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: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation. (CMS–1771–P; 87 Fed. Reg. 28108, May 10, 2022)

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 2023 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System (LTCH PPS). Our detailed comments are below.

In summary:

- The AMA recognizes that racial and ethnic health disparities are a major public health problem in the United States and act as a barrier to effective medical diagnosis and treatment. The AMA also recognizes that achieving health equity, defined as optimal health for all, is a vital need and one which will be greatly aided by engaged hospital systems.
- The AMA urges CMS to consider the risk/benefits of the Hospital Commitment to Health Equity measure and how it may burden systems that are under-resourced. The AMA also urges CMS to consider the number of items it is requiring to achieve a maximum score, especially if CMS desires meaningful outcomes.
- The AMA would like to contribute our expertise to the development phase and be included in further implementation of the "birthing-friendly" designation for the Maternal Morbidity Structural measure.
- The AMA believes there may be value in the creation of Conditions of Participation (CoPs) specifically for labor and delivery and recommends that CMS explore options with relevant stakeholders to establish such conditions for participating hospitals.

- The AMA urges CMS to consider the potential harm to the patient-physician relationship when incentivizing data collection by health systems; we cannot allow the ostensibly good intentions of data collection to override our responsibilities to maintain patient trust.
- The AMA applauds CMS for the Medicare Graduate Medical Education (GME) Affiliation Agreements and Rural Training Tracks proposals and supports CMS reassessing this proposed policy in the future once Full-time Equivalent (FTE) caps for the Consolidated Appropriations Act (CAA, 2021) rural training programs (RTPs) are set.
- The AMA strongly urges CMS to take a wait-and-see approach prior to considering any Trusted Exchange Framework and Common Agreement (TEFCA) requirements within its Performance Improvement Project (PIP). Positive incentives, such as optional PIP measures, should be utilized for several years. CMS should make informed decisions based on data prior to any TEFCA PIP measure or objective requirement proposals.
- The AMA reiterates our support for positive incentives to assist in better integrating prescription drug monitoring programs (PDMP) into physicians' electronic health records (EHR). However, the evidence is clear that requiring physicians to check a PDMP ignores the inadequacies of PDMPs and will likely increase the level of stigma and exacerbate longstanding health inequities.
- The AMA urges CMS to refrain from imposing progression requirements on hospitals until it has a clear and informed understanding of the public health agency (PHA) or clinical data registry (CDR) landscape, hospital needs, and barriers that must be overcome.

Please see our detailed comments below on the following topics:

I. Hospital Inpatient Quality Reporting (IQR) Program Measure Set

a. New Measure Proposals: Hospital Commitment 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. As such, CMS is proposing to adopt an attestation-based structural measure entitled Hospital Commitment to Health Equity. This measure will assess five domains with the goal of achieving health equity for racial and ethnic minority groups, people with disabilities,

members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. The five domains include:

- Equity is a Strategic Priority;
- Data Collection;
- Data Analysis;
- Quality Improvement; and
- Leadership Engagement.

For a hospital to affirmatively attest to a domain, and receive credit for that domain, the hospital would need to evaluate and determine whether it engages in each of the elements that comprise the domain. CMS is proposing that each of the domains be represented in the denominator as a point, for a total of five points.

The AMA recognizes that achieving health equity, defined as optimal health for all, is a vital need and one which will be greatly aided by engaged hospital systems. Although we support the need for hospital leadership to commit to collecting health equity performance data and to influence a culture of equity, the AMA is concerned with the one size fits all approach CMS is taking with the structure and implementation of the measure. **The AMA urges CMS to consider the risk/benefits of this model and how this measure may burden systems that are under-resourced. We also urge CMS to reconsider the amount of items required to achieve a maximum score, especially if CMS desires meaningful outcomes.**

If CMS does move forward with the measure, we recommend CMS refine the measure to allow more flexibility in their implementation. As organizations begin to build out their health equity strategy, the AMA recommends and encourages the opportunity for hospitals to take a more measured/modest approach and expand after the hospital system can demonstrate improved outcomes, or at least provide a trial period where the outcomes are not "counted" so both the hospital and CMS can judge how the different measures and hospital perform. For instance, the first few years a hospital would prioritize 2-3 domains with the goal in several years to positively attest to all five domains. Additionally, we encourage CMS to provide resources/technical assistance to support each activity with priority given to safety net facilities.

Although quality improvement (QI) activities are important, the attestation element in Domain 4 (hospital participation in local, regional, or national activities) appears resource intensive, especially for under-resourced hospitals. Therefore, **we recommend the required element focus either on attesting equity is embedded in the hospital's QI processes and workflows and/or attest to having initiatives focused on addressing an inequity they have identified in their data analysis**. Participation in local, regional, or national QI activities should be optional. If this aspect is required, then supplemental resources should be provided to safety net facilities to participate.

We are also disappointed with the lack of consideration and the need for training and education on how to implement and structure a program regarding leadership engagement in improving health equity. For example, under leadership engagement (Domain 5), if senior leaders and the board of trustees do not understand the foundations of health equity and the impact of social and structural drivers of health, they will not know what to look for or how to advance the culture of equity when they review the strategic plan and KPIs, which could potentially lead to the unintended consequence of developing a new inequity.

Furthermore, Domain 2 (Data Collection) is a duplicative requirement of CMS' considerations to require hospitals to document Social Determinants of Health (SDOH) related ICD-10 Z codes and two social screening measures. If CMS moves forward with the Z codes and social screening quality measures, there is no need to attest to data collection and analysis. **However, the AMA reiterates our lack of support for the two social screening measures given the design of the measures and the lack of adequate specification and testing and would prefer the attestation-based data collection approach**.

Lastly, Domain 3 (Data Analysis) is a duplicative requirement of hospitals given that the Hospital Readmission Reduction Program (HRRP) provides hospitals with risk-stratified reports and are currently scored within one of five peer groups based on their proportion of dually eligible beneficiaries. It will be further duplicative if CMS moves forward with its proposals for updating the HRRP to better incorporate hospital performance based on social risk factors of patients.

b. Proposed Establishment of a Publicly Reported Hospital Designation to Capture the Quality and Safety of Maternity Care

CMS is proposing to establish a hospital quality designation of "birthing-friendly" that would be publicly reported on a CMS website beginning in Fall 2023. The designation of "birthing-friendly" would be awarded to hospitals based on them reporting that they participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery, and post-partum care; and that they have implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis. If both criteria are met, per reporting on the Maternal Morbidity Structural measure under the Hospital IQR Program, the hospital or hospital system would be designated as "birthing-friendly."

The AMA supports CMS' efforts to address inequity and decrease maternal morbidity and mortality but question whether this additional designation contributes to informing patients and family members beyond what is currently available and reported on Care Compare. While the initial designation would be straightforward since it is based solely on the current structural measure, it is not clear how future iterations would be used to determine whether a hospital earned the designation and how patients will understand the difference between this status and the star rating a hospital receives.

Furthermore, the designation "birthing-friendly" will likely elicit a certain reaction in patients and expecting mothers and the AMA believes that if this designation is implemented it will be extremely important to increase patient understanding around this term so that patients are not deterred from going to hospitals closer to their residence where they could receive care. This may be especially true in rural parts of the United States where there may be a limited number of obstetricians or maternal-fetal medicine specialists. In any iteration that may include additional designations, it should be ensured that the public understands the levels are not in themselves a designation of quality maternity care, but rather a stratification of services by maternal health complexity. **CMS and the AMA should engage in further conversations regarding the potential maternity care quality improvement activities within the IQR and Hospital Compare programs.**

It appears that CMS is interested in expanding the potential set of measures that would be used to create this designation. This raises additional questions including: would any additional measure be submitted through the Measures Under Consideration process and be required to meet the minimum set of criteria for consideration in a CMS quality program? These additional questions and concerns must be addressed before moving forward with any new program or classification.

c. Solicitation of Comments on Designation Name and Additional Data Sources to Consider for Purposes of Awarding this Publicly Reported Hospital Designation

CMS intends to continue to designate "birthing-friendly" hospitals and hospital systems based initially on data collected on the Maternal Morbidity Structural measure. However, CMS would like to expand the criteria it uses to award this designation so that it more comprehensively captures the quality and safety of the maternity care delivered by hospitals. As such, CMS is considering a number of different measures including quality measurement data sources, relevant patient experience measures, patient experience measures that are currently in use in care settings, patient experience measures that have been developed but require additional testing in pilot settings, and other measures of patient experience that would be appropriate for inclusion to develop new criteria.

The AMA understands the importance of decreasing maternal mortality and morbidity. The United States has the highest maternal mortality rate among developed countries, and according to the Centers for Disease Control and Prevention (CDC), 60 percent or more of these maternal deaths are preventable.[1] Furthermore, CDC data shows that Black and Indigenous women are three to four times more likely to die from pregnancy-related causes than White women.[2] Approximately 700 women in the United States die annually as a result of pregnancy or related complications. As such, the AMA understands the importance of increasing access to maternal care. **However, we are concerned about how this standard will be implemented in the future. As this standard continues to develop, the AMA would like to lend our expertise to the development phase and would like to be included in the further implementation of the "birthing-friendly" designation**.

For example, as the criteria continues to be refined, we believe that differing standards should be provided for small hospitals, especially those in rural and underserved areas. Safe maternity care requires access to hospitals with quality obstetric units and access to appropriately trained medical teams led by obstetric physicians. Concurrent with the increased focus on maternal care delivery, hospitals with smaller maternity units have been closing. According to a policy brief by the University of Minnesota Rural Health Research Center, the percent of rural counties without obstetric services rose from 45 to 54 percent between 2004 and 2014. Moreover, only 30 percent of the rural noncore counties (areas with less than 10,000 residents) had continual access to obstetrics services.[3] As a result, women in rural areas of the United States must travel greater distances for prenatal, obstetrical, and postpartum care. This trend of obstetric unit closures in the United States is true for both urban and rural maternity units. Further, data from the American Hospital Association (AHA) reveals that more than 10 million women of color live in rural communities in the United States.[4] Additionally, research has indicated that rural counties with large populations of Black women have higher rates of obstetric unit closures.[5] As such, rather than penalizing these small hospitals for lacking the same resources as larger hospitals and hospital systems, additional funding should be provided to help ensure that these practices do not close, and that women do not have to travel extreme distances to receive care. **Therefore, "birthing-friendly" designations should only apply to hospitals and hospital systems of a certain size, or at a minimum, the "birthing friendly" designation should make allowances for small and rural hospitals.**

[1] https://www.cdcfoundation.org/sites/default/files/upload/pdf/MMRIAReport.pdf.
[2] https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6835a3-H.pdf.
[3] http://rhrc.umn.edu/wp-content/files_mf/1491501904UMRHRCOBclosuresPolicyBrief.pdf.
[4] https://www.aha.org/system/files/media/file/2020/05/cms-rfi-on-maternal-health-in-rural-areas-letter-5-28-2020.pdf.
[5] https://www.ajmc.com/view/role-of-racial-and-geographical-bias-in-rural-maternity-care.

Moreover, as these measures are developed it is important to take into consideration that many factors remain outside the control of the treating physician. For example, individuals choose to see midwives, or non-physician practitioners, for their delivery and care rather than a physician. As such, if advanced complications arise late in pregnancy, or during labor and delivery, mothers may have to engage with physicians even if their primary provider had been a non-physician up to that point in the pregnancy. If a mother is switching care providers late in her pregnancy due to complications that means that the physician is picking up a high-risk case, with the greater potential for a negative outcome. Therefore, additional metrics should consider and take into account these, and other factors such as length of care and provider type, when developing future maternal health metrics.

In addition, the AMA believes that hospitals should be encouraged to demonstrate that they have policies and procedures in place to support individuals and families with substance use disorders (SUD) especially when they are pregnant, post-partum, and parenting. This includes ensuring that the hospital has policies and procedures to implement Plans of Safe Care in an equitable, non-punitive manner. The AMA supports assurances/conditions that pregnant, postpartum, and parenting individuals receive medications for opioid use disorder (MOUD) and other medications when recommended by the individual's physician. To the extent that entities receive federal money, they should be required to attest that either they provide MOUD or that if they do not provide MOUD, and that the entities do not discriminate or exclude individuals receiving MOUD from receiving any services or benefits.

Moreover, as designations continue to be developed, CMS should also consider the impact of attribution of particular quality metrics. With the current foundation of the Maternal Morbidity Structural Measure, attribution related to the designation is placed firmly at the hospital-level. **The AMA cautions that physician-level metrics and measures should not be added to the measure portfolio for designation as doing so will result in unclear or inappropriate attribution of performance. Physicians should not be singled out within the designation, especially considering how many different factors are present when determining maternal mortality and morbidity rates. We therefore urge CMS to maintain the designation at the hospital level and continue to engage with stakeholders prior to proposing changes to the birthing-friendly designation.**

II. Additional Activities to Advance Maternal Health Equity—Request for Information

CMS is looking to explore how they can address the United States maternal health crisis through policies and programs, including, but not limited to, the Conditions of Participation (CoPs) and through measures in their quality reporting programs.

a. Are there new requirements that could be established in the CoPs that would require hospitals to address and improve the quality of postpartum care and support provided to patients? How can the CoPs specifically address the need to improve behavioral health services and monitoring offered during prenatal and postpartum care?

CoPs are employed by CMS to certify providers and suppliers of Medicare and Medicaid services in order to receive payment and help to establish minimum health and safety standardization across participating entities and institutions. These conditions can vary across spectrums of care such as surgical services. A number of strategies that the AMA has been working on can be facilitated through CoPs and can be used to improve quality of care and behavioral health services including:

- Standardization of patient intake and screening tools to increase rates of behavioral health screenings and identification of people with behavioral health needs.

- Integrate behavioral health screening, diagnosis, and treatment into care workflows, including clinical decision support tools into electronic health records (EHRs), to make it easier to provide evidence-based care.

- Adoption of established approaches such as virtual interprofessional consultations and Project ECHO (Extension for Community Healthcare Outcomes) to empower OB/GYN care teams to collaborate with psychiatrists and other behavioral health providers to provide behavioral health treatment.

- Use measurement-based standardized instruments [e.g., PHQ-9, General Anxiety Disorder-7 (GAD-7) and Patient-Reported Outcomes Measurement Information System (PROMIS) tools] to measure, assess and track patient symptoms and outcomes over a period of time and tailor patient treatment accordingly (i.e., "treat to target").

Therefore, the AMA believes 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.

b. Do hospitals have readily available referral relationships and points of contact with community resources or community-based organizations to address additional services that a postpartum patient may need upon discharge? This could include the consideration of behavioral and mental health services or resources to address health-related social needs, such as food insecurity, housing instability, and transportation challenges. If hospitals do not have readily available referral relationships and points of contact within the community, what barriers and facilitators impact hospital relationships with community resources or community-based organizations?

The AMA encourages that—as part of the development of a plan of safe care—hospitals work to develop available referral relationships and points of contact with community resources and community-based organizations to address additional medical and social needs services that a postpartum patient may need upon discharge and throughout the postpartum period. This includes the availability and access to behavioral and mental health services and resources to address social determinants of health, which may include food insecurity, housing instability, transportation challenges, and other necessary services. **The AMA further urges that the hospital work with the medical community to work to remove barriers that may impede provision of these services**.

c. What best practices exist for ensuring systemic racism and biases, including implicit bias are not perpetuated in maternity care?

A commitment to health equity means we must address the SDOH, and we must elevate and name the root causes of why health inequities exist and how they came to be both in society and at the institutional level. Healthy People 2030 defines SDOH as "the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks."[6] As the CDC explains, differences in SDOH contribute to the stark and persistent

[6] Office of Disease Prevention and Health Promotion, US Department of Health and Human Services. Social Determinants of Health. Healthy People 2030. Social Determinants of Health. Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health.

chronic disease disparities in the US among racial, ethnic, and socioeconomic groups, systematically limiting opportunities for members of some groups to be healthy.[7]

Ending systemic racism and biases perpetuated in maternity care must be a holistic approach. The reasons for the overall increase in maternal mortality rate (MMR) and severe maternal morbidity (SMM) are complex and multifactorial. According to the CDC, for every pregnancy-related death, an average of three to four contributing factors were identified, at multiple levels, including community, health facility, patient/family, provider, and system. Studies adjusting for sociodemographic and reproductive factors have not explained the racial gap in pregnancy-related mortality in most studies. For example, Black women have been found to be at an elevated risk regardless of income, education, or geographical location. The health care community is increasingly recognizing the role that structural racism and implicit bias inherent in American society, including in the health care system, play in contributing to stark health inequities. To address systemic racism and biases in maternity care a number of issues will have to be tackled including enhancing data tracking and analysis of maternal and pregnancy-related morbidity and mortality events in order to stop preventable complications; integrating structural competency, increasing cultural sensitivity and implicit bias training opportunities; expanding access to affordable health insurance; and working with partners from different sectors and with patients to better inform system changes and improvements. Additionally, narratives from the lived experiences of Black women indicate there is a rupture of trust between Black women and the health care system that must also be addressed.

Health insurance is critical to obtaining access to maternal health care. Insurance coverage for births in the United States is essentially split between private insurance (49 percent of births in 2018) and Medicaid (43 percent of births in 2018).[8] However maternity coverage under Medicaid ends at 60 days postpartum.[9] While some women successfully transition to other sources of coverage, many are left uninsured shortly after the major medical event of childbirth.[10] In general, one in three women in the United States experiences discontinuous insurance coverage ("churn") before, during, or after pregnancy.[11] Reducing this churn in the postpartum period can help to decrease disparities in maternal health outcomes. [12] Additionally, more than half of pregnancy-related deaths occur after the birth of the infant.[13] Specifically, and critical to policy decisions regarding postpartum care, support, and insurance coverage, approximately 16 percent of pregnancy-related deaths occurred between 1-6 days postpartum, 19 percent occurred between 7-42 days postpartum, and 24 percent occurred between 43-365 days postpartum.[14] The American College of Obstetricians and Gynecologists (ACOG) recommends that postpartum care be an ongoing process, rather than a single visit, with services and support tailored to

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[7] Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Social Determinants of Health. Available at: https://www.cdc.gov/chronicdisease/programs-impact/sdoh.htm.

[8] MACPAC. Medicaid's Role in Financing Maternity Care: Fact Sheet. January 2020. Available at: https://www.macpac.gov/wp-content/uploads/2020/01/Medicaid%E2%80%99s-Role-in-Financing-Maternity-Care.pdf.

[9] Emily Eckert. Preserving the Momentum to Extend Postpartum Medicaid Coverage. *Womens Health Issues*. 2020 November-December; 30(6): 401–404. Published online 2020 Sep 9. doi: 10.1016/j.whi.2020.07.006. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7480528/.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] American College of Obstetricians and Gynecologists. Optimizing Postpartum Care. ACOG Committee Opinion Number 736. May 2018. Available at:https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care.

[14] Davis NL, et. al. Pregnancy-Related Deaths: Data from 14 U.S. Maternal Mortality Review Committees, 2008-2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2019. Available at: https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/MMR-Data-Brief_2019-h.pdf.

each woman's needs.[15] Nevertheless, approximately 40 percent of women do not attend a postpartum visit.[16] Critical barriers to obtaining postpartum care include lack of child care, inability to obtain an appointment, mistrust of health care providers, and limited understanding of the value of the visit.[17] These barriers are even more challenging for patients with limited resources, decreasing attendance rates and contributing to disparities.[18] Notably, 23 percent of employed women return to work within 10 days of giving birth, and an additional 22 percent return to work between days 10 and 42 postpartum. Only 14 percent of American workers—and only five percent of low-wage workers—have access to paid leave.[19] The AMA agrees with ACOG in recommending that obstetric care physicians ensure that women, their families, and their employers understand the need for continued recovery and support for postpartum women.[20] Recognizing the burden of traveling to and attending an office visit, especially with the new responsibility of an infant, ACOG explains that in-person care may not always be required.[21] Telephone support during the postpartum period can reduce depression, improve breastfeeding outcomes, and increase patient satisfaction.[22]

Moreover, a lack of insurance can lead to negative health outcomes and increase inequities in maternal care. Uninsurance challenges during and after pregnancy are due, in part, to the patchwork nature of publicly supported coverage options potentially available for pregnant and postpartum women that vary by state of residence, income, and immigration status.[23] For women with higher incomes, a steep "subsidy cliff" makes premium payments for Marketplace plans far more expensive as soon as income exceeds 400 percent FPL, potentially preventing women from obtaining affordable insurance.[24] This can be especially challenging when women unexpectedly lose access to employer-sponsored insurance, as has frequently been the case during the COVID-19 pandemic.[25] Coverage options for women with lower incomes are even more complicated. In all but two states, the income thresholds for Medicaid and State Children's Health Insurance Program (CHIP) qualification are higher for pregnancy-related coverage than for nonpregnant parents or other adults.[26] As a result, women who were insured by Medicaid or CHIP due to their pregnancy status, but who lose access to pregnancy-related coverage at 60 days postpartum, experience insurance churn in several ways:[27]

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[15] American College of Obstetricians and Gynecologists. ACOG Postpartum Toolkit. Available at: https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/publications/2018-postpartum-toolkit.pdf.
[16] *Id.*
[17] *Id.*
[18] American College of Obstetricians and Gynecologists, *supra* note 13.
[19] American College of Obstetricians and Gynecologists, *supra* note 15.
[20] American College of Obstetricians and Gynecologists, *supra* note 13.
[21] *Id*.
[22] *Id*.
[23] Johnston et. al. Closing Postpartum Coverage Gaps and Improving Continuity and Affordability of Care through a Postpartum Medicaid/CHIP Extension. Urban Institute. January 2021. Available at: https://www.urban.org/sites/default/files/publication/103560/closing-postpartum-coverage-gaps-and-care-through-postpartum-medicaid-chip-extension_2.pdf.
[24] Daniel McDermott. Impact of Key Provisions of the American Rescue Plan Act of 2021 COVID-19 Relief on Marketplace Premiums. KFF. March 15, 2021. Available at: https://www.kff.org/health-reform/issue-brief/impact-of-key-provisions-of-the-house-covid-19-relief-proposal-on-marketplace-premiums/.
[25] Paul Fronstin and Stephen A. Woodbury. Update: How Many Americans Have Lost Jobs with Employer Health Coverage During the Pandemic? The Commonwealth Fund. January 11, 2021. Available at: https://www.commonwealthfund.org/blog/2021/update-how-many-americans-have-lost-jobs-employer-health-coverage-during-pandemic.
[26] Johnston et. al., *supra* note 23.
[27] *Id.*

- In states that expanded Medicaid, some women will be able to continue Medicaid coverage postpartum.[28] For other women, premium tax credits could help them purchase subsidized insurance through the Marketplace.[29] However, Marketplace plans may require women to incur additional out-of-pocket costs and/or change physicians, and women recovering from giving birth and caring for an infant may not undertake the effort of finding a suitable Marketplace plan.[30]

- In states that have not expanded Medicaid, adult Medicaid eligibility is typically below the FPL. Low-income residents in these states fall into a "coverage gap," having incomes that are too high to qualify for their state's Medicaid but that are below the FPL, which is the minimum threshold for subsidized Marketplace coverage.[31] When women lose pregnancy-based Medicaid, they may not have an affordable coverage option.

- Six states build on Medicaid's foundation and offer CHIP coverage to pregnant women at higher income levels.[32] Accordingly, to protect new mothers in these six states, policies to extend public coverage until 12 months postpartum must reference both Medicaid and CHIP.

- Due to their immigration status, some women will not qualify for Medicaid, CHIP, or subsidized insurance through the Marketplace, even if they meet the income qualifications.[33] Accordingly, they may not have an affordable coverage option.

Of course, women's need for medical care and insurance does not end at the 60th day postpartum. As outlined above, women are at elevated physical and behavioral health risk for 12 months following childbirth, so access to health care, and insurance coverage for that care, is essential. **As such, a clear policy improvement is to extend Medicaid and CHIP to cover new mothers for the full 12-month postpartum period.**

If Medicaid and CHIP coverage were extended for the entire year of the postpartum period, an estimated 70 percent of uninsured new mothers would be eligible for some kind of publicly subsidized coverage.[34] Notably, non-expansion states are home to 83 percent of the uninsured new mothers who would become newly eligible for Medicaid/CHIP under a postpartum extension.[35] It is also essential to recognize that while a Medicaid/CHIP extension would help reduce maternal health disparities, it cannot eliminate the inequities that persist due to race, ethnicity, immigration status, and geography (such as proximity to a hospital with obstetric care).[36] **As such, beyond a full 12-month postpartum coverage period, a mechanism should be developed to allow for presumptive assessment of eligibility and retroactive coverage to the time at CHIP which an eligible person seeks medical care, and pregnancy should be included as a qualifying life event for special enrollment in the health insurance marketplace.**

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[28] *Id.*
[29] Maggie Clark. Medicaid and CHIP Coverage for Pregnant Women: Federal Requirements, State Options. Georgetown University Health Policy Institute Center for Children and Families. November 2020. Available at: https://ccf.georgetown.edu/wp-content/uploads/2020/11/Pregnancy-primary-v6.pdf.
[30] *Id.*
[31] Johnston et. al., *supra* note 23.
[32] Maggie Clark., *supra* note 29
[33] Johnston et. al., *supra* note 23.
[34] *Id.*
[35] *Id.*
[36] *Id.*

Additionally, collection of data is important to allow for greater understanding of the root causes of MMM and the stark racial and ethnic disparities in maternal health. As outlined by the CDC, there are three essential sources of data on maternal mortality: (1) CDC's National Center for Health Statistics' National Vital Statistics System (NVSS), (2) the CDC's Pregnancy Mortality Surveillance System (PMSS), and (3) state and local Maternal Mortality Review Committees (MMRCs).[37] The data collected by each of these sources are not standardized—they apply different definitions of maternal mortality, and they draw on different sources. **Therefore, a standardized definition of maternal mortality should be developed and there should be additional resources provided to collect and analyze maternal mortality data to enable better understanding of the causes of maternal deaths and inform evidence-based policies to improve health outcomes and promote health equity. Moreover, additional funding and support should be provided to MMRCs so that accurate data can continue to be collected.**

In addition, there is no systematic ongoing data collection for population-based maternal morbidity in the US.[38] The source of data for CDC's national SMM estimates is the Nationwide Inpatient Sample (NIS). The Pregnancy Risk Assessment Monitoring System (PRAMS) also provides insights into health problems among mothers and babies. Contributing to data challenges is the fact that while patient identity data such as race, ethnicity, and language is essential to understanding sources of disparities, patients may be hesitant to divulge private information, especially if they do not know how their data may be used.[39] Moreover, for these data to be useful, they must elicit information that accurately reflects the diversity within racial and ethnic categories, and they must be collected and reported consistently. Accordingly, it is critical to educate health care staff responsible for data collection on best practices to earn patient trust, elicit candid responses, and accurately record and report the information. Similarly, data collection and reporting legal requirements and policy must also include anti-discrimination protections to ensure that the collection of race, ethnicity, and language data is used to reduce, rather than create or exacerbate, inequities that harm individuals and populations. Overall, research should be bolstered and include the impacts of societal (e.g., racism or unaffordable health insurance), geographical (e.g., neighborhood stress score, poverty, or segregation), facility-level (e.g., hospital quality), clinician-level (e.g., implicit bias), and patient-level (e.g., comorbidities, chronic stress, or lack of transportation) barriers to optimal care that contribute to adverse and disparate maternal health outcomes, as well as research testing the effectiveness of interventions to address each of these barriers.

Furthermore, to provide optimal care for diverse patients, greater diversity is needed on physician-led health care teams. For example, research indicates that race and language concordance between patients and clinicians, such as Obstetrician-Gynecologists (OB/GYNs) may improve communication and outcomes.[40] A recent study found that while maternal health care physician-led teams are making strides in gender representation (approximately 59 percent of practicing OB/GYNs are women), they are lacking

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[37] Pregnancy Mortality Surveillance System. Frequently Asked Questions. Centers for Disease Control and Prevention (CDC). November 25, 2020. Available at: https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm#faqs.

[38] Andreea A. Creanga, et. al. Maternal Mortality and Morbidity in the United States: Where Are We Now? *J Womens Health (Larchmt)*. 2014 Jan 1; 23(1): 3–9. doi: 10.1089/jwh.2013.4617. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880915/.

[39] Consensus Statement. Elizabeth A. Howell, et. al. Reduction of Peripartum Racial and Ethnic Disparities: A Conceptual Framework and Maternal Safety Consensus Bundle. Obstetrics & Gynecology: May 2018 - Volume 131 - Issue 5 - p 770-782 doi: 10.1097/AOG.0000000000002475. Available at:https://journals.lww.com/greenjournal/Fulltext/2018/05000/Reduction_of_Peripartum_Racial_and_Ethnic.4.aspx.

[40] The American College of Obstetricians and Gynecologists. Racial and Ethnic Disparities in Obstetrics and Gynecology. Committee Opinion Number 649. December 2015. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/12/racial-and-ethnic-disparities-in-obstetrics-and-gynecology.

in racial and ethnic diversity (only approximately 11 percent of OB/GYNs are Black and only approximately 6 percent are Hispanic).[41] Moreover, 49 percent of the counties in the US, home to more than 10 million women, lack an OB/GYN.[42] In addition to OB/GYNs, family medicine physicians can play an essential role in reducing inequities in MMM due to their training in providing comprehensive care across the life course, including prenatal, perinatal, and postpartum care for the individuals in the communities where they live.[43] At the same time, the American Academy of Family Physicians (AAFP) has highlighted studies finding that while recent family medicine graduates have felt more prepared than previous cohorts, family medicine graduates are providing significantly less OB care.[44] Only approximately eight percent of family medicine physicians include OB deliveries in their practice, and this is especially challenging in rural areas where family medicine physicians provide the majority of maternity care and where labor and delivery units are closing.[45] With this in mind adequate coverage and payment from all payers for the full spectrum of evidence-based pre-pregnancy, prenatal, peripartum, and postpartum physical and behavioral health care should be provided so that these vital labor and delivery units can remain open.

Additionally, collaborating with community leadership is important in helping to diminish inequities in maternal health. There is growing evidence that programs that partner with communities may have a substantial impact on improving quality of care and reducing disparities.[46] Collaboration among clinicians, public health professionals, and community partners (including nonprofit organizations, faith-based organizations, and residents) has been essential in efforts to improve maternal health and reduce disparities.[47] ACOG specifically suggests that physicians work to educate staff and colleagues about community resources available to patients and that they work collaboratively with local public health authorities to address disparities in environmental exposures, health education and literacy, and women's health services and outcomes.[48] Community-engaged interdisciplinary initiatives can cultivate trust and promote education, and they can also leverage a variety of innovative and traditional methods to do so. For example, New York City recently implemented the Severe Maternal Morbidity Project (Project), which worked directly with clinical and community partners to improve maternal outcomes, promote health equity, and reduce racial/ethnic disparities in SMM in New York City.[49] The Project team worked to cultivate trust and it engaged with the community via innovative social media projects and in-person

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[41] ACOG Releases New Study on OB/GYN Workforce. Contemporary OB/GYN. July 2017. Available at: https://www.contemporaryobgyn.net/view/acog-releases-new-study-obgyn-workforce.

[42] *Id.*

[43] The American Academy of Family Physicians. Striving for Birth Equity: Family Medicine's Role in Overcoming Disparities in Maternal Morbidity and Mortality. Available at: https://www.aafp.org/about/policies/all/birth-equity-pos-paper.html.

[44] *Id.*

[45] Barreto TW, et. al. Opportunities and Barriers for Family Physician Contribution to the Maternity Care Workforce. Fam Med. 2019;51(5):383-388. Available at: https://doi.org/10.22454/FamMed.2019.845581.

[46] Elizabeth A Howell. Reducing Disparities in Severe Maternal Morbidity and Mortality. *Clin Obstet Gynecol.* Author manuscript; available in PMC 2019 Jun 1. Published in final edited form as: *Clin Obstet Gynecol*. 2018 Jun; doi: 10.1097/GRF.0000000000000349. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/ .

[47] Hannah Emple, Sarah Cremer. Innovative Strategies for Community Engagement: Raising Awareness to Reduce Severe Maternal Morbidity. New York City Department of Health and Mental Hygiene. December https://www1.nyc.gov/assets/doh/downloads/pdf/csi/strategies-for-community-engagement-raising-awareness-severe-maternal-morbidity.pdf .

[48] The American College of Obstetricians and Gynecologists. Racial and Ethnic Disparities in Obstetrics and Gynecology. Committee Opinion Number 649. December 2015. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/12/racial-and-ethnic-disparities-in-obstetrics-and-gynecology.

[49] Hannah Emple, Sarah Cremer. Innovative Strategies for Community Engagement: Raising Awareness to Reduce Severe Maternal Morbidity. New York City Department of Health and Mental Hygiene. December https://www1.nyc.gov/assets/doh/downloads/pdf/csi/strategies-for-community-engagement-raising-awareness-severe-maternal-morbidity.pdf .

community public meetings. The social media initiatives amplified the voices and experiences of women navigating maternal care and provided an educational platform for content from the Preeclampsia Foundation and District II of ACOG. In-person presentations intended to increase awareness were delivered at community board meetings in neighborhoods experiencing the highest rates of SMM and those adjacent to Project-affiliated hospitals. With this in mind, collaboration with non-clinical community organizations with close ties to minoritized and other at-risk populations should be leveraged to identify opportunities to support pregnant persons and new families. Moreover, there should be increased participation in maternal safety and quality improvement initiatives such as the Alliance for Innovation on Maternal Health program and state perinatal quality collaboratives. There should also be verified evidence-based levels of maternal care to increase access to risk-appropriate care. In addition, resources should be developed, and funding should be provided for initiatives to help pregnant individuals, their families, communities, and workplaces (1) recognize the value of maternal physical and behavioral care, (2) reduce barriers to care, and (3) highlight care available at minimal patient cost. Furthermore, there should be peer support specialists readily available and additional resource should be used to encourage the utilization of state Child Psychiatry Access Programs, such as MCPAP for Moms, which can help promote maternal mental health during and after pregnancy.

Finally, 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.[50]

Effective communication can have a profound impact on how patients and families perceive their care.[51] Research demonstrates that patient engagement in health care leads to measurable improvements in safety and quality.[52] Open communication between the medical team and patients and families can broaden perspectives and reduce patient avoidance of physicians/facilities and/or medical care in general.[53] To promote patient engagement, the Agency for Healthcare Research and Quality (AHRQ) developed an evidence-based resource called, "The Guide to Patient and Family Engagement in Hospital Quality and Safety" to help hospitals partner with patients and families.[54] The Guide was developed, implemented, and evaluated with the input of patients, family members, clinicians, hospital staff, and hospital leaders, and it includes sections devoted to improving communication among patients, family members, and clinicians and preparing patients and families to transition from hospital to home. Similarly, AHRQ developed a "Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families" with evidence-based strategies including those to improve communication, engagement, health literacy, and handoffs among the health care team.[55]

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[50] Elizabeth A Howell. Reducing Disparities in Severe Maternal Morbidity and Mortality. *Clin Obstet Gynecol.* Author manuscript; available in PMC 2019 Jun 1. Published in final edited form as: *Clin Obstet Gynecol*. 2018 Jun; doi: 10.1097/GRF.0000000000000349. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5915910/.

[51] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.

[52] Agency for Healthcare Research and Quality. Guide to Patient and Family Engagement in Hospital Quality and Safety. Content last reviewed December 2017.https://www.ahrq.gov/patient-safety/patients-families/engagingfamilies/guide.html.

[53] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at:https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.

[54] Agency for Healthcare Research and Quality. Guide to Patient and Family Engagement in Hospital Quality and Safety. Content last reviewed December 2017.https://www.ahrq.gov/patient-safety/patients-families/engagingfamilies/guide.html.

[55] Agency for Healthcare Research and Quality. Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families. Content last reviewed April 2018. Available at: https://www.ahrq.gov/patient-safety/reports/engage/strategies.html.

The mutual trust built between pregnant patients and their physicians is essential, but maternal health care presents unique continuity of care challenges where patients may be handed off from their primary physician to an in-hospital clinical team for delivery, and then handed again to their primary team for postpartum care. Accordingly, effective clinician-to-clinician communication is imperative to strengthen continuity of care, eliminate preventable errors, and provide a safe patient environment.[56] There is clear room for improvement, as a systematic review found that timely communication of discharge summaries between hospital-based and primary care physicians was low, and approximately ten percent of discharge summaries were never transferred.[57] Use of structured and codified communication practices can promote consistent communication among clinicians and reduce risk of adverse events stemming from breakdowns in communication.[58] With due attention paid to the privacy of maternal health information, health information technology, including electronic health records (EHRs) and technology enabling women to access their health information from any place at any time, can also help to build information bridges during potentially fragmented maternal health care.[59]

In addition to effective clinician-to-clinician communication, striving toward optimal patient-clinician communication is also essential. Patient-centered communication, cultural humility, and trauma-informed care offer principles that can improve communication and build trust. Patient-centered communication that offers options and asks patients about how they can be made most comfortable can lessen anxiety and promote trust and rapport.[60] Additionally, the patient-centered care approach of "centering at the margins" facilitates clinicians engaging with "the experience of disenfranchised groups and [acknowledging] the role of society and history in influencing both their own understanding of their patient and their patient's understanding of them."[61]

Cultural humility is an approach that focuses on optimizing interactions between patients and clinicians with different values, backgrounds, and experiences, and it has been shown to strengthen the therapeutic alliance and improve outcomes.[62] Hallmark features of cultural humility include critical self-reflection, openness, nonjudgment, and curiosity.[63] Researchers and clinicians have developed a variety of resources to support the adoption of cultural humility in clinical practice, from clinician coaching tools to assessment measures.[64] A focus on structural determinants of health and health inequities in medical

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[56] The American College of Obstetricians and Gynecologists. Approaches. Communication Strategies for Patient Handoffs. Committee Opinion Number 517. February 2021, Reaffirmed 2016. Available at: https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2012/02/communication-strategies-for-patient-handoffs.pdf.

[57] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.

[58] PSNet Patient Safety Network. Perspectives on Safety. Approach to Improving Patient Safety: Communication. March 2021. Available at: https://psnet.ahrq.gov/perspective/approach-improving-patient-safety-communication.

[59] Consensus Statement. Elizabeth A. Howell, et. al. Reduction of Peripartum Racial and Ethnic Disparities: A Conceptual Framework and Maternal Safety Consensus Bundle. Obstetrics & Gynecology: May 2018 - Volume 131 - Issue 5 - p 770-782 doi: 10.1097/AOG.0000000000002475. Available at: https://journals.lww.com/greenjournal/Fulltext/2018/05000/Reduction_of_Peripartum_Racial_and_Ethnic.4.aspx.

[60] The American College of Obstetricians and Gynecologists, *supra* note 40.

[61] Joia Crear-Perry, et. al. Social and Structural Determinants of Health Inequities in Maternal Health. *Journal of Women's Health*. February 202. doi: 10.1089/jwh.2020.8882. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8020519/.

[62] Opemipo Akerele, et. al. Healing Ethno-Racial Trauma in the Black Community Cultural Humility as a Driver of Innovation. *JAMA Psychiatry*. April 21, 2021. doi:10.1001/jamapsychiatry.2021.0537. Available at: https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2778478.

[63] *Id.*

[64] *Id.*

education and clinical training may facilitate cross-cultural understanding of individual patients and shift the way clinicians recognize the social and economic forces that produce health outcomes.[65]

A trauma-informed approach to care has been defined as, "a strengths-based service delivery approach that is grounded in an understanding of and responsiveness to the impact of trauma, that emphasizes physical, psychological, and emotional safety for both practitioners and survivors, and that creates opportunities to rebuild a sense of control and empowerment."[66] ACOG highlights high rates of trauma experienced across communities.[67] For example, a survey of adults who had completed high school found that approximately 83 percent of the respondents reported at least one standard or community-level adversity, and approximately 37 percent reported four or more.[68] Traumatic birth experiences, which may include unexpected outcomes, procedures, obstetric emergencies, and neonatal complications continue to impact patients.[69] ACOG also notes the impact of "obstetric violence," which is a nonmedical term that is used to refer to situations in which a pregnant or postpartum individual experiences disrespect, indignity, or abuse from a health care practitioner or system that can stem from and lead to loss of autonomy.[70] Experiences of trauma can affect individuals' physical and behavioral health and such experiences can profoundly impact their attitude toward medical care, leading to anxiety related to specific examinations or procedures or anxiety about being in a medical setting.[71] ACOG emphasizes, "True trauma-informed care empowers individuals by recognizing the significance of power differentials and the historical diminishing of voice and choice in past coercive exchanges."[72]

Public health communication is essential to raising awareness among both clinicians and patients regarding maternal health challenges. The CDC recently launched the Hear Her campaign to raise awareness of potentially life-threatening warning signs during and after pregnancy and improve communication between patients and their medical teams.[73] The Hear Her campaign also provides guidance and resources specifically for health care providers including: guidance to promote communication with patients about urgent maternal warning signs, guidance regarding management of chronic conditions, opportunities to get involved with ACOG's "Every mom. Every time." awareness campaign, professional education regarding post-birth warning signs, information about toolkits and safety bundles, and information about causes and contributors to maternal mortality.[74] In line with that, **the AMA believes that additional continuing medical education (CME) and other educational activities aimed at addressing the root causes of inequities, including racism and other structural determinants of health would help to increase physician understanding surrounding maternal health disparities**.[75] Moreover, there should be additional development and implementation of training regarding implicit bias, and diversity and inclusion in all medical schools and residency programs. This training should include educating residents in all specialties about disparities in their fields related to race,

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[65] Joia Crear-Perry, et. al., *supra* note 61.
[66] The American College of Obstetricians and Gynecologists. Caring for Patients Who Have Experienced Trauma. ACOG Committee Opinion Number 825. April 2021. Available at: https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2021/04/caring-for-patients-who-have-experienced-trauma.pdf.
[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*
[72] *Id.*
[73] Centers for Disease Control and Prevention. Hear Her About the Campaign. Available at: https://www.cdc.gov/hearher/about-the-campaign/index.html.
[74] *Id.*
[75] AMA Ed Hub™ Health Equity Education Center. Available at: https://edhub.ama-assn.org/health-equity-ed-center.

ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as strategies for managing the implicit biases of patients and their caregivers. 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.

III. Data Privacy and Increased Data Collection

As CMS considers methods to incentivize hospitals to collect patient data, there must be a corresponding effort to ensure that data is not used or accessed inappropriately. As mentioned earlier in this letter, the AMA understands the importance of decreasing maternal mortality and morbidity and recognizes the need to capture and utilize high-quality data for CMS' program design and participation. However, we also stress that CMS must consider the unintended consequences of incentivizing data collection without robust data privacy and security protections in place. Recognizing that Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules regulate hospitals and other covered entities, an ever-increasing amount of data is being accessed, exchanged, and used outside the "four walls" of the clinical environment. **Therefore, data privacy considerations must be tightly incorporated within CMS' policies with particular focus on non-HIPAA covered entity access, use, or exchange.**

We learn more each day that personal health information is no longer private. Social media platforms, wearable fitness trackers, and applications (apps) allowing patients to download health records from EHRs and manage health conditions all collect data that are not protected by HIPAA. That means these data can be shared for a wide range of purposes, including advertising and marketing. Sharing health information with data brokers, who can combine it with other consumer information (such as credit score, level of education, and even something as simple as a zip code), creates the perfect recipe for harmful profiling and discrimination.[76] Data mining by insurers and employers leads to the creation of health or "risk" scores, which can result in harmful profiling and discrimination. Social media platforms, Internet search engines, wearable fitness trackers, and apps to manage pregnancy and mental health all pool personal data, turning it into a valuable commodity. For example, a recent evaluation of the 23 most popular women's mobile health (mHealth) apps on the market has shown that all collect personal health-related data. All apps allowed behavioral tracking and over 60 percent allowed location tracking. Only 52 percent requested consent from users and 13 percent collected data before obtaining consent.[77] At a time when women's reproductive rights are in jeopardy, the fact that popular women's mHealth apps lack data privacy, sharing, and security standards is concerning.

Indeed, there is growing awareness among patients of how companies monetize individuals' health and other personal information. A 2019 Morning Consult national survey showed that 94 percent of people feel privacy and security of their medical information are important,[78] while a 2019 study by Rock Health and Stanford's Center for Digital Health shows consumers have become more reticent to share their health data.[79] Among health care stakeholders, consumers are most willing to share their health data with

[76] Favaretto, M., De Clercq, E. & Elger, B.S. Big Data and discrimination: perils, promises and solutions. A systematic review. J Big Data 6, 12 (2019). https://doi.org/10.1186/s40537-019-0177-4.

[77] Alfawzan N, Christen M, Spitale G, Biller-Andorno N Privacy, Data Sharing, and Data Security Policies of Women's mHealth Apps: Scoping Review and Content Analysis (May 2022), available at https://mhealth.jmir.org/2022/5/e33735.

[78] Morning Consult National Tracking Poll (June 20-22, 2019), available at https://www.uschamber.com/sites/default/files/190645_topline_adults_v2_jb.pdf.

[79] Digital Health Consumer Adoption Report 2019, available at https://rockhealth.com/reports/digital-health-consumer-adoption-report-2019/.

physicians, but that sentiment has slipped since 2017, possibly due to spillover from privacy and security breaches in other sectors and general distrust of "big tech."[80] A 2017 Black Book survey reports that:

- 87 percent of patients were unwilling to comprehensively share all of their health information with their physicians;
- 89 percent of consumers who had visited a health care provider in 2016 said they had withheld some information during their visits;
- 81 percent were concerned that information about chronic conditions was being shared without their knowledge; and
- 99 percent were concerned about the sharing of mental health notes.[81]

CMS must consider the potential harm to the patient-physician relationship when incentivizing data collection by health systems; we cannot allow the seemingly good intentions of data collection to override our responsibilities to maintain patient trust.

New survey data from the AMA and Savvy Cooperative, a patient-owned co-op that connects people with opportunities to share their health experiences, found that nearly three-quarters of surveyed patients are concerned about the privacy of their health data. Additionally, 59 percent of patients are worried about health data being used by companies to discriminate against them or their loved ones or to exclude them from opportunities to find housing, gain employment, and receive benefits. Over half of surveyed patients stated that they are very or extremely concerned about negative repercussions related to insurance coverage, employment, or opportunities for health care resulting from access to their health data. When asked to indicate how comfortable they are with certain types of companies gaining access to their health data, survey patients were overwhelmingly most comfortable with their physician's office having such access. Conversely, patients were least comfortable with social media sites, employers, and big technology companies receiving access to their health data.

Together, these findings indicate that carelessness and lack of transparency in how patient information is handled and used has likely influenced what information a patient shares with his or her physician. **This should serve as a warning to policymakers that patients take their health data privacy seriously and that privacy safeguards are critical to preserving patient trust.[82] As CMS starts to frame its policies around maternal health equity, the AMA strongly encourages CMS to build upon a strong pillar of data access and data privacy.** CMS should establish a national campaign to educate individuals about their rights to data and methods to help protect themselves from data misuse. We are encouraged by CMS' desire to promote health equity, but unfortunately it is often the marginalized and minoritized that suffer when data privacy is abused. Furthermore, CMS should provide targeted outreach and educational materials to hospitals and patients explaining the best practices to protect data. The AMA has developed a set of privacy principles which could serve as a basis for good data protection practices.[83] The AMA is willing to assist CMS in developing and disseminating these concepts among the physician community.

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[80] Sean Day and Megan Zweig, Rock Health, *Beyond Wellness for the Healthy: Digital Health Consumer Adoption 2018*, available at https://rockhealth.com/reports/beyond-wellness-for-the-healthy-digital-health-consumer-adoption-2018/.

[81] Black Book Market Research, *Healthcare's Digital Divide Widens* (Jan. 3, 2017), available at https://blackbookmarketresearch.newswire.com/news/healthcares-digital-divide-widens-black-book-consumer-survey-18432252.

[82] "Incomplete medical histories and undisclosed conditions, treatment or medications raises obvious concerns on the reliability and usefulness of patient health data in application of risk based analytics, care plans, modeling, payment reforms, and population health programming." Doug Brown, Black Book Managing Partner, available at https://www.prnewswire.com/news-releases/healthcares-digital-divide-widens-black-book-consumer-survey-300384816.html.

[83] https://www.ama-assn.org/system/files/2020-05/privacy-principles.pdf.

IV. Graduate Medical Education (GME) Proposals

CMS is proposing a modified policy to be applied prospectively for all teaching hospitals, as well as retrospectively for certain providers and cost years. The proposed modified policy would address situations for applying the Full-time equivalent **(**FTE) cap when a hospital's weighted FTE count is greater than its FTE cap, but would not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. CMS is proposing to allow an urban and a rural hospital participating in the same rural training program (RTP) to enter into an "RTP Medicare GME affiliation agreement" effective for the academic year beginning July 1, 2023.

The AMA applauds the proposed rule which appears to be well thought out. This proposal will allow hospitals to recoup compensation that they were rightfully owed for training residents. As such, the AMA supports the proposals put forth by CMS in this section and believes that this will be advantageous for the training of additional residents in the future.

V. Medicare GME Affiliation Agreements and Rural Training Tracks

Rural track programs (RTP) are designed to encourage the training of residents in rural areas. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine RTP programs 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. There are provisions of law and regulations that allow urban and rural hospitals to receive adjustments to their caps for newly established RTPs. The adjustments for RTPs are determined in the same way as hospitals that are newly training residents in newly established training programs—based on the division of residents among the urban and rural hospitals during the 5th year of resident training. As such, CMS is proposing, to allow urban and rural hospitals that participate in the same separately accredited 1-2 family medicine rural track program and have rural track FTE limitations to enter into "Rural Track Medicare GME Affiliation Agreements." Additionally, CMS is proposing that programs that are not separately accredited in the 1-2 format and are not in family medicine would not be permitted to enter into "Rural Track Medicare GME Affiliation Agreements" under this proposal. CMS further proposes to add new definitions at 42 CFR 413.75(b) of rural track Medicare GME affiliated group and rural track Medicare GME affiliation agreement. CMS also is proposing to require that the responsible representatives of each urban and rural hospital entering into the rural track Medicare GME affiliation agreement must attest in that agreement that each participating hospital's FTE counts and rural track FTE limitations in the agreement do not reflect FTE residents nor FTE caps associated with programs other than the rural track program. In addition, CMS is proposing to only allow urban and rural hospitals to participate in rural track Medicare GME affiliated groups if they have rural track FTE limitations in place prior to October 1, 2022. Finally, CMS is proposing that eligible urban and rural hospitals may enter into rural track Medicare GME affiliation agreements effective with the July 1, 2023, academic year.

The AMA applauds CMS for this proposal and supports the proposal in whole. The AMA is particularly supportive of CMS being willing to reassess this proposed policy in the future once FTE caps for the Consolidated Appropriations Act (CAA, 2021) RTPs are set, since the CAA allowed for cap adjustments for RTPs other than those that are separately ACGME accredited in family practice and for new training sites added to existing RTPs.

VI. Reasonable Cost Payment for Nursing and Allied Health Education Programs

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or are recognized by a national accrediting body. Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides that direct GME payments for Medicare+Choice utilization are reduced to the extent that these additional payments are made for nursing and allied health education programs. As such, Medicare pays for provider-operated nursing and allied health education programs on a reasonable cost basis. Under the reasonable cost payment methodology, a hospital is paid Medicare's share of its reasonable costs. Provisions of law enacted in 1999 and 2000 required that CMS include Medicare Advantage (MA) utilization in determining the Medicare share of reasonable cost nursing and allied health education payments. These additional payments for nursing and allied health education attributed to MA utilization were funded through a reduction to analogous payments made to teaching hospitals for Direct Graduate Medical Education (DGME) and limited to $60 million per year.

The AMA understands that reducing DGME payments for nursing and allied health professionals' education in this context has been a long-established practice. While we greatly value the contribution of nursing and allied health professionals to the physician-led care team we do not support the reduction of DGME funding every year by $60 million. Workforce experts predict that the United States will face a significant physician shortage for both primary care and specialty physicians over the next 13 years. In particular, the AAMC predicts a shortage of 124,000 physicians by 2034, including a projected shortage of primary care physicians of between 17,800 and 48,000.[84] The $60 million that is taken from DGME funds could be used to create additional residency slots and help to curtail the current and impending physician shortage. Therefore, we believe that the $60 million dollars taken from DGME funds should be maintained for the education of residents and used to bolster the physician workforce.

VII. Hospital Readmission Reduction Program

The AMA supports exploring additional or alternative approaches to examining clinical outcomes for beneficiaries with social risk factors. We continue to support the use of dual eligibility as the primary variable used to stratify results but acknowledge that it continues to serve as a proxy. As data on social risk factors are improved, we support exploring other factors or data sources that could provide information that more accurately reflects the patients served by a specific hospital and directly measures the social risk factors relevant to the outcome. We caution CMS to carefully examine the degree to which any new variable is duplicative to dual eligibility but would not serve as an adequate replacement. There is the potential that its use would provide similar but contrary results. CMS should not put forward new stratification that sends mixed or varying results that cannot be explained or used for quality improvement.

Regarding the preferred approach to link payment reductions to performance in caring for socially at-risk populations, we support positive upfront payments that would allow hospitals to leverage the needed resources to provide additional services and supports to these individuals. CMS states that one of the goals of this work is to avoid disincentivizing providers to treat these patients. **In addition, we continue to believe that there is value in providing the results using both the Within-Hospital and Across-Hospital methods. Both approaches provide useful information that could guide a hospital's quality improvement efforts as well as continue to track their progress against their peers.**

[84] https://searchlf.amaassn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS.

VIII. Hospital IQR Program Measure Set

a. New Measures Being Proposed for the Hospital IQR Program Measure Set

- *Screening for Social Drivers of Health*
- *Screen Positive Rate for Social Drivers of Health*

The AMA supports the intent of the measures to begin to address the social drivers that can also impact an individual's health outcomes. While we appreciate the urgency, we are concerned that doing something prematurely will impede progress on the issue. We are worried that people are placing too much emphasis on asking patients about their social needs/SDOH and not enough emphasis on addressing those needs. Too many organizations are leaving patients to "navigate to nowhere," which will just make things worse. We need a coordinated effort across the health care ecosystem including how to handle intervention.

We appreciate CMS providing further details on the numerator and denominator than what was presented on the 2021-2022 Measure Application Partnership (MAP) Measure Under Consideration (MUC) list, and upon review we continue to have significant concerns on how the measures are designed and the lack of adequate specification and testing. Each measure will continue to produce results that are not reliable and valid as currently specified. For example, the Screening for Social Drivers of Health measure's numerator definition allows a hospital to screen a patient on "one or all" of the five factors and the positivity rate will be based on this same approach (one factor or up to five). There is significant risk that comparisons will be made where one hospital only focuses on screening on one health-related social need while others focus on all five factors.

In addition, we believe that there is a flaw in the proposed measure calculation in the positivity screen rate. The first measure on screening allows hospitals to select whether they will report on one or all of the five items using any tool, but this subsequent measure assumes that hospitals will screen on all five. As a result, it remains unclear whether there will be sufficient denominator sizes to enable reliable and valid comparisons. The measures also currently do not exclude patients whose length of stay is only one or two days, which makes it far more difficult for a hospital to administer this screening in addition to all the other important clinical activities that may take place during an admission.

Furthermore, based on feedback we received from Gravity Project subject matter experts, for applicable domains quality measures should only include tools that have been psychometrically tested, including sensitivity and specificity, against gold stand tools. Therefore, the drivers/domains included in the measure should align with data standards such as the HL7 Gravity Project and USCDI.

- At this time, only food insecurity has been finalized and uses a gold standard tool. This is food insecurity with the USDA Food Security Module.

- Housing instability and transportation remain in a draft phrase.
    - HUD has a gold standard tool for Housing Instability in development.

- There are tools currently in the food security domain that have not been fully tested. They may meet content and face validity (the Gravity Project base standard), but they have not been tested for sensitivity and specificity against the USDA module and thus may create concerning levels of false positives, and more importantly false negatives.

The lack of standardization of the tool or factors assessed, adequate denominator exclusions, or testing for reliability and validity goes against fundamental measure development principles outlined by NQF and the CMS Blueprint. CMS would be better served to focus on the typical measure development process for these measures rather than the trial-and-error data submission and reporting approach currently proposed. Ideally, a gold standard screening instrument across all domains should be developed that implements the standards Gravity has recommended. This could be a compilation of multiple standardized and validated tools. Efforts related to SDOH, must also begin to consider and address broadband access so we are not creating a digital divide when it comes to access to telehealth and digital tools. In addition, prior to holding providers accountable for screening patients and the associate data collection, there needs to be an education effort explaining the importance of the information, best practices for collecting the data and intentions for use, as well as education related to privacy and security.

- *Cesarean Birth eCQM*

The AMA supports the inclusion of this measure unless it does not achieve endorsement by NQF in this upcoming review cycle. In addition, we encourage CMS to work with the measure developer to continue to evaluate the feasibility of data capture and validity of the individual data elements across a larger set of electronic health record systems and demonstrate reliability of the performance scores.

- *Severe Obstetric Complications eCQM*

The AMA remains committed to addressing inequity and decreasing maternal morbidity and mortality and we believe that this measure in addition to initiatives such as the CDC Alliance for Innovation on Maternal Health (AIM) bundles will drive improvements in maternal complications and death. We request that CMS reconsider whether inclusion of some of the risk factors, specifically severe and other preeclampsia and obstetric VTE, are appropriate since their inclusion could mask potentially avoidable severe maternal morbidity.

- *Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e)*

The AMA questions whether this measure has a sufficient variation and performance gap to support its use for accountability purposes. The recent submission to the NQF reported performance scores across six hospitals that ranged between 0.11 to 0.45 percent. As a result, the AMA does not believe that this measure will provide meaningful data to hospitals and patients and does not support inclusion of the measure into the IQR program.

- *Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559)*

The AMA supports the assessment of patient-reported outcomes but believes that the burden of data collection both to the hospital and the patient must be adequately addressed prior to any reporting of this measure in a quality program. In the NQF endorsement review of this measure, the developer did not adequately assess the feasibility and potential data collection burden both to the hospital and patient. Specifically, the responses to the questions on feasibility do not discuss how the testing sites coordinated data collection across settings or whether the responsibility of the multiple data elements from additional patient-reported surveys used in the risk adjustment approach was placed on the hospital. This question is particularly important since the specifications require hospitals to collect data for one measure from 90

days pre-operatively to up to one-year post-operative. More importantly, we would have liked to see an assessment from the patient's perspective on whether the timing and number of items solicited throughout this process were appropriate and do not result in survey fatigue. For example, if these data were collected on the morning of the surgery, could stress and anxiety have impacted responses or would the number of surveys throughout the pre-, intra-, and post-operative timeframes lead them to be less likely to complete other surveys such as HCAHPS? We believe that it is critical to understand the potential impact and burden that could be experienced. While it may seem reasonable for one measure, if this measure is an example of how future measures could be specified, what is the potential long-term impact on patients and hospitals as more and more patient-reported outcome performance measures are implemented?

These concerns are especially valid given the proposed timelines for the voluntary and subsequent mandatory reporting for this measure, particularly for those hospitals that rely on CMS to aggregate the data and provide the results. Based on the requirements outlined in the Data Submission and Reporting of the Hospital Inpatient Quality Reporting program section of this proposed rule, hospitals must submit data for 50 percent of their eligible patients. Unless a hospital has past experience with this measure and its required surveys, it may be extremely challenging for some facilities to meet this requirement. If the goal of this voluntary period is to provide hospitals time to gain experience collecting the required data, then we recommend further flexibility in the reporting requirements. Specifically, CMS should be willing to revisit the reporting requirements based on the number of hospitals who elect to report the measure for CY2023 and 2024 as well as the degree to which response rates are not negatively impacted due to the length of follow-up time. We are concerned that it may take longer than two years for hospitals to be ready to report a measure of this complexity. In addition, hospitals who are able to successfully report data to CMS in the first year of reporting will only have received results once by the time that mandatory reporting is proposed to begin and those who elect to start reporting in CY2024 will not have received any reports or feedback from CMS. The AMA recommends that CMS reconsider the reporting requirements and provide a longer timeframe to begin voluntary reporting and then the subsequent move to mandatory reporting.

- *Substantive Measure Refinement and Reintroduction: Medicare Spending Per Beneficiary (MSPB) Hospital (NQF #2158)*

The AMA does not support the inclusion of this updated measure currently. We continue to believe that the current risk adjustment model is not adequate due to the unadjusted and adjusted R-squared results ranging from 0.11 to 0.67 across the Major Diagnostic Categories nor is the measure adequately tested and adjusted for social risk factors. It is unclear to us why the developer would test social risk factors after adjusting for clinical risk factors rather than assessing the impact of both clinical and social risk factors in the model at the same time. These variations in how risk adjustment factors are examined could also impact how each variable (clinical or social) perform in the model and remain unanswered questions. In addition, we note in the information submitted to NQF during the recent endorsement maintenance review hospitals' measure scores shifted when some or all of the social risk factors were applied within the risk model and particularly just over 15 percent of safety-net hospitals moved above or below the delta. We believe that this concern must be addressed prior to its inclusion in the Hospital IQR program.

In addition, we remain concerned that there will be two different performance scores publicly reported until CMS is able to replace the existing measure with this new one. We believe that CMS should halt reporting of the existing measure including any public release of performance results once this updated measure is publicly reported. Continued use of the existing measure would be inappropriate and could produce conflicting information to providers and patients.

- *Substantive Measure Refinement and Reintroduction: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) (THA/TKA Complication Measure)*

The American Medical Association recommends that the CMS reconsider the addition of the ICD-10 codes for mechanical complications if the National Quality Forum Standing Committee does not agree and continue to monitor whether their addition impacts the reliability and validity of the measure.

In addition, we remain concerned that there will be two different performance scores publicly reported until CMS is able to replace the existing measure with this new one. We believe that CMS should halt reporting of the existing measure including any public release of performance results once this updated measure is publicly reported. Continued use of the existing measure would be inappropriate and could produce conflicting information to providers and patients.

b. Current Measure Refinements

- *Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA (NQF #3474) (THA/TKA Payment Measure)*

The AMA recommends that CMS reconsider the addition of the ICD-10 codes for mechanical complications if the National Quality Forum Standing Committee does not agree and continue to monitor whether their addition impacts the reliability and validity of the measure.

- *Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) (NQF #2881) (AMI EDAC)*

The AMA appreciates CMS' efforts to ensure that this measure produces reliable performance scores. Even with the increase of cases to a minimum of 50, we do not believe that the measure meets what we consider to be the acceptable interclass correlation coefficients threshold of 0.6. Because the minimum number of cases that would be required to achieve this threshold is 300, we anticipate that it will significantly reduce the number of hospitals to which the measure would apply. As a result, the AMA does not believe that the measure is appropriate for this program and should be removed.

c. Potential Future Measures

- *Clostridioides difficile CDC NHSN Health-Associated Infection (HA-CDI) Outcome Measure*
- *CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure*

The AMA supports the further refinement of the numerator requirements to improve the validity of the Healthcare-Associated Clostridioides difficile Infection Outcome Measure. Regarding future inclusion of these measures within any of the CMS hospital quality program, we believe that each measure must be adequately evaluated to ensure that each is feasible for hospitals to collect and report the required data elements. These feasibility assessments are particularly important since at least one of the measures (the Hospital-Onset Bacteremia & Fungemia Outcome Measure) is proposed to use Admission-Discharge-Transfer data using Fast Healthcare Interoperability Resources (FHIR) or other standards. To our knowledge, CMS and the CDC have not leveraged these data sources for quality measure reporting in the past. While the AMA generally supports moving toward measures that minimize reporting burden on

hospitals, we only support the inclusion of these measures once feasibility of electronic reporting and reliability and validity of the data elements and performance scores are demonstrated.

IX. Social Determinants of Health (SDOH) ICD-10 Z Codes

While the AMA supports data collection efforts to improve the reporting of SDOH to advance the ability to recognize severity of illness, complexity of service, and/or utilization of resources, we believe it is premature to mandate reporting of SDOH ICD-10 Z codes on all claims. There are several administrative factors that must be considered first to standardize the data and improve the reliability and validity of the coded data, including in support of efforts to advance health equity. The data collected must be high quality to ensure that social needs are more accurately identified and managed to, ultimately, improve health outcomes and reduce data collection burden.

a. Reduce variability in screening intake and diagnosis/condition coding as a result of screening

Screening questions and answers that have pre-identified ICD-10-CM codes associated with positive screens are preferred over screening responses that require further human interpretation and coding. Focused collections of ICD-10-CM Z-codes should be sourced from an evidence-based consensus driven process like that of the Gravity Project. Furthermore, at a future state, the logic for how to convert from a set of screening responses to health concerns/condition codes, should be maintained by each screening instrument "owner" and published alongside the codified screening instrument in LOINC so that (1) screening can be more automated and (2) different implementations of the same screening instrument will produce consistent health concern and diagnosis coding.

b. Reduce variability in screening instruments

Ideally a single, evidence-based screening instrument for each SDOH domain would be used. This does not currently exist, but work has been done in Gravity to identify questions and answers from various screening instruments that could be used as input in the creation of a single, consistent, multi-domain screening instrument for use in the United States.

c. Increase interoperability of screening responses

Screening instruments should be codified in LOINC to make it possible to exchange using FHIR SDOH Clinical Care implementation guide.

d. Information economics

Provider services and resources related to SDOH screening, SDOH diagnosis, SDOH goals, SDOH interventions and, ultimately, SDOH outcomes should be accounted for via relevant payment models. This requires that the tracking data be maintained and kept current to maximize its value and utility. There are 4 categories of activities related to screening and managing SDOH conditions. There are opportunities in each service category to collect data and there needs to be appropriate reimbursement for these services to improve the reliability and validity of the data. The 4 service categories are:

1. Screening.

2. Delivery of clinical services inpatient and outpatient in the presence of social needs/SDOH diagnoses.

3. Coordination of care between clinical and extra-clinical (e.g., community-based organizations) resources to ensure SDOH conditions are being addressed and to provide appropriate visibility into progress to clinical from extra-clinical.

4. Delivery of services to address an SDOH diagnosis—enrollment in food pantry, mitigate mold in the home, fix heating in the home, etc. This is not covered systematically across health care. SNOMED CT and 211 LA taxonomy have some codified content to capture these types of services, but there is no RUC likely process to value these services. Such a valuation process is likely needed.

As mentioned above, there is also a need for coordination of care between clinical and extra clinical resources to ensure SDOH conditions are being addressed. CMS' discussion on the importance of collecting SDOH gives no consideration regarding whether patients are connected to and provided the resources to assist with SDOH. In some cases, the presence of an SDOH diagnosis code may affect the complexity of inpatient clinical services. For example, managing a patient with malnutrition related to food insecurity is an additional factor in their hospital course and discharge planning effort. In other cases, the presence of an SDOH diagnosis code may require social services support to address a need post-discharge, but the complexity of the inpatient clinical services is not affected. For example, a diabetic patient may screen positive for transportation issues and a social worker will refer them to a ride service for routine follow ups, but the clinical management of the patient's soft tissue infection (reason for admission) was not affected. In some cases, a patient may require more complex clinical services and social services because of the presence of an SDOH diagnosis code. For example, the patient with malnutrition related to food insecurity may also require additional social services in preparation for discharge.

e. Reporting of certain Z codes—and if so, which ones—to be reported on hospital inpatient claims to strengthen data analysis? CMS believes a potential starting point for discussion is consideration of the SDOH Z diagnosis codes describing homelessness.

Currently, we believe it is premature to require reporting of certain Z codes on hospital inpatient claims. The current HIPAA-adopted 5010 version of the institutional claim (837I) allows for reporting 1 ICD-10 code for principal diagnosis, 1 ICD-10 code for admitting diagnosis (for inpatient admission), 3 ICD-10 codes for patient's reason for visit (for outpatient visits), 12 ICD-10 codes for external causes of injury, and 12 ICD-10 codes for other diagnosis information for coexisting conditions or ones that develop during the encounter. Therefore, there are not a lot of fields for a complex patient. Adding a requirement to report SDOH ICD-10 codes in the 837I will likely max out the existing fields resulting in codes not being reported or the need to find another place in the claim to report the overflow codes. Both options could result in capturing incomplete SDOH data on the patient and not lead to the goal of strengthening data analysis or resource use.

While documenting for homelessness or housing instability may impact a treatment plan, particularly post-operation, or discharge from a facility, it is early to require documentation of homelessness on a claim since there is no official standardized tool to screen for it. Housing instability and transportation

remain in a draft phase—HUD has a gold standard tool for Housing Instability in development. At this time, only food insecurity has been finalized and uses a gold standard tool. This is food insecurity with the USDA Food Security Module.

Any requirement to report certain Z codes should track and align with the efforts of the HL7 Gravity Project and USCDI and only include codes that have associated screening tools that have been psychometrically tested, including sensitivity and specificity.

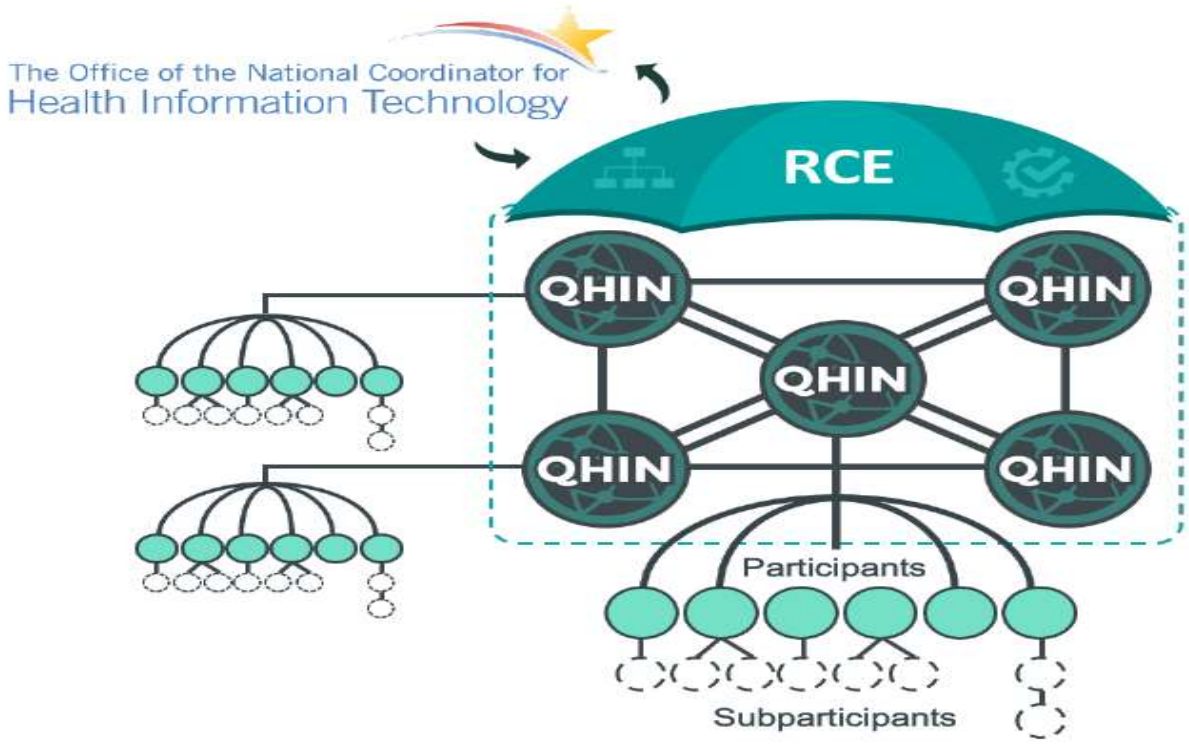
f. The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries.

Having to report any additional codes adds to the work effort to code the patient's record and enter the data in the claim. Reporting the codes in the 837I vs. a different reporting tool would likely be less burdensome because the claim is already being compiled and sent to the payer. Having to report the codes in a different reporting tool adds the burden of another workflow to capture and transmit the data. The benefit of documenting and reporting the SDOH codes is that the information is being addressed within the scope of the patient's overall care and treatment.

X. Proposed New Enabling Exchange Under Trusted Exchange Framework and Common Agreement (TEFCA) Measure

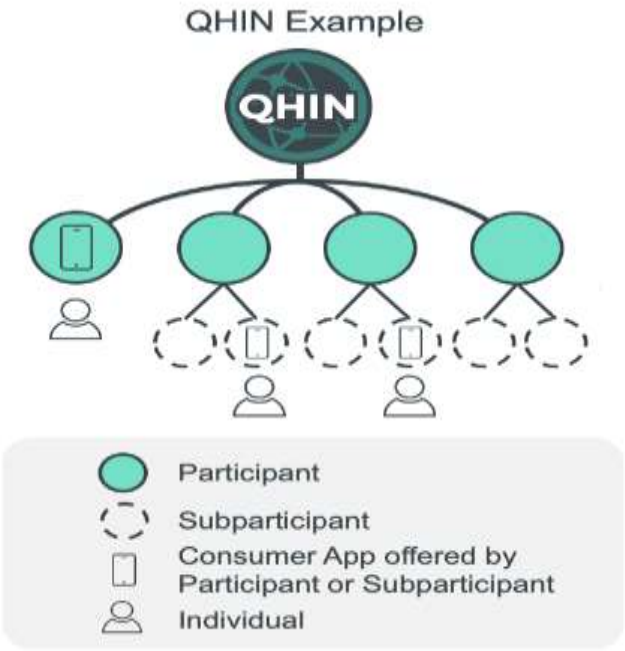
The AMA supports CMS' proposal to add an alternative measure to the Health Information Exchange (HIE) Objective under the Performance Improvement Project (PIP) for enabling exchange under the Trusted Exchange Framework and Common Agreement (TEFCA). **The AMA agrees with CMS that including TEFCA as an optional measure will likely play an important role in hospitals enabling bi-directional health information exchange.** Further, the AMA supports CMS in using an attestation-based approach rather than requiring numerator/denominator measurement for PIP reporting. However, as CMS explores ways to provide additional guidance or update this measure to promote future HIE and TEFCA participation, **CMS should consider the unintended consequences if TEFCA participation itself becomes unstable.**

The AMA agrees with CMS that stakeholders across the care continuum will have increasing opportunities in 2023 to enable exchange under TEFCA. Early in 2022, The Office of the National Coordinator for Health Information Technology (ONC) published information outlining the hierarchical structure of the TEFCA where:



- ONC defines overall policy and certain governance requirements.
- Recognized Coordinating Entity (RCE) provides oversight and governing approach for QHINs.
- Qualified Health Information Networks (QHINs) connect directly to each other to facilitate nationwide interoperability.
- Each QHIN connects Participants, which connect Subparticipants.

While this structure allows for a "trickledown" of policies and technical requirements originating from ONC to subparticipants, it also creates a situation where the termination or removal of one entity can create a domino effect and impact the operations of several entities down the line. For example, a QHIN can support a broad range of participants, including health care organizations, HIEs, EHR systems, pharmacy health information technology (IT) systems, and a consumer applications (app). Each participant may support dozens or hundreds of subparticipants who, in turn, may also support hundreds or thousands of individuals. If, for instance, an EHR system ceases to participate in the TEFCA, subparticipants would likely be impacted. As a result, there could be delays in accessing, exchanging, or using needed electronic health information (EHI) or direct harm to patients and other individuals relying on EHI.



As entities incorporate TEFCA within their environments, they will likely become dependent on EHI data feeds provided by TEFCA participation. Moreover, the AMA expects several entities and health IT systems to utilize TEFCA participation to further automate administrative and clinical exchanges, e.g., prior authorization, transitions in care, or public health reporting. As a result, and like a Jenga tower, if one entity is removed the entire TEFCA stack could be in jeopardy.

ONC contemplates the "Stability of the QHIN Network" within its Principles for Trusted Exchange.[85] For instance, ONC's terms allow a QHIN to terminate its participation in the TEFCA within 90 days of notice to the Recognized Coordinating Entity (RCE)—a critical component of the TEFCA. Termination would result in the prompt removal of the QHIN, its participants, subparticipants, and individuals from the HIE network. Termination may also result in a lack of funding. ONC's terms state that "there are no guarantees that the RCE will continue unless a financial sustainability model has been put in place." The RCE may also terminate a QHIN immediately and suspend each entity's right to engage in any QHIN-to-QHIN exchange activities. Likewise, a participant or subparticipant is granted the same authority as the RCE to suspend any party's right to engage in the TEFCA.

While terms and conditions like these are important factors in a data governance framework, and the AMA does not expect a high occurrence of entity termination, we do encourage CMS to consider the following:

- Physicians and hospitals who choose to use TEFCA participation to meet the HIE Objective under PIP should be provided a hardship exception in instances when:
    - A physician or hospital's participation in TEFCA is limited or terminated due to a termination or suspension of an entity that precedes them in their local TEFCA hierarchy, or
    - A physician or hospital's participation in TEFCA is limited or impacted due to a termination or suspension of an entity elsewhere in the larger TEFCA network and relied on by that physician or hospital, e.g., a physician's practice under one QHIN relying on admit, discharge, or transfer messaging from a hospital under a separate QHIN.

Local or TEFCA-wide disruptions to EHI exchanges could compromise PIP participants' attestations, TEFCA measure reporting, and HIE Objective success. **PIP participants should not be held accountable for disruptions that are out of their control and that could impact the bi-directional exchange of information necessary for their PIP measure success.**

[85] https://www.federalregister.gov/documents/2022/01/19/2022-00948/notice-of-publication-of-the-trusted-exchange-framework-and-common-agreement.

Additionally, the impact of TEFCA instability should be strongly considered as CMS explores future TEFCA polices. For instance, the AMA would not support CMS requiring TEFCA participation under the HIE Objective. As previously stated, the AMA supports optional and voluntary measures coupled with attestation-based reporting. We also expect TEFCA to undergo modifications and improvements as participation increases. The success of TEFCA will lie in its ability to conform to the needs of the end user, e.g., patients and physicians. This will likely take time and several technical and legal iterations. CMS should refrain from "locking down" the TEFCA by attaching prescriptive federal PIP requirements to TEFCA participation. More work is also needed to understand the utility of TEFCA participation. Data is needed to monitor privacy and security considerations, functional interoperability, network resilience, costs, and fees, evolving technical requirements, and end-user satisfaction. **The AMA strongly urges CMS to take a wait-and-see approach prior to considering any TEFCA requirements within its PIP. Positive incentives, such as optional PIP measures, should be utilized for several years. CMS should make informed decisions based on data prior to any TEFCA PIP measure or objective requirement proposals.**

XI. Proposal to Require the Query of PDMP Measure

CMS is proposing to require the reporting of the Query of prescription drug monitoring program (PDMP) measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program (PIP). CMS further proposes to expand the Query of PDMP measure to include Schedule III and IV drugs.

The AMA continues to support PDMP Query as an optional measure in the Medicare PIP. As CMS points out, AMA research has shown that physician registration and use of PDMPs has increased in every state whether there is a mandate or not.[86] We agree with CMS' historical perspective that using positive incentives to advance the integration and use of PDMPs is warranted. Using positive incentives, such as PDMP reporting as an optional measure in PIP, should be retained. However, **the AMA does not support CMS' proposal to require the reporting of the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare PIP.** Requiring more PDMP use will unnecessarily increase administrative burdens and may harm and detract from CMS' policy goals to reduce drug overdose and death.

While PDMPs can provide helpful information, they are not diagnostic tools. Physicians have reduced opioid prescribing in every state for 10 consecutive years while increasing the use of state PDMPs in every state for the past five years. Despite these efforts, drug-related mortality continues to rise.[87] The data show that there is no correlation between increased PDMP use and decreased mortality, increased access to evidence-based care for pain or opioid use disorder (OUD), or any other positive outcomes. Moreover, an AMA survey of every state PDMP's data show that PDMPs were queried more than 910 million times in 2021, and yet, the overdose epidemic became worse—primarily due to the use of illicit fentanyl, methamphetamine, and cocaine—substances that are not contained in state PDMPs.[88] **Simply using policy levers to require that physicians and other health care professionals check PDMPs with increased frequency will not translate to a reduction in drug overdoses or deaths.**

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[86] https://end-overdose-epidemic.org/wp-content/uploads/2021/09/AMA-fact-sheet-PDMP-2014-2020-blue-FINAL.pdf.
[87] https://www.ama-assn.org/delivering-care/overdose-epidemic/physicians-progress-toward-ending-nation-s-drug-overdose-epidemic.
[88] https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

Ending the drug overdose epidemic requires removing barriers to evidence-based care. This includes removing prior authorization for medications to treat OUD, ending the federal "x-waiver" to treat patients with buprenorphine for OUD, increasing access to evidence-based care for patients with pain (including opioid therapy), and increasing access to harm reduction services (e.g., naloxone, fentanyl test strips, syringe services programs). These are the policy interventions that are proven to reduce mortality and improve outcomes. CMS payment systems should reduce payment barriers like prior authorization for buprenorphine and provide more support and positive incentives for physicians to provide comprehensive, multimodal, team-based care for patients with substance use disorders and/or pain. A federal mandate to use PDMPs will not reduce mortality or improve outcomes, but it might further increase stigma for patients with pain, reduce access to evidence-based care, and take away important resources from initiatives that will have a positive effect.

There is considerable concern and emerging data showing that PDMPs have a direct effect on stigmatizing patients with pain, causing physicians to discharge patients receiving opioid therapy, and leading to increased fear of treating patients with opioid therapy. The main platform for PDMPs—Bamboo Health (formerly Appriss)—uses a proprietary and opaque algorithm that is likely contributing to the negative uses of PDMP. NarxCare, Bamboo Health's flagship product, is an overdose risk algorithm that generates a "risk score" which claims to predict a patients' risk of prescription drug overdose. Yet, there is mounting evidence that patients with complex medical histories and chronic pain are seeing their pain suddenly go undertreated. This can be attributed to a high-risk NarxCare score.

A 2021 *WIRED* Magazine investigation found that patients with high-risk scores tended to have chronic illnesses and disabilities and happened to be overwhelmingly women. Rather than having substance use disorder, they were more often high health care utilizers due to their underlying complex chronic conditions. **Their risk scores were identified as a reason to deny pain relief.** According to *WIRED*, many researchers believe that NarxCare scores and other similar screening tools are "profoundly flawed."[89] Researchers stated that "patients who are most likely to be flagged as doctor-shoppers actually have cancer, which often requires seeing multiple specialists." Moreover, An October 2021 study published in *Drug and Alcohol Dependence* found that the NarxCare scores had a false-positive rate of 17.2 percent and a false-negative rate of 13.4 percent—**with nearly one-third of patients being misclassified.**[90]

In an *Annals of Emergency Medicine* article, experts in substance use disorders reported that "the single best predictor of a future overdose is an overdose in the past. However, that risk factor does not appear in the PDMP databases and, therefore, does not figure into the algorithm's overdose risk score." Experts also stated that "the vast majority of overdose deaths today involve illicitly manufactured fentanyl or other drugs purchased in the illegal market, such as methamphetamine. This means that those with the most risk of overdose could have a risk score of 0 because the drugs they use are not prescribed by doctors."[91]

Concerns continue to emerge that the algorithm may exacerbate longstanding inequities in pain care facing Black and Brown Americans. Patients with painful conditions need to be treated as individuals. They need access to multimodal therapies including restorative therapies, interventional procedures, and medications. These include non-opioid pain relievers, other agents, and opioid analgesics when

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[89] https://www.wired.com/story/opioid-drug-addiction-algorithm-chronic-pain/.
[90] Cochran G., Brown J., Yu Z., et al. Validation and threshold identification of a prescription drug monitoring program clinical opioid risk metric with the WHO alcohol, smoking, and substance involvement screening test. Drug Alcohol Depend. 2021; 228: 109067.
[91] https://www.annemergmed.com/article/S0196-0644(22)00243-8/fulltext#relatedArticles.

appropriate. **Patients with sickle cell disease, cancer, terminal conditions, and those on long-term opioid therapy are often stigmatized, mistreated, and undertreated because of the narrow focus on checking PDMPs.**

We agree that there may be value in encouraging clinicians to check state PDMPs; however, CMS is improperly conflating this intervention with the idea that it will reduce the number of deaths from opioid prescriptions. **Increasing the number of times a clinician checks a state PDMP does not reduce drug-related mortality and there is no meaningful data suggesting PDMPs improve the quality of pain care.** Additionally, physicians have reduced opioid prescribing by more than 44 percent since 2012, but the drug overdose epidemic has gotten worse. This is because the overdose epidemic is not being driven by prescription opioid analgesics; rather, it is now mostly fueled by illicitly manufactured fentanyl, fentanyl analogs, heroin, methamphetamine, and cocaine. One study found that "although the PDMPs' intermediary purpose to reduce prescribing has been achieved by reducing opioid distribution by 7.7 percent, they have had inconsistent effects on prescription opioid overdoses, while increasing total opioid overdoses by 17.5 percent due to increasing mortality from the black market varieties by 19.8 percent" and concludes that "[s]ince PDMPs fail to achieve their ultimate goal of reducing opioid overdoses, [resources] should be re-appropriated to more effective mechanisms to reduce addiction and overdose rates, such as providing access to prescription quality opioids for medication-assisted treatment (MAT)."[92]

The AMA reiterates its support for positive incentives to assist in better integrating PDMPs into physicians EHRs. However, the evidence is clear. Requiring physicians to check a PDMP ignores the inadequacies of PDMPs and will likely increase the level of stigma and exacerbate longstanding health inequities. **Checking a PDMP will not address illicit drug use, can result in the denial of care for chronic individuals, and can lead to patient mistreatment.** More must be done to support physicians treating drug overdoses, but additional PIP check-the-box measures are not the answer.

XII. Proposed Revisions and Reporting Requirements for Level of Engagement

CMS currently allows three options for hospitals to demonstrate active engagement with a public health agency (PHA) or clinical data registry (CDR). Those include (1) complete registration to submit data, (2) test and validate electronic submission of data, and (3) complete testing and validation of the electronic submission and electronically submit production data. CMS proposes to consolidate options (1) and (2) into a new option, i.e., "Option 1 Pre-production and Validation". Current option (3) would be renamed "Option 2 Validated Data Production." In addition, CMS proposes to require eligible hospitals and CAHs to submit their level of active engagement. Lastly, CMS proposes that eligible hospitals and CAHs may spend only one EHR reporting period at the Pre-production and Validation level of active engagement, and that they must progress to the Validated Data Production level for the next EHR reporting period.

While the AMA supports CMS' proposal for hospitals to submit their level of active engagement and recognizes CMS desire for hospitals to progress from testing to validation and to production stages of PHA and CDR engagement, **we are concerned CMS' proposal to limit hospitals' Pre-production and Validation level of active engagement to only one EHR reporting period is shortsighted.**

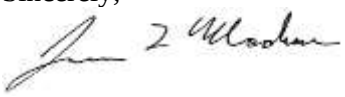
[92] Reason Foundation, Prescription Drug Monitoring Programs: PDMP Effects on Opioid Prescribing and Drug Overdose Mortality, by Jacob James Rich and Robert Capodilupo (July 2021), available at https://reason.org/wpcontent/uploads/prescription-drug-monitoring-programs-effects-on-opioid-prescribing-and-drug-overdosemortality.pdf.

As CMS notes within its proposed rule, CMS lacks information and is unaware of the current readiness or active engagement level of eligible hospitals, PHAs, and CDRs. CMS states that "eligible hospitals and CAHs currently are not required to report their level of active engagement," and that "knowing the level of active engagement that an eligible hospital or CAH selects would provide information on the types of registries and geographic areas with health care providers in the Pre-production and Validation stage." Furthermore, CMS believes that "information regarding the level of active engagement would be helpful as it would enable HHS to identify registries and PHAs which may be having difficulty onboarding eligible hospitals and CAHs." CMS believes if it collects the necessary information it "will be able to identify the barriers that prevent [hospitals] from moving to the Validated Data Production stage and work to develop solutions to overcome the barriers." Given CMS' own statements, it appears that **CMS currently lacks insight on hospital, PHA, and CDR readiness and CMS is seeking information to help "develop solutions" to support hospital active engagement progression.**

It is counterintuitive for CMS to discuss a lack of hospital, PHA, and CDR engagement awareness and to propose new information collection requirements, and yet, propose engagement progression requirements on hospitals, PHAs, and CDRs without the necessary information to justify its own proposal. This seems to be putting the cart before the horse. **The AMA recognizes CMS needs to capture engagement information and supports CMS' proposal to require hospital reporting. However, the AMA does not support CMS' proposal to require that hospitals progress to the Validated Data Production level after only one EHR reporting period.** Again, it is unclear how CMS can justify hospital progression requirements without an informed baseline understanding of the PHA and CDR landscape. Once CMS collects active engagement information from hospitals in 2023 and beyond, CMS would likely then have sufficient information to inform future policy decisions, including solutions to help hospitals "overcome the barriers" and identify registries and PHAs that are "having difficulty onboarding eligible hospitals." **CMS should refrain from imposing progression requirements on hospitals until CMS has a clear and informed understanding of the PHA and CDR landscape, hospital needs, and barriers that must be overcome.**

We greatly appreciate this opportunity to share the views of the AMA regarding the proposals, issues, and questions that CMS has raised in the 2023 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Proposed Rule. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD