C. Maternity Care Request for Information (RFI)

1. Overview

As described in the White House Blueprint for Addressing the Maternal Health Crisis and in the CMS Maternity Care Action Plan we are committed to reducing maternal health disparities and improving maternal health outcomes during pregnancy, childbirth, and the postpartum period.[762, 763] In alignment with our commitment to addressing the maternal health crisis, this RFI seeks to gather information on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients as compared to non-Medicare patients. To the extent that the resources required differ between patient populations, we also wish to gather information on the extent to which non-Medicare payers, or other commercial insurers, may be using the IPPS as a basis for determining their payment rates for inpatient pregnancy and childbirth services and the effect, if any, that the use of the IPPS as a basis for determining payment by those payers may have on maternal health outcomes.

2. Use of Medicare Data for the Calculation of the IPPS MS-DRG Relative Weights

As explained in section II.A. of the preamble of this proposed rule, section 1886(d)(4) of the Act requires the Secretary to establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. We refer to these groups of diagnoses as the IPPS Medicare Severity Diagnosis Related Groups (MS-DRGs). For each MS-DRG, the Secretary is required to assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. The Secretary is also required to adjust the MS-DRG classifications and weighting factors at

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[762] White House. White House Blueprint for Addressing the Maternal Health Crisis. 2022. Accessed January 2, 2024. https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf

[763] CMS. CMS Cross Cutting Initiative: Maternity Care Action Plan. 2022. Accessed January 2, 2023. https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf

least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58652), our goal is always to use the best available data overall for ratesetting, including the calculation of the IPPS MS-DRG relative weights. We primarily utilize Medicare claims data and Medicare cost report data for IPPS ratesetting for inpatient hospital services. The claims data we utilize is specific to the Medicare beneficiaries population, which includes people 65 and older or people with disabilities, End-Stage Renal Disease, or amyotrophic lateral sclerosis (ALS) that qualifies them for Medicare earlier than the age of 65. [764] Although most Medicare beneficiaries are 65 and older, in 2021 around 13% of the total share of Medicare beneficiaries were under the age of 65.[765] Therefore, people of reproductive age may have Medicare as their primary health insurance. Notably, a study from the National Institutes of Health found that pregnant women with disabilities have higher risks for maternal mortality and severe complications during birth and pregnancy compared to other pregnant women.[766] Thus, considering we utilize data that is specific to the Medicare beneficiary population in our ratesetting for inpatient hospital services we caution against using the IPPS rates and DRGs without first taking into account the characteristics of the Medicare beneficiary population.

3. Request for Information

This RFI seeks to gather information on differences between the resources required to provide inpatient obstetrical services to Medicare patients, on which the IPPS MS-DRGs relative weights for those services are based, as compared to non-Medicare patients. To the extent that the resources required differ, we also seek information regarding the extent to which non-

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[764] Who's eligible for Medicare? U.S. Department of Health and Human Services. Accessed January 2, 2024. https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html
[765] Medicare Beneficiaries at a Glance 2023 Edition. Centers for Medicare and Medicaid Services. https://data.cms.gov/infographic/medicare-beneficiaries-at-a-glance
[766] Gleason JL, Grewal J, Chen Z, Cernich AN, Grantz KL. Risk of Adverse Maternal Outcomes in Pregnant Women With Disabilities. JAMA Netw Open. 2021;4(12):e2138414. Published 2021 Dec 1. doi:10.1001/jamanetworkopen.2021.38414

Medicare payers, such as state Medicaid programs, may be using the IPPS MS-DRG relative weights to determine payment for inpatient obstetrical services and the effect, if any, that the use of those relative weights by those payers may have on maternal health outcomes. For instance, what types of modifications or assumptions, if any, are being made by payers when they are using the IPPS MS-DRG relative weights to account for the fact they are based on the Medicare beneficiary population? For example, one area where we are seeking additional information is the extent to which the use of the IPPS MS-DRG relative weights by state Medicaid programs may influence the number of low-risk cesarean deliveries for Medicaid patients. There are state Medicaid programs that have implemented payment initiatives, such as bundled payment models, blended payments, reduced payment or nonpayment for some procedures, and pay-for-performance models to improve maternal health outcomes. Some initiatives have demonstrated improved outcomes, such as a reduction in unnecessary cesarean deliveries.[767] Does the use of the IPPS MS-DRG relative weights as the basis for setting rates for other payers, to the extent it occurs, impact efforts to reduce low-risk cesarean deliveries? For example, if the differential between the hospital resources required for vaginal versus cesarean births is not the same for Medicare and non-Medicare patients, does the use of the IPPS MS-DRG relative weights for non-Medicare patients impact the number of low-risk cesarean deliveries? If so, how? For reference, IPPS MS-DRG relative weights and arithmetic length of stay for MS-DRGs for vaginal births and cesarean births are shown in Table X.C.-01.[768]

In summary, we pose the following questions to help facilitate feedback. We note that posing these questions to facilitate feedback in no way alters our longstanding principle, reiterated each year in the IPPS rulemaking, that facilities should not consider differences in relative weights when making treatment decisions.

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[767] MACPAC. Medicaid Payment Initiatives to Improve Maternal and Birth Outcomes. MACPAC. Published April 2019. https://www.macpac.gov/wp-content/uploads/2019/04/Medicaid-Payment-Initiatives-to-Improve-Maternal-and-Birth-Outcomes.pdf

[768] For other obstetrics MS-DRGs not listed in the table, refer to MS-DRG Definitions Manual: MDC 14 Pregnancy, childbirth and the puerperium located at: https://www.cms.gov/icd10m/FY2024-nprmversion41.0-fullcode-cms/fullcode_cms/P0017.html

- What policy options could help drive improvements in maternal health outcomes?
- How can CMS support hospitals in improving maternal health outcomes?
- What, if any, payment models have impacted maternal health outcomes, and how?
- What, if any, payment models have been effective in improving maternal health outcomes, especially in rural areas?
- What factors influence the number of vaginal deliveries and cesarean deliveries?
- To what extent do non-Medicare payers, such as state Medicaid programs, use the IPPS MS-DRG relative weights to determine payment for inpatient obstetrical services? What effect, if any, does the use of those relative weights by those payers have on maternal health outcomes?
- To what extent are Medicare claims and cost report data reflective of the differences in relative costs between vaginal births and cesarean section births for non-Medicare patients?
- Are there other data beyond claims and cost reports that Medicare should consider incorporating in development of relative weights for vaginal births and cesarean section births?
- What impact, if any, does the relatively lower numbers of births in Medicare have on the variability of the relative weights?
- What effect, if any, does potential variability in the relative weights on an annual basis have on maternal health outcomes?

TABLE X.C.-01: IPPS MS-DRG RELATIVE WEIGHTS AND GEOMETRIC MEAN LENGTH OF STAY (LOS) FOR VAGINAL AND CESAREAN DELIVERIES (FY 2021 - FY 2025)

			Proposed FY 2025		FY 2024		FY 2023		FY 2022		FY 2021	
MS-DRG[1]	**Delivery Type[2]**	**Annual Medicare Cases[3]**	**Weight**	**LOS**	**Weight**	**LOS**	**Weight**	**LOS**	**Weight**	**LOS**	**Weight**	**LOS**
783	Cesarean Section with MCC	112	1.8421	4.6	1.7718	4.5	1.9297	4.7	1.8749	4.8	1.8727	4.8
796	Vaginal Birth with MCC	10	1.2766	2.9	1.4184	2.5	1.3130	3.6	1.0708	3.6	1.0679	3.6
784	Cesarean Section with CC	265	1.0735	3.1	1.0241	3.1	1.0440	3.1	1.0959	3.3	1.0949	3.3
797	Vaginal Birth with CC	40	0.9683	2.3	0.9959	2.4	0.9279	2.1	0.9194	2.4	0.9199	2.4
785	Cesarean Section without MCC/CC	202	0.8731	2.5	0.8663	2.5	0.9121	2.6	0.9168	2.7	0.9153	2.7
798	Vaginal Birth without MCC/CC	32	0.9683	2.3	0.8112	2.0	0.9279	2.1	0.8275	2.1	0.8273	2.1
786	Cesarean Section with MCC	398	1.5746	4.2	1.7495	4.3	1.6150	4.2	1.5944	4.3	1.5911	4.3
805	Vaginal Birth with MCC	312	0.9931	2.8	1.0082	2.8	1.0056	2.8	1.0299	2.9	1.0268	2.9
787	Cesarean Section with CC	981	1.0577	3.3	1.0511	3.3	1.0653	3.2	1.0644	3.5	1.0627	3.5
806	Vaginal Birth with CC	1153	0.7205	2.3	0.7467	2.3	0.6978	2.3	0.7346	2.3	0.7339	2.3
788	Cesarean Section without MCC/CC	700	0.9011	2.9	0.8550	2.7	0.8724	2.7	0.8874	3.0	0.8871	3.0
807	Vaginal Birth without MCC/CC	1534	0.6340	2.0	0.6543	2.0	0.6314	2.0	0.6423	2.1	0.6411	2.1

[1] MS-DRG definitions can be located in the ICD-10 MS-DRG Definitions Manual Files V41.1 located at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software

[2] CC refers to complications and comorbidities. MCC refers to major complications and comorbidities.

[3] For purposes of illustrating the approximate annual number of Medicare FFS cases in each MS-DRG, this column shows case counts based on the data used to develop the proposed FY 2025 MS-DRG relative weights, as discussed in section II.D. of the preamble of this proposed rule.

D. Request for Information on Obstetrical Services Standards for Hospitals, CAHs, and REHs

1. Background

CMS establishes health and safety requirements for Medicare-certified providers and suppliers and selected Medicaid provider types. The requirements apply to all patients served by these facilities and must be met in order for facilities to participate in the Medicare and Medicaid programs. Conditions of participation (CoPs) for hospitals, CAHs, and rural emergency hospitals (REHs) set regulatory standards for many of the basic functions of such hospitals, as well as for some optional services that hospitals are not required by law to provide. Hospital CoPs at 42 CFR part 482 include standards regarding the responsibilities of the governing body, requirements for protecting patient rights, quality assessment and performance improvement requirements (QAPI), medical staff standards, and infection prevention and control and antibiotic stewardship requirements. All of these current standards together exist to protect patient health and safety, including the health and safety of pregnant, postpartum, and birthing patients. Similar provisions for CAHs and REHs are found at 42 CFR 485 subparts F and E, respectively.

Currently, there are no baseline care requirements for hospitals, CAHs, and REHs that are specific to maternal-child services (that is, labor and delivery, prenatal and post-partum care, and care for newborn infants, alternately referred to in this discussion as obstetrical services, obstetrics, maternal health, or maternity care). In addition to obstetrical units, care for pregnant and postpartum patients may also occur in other parts of facilities such as other inpatient wards, emergency departments, hospital-associated outpatient departments, as well as in facilities without obstetrical units and/or emergency services. Such care may occur before, during, or after delivery. Given the ongoing concerns about the delivery of maternity care in Medicare and Medicaid certified hospitals, CAHs, and REHs, CMS plans to propose baseline health and safety standards for obstetrical services in the calendar year (CY) 2025 Outpatient Prospective Payment System/Ambulatory Surgical Center (ASC) proposed rule.

Access to maternity care in the U.S. has continued to decline in recent years. Specifically, it is estimated that up to 6.9 million women have low to no access to maternity care.[769] From 2014 to 2018, 53 rural counties experienced closures of their hospital-based obstetrical (OB) services. This is in addition to the 1,045 counties that already did not have obstetric services in 2014.[770] Furthermore, 200 urban counties lost one or more obstetric units between 2019 and 2020.[771] The March of Dimes published a report which found that there were closures across 12 states from 2019 to 2020, in which 21 rural counties lost one or more hospital obstetric units.[772] In 2019, an estimated 58.7 percent of rural counties had no obstetricians, 81.7 percent had no advanced practice midwives, 86.3 percent had no midwives, and 56.9 percent had no family physicians who delivered babies, and nearly a third of rural counties (608, 30.8 percent) had none of these types of OB clinicians.[773] Explanations for these closures include shortages of obstetricians and family physicians, low volume of births, and low-income/poor payer-mix in these communities.[774] When these units close, women must travel long distances to a hospital that has obstetrical services. Specifically, in a survey of 133 hospital administrators, those in areas that lost access to inpatient obstetric services also reported limited access to many supports and services (such as midwifery and doula care) indirectly related to inpatient obstetric care that have strong evidence of improving maternal and infant health outcomes.[775] Factors that affect the availability of rural hospital-based obstetric care include labor costs, liability insurance costs, a high proportion of births to people who are uninsured or covered by Medicaid, and low payment

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[769] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf
[770] Kozhimannil KB, Interrante JD, Tuttle MKS, Henning-Smith C. Changes in Hospital-Based Obstetric Services in Rural US Counties, 2014-2018. JAMA. 2020;324(2):197-199.
[771] American Hospital Association, 2019-2020.
[772] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf
[773] https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2020/06/RHRC_PB168_Patterson.pdf
[774] Nowhere to Go: Maternity Care Deserts Across the U.S. 2022 Report. March of Dimes. https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf and American Hospital Association, 2019-2020.
[775] https://rhrc.umn.edu/wp-content/uploads/2022/12/UMN_Infographic_Comparison-of-Evidence-based-supports.pdf

rates for maternity care services.[776] Lack of access contributes to women in rural areas having a nine percent increased probability of maternal mortality or morbidity as compared to women in urban areas.[777] Poor maternal health access disproportionately affects non-Hispanic black women, American Indian and Alaska Native women (AI/AN), low-income women and women with disabilities. For example, in 2021, the maternal mortality rate for non-Hispanic Black women was 69.9 deaths per 100,000 live births, 2.6 times the rate for non-Hispanic White women. Rates for Black women were significantly higher than rates for White and Hispanic women. The increases from 2020 to 2021 for all race and Hispanic-origin groups were significant.[778] CMS considers it imperative to address disparities in care when discussing policy changes for improving maternal health care.

In Fall 2023, CMS launched the first-ever "Birthing-Friendly" designation icon on CMS's Care Compare online tool to describe facilities with high-quality maternity care. To earn the designation, hospitals and health systems report their progress on our Maternal Morbidity Structural Measure to the Hospital Inpatient Quality Reporting (IQR) Program. The measure identifies whether a hospital or health system has participated in a statewide or national perinatal quality improvement collaborative program and implemented evidence-based quality interventions in hospital settings to improve maternal health, such as maternal safety bundles. Maternal safety bundles have demonstrated success in driving improvements, particularly with regards to obstetric hemorrhage, severe hypertension in pregnancy, and non-medically indicated Cesarean deliveries.[779,780,781] Hospitals and health professionals also have access to evidence-

[776] The Government Accountability Office, GAO-23-105515, MATERNAL HEALTH: Availability of Hospital-Based Obstetric Care in Rural Areas, https://www.gao.gov/assets/gao-23-105515.pdf.
[777] Hostetter M, Klein S. Restoring Access to Maternity Care in Rural America. The Commonwealth Fund. September 20, 2021. Available at: https://www.commonwealthfund. org/publications/2021/sep/restoring-access-maternity-careruralamerica. Accessed May 17, 2022.
[778] https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm
[779] Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.
[780] Elliott K. Main et al. Reduction of severe maternal morbidity from hemorrhage using a state perinatal quality collaborative. Am J Obstet Gynecol 2017;216(3):298.e1-298.e11.
[781] Patricia Lee King et al. Reducing time to treatment for severe maternal hypertension through statewide quality improvement. Am J Obstet Gynecol 2018;218:S4.

based best practices for determining the risk of obstetric hemorrhage and hypertension and for managing patients with these complications (including in the emergency setting). Yet, these best practices are not universally utilized nor incorporated into facilities' standards of care.[782] We direct readers to the quality, safety, and oversight memorandum (QSO-22-05-Hospitals) released by CMS,[783] which encourages hospitals to consider implementation of evidence-based best practices for the management of obstetric emergencies, along with interventions to address other key contributors to maternal health disparities, to support the delivery of equitable, high-quality care for all pregnant and postpartum individuals. Facilities could implement these best practices voluntarily as part of a hospital's QAPI program (§482.21), which requires that hospitals develop, implement, and maintain an effective, ongoing, hospital wide, data-driven quality assessment and performance improvement program. The Quality Safety and Oversight (QSO) memo (QSO-22-05-Hospitals) further directs hospitals to a variety of resources available to assist in improvement efforts. These include the following:

- Agency for Healthcare Research and Quality Toolkit for Improving Perinatal Safety https://www.ahrq.gov/patient-safety/settings/labor-delivery/perinatal-care/index.html
- Centers for Disease Control and Prevention-Funded Perinatal Quality Collaboratives https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pqc.htm
- HRSA-Funded AIM Program Patient Safety Bundles https://saferbirth.org/
- HRSA-Funded Rural Health Information Hub Rural Maternal Health Toolkit https://www.ruralhealthinfo.org/toolkits/maternal-health
- Institute for Healthcare Improvement Tools https://www.ihi.org/resources/tools
- National Institute for Children's Health Quality National Network of Perinatal Quality Collaboratives https://nichq.org/project/national-network-perinatal-quality-collaboratives

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[782] Jennifer A. Callaghan-Koru et al. Implementation of the Safe Reduction of Primary Cesarean Births safety bundle during the first year of a statewide collaborative in Maryland. Obstet Gynecol 2019;134:109–19.

[783] https://www.cms.gov/files/document/qso-22-05-hospitals.pdf

- The Joint Commission Provision of Care, Treatment, and Services Standards for Maternal Safety https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/
- U.S. Department of Health and Human Services and March of Dimes Public-Private Partnership, Maternal Health Collaborative to Advance Racial Equity (Maternal HealthCARE), Quality Improvement Initiative https://www.maternalhealthcare.org/

This list is not exhaustive. We recommend that hospitals also explore other national resources, as well as those specific to their state and region.

In the FY 2023 IPPS/LTCH PPS proposed rule, we published a maternal health RFI that solicited feedback on a wide range of maternal health issues and opportunities for CMS to improve maternal health care (87 FR 28549).[784] In response, some commenters were concerned that failure to comply with the new CoP would result in the loss of Medicare certification, that access to obstetrical care would be negatively impacted, that a new CoP may potentially exacerbate rates of maternal morbidity/mortality, and that a new maternal health CoP would exacerbate disparities in obstetrical care. Other commenters, including the American College of Obstetrics and Gynecology (ACOG) and the American Medical Association (AMA) supported the creation of a CoP specifically for labor and delivery, recognizing that CoPs establish minimum health and safety standards across participating entities and institutions, and recommending that CMS explore options to establish such CoPs for participating hospitals with relevant stakeholders.[785]

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[784] 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 NonQualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation, May 10, 2022 (87 FR 28549). https://www.govinfo.gov/content/pkg/FR-2022-05-10/pdf/2022-08268.pdf

[785] Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 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, (August 10, 2022; (87 FR 49291)) https://www.govinfo.gov/content/pkg/FR-2022-08-10/pdf/2022-16472.pdf

2. Obstetrical Services CoP

With this RFI, we hope to further explore such options and plan to propose a targeted obstetrical services CoP to establish baseline requirements for obstetrical care within participating facilities in the CY 2025 OPPS/ASC proposed rule based in part on public comments received in response to this RFI. The comments that we receive on this RFI will help to inform CMS on potential proposals that may be included in the proposed rule. Therefore, we are seeking public comment on potential solutions that could reduce the rates of maternal mortality and reduce disparities in maternal mortality and morbidity, which can be implemented through the hospital CoPs. We believe it is necessary to develop a standard by which obstetrics care delivery is performed in order to address well-documented concerns regarding maternal morbidity, mortality, and maternity care access in the United States. The goal would be to ensure that any policy change to obstetrical services improves maternal health care outcomes and addresses preventable disparities in care but does not exacerbate access to care issues. We recognize that section 1801 of the Act prohibits federal interference in the practice of medicine and therefore we are seeking comment on interventions that do not interfere in medical practice.

Specifically, we are soliciting comment on what should be the overarching requirement, scope, and structure for an obstetrical services CoP. What types of facilities and care settings should such a CoP apply to (that is, all hospitals, hospitals with/without OB units, hospitals with/without emergency services, CAHs, REHs, outpatient settings, which may include inpatient and outpatient prenatal, postpartum, emergency, and birthing care services)? CoP policy options could include (but are not limited to) the following. We welcome data, alternatives, benefits, and descriptions of possible unintended consequences on these potential options:

- Creating an optional services CoP specific to obstetrical services, similar to the current Optional Services CoPs for Surgical services (42 CFR 482.51), Anesthesia services (42 CFR 482.52), Outpatient services (42 CFR 482.54), or Emergency services (42 CFR 482.55). In this case, hospitals providing obstetrical services would be required to ensure that obstetrical services

are well organized and provided in accordance with nationally recognized standards of care and evidence-based best practices. Such a requirement would be flexible enough to be tailored to hospitals of differing sizes and capabilities. The organization of OB services would be required to be appropriate to the scope of the services offered, and to integrate the OB services with other departments of the hospital, as appropriate. Policies governing obstetrical care would need to be designed to assure the achievement and maintenance of high standards of medical practice and patient care and safety.

- Modelling an OB services CoP after infection prevention and control stewardship program CoPs (42 CFR 482.42). This could include requirements relating to service organization and policies, leadership responsibilities, and application to multi-hospital systems.
- Requiring hospitals to develop standard processes for managing pregnant, birthing, and postpartum patients with or at risk for: (1) obstetric hemorrhage (a leading cause of maternal mortality); and (2) severe hypertension (a common pregnancy complication). Best practices for handling these issues, such as those highlighted in the resources cited above, already exist and CMS could require that hospitals establish policies that adopt or are consistent with existing accredited protocols.

Additionally, we solicit public comment on the following questions:

- What are existing acceptable standards of practice, organization, and staffing for obstetrical services (including staff qualifications and scope of practice considerations) in hospital obstetrical wards, emergency departments, CAHs, and REHs?
- What are existing regulatory barriers to quality care for pregnant and postpartum patients in hospital obstetrical wards, hospitals and CAHs that do not operate obstetrical wards, emergency departments, and in REHs?
- What regulatory changes are needed to ensure quality care for all pregnant, laboring, and postpartum patients across all care settings? Would establishing regulatory standards for organization, staffing, and for delivery of services for obstetrical units, similar to the existing

standards for surgical services, advance this goal? What additional standards should be considered?

● How could CMS better understand patients' experience of maternity care? What tools or instruments exist to understand individuals' experience of maternity care? How might CMS incorporate these tools or instruments into an obstetrical CoP?

● How would an obstetrical services CoP impact access to care for pregnant, birthing, and postpartum individuals? How will the CoP impact hospitals with respect to factors that have led some facilities to close their maternity units, including high costs, labor shortages, and declining birth rates?

● What policy options would help alleviate any potential unintended consequences of an obstetrical services CoP and the impact on maternity care access and workforce? How should these policy options account for variation in hospital size, volume, and complexity of services? What other hospital-specific factors should be accounted for?

● How would the growth in the number of birth centers affect the impact of establishing an obstetrical services CoP? As of February 2022, 400 midwifery-led birth centers exist across 40 states and Washington DC, with their numbers more than doubling in the last decade (representing 0.52 percent of births in 2017).[786] Birth centers, which are not subject to the Emergency Medical Treatment and Labor Act (EMTALA),[787] treat primarily low risk pregnancies. However, in approximately 18 percent of cases birth centers will direct or transfer pregnant or postpartum individuals or newborns to a hospital.[788]

● What should minimum oversight requirements be for an obstetrical unit? We believe it is necessary to require that obstetrical units (including patient rooms/suites, operation rooms, and postpartum/recovery rooms whether combined or separate) be supervised by an experienced

[786] MacDorman MF, Declercq E. Trends and state variations in out-of-hospital births in the United States, 2004-2017. Birth. 2019 Jun;46(2):279-288. doi: 10.1111/birt.12411. Epub 2018 Dec 10. PMID: 30537156; PMCID: PMC6642827.
[787] https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/emtala.pdf
[788] https://www.birthcenters.org/news/nbcs2.

certified nurse practitioner, physician assistant, certified nurse midwife, or a doctor of medicine or osteopathy. Experienced oversight is necessary to ensure safe, high-quality care. However, we welcome comments on staffing and oversight requirements for obstetrical units, including whether these oversight requirements in an obstetric unit lead to improved quality outcomes for the mother and the baby or may result in unintended consequences. We also welcome comments on whether there should be similar or different oversight requirements for small hospitals, CAHs, and REHs.

- What should be required with respect to credentialling of health professionals to provide obstetrical services within a specific facility? We understand that health professionals (midwives, advanced practice providers, physicians, doulas, etc.) have differing skill sets and expertise. Therefore, we would expect that facility credentialling of health professionals to provide obstetrical services, consistent with state law, must be delineated for all practitioners providing obstetrical care in the facility in accordance with the competencies of each practitioner and that the facility maintain a roster of practitioners specifying the duties and privileges of each practitioner. Such a requirement would be consistent with the existing surgical services CoP (42 CFR 482.51(a)(4)).

- Should obstetrical units be required to maintain a minimum set of obstetrical care equipment and supplies? We recognize that facilities have different capacities and populations, and we are seeking comment on whether there is a core set of equipment and supplies that could enhance obstetrical readiness. For example, facilities might need to ensure that all delivery rooms have a call-system, fetal monitoring capabilities, adult and neonatal resuscitation equipment, accessible medical equipment, and adequate provisions for emergent/precipitous deliveries, obstetrical emergencies (such as hypertensive emergencies and hemorrhage), and immediate post-delivery care. Should hospitals and CAHs without obstetrical units, emergency departments, and REHs have similar requirements? Such requirements would be consistent with the existing surgical services CoP (42 CFR 482.51(b)(3)).

● Beyond what is already required for emergency department (ED) patients under EMTALA, should a hospital obstetrical services CoP include a requirement for transfer protocols for when a non-ED patient needs care that exceed the capability of the hospital (that is, inpatient to inpatient transfers)? Should a similar requirement apply to hospitals and CAHs without emergency services and/or obstetrical services?

● Are there additional ways the CoPs could improve or address the health and safety of pregnant and postpartum patients across all care settings?

● Are there refinements to Medicare and/or Medicaid payment structures for obstetrics care, and/or perinatal care that could improve the delivery of maternal care, and also address existing disparities? We are interested in specific refinements that are within CMS statutory authorities.

3. Staff Training

According to the AHA, between 2015 and 2019, there were at least 89 obstetric unit closures in the U.S.,[789] with a disproportionate impact on rural and underserved communities. [790,791,792,793] Given the increasing number of areas across the country with limited to no access to maternal health care, emergency departments, CAHs, and REH and non-obstetrical professionals working in these settings may experience a higher acuity and frequency of patients needing obstetrical care. Moreover, a number of emergency departments, CAHs, and REHs, especially in rural areas, may be staffed by clinicians with less training in obstetrical emergencies.[794,]

[789] American Hospital Association Infographic https://www.aha.org/system/files/media/file/2022/04/Infographic-rural-health-obstetrics-15ap22.pdf accessed 12/06/2023.
[790] https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf
[791] https://jamanetwork.com/journals/jama/fullarticle/2674780
[792] https://pubmed.ncbi.nlm.nih.gov/32473598/
[793] https://jamanetwork.com/journals/jama/fullarticle/2674780
[794] https://ilpqc.org/ILPQC%202020+/HTN/OB%20triage%20Wolf%20Delao%20Baker%20and%20Zavotsky%202021.pdf

[795,796,797,798] Rural hospitals with and without obstetric units report that their greatest concerns in responding to local obstetric emergencies include a lack of specialty care providers and a lack of skills to address emergency births.

We note that existing hospital CoPs for emergency services (42 CFR 482.55) already require that "there must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility." In addition, EMTALA requires Medicare-participating hospitals, CAHs, and REHs with emergency departments to "provide a medical screening examination (MSE) [...] for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. Applicable facilities are then required to provide stabilizing treatment for patients with EMCs."[799] Furthermore, existing the Joint Commission (TJC) standards on the provision of care, treatment, and services standards for maternal safety require the education of all staff and providers who treat pregnant/postpartum patients on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.[800] The standards also recommend that hospitals use in-situ training and drills that include multidisciplinary teams. We expect that facilities will ensure their emergency staff are trained to handle obstetrical related emergencies in compliance with CMS' CoPs, EMTALA, and TJC standards.

Despite these existing regulations and standards, several organizations have cited that obstetrical readiness for hospitals with and without obstetrical services is suboptimal.[801,802,803] In these situations, appropriate training, best practice protocols (such as recognizing early warning

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[795] https://www.cdc.gov/wcms/video/low-res/hearher/2022/819819Role-EmergMed-Specialists.mp4
[796] https://www.awhonn.org/wp-content/uploads/2020/11/ENA-AWHONN-Consensus-Statement-Final-11.18.2020.pdf
[797] https://kffhealthnews.org/news/article/doctors-are-disappearing-from-emergency-rooms-as-hospitals-look-to-cut-costs/
[798] https://www.annemergmed.com/article/S0196-0644(18)30267-1/fulltext
[799] https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act
[800] https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/
[801] https://www.acog.org/news/news-articles/2022/01/commitment-to-action-eliminating-preventable-maternal-mortality
[802] https://rhrc.umn.edu/wp-content/uploads/2021/09/UMN-emOB-Training-Needed_11.12.20_508.pdf
[803] https://www.cdcfoundation.org/sites/default/files/files/ReportfromNineMMRCs.pdf

signs of hemorrhage and other adverse events associated with pregnancy and birth), and transfer protocols are critical to averting avoidable maternal complications and deaths, establishing and maintaining facilities' obstetrical readiness,[804] and ensuring compliance with existing CoP and EMTALA regulations.

We are interested in feedback on requiring additional training, protocols, or equipment for hospital non-OB unit, emergency department, CAH, and REH staff that treat pregnant and postpartum patients as a stop-gap measure to ensure individuals living without access to maternal health care can safely and effectively receive necessary services. Training requirements could encompass training in common obstetrical conditions and emergencies or training on methods for improving the respectful delivery of care to pregnant and postpartum patients or both. This could be connected to the hospital emergency services CoPs or applied more broadly to all or a subset of hospital, CAH, and REH staff and require that such facilities demonstrate that staff have adequate or minimum obstetrical training as well as training in hospital protocols, such as transfer protocols for when a pregnant, birthing, or postpartum persons under the facilities' care (including emergency department patients) need a higher level of obstetrical care than the hospital is able to provide. We also seek feedback on how potential challenges with such a requirement could be mitigated.

We note that since hospitals are neither required to provide obstetrical services nor emergency services, we are interested in ways to mitigate potential impacts and costs to hospitals in implementing such a possible requirement. We seek feedback from the public to learn more about the impact of this particular potential requirement and evidence supporting the need for such a requirement.

Therefore, we are seeking public comment specifically on the following:

● Should minimum OB staff training requirements (both initial and ongoing) be included in an obstetric services CoP? The Joint Commission (TJC) requires the education of all staff and

[804] https://saferbirth.org/aim-obstetric-emergency-readiness-resource-kit/

providers who treat pregnant/postpartum/birthing patients on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.[805] Should a similar requirement be included in an OB services CoP? Are there other requirements for training that should be included, such as neonatal resuscitation?

- Given the rate of OB unit closures, should CMS require a minimum obstetrical training standard for hospital/CAH non-OB unit, emergency department, REH, or other non-OB staff that may care for pregnant, birthing, and postpartum patients to improve maternal health outcomes? What evidence exists to support the need for further or baseline obstetrical training for these non-obstetrical health professionals? What might this training entail? Which clinical staff and which facility types should such requirements apply to? What intervals should such training be required? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-based trainings, best practice standards, and protocols are currently available? What are the barriers to accessing such obstetrical training, including in rural areas? What are policy options to mitigate any potential unintended consequences or provider burden of such a requirement? Should this training apply to all hospitals or a subset (that is, those with emergency services; or those with emergency services but no obstetrical services)? For example, the existing Emergency Services CoP at 42 CFR 482.55 could be revised to require that hospitals with emergency services (which would include hospitals with and without obstetrical services units) establish best practice protocols, transfer protocols, and regular staff training for management of common obstetrical conditions and emergencies.

- Should such additional staff training include separate training on methods for providing respectful care for pregnant, birthing, and postpartum patients in an effort to improve maternal health outcomes? Which staff should this apply to? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-

[805] https://www.jointcommission.org/standards/r3-report/r3-report-issue-24-pc-standards-for-maternal-safety/

based trainings on respectful care for pregnant, birthing, and postpartum patients are currently available?

- Should staff also be trained on implicit bias, trauma-informed care, or other specific training topics aimed at addressing bias and reducing disparities in maternity care? Which staff should this apply to? Is there data and evidence that demonstrates that implicit bias and trauma-informed care training improves maternal health care outcomes? If so, what evidenced-based trainings are currently available?

- Should additional staff training include separate training on the screening, assessment, treatment, and referral for maternal depression and related behavioral health disorders by staff? Which staff should this apply to? Is there data and evidence that demonstrates that such training improves maternal health care outcomes? If so, what evidenced-based trainings are currently available?

- For all possible training topics discussed in above bullets of this section, what is the recommended frequency of staff training needed to balance maintaining skills and teamwork with minimizing associated burdens (i.e. staff time, costs), especially for rural facilities?

- What additional policies should CMS consider to support the obstetrical readiness of hospitals with and without labor and delivery units for obstetrical emergencies, high-risk pregnancy related conditions, and common obstetrical conditions?4. Data

We are also interested in understanding if and how requiring hospitals to submit data related to maternal morbidity and mortality could be incorporated into any maternal services CoP. In January 2010, the Transforming Maternity Care Symposium Steering Committee issued a Blueprint for Action that included improving the availability and ease of collection of standardized maternity care data in order to encourage high quality clinical care, allow performance measurement and comparison, and support creation and implementation of a national public reporting system for maternity care data available to all relevant stakeholders in

order to drive improvements in maternity care.[806] Maternal health advocates have stated that the lack of maternal morbidity and mortality data limits where meaningful changes can occur. Currently, Maternal Mortality Review Committee (MMRC) data reporting is dependent upon state requirements and often voluntary reporting by health care facilities. While there are concerns about a lack of data, some parties have suggested that, though voluntary, MMRC data collection from facilities is robust and timely. We encourage facilities to report data to their state MMRC, where they exist and in alignment with requirements in their specific states. However, not all states have an MMRC. We believe that improving the available data would enable facilities to compare data and conduct more complete assessments of their maternal health readiness and opportunities for growth and improvement. To that end, we are interested in public comment on the following:

- How could CMS help improve data collection related to maternal morbidity and mortality across all demographics?
- Should hospitals be required to directly report to MMRCs when available? (https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/index.html#maternal-mortality-review)
- Could such a data collection requirement be incorporated into an obstetrical services CoP, or would it be more appropriately incorporated into another existing hospital CoP, such as QAPI?
- Are there common critical data elements that would be most important and appropriate to collect through a CoP aimed at improving maternal health data? Are there data standards currently available or under development that can support standardized reporting? How do we ensure data collection encompasses all demographics?

[806] Angood P. B, Armstrong E. M., Ashton D, Burstin H., Corry M. P, Delbanco S. F, et al. Blueprint for action: Steps toward a high-quality, high-value maternity care system. Women's Health Issues. 2010;20(1) (Suppl. 1): S18-S49.

- How can any associated burden of possible future data collection and reporting requirements for providers be mitigated?