical evidence to

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[52] https://www.ama-assn.org/system/files/bhi-workflow-how-to-guide.pdf.
[53] https://jamanetwork.com/journals/jama/fullarticle/2799164.
[54] https://www.nih.gov/news-events/news-releases/overdose-deaths-increased-pregnant-postpartum-women-early-2018-late-2021.
[55] https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2811811.
[56] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7945667/.
[57] Bronson J, Stroop J, Zimmer S, Berzofsky M. Department of Justice Office of Justice Programs, Bureau of Justice Statistics Special Report. Drug Use, Dependence, and Abuse Among State Prisoners and Jail Inmates, 2007-2009 Revised August 10, 2020.
[58] Justice Department Issues Guidance on Protections for People with opioid Use Disorder under the Americans with Disabilities Act. U.S. Department of Justice Civil Right Division. April 5, 2022. Available at https://www.justice.gov/opa/ pr/justice-department-issues-guidance-protections-people-opioid-use-disorder-under-americans; the full guidance, "The Americans with Disabilities Act and the Opioid Crisis: Combating Discrimination Against People in Treatment or Recovery," is available at

force individuals to undergo discontinuation or abrupt cessation of MOUD, leading to withdrawal, which is associated with both physical and psychological harm. **The AMA encourages the Administration to help ensure pregnant people in jails and prisons have access to their rights under the law, including access to MOUD during pregnancy and postpartum periods.**[59]

The AMA commends the Administration for creating a pathway for states to use Section 1115 Medicaid demonstrations to provide Medicaid financed pre-release services in state or local correctional facilities to support reentry to the community. This type of flexibility allows states to design state-specific, justice-involved reentry demonstrations for Medicaid-eligible individuals, including prerelease case management services, MOUD; and a 30-day supply of all prescription medications at the point of release. **The AMA also supports the ability of states to provide family planning services, rehabilitative or preventive services, screening for chronic conditions that are likely to impact the carceral population (i.e., hypertension, diabetes, hepatitis C or HIV), treatment for hepatitis C, and durable medical equipment.** As of December 2023, both California and Washington have secured approval from CMS to provide reentry services to justice-involved populations, and 15 other states have submitted reentry demonstration requests. This is the type of state-federal partnership that helps improve care for pregnant people and their families. We urge the Administration to work with all states to support these beneficial initiatives.

The AMA also recommends that the Administration implement the recommendations of the HHS Interagency Pain Management Best Practices Task Force, which highlighted pregnant women as a special population.[60] The Task Force report recommended more research and innovation to address pain management in peripartum women, and that women of childbearing age be counseled on the risks of opioids and non-opioid medications in pregnancy, including balancing the risks and benefits to the pregnant person, fetus and newborn. The AMA cautions, however, that pregnancy is not a reason to avoid evidence-based treatment for pain. To help guide policymakers, the AMA relies on guidance from professional medical associations, including ACOG, American Academy of Family Physicians, American Academy of Pediatrics and American Society of Addiction Medicine. At their core, each of these societies highlight the need for individualized patient care decisions made between the physician and patient—a guiding principle the AMA strongly supports.

How could CMS help improve data collection related to maternal morbidity and mortality across all demographics?

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https://archive.ada.gov/opioid_guidance.pdf; See, Smith v. Aroostook County. U.S. Court of Appeals. First Circuit. No. 19-1340. Ms. Smith was to be denied continuing to receive buprenorphine while incarcerated. On appeal, the court affirmed the District Court decision requiring the jail to ensure Ms. Smith's access to buprenorphine.

[59] The AMA recently issued a comprehensive set of recommendations to enhance access to care for individuals with an opioid use disorder who are pregnant or postpartum. "Improving Access to Care for Pregnant and Postpartum People with an Opioid Use Disorder: Recommendations for Policymakers" is available here: https://end-overdose-epidemic.org/wp-content/uploads/2024/02/AMA-Manatt-2024-Improving-Access-to-Care-Pregnant-Parenting-People-with-SUD.pdf

[60] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/sites/default/files/pain-mgmt-best-practices-draft-final-report-05062019.pdf.

The AMA strongly supports increased accuracy in maternal health data across the spectrum. However, our support for additional data does not mean that we support a COP in this space. With this being noted, i**t is essential that maternal mortality and maternal morbidity have a standard definition across all federal, state, local, and private organizations** so that data from every source can be combined, and a more complete picture of maternal health can be discovered. However, currently there is not a set definition for maternal morbidity, severe maternal morbidity, or maternal mortality/death.
Please see the chart below for examples of some of the various definitions that exist for maternal morbidity, severe maternal morbidity, and maternal mortality:

Organization	Maternal Morbidity Definition	Severe Maternal Morbidity (SMM) Definition	Maternal Mortality/Death Definition
U.S. Centers for Disease Control and Prevention (CDC) Pregnancy Mortality Surveillance System (PMSS)		The unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.	The death of a woman while pregnant or within 1 year of the end of a pregnancy regardless of the outcome, duration, or site of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.
CDC's National Center for Health Statistics' National Vital Statistics System (NVSS)		Serious complications of delivery that result in short- or long-term consequences to a patient's health.	A death while pregnant or within 42 days of the end of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.
National Institutes of Health (NIH)	Any short- or long-term health problems that result from being pregnant and giving birth.	Life-threatening health problems that are present at delivery.	The death of a woman from complications of pregnancy or childbirth that occur during the pregnancy or within six weeks after the pregnancy ends.
World Health Organization	Any health condition attributed to or complicating pregnancy, childbirth or following pregnancy that has a negative impact on the woman's well-being or functioning.	A maternal near miss – a woman who nearly died but survived a complication that occurred during pregnancy, childbirth, or within 42 days of termination of pregnancy.	The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from unintentional or incidental causes.
Nebraska Department of Health and Human Services		Significant negative health consequences of labor and delivery. SMM includes unexpected outcomes of labor and delivery that result in significant short-or long-term consequences to a woman's health.	A pregnancy-associated death is the death of a person within one year of the end of a pregnancy from any cause. Pregnancy-associated deaths represent the broadest category of maternal deaths and can be broken down further into two main categories: pregnancy-related deaths and deaths unrelated to pregnancy. A pregnancy-related death is a maternal death due to a pregnancy complication. More specifically, these deaths occur during pregnancy or within a year of the end of a pregnancy and are due to a chain of events initiated by the pregnancy or the

			aggravation of an unrelated condition by the physiologic effects of pregnancy.
Minnesota Department of Health		"A near miss," such as injuries or incidents related to pregnancy or childbirth that did not result in death.	A death during or within one year of pregnancy, from a pregnancy complication, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy.
New Jersey Department of Health		Unexpected outcomes of labor and delivery that result in significant short- or long-term consequences to a woman's health.	Deaths from any cause related to or aggravated by pregnancy or its management (excluding accidental or incidental causes) during pregnancy and childbirth or within 365 days of termination of pregnancy, irrespective of the duration and site of the pregnancy.

As shown above, the definitions in the maternal health space vary quite dramatically. For example, the definition of maternal mortality ranges from a death occurring from one year post-delivery all the way down to a mere six weeks post-delivery.

Without one standard definition, it is difficult for data from different sources to be compiled and universally applied. As such, to ensure a complete and thorough review of maternal health data, the **definition of maternal mortality should be standardized.**

Moreover, as noted above in the chart, some entities do not have a definition, or do not have an easily identifiable definition, for maternal morbidity. It is important to ensure that there is a set definition for this term since it is commonly used within the maternal health space and, if properly defined, could provide better early indicators for individuals that need additional maternal care. To help and create a universal definition for maternal morbidity, it could be beneficial to develop a definition similar to that used by the CDC for severe maternal morbidity.

Data Standardization and the United States Core Data for Interoperability (USCDI)

Additional resources should be used to standardize the maternal health data that is captured for comparative analysis within the USCDI. Therefore, to strengthen the collection of maternal mortality and maternal morbidity data, **additional data capture points should be added to the USCDI that further incorporate maternal morbidity, severe maternal morbidity, and maternal mortality information.**

Data Governance and Privacy

Prior to initiating a data collection effort or expanding the type of data collected, **an entity must first evaluate if the necessary technical, governance, and legal protections are in place to maintain an individual's privacy and trust**. Without guardrails in place, the misuse of data could further disparities and decrease individuals' confidence in government data collection efforts. Therefore, in efforts to promote maternal health care, **the Administration must consider what steps it can take to reassure individuals that their personal information, including maternal and infant health information, remains private and secure**. Moreover, **any efforts to increase maternity health information exchange should ensure patient data are protected, safe, and secure**.

V. Distribution of GME residency slots under section 4122 of the Consolidated Appropriations Act (CAA), 2023

Pro Rata Distribution and Limitation on Individual Hospitals

The CAA, 2023 requires the distribution of 200 additional residency slots hospitals. Of these 200 slots, 100 of these slots must be distributed to psychiatry or psychiatry subspeciality residency training programs. As such, the IPPS is proposing refinement and initiation of the guidelines by which these slots will be distributed.

As part of this distribution process, the Administration has proposed that each qualifying hospital that submits a timely application will receive at least a fraction of 1 of the positions made available before any qualifying hospital receives more than 1 new slot, with the distribution of these slots being prorated. The pro-rata distribution would award up to 1.0 full-time equivalent (FTE) resident cap slots to qualifying hospitals and distribute any remainder of slots to hospitals based the HPSA scores of the pool of applying hospitals. If slots remain, CMS will award slots to hospitals with the next highest HPSA score until all remaining slots are awarded.

In the proposed distribution for Section 126 slots, CMS attempted to award slots in a similar manner, limiting the award to each qualifying hospital to 1.0 FTE.[61] There was consensus from the GME community that the 1.0 limitation on awards would not be a meaningful increase for institutions. Additionally, because of the longitudinal requirement to train residents over the course of several years, the limitation to 1.0 FTE limits the development of a full complement in subsequent postgraduate years. Ultimately, this policy would require hospitals awarded a pro-rata distribution of 1.0 FTE under this section to self-fund full complement increases beyond the 1.0 FTE awarded.

Additionally, HPSA prioritization is not the right mechanism with which to determine the distribution of slots in this case because "HPSA scores speak to the need for more practitioners in a given [region] but do not speak to the ability of the hospitals in those states to train more residents or to provide care for patients who live in HPSAs."[62] Over the last two distribution cycles teaching hospitals that are adjacent to HPSAs, and serve individuals that live in HPSAs, have not been able to benefit from these additional slots despite the fact that they are some of the main physicians caring for this underserved population.

CMS has also provided an alternative distribution proposal under which CMS would award .01 FTE to each qualifying hospital that applies, and if slots remain, will distribute the rest based on Section 126 HPSA prioritization. With significant projected physician workforce shortages, it would be ill-advised to award fractions of FTEs that will diminish the substantive distribution of slots to hospitals.[63] The statutory language under 1886(h)(10)(C)(ii) states that hospitals awarded slots under Section 4122 agree "to increase the total number of full-time equivalent residency positions under the approved medical residency training program of such hospital by the number of such positions made available by such

[61] In the FY 2022 IPPS proposed rule, CMS stated that "…we are proposing to limit the increase in the number of residency positions made available to each individual hospital to no more than 1.0 FTE each year." After reviewing comments from stakeholders, CMS chose not to finalize this policy. 86 FR 25508.

[62] Association of American Medical Colleges, *Medicare Inpatient Prospective Payment System Fiscal Year 2022 Proposed Rule*, June 28, 2021.

[63] The Complexities of Physician Supply and Demand: Projections From 2021 to 2036, Association of American Medical Colleges, March 2024.

increase under this paragraph." As such, hospitals could be obligated to demonstrate an increase in the applying program resident FTE count consistent with an award.

As such, the AMA requests that CMS provide a minimum of 1.0 FTE and prioritize those hospitals that meet all four qualifying criteria first, and then hospitals that meet three criteria, and so on until all the available slots are distributed.

Proposed Modifications to the Criteria for New Residency Programs and Requests for Information

CMS is proposing to establish rules for the direct GME cap, and IME adjustment, calculation for a hospital that begins training residents in a new medical residency training program. A new medical residency training program is currently defined as "a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995." Additionally, for a program to be considered a "new" program for which new cap slots would be created, a previously non-teaching hospital would have to ensure that the program meets three primary criteria: the residents are new, the program director is new, and the teaching staff are new.

The stakes for new teaching hospitals and hospitals that start new programs eligible to receive FTE cap adjustments are incredibly high. The cost of developing new programs is completely assumed by the institutions; the Medicare program does not reimburse hospitals for these start-up costs, and hospitals do not receive reimbursement until residents rotate to the hospital.[64] Moreover, the cost of developing new programs or becoming a new teaching hospital is significant, and as such, a considerable amount of resources are put into the development of new programs.[65] Most new teaching hospitals rely on Medicare funding to help offset the substantial costs associated with training residents. However, if a program receives a determination that it is not new, the hospital may not count the resident FTEs participating in that program towards establishing its FTE caps.

To determine if the residents are new CMS is proposing to require at least 90 percent of the residents training in the new program during the five-year cap building timeframe to not have previously trained in the same specialty. Due to the considerable time and resources it takes to build up a residency training program, **CMS should give programs the presumption of newness if they can demonstrate that at least 90 percent of trainees do not have previous experience in the new program specialty, and for those programs that do not meet the 90 percent threshold hospitals should be granted the ability to prove that they have "new" residents through other factors** that have been highlighted by the Association of American Medical Colleges (AAMC) including a program letter of accreditation, a reduced 50 percent "newness of residents" for small programs, no overlap between program director, administrative staff, and the residents in a prior program and other factors. Moreover, CMS should also accept certain mitigating factors when a hospital does not meet the 90 percent threshold, such as limitations due to program size, or matched residents who did not disclose prior training experiences.

CMS is also looking to determine the newness of faculty and program directors. CMS has stated that the percentage of faculty with no previous experience teaching in a program in the same specialty should probably be less than 90 percent. CMS is also proposing that up to 50 percent of the teaching staff in a

[64] Physician Workforce Caps on Medicare-Funded Graduate Medical Education at Teaching Hospitals, Government Accountability Office Report to Congress, May 2021.

[65] *Id*. The Government Accountability Office (GAO) found that "[h]ospitals starting their first GME training program spend an estimated $2 million to $8 million over 3 to 7 years to establish GME programs, according to information from hospital representatives."

new program may come from a previously existing program in the same specialty, but that each of these experienced staff members should come from different previously existing programs. CMS did mention a potential exception for individuals that have had a certain amount of time pass since they, as experienced staff, have taught in a program in the same specialty.

Policy that restricts the prior experience of faculty members removes the ability for residency teaching programs to select the best candidates to lead and shape these newly created programs. In some instances, especially for those programs outside of major metropolitan areas or those with highly specialized programs, there are a limited number of qualified physicians able to participate as staff or directors. AAMC shared with us that they reached out to their members to discuss this requirement and their members emphasized that holding a program director or faculty member position requires a commitment to continuous learning and professional development. As such, requiring program directors or faculty to spend a certain amount of time away from one program before they can be considered new by CMS means that those physicians are likely less qualified to hold a faculty position than someone who has continually worked with a residency training program. Therefore, **time away from a program is an unnecessary requirement** when prior experience is not determinative that a program has been transferred.

Moreover, **the proposed faculty newness requirement is likely to negatively impact the recruitment and quality of both large urban programs and smaller rural programs.** Several members of larger academic health systems have highlighted a scenario in which the system and associated medical school(s) have partnered with a new non-teaching hospital. These established health systems have well-qualified faculty that could participate in the development of a new residency program, but the rules as proposed would mean those faculty members jeopardize the program's newness. Furthermore, a small, rural-focused academic health system expressed the same concern, due to a shortage of available faculty. The physicians available in a rural area that are willing to participate in graduate medical education training are already doing so, as faculty in established programs. Though there are non-teaching hospitals in the region that could expand training, it would not be possible if they had to meet CMS' proposed definition for new faculty and new program director.

Furthermore, it is concerning that CMS is proposing a policy that would require hospitals to hire program directors or faculty members who lack previous experience in those roles. The prime concern for new programs is maintaining accreditation. That means meeting Accreditation Council for Graduate Medical Education (ACGME) requirements for faculty education, experience level, board certifications, etc. The ACGME requirements in this space set the appropriate standards and qualifications for these roles. These requirements are in place to protect learners and ensure the educational mission of the training program. As such, CMS is proposing a policy that unnecessarily limits the choice of leadership and teaching faculty for newly developed residency programs. Additionally, the currently proposed definition by CMS of newness, meaning no previous experience as a program director, does not align with past interpretations of newness in this space nor does it lend itself to the best outcome for the success of these new programs. Instead, the determining factor should continue to be whether or not the "new" program was part of any existing hospital's FTE cap determination. As such, **the AMA suggests refinement of this policy to allow teaching hospitals the flexibility to hire the faculty and program directors that will best ensure the success of the new program and the new residents.**

<u>Medicare Advantage Nursing and Allied Health Education Payments</u>

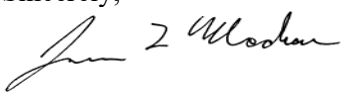
CMS is providing notification of the proposed rate reduction to GME to provide payment for nursing and allied health education programs. Per the reasonable cost payment methodology, a hospital is paid

Medicare's share of its reasonable costs for GME related expenses including Medicare Advantage (MA) utilization for nursing and allied health education payments. These MA utilization payments for nursing and allied health professionals are funded through a reduction in payments made to teaching hospitals for direct GME (DGME) and are supposed to be capped at $60 million per year.

This year, the percent reduction to MA DGME payments, based on CY 20203, is set to be 2.73 percent. The AMA believes that no money should be siphoned away from DGME funding to pay for nonphysician training. The $60 million that is taken away from DGME funding every year results in significantly fewer physicians being trained each year. Though we appreciate the role that nonphysician providers play, they should have their own funding source separate from GME funding.

Thank you for the opportunity to provide our comments. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org.

Sincerely,



James L. Madara, MD