

Availability of Outpatient Maternal Fetal Medicine and Specialty Care for Women with High-Risk Pregnancies

Section 1. Basic Measure Information

1.A. Measure Name

HROB V: Availability of Outpatient Maternal Fetal Medicine and Specialty Care for Women with High-Risk Pregnancies

1.B. Measure Number

0133

1.C. Measure Description

Please provide a non-technical description of the measure that conveys what it measures to a broad audience.

The extent to which women with high-risk pregnancies have outpatient visits with a maternal fetal medicine specialist or specialist during pregnancy.

1.D. Measure Owner

Collaboration for Advancing Pediatric Quality Measures (CAPQuaM).

1.E. National Quality Forum (NQF) ID (if applicable)

Not applicable.

1.F. Measure Hierarchy

Please note here if the measure is part of a measure hierarchy or is part of a measure group or composite measure. The following definitions are used by AHRQ:

- 1. Please identify the name of the collection of measures to which the measure belongs (if applicable). A collection is the highest possible level of the measure hierarchy. A collection may contain one or more sets, subsets, composites, and/or individual measures.**

This measure belongs to the Availability of High-Risk Obstetric Services Collection #1.

- 2. Please identify the name of the measure set to which the measure belongs (if applicable). A set is the second level of the hierarchy. A set may include one or more subsets, composites, and/or individual measures.**

Availability of Specialty Care for High-Risk Pregnant Women.

- 3. Please identify the name of the subset to which the measure belongs (if applicable). A subset is the third level of the hierarchy. A subset may include one or more composites, and/or individual measures.**

Process subset.

- 4. Please identify the name of the composite measure to which the measure belongs (if applicable). A composite is a measure with a score that is an aggregate of scores from other measures. A composite may include one or more other composites and/or individual measures. Composites may comprise component measures that can or cannot be used on their own.**

Not applicable.

1.G. Numerator Statement

This measure has eight sub-measures for which the numerator is constructed as the number of eligible high-risk pregnant women who have the specified number of maternal fetal medicine or indicated subspecialty visits during their pregnancy. The last sub-measure describes the extent to which high-risk pregnant women lack prenatal care.

Numerator Elements

- Maternal ICD-9 codes to identify qualifying pregnancies, outpatient visits, and provider specialty.

Provider or specialty designation should be identified using data available before analysis, according to local (State) standards for specialty identification, credentialing and licensure.

When more than one clinician is associated with a single clinical encounter, all associated specialties or disciplines should be considered to have been seen.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

Overall number of eligible qualifying high-risk pregnancies using the indicated look-back period.

Eligible high-risk pregnancies are identified using maternal ICD-9 codes specified in the Detailed Measure Specifications (see Supporting Documents); the look-back period is also identified in the specifications.

Denominator Elements

- Number of deliveries.
- Maternal and infant ICD-9 codes.
- Maternal DRG, CPT codes, and revenue codes when available; Specialty/Provider codes.

1.J. Denominator Exclusions

Denominator exclusions are identified using maternal ICD-9 codes specified in the Detailed Measure Specifications (see Supporting Documents).

1.K. Data Sources

Check all the data sources for which the measure is specified and tested.

Administrative data (e.g., claims data); paper medical record; electronic medical record.

If other, please list all other data sources in the field below.

Not applicable.

Section 2: Detailed Measure Specifications

Provide sufficient detail to describe how a measure would be calculated from the recommended data sources, uploading a separate document (+ Upload attachment) or a link to a URL. Examples of detailed measure specifications can be found in the CHIPRA Initial Core Set Technical Specifications Manual 2011 published by the Centers for Medicare & Medicaid Services. Although submission of formal programming code or algorithms that demonstrate how a measure would be calculated from a query of an appropriate electronic data source are not requested at this time, the availability of these resources may be a factor in determining whether a measure can be recommended for use.

Please see Supporting Documents for detailed measure specifications.

Section 3. Importance of the Measure

In the following sections, provide brief descriptions of how the measure meets one or more of the following criteria for measure importance (general importance, importance to Medicaid and/or CHIP, complements or enhances an existing measure). Include references related to specific points made in your narrative (not a free-form listing of citations).

3.A. Evidence for General Importance of the Measure

Provide evidence for all applicable aspects of general importance:

- **Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).**
- **Potential for quality improvement (i.e., there are effective approaches to reducing the quality gap or disparity in quality).**
- **Prevalence of condition among children under age 21 and/or among pregnant women.**

- **Severity of condition and burden of condition on children, family, and society (unrelated to cost).**
- **Fiscal burden of measure focus (e.g., clinical condition) on patients, families, public and private payers, or society more generally, currently and over the life span of the child.**
- **Association of measure topic with children’s future health – for example, a measure addressing childhood obesity may have implications for the subsequent development of cardiovascular diseases.**
- **The extent to which the measure is applicable to changes across developmental stages (e.g., infancy, early childhood, middle childhood, adolescence, young adulthood).**

CAPQuaM was assigned the topic of availability of high-risk obstetrical services as a PQMP priority by AHRQ and the Centers for Medicare & Medicaid Services (CMS). We developed a measure set in close collaboration with our expert panel that describes the availability of specialty physician services for high-risk pregnant women.

Optimal health of children in the United States is fostered by healthy pregnancies and healthy deliveries. Appropriate availability of specific aspects of care for pregnant women, in particular those in need of high-risk obstetric services, is necessary to achieve desired outcomes. The focus of the CAPQuaM measures are on outpatient care for women with chronic illness and pregnancy-related complications. For this measure we include eight sub-measures: a summary measure that describes the extent to which high-risk pregnant women have outpatient visits with maternal fetal medicine specialists or subspecialists, six sub-measures that describe the extent of such services for specific subgroups of high-risk women, and a sub-measure that describes the extent to which high-risk pregnant women lack prenatal care. The eight sub-measures indicate the percentage of:

- High-risk pregnant women who have zero, one, or two or more outpatient visits with a maternal fetal medicine specialist (MFM) or an indicated subspecialist during their pregnancy.
- Pregnant women with HIV disease who have zero, one or two or more visits with an MFM or an infectious disease specialist during their pregnancy.
- Pregnant women with cardiac disease who have zero, one, or two or greater visits with an MFM or a cardiologist during their pregnancy.
- Pregnant women with a mood disorder or mental health disorder complicating pregnancy who have zero, one, or two or more visits with an MFM or psychiatrist, psychologist, or licensed therapist.
- Pregnant women with substance⁴ dependency who have zero, one, or two or more visits with an MFM or psychiatrist, psychologist, or licensed therapist during their pregnancy.
- Pregnant women with specified poor obstetrical history who have zero, one, or two or more visits with an MFM during their pregnancy.

- Pregnant women with epilepsy who have zero, one, or two or more visits with an MFM or neurologist during their pregnancy.
- High-risk pregnant women who have no outpatient visits with any provider during their pregnancy.

The burden of certain diseases and chronic illnesses is rising among women (e.g., hypertension, cardiac disease, HIV, diabetes, mental disorders, epilepsy, infectious diseases, placenta previa), increasing women's risk for morbidity and mortality (Hankins, Clark, Pacheco, et al., 2012). Over the past decade, maternal mortality has increased in the United States, and striking racial disparities persist (Berg, Callaghan, Syverson, et al., 2010; Callaghan, Creanga, Kuklina, 2012). For every maternal death, 100 or more women suffer severe maternal morbidity, a potentially life-threatening diagnosis, or a life-saving procedure that is associated with pregnancy. Severe maternal morbidity is rising and affects approximately 52,000 women annually in the United States. Similar to maternal mortality, minority women are more likely to suffer severe maternal morbidity than white women (Callaghan, et al., 2012).

Quality of care is an important lever to address maternal morbidity and mortality, as research suggests that one-half of maternal deaths in the United States may be preventable through improvements in quality and safety of care (Berg, Atrash, Koonin, et al., 1996; Hoyert, Danel, Tully, 2000; Nannini, Weiss, Goldstein, et al., 2002). Additional studies suggest that on the continuum of care to adverse pregnancy outcomes, there are a number of points that can be impacted by improved quality (American Academy of Pediatrics [AAP], 2012; Joint Commission, 2010), and improved access to medical care is considered to be an important factor in preventing complications due to chronic conditions and pregnancy-related morbidity (Berg, Harper, Atkinson, et al., 2005). Our measure is critical to ensure the safety of mothers and babies by focusing on maternal pre-delivery chronic conditions and complications of pregnancy.

To improve care for women with chronic conditions, it is imperative for quality measures to address the availability of high-risk obstetrical services by assessing a patient's access to an MFM and subspecialists. MFMs play a key role in identifying women with chronic illness who are at risk. They are instrumental in managing illness and referral of high-risk women to subspecialists (Antony, Dildy III, 2013; Russo, Krenz, Hart, et al., 2011; Society for Maternal-Fetal Medicine, 2015). In settings where other specialists are not available, MFMs play a crucial role in developing structures and protocols to enhance quality and safety for patients (Antony, Dildy III, 2013). It is recommended that women with chronic conditions visit an MFM regularly (Antony, Dildy III, 2013; D'Alton, Bonanno, Berkowitz, et al., 2013; Russo, Krenz, Hart, et al., 2011; Sullivan, Hill, Newman, et al., 2005). Studies have shown that the density of MFMs is significantly and inversely associated with maternal mortality ratios (Sullivan, et al., 2005).

Appropriate availability of specialized services beyond MFMs (e.g., cardiologists, infectious disease specialists, neurologists, psychologists/psychiatrists/licensed therapists) and care for pregnant women with chronic diseases is also important for healthy pregnancies. The literature has shown that less frequent visits to a subspecialist for women with chronic illness results in adverse pregnancy outcomes (Balsells, Garcia-Patterson, Corcoy, 2009; Pergam, Wang, Gardella, et al., 2008). Maternal and fetal outcomes are improved when more specialty care is

available and provided (Nguyen, O’Sullivan, Fournier, 1991). However, data demonstrate that many women do not see a subspecialist when one is necessary. According to the Centers for Disease Control and Prevention (CDC), from 2003–2007, only 62 percent of women with HIV had at least one prenatal visit with an MFM (CDC, 2013a). Many women are not referred to an MFM despite having chronic conditions (Vintzileos, Ananth, Smulian, et al., 2001). In a recent survey, 31 percent of generalist obstetrician/gynecologists (OB/GYNs) were not satisfied with the MFM services available to them for their patients (D’Alton, et al., 2013; Wenstrom, Erickson, Schulkin, 2012). Many practices do not have the trained personnel and/or referral sites to meet the psychosocial needs of women with chronic illnesses, such as HIV and mental health disorders (Byatt, 2012; Nichols, Bhatta, Lewis, et al., 2002).

Prenatal care is very important for high-risk pregnant women, as antenatal access to MFM specialists and subspecialists is recommended to improve outcomes among pregnant women with chronic illness and pregnancy-related complications (Alexander, Milton, 2001; Balsells, et al., 2009; Moons, Werner, Costermans, et al., 1999; Nichols, et al., 2002; Pergam, et al., 2008). Lack of prenatal care for high-risk pregnant women represents a safety failure, as all pregnancies are at higher risk for adverse outcomes when there is no prenatal care (Chang, Elam-Evans, Berg, et al., 2003; Gei, Hankins, 2001; Goler, Armstrong, Taillac, et al., 2009).

The CAPQuaM measure development process sought to ground this measure in a definitional framework of what constitutes a high-risk specialty obstetrical service and what high-risk conditions/complications can be effectively managed before delivery. We first established a construct of conditions (chronic illness and pregnancy-related problems) that potentially can be considered as high risk, increasing the risk of maternal and/or infant morbidity and mortality. We convened a multidisciplinary panel of national experts to provide leadership, including helping to establish definitions for availability of subspecialty and high-risk obstetrical services. The panel held a telephone meeting, conducted pre-work via email, and participated in a 2-day face-to-face meeting. By the conclusion of the meeting, the panel had highlighted which chronic diseases and pregnancy-related problems were most important to focus on, as well as the importance of multidisciplinary care. This is the first measure that we are aware of that addresses specifically the availability of high-risk obstetrical care for women with chronic illness and pregnancy-related problems. It reflects our perspective that the optimal health of children in the United States is fostered by healthy pregnancies and deliveries.

3.B. Evidence for Importance of the Measure to Medicaid and/or CHIP

Comment on any specific features of this measure important to Medicaid and/or CHIP that are in addition to the evidence of importance described above, including the following:

- **The extent to which the measure is understood to be sensitive to changes in Medicaid or CHIP (e.g., policy changes, quality improvement strategies).**
- **Relevance to the Early and Periodic Screening, Diagnostic and Treatment benefit in Medicaid (EPSDT).**
- **Any other specific relevance to Medicaid/CHIP (please specify).**

Consortium partners at the New York State Department of Health, including the Office of Health Insurance Programs/New York State Medicaid, steering committee, and scientific team have played central roles to the development of these measures. Evidence for a high level of interest in this work in particular was demonstrated by the fact that the CAPQuaM team was asked to present this work in development to the CMS Expert Panel on Improving Maternal and Infant Health Outcomes in Medicaid/CHIP Data, Measurement, and Reporting Workgroup.

More generally, childbirth is the largest category for hospital admissions for commercial payers and Medicaid programs; the estimated annual hospital costs associated with childbirth and newborn care are over \$80 billion annually in the United States (Andrews, 2006; DeFrances, Cullen, Kozak, 2007). In New York State, 48.6 percent of deliveries in 2011 occurred in women insured by Medicaid (NY State Department of Health, 2015).

Providing high quality care to women with high-risk pregnancies has the potential both to improve outcomes and to narrow disparities, important national priorities for CMS. In fact, leaders in obstetrics emphasize the need for improved access to specialty physician services for women who are at high risk. Our proposal is in conjunction with the leaders in obstetrics' proposals to improve integrated maternal-fetal-neonatal networks that optimize regionalization.

As mentioned previously, studies have shown that the density of MFMs is significantly and inversely associated with maternal mortality ratios (Sullivan, et al., 2005). In addition, the literature has shown that less frequent visits to subspecialists or lack of pregnancy care for women with chronic illness results in adverse pregnancy outcomes (Balsells, et al., 2009; Moons, et al., 1999; Nichols, et al., 2002; Pergam, et al., 2008). Women with Medicaid and those who are uninsured are more likely to suffer from chronic conditions (Kaiser Family Foundation, 2011). Therefore, the proposed measures have the potential to have a significant impact on the health of mothers and infants covered by Medicaid. High-risk deliveries disproportionately impact women insured by Medicaid as compared with those who have private insurance. Risk factors identified to be associated with high-risk deliveries (e.g., hypertension, delivery of low birth weight infants) are all factors that are more prevalent among the Medicaid population. Given the fact that childbirth is the leading category for hospital admissions for Medicaid programs and the fact that high-risk deliveries disproportionately occur among women insured by Medicaid, quality measures targeting high-risk women have the potential to improve quality of care for a sizeable portion of the Medicaid program.

One key decision that our expert panel made that is particularly important for the vulnerable Medicaid population was establishing that high-risk obstetrical services extend from preconception (e.g., managing the cessation of teratogenic medications) through delivery and the early postpartum period. The Expert Panel offered definitions regarding which conditions established that a pregnancy required high-risk obstetrical services. They further endorsed constructs important to assessing the availability of high-risk obstetrical (HROB) services. Among those constructs, the panel endorsed the importance of specialty services being available to women with comorbid conditions and who have pregnancy-related problems. In particular, they endorsed the importance of the availability and services of MFMs, cardiologists, infectious disease specialists, neurologists, and psychologists/psychiatrists. A working draft of the Panel Summary after the second round of voting is available as an Appendix to this report (see

Supporting Documents). Not specifically incorporated in this summary was the breadth of dialogue regarding what it means to assess availability in this context.

The conclusion that guided much of the subsequent conversation was that the role of these measures assessing availability of specialty physician services should be used to describe availability at a population level even though the unit of analysis that we were to measure directly was an individual pregnancy. There are two key implications – these measures are not intended to assess the quality of care for a given pregnancy. They are intended to generate a gradient along which availability of HROB services can be assessed. So while the measures have a concrete interpretation, over time the full nuance of their capacity to describe availability will be enhanced by the establishment of benchmarks in medically and geographically diverse populations and communities.

The co-leads of this measure development, a pediatrician and an obstetrician, collaboratively operationalized these constructs into the measures in the current measure set, working with the CAPQuaM stakeholders, including New York Medicaid, and consulting the expert panelists as appropriate. Using ICD-9 codes and a publicly available grouping system, AHRQ's Clinical Classification Software (<http://hcup-us.ahrq.gov/toolsoftware/ccs/ccs.jsp>), the various conditions that could classify a pregnancy as in need of HROB services were specified into those seen in this measure. The eight sub-measures in this measure incorporate these high-priority conditions and services and address the capacity to have specialty physician services available for high-risk women during their pregnancies.

The New York State Office of Health Insurance Programs is an active CAPQuaM partner and has been engaged in the conceptualization and development of these measures. Our testing occurred in Medicaid data and is described below.

3.C. Relationship to Other Measures (if any)

Describe, if known, how this measure complements or improves on an existing measure in this topic area for the child or adult population, or if it is intended to fill a specific gap in an existing measure category or topic. For example, the proposed measure may enhance an existing measure in the initial core set, it may lower the age range for an existing adult-focused measure, or it may fill a gap in measurement (e.g., for asthma care quality, inpatient care measures).

Previously, we developed measures based on institutional self-report of whether there is 24-hour, 7-day-a-week availability of structural characteristics at the facility in which the woman gave birth. This new set of measures focuses on the availability of specialty physician services for high-risk pregnant women. This measure and a second HROB measure focus on multidisciplinary care and specialty prenatal care help to describe service utilization for high-risk pregnancies. These measures will supplement the collection of measures focused on HROB services available at the hospital of birth to further evaluate and enhance the safety and care provided to high-risk women, regardless of birth outcome. The selection of these topics is valid and justified by evidence summarized briefly below. All were prioritized during our formal expert process.

The burden of having certain diseases and chronic illnesses is rising among women, and these diseases and illnesses increase women's risk for morbidity and mortality (Hankins, et al., 2012). In one study conducted by the Center for Health Quality Outcomes and Economic Research, 27 percent of pregnant women reported having a chronic illness/condition (Chatterjee, Kotelchuck, Sambamoorthi, 2008). According to the CDC, the number of women with HIV giving birth in the United States increased approximately 30 percent, from 6,000–7,000 in 2000 to 8,700 in 2006 (Vintzileos, et al., 2001). With the prevalence of chronic illness and pregnancy-related problems continuing to increase, it is imperative that measures related to HROB, specifically those related to essential specialty physician services, are developed.

The causes of pregnancy-related deaths in the United States are as follows: cardiovascular diseases (14.6 percent), infection/sepsis (14.0 percent), non-cardiovascular diseases (11.9 percent), cardiomyopathy (11.8 percent), hemorrhage (11.0 percent), hypertensive disorders of pregnancy (9.9 percent), thrombotic pulmonary embolism (9.4 percent), cerebrovascular accidents (6.1 percent), amniotic fluid embolism (5.4 percent), and anesthesia complications (0.6 percent) (CDC, 2013b). Many of these pregnancy-related deaths reflect complications and conditions associated with women who are classified as high risk and therefore should be seeking higher level physician services throughout their pregnancies. Having the appropriate and essential subspecialty services available to help identify risk factors and manage conditions for women with high-risk pregnancies will reduce maternal and neonatal mortality. The role that maternal fetal medicine doctors and subspecialty doctors play in the care for women with chronic illness or pregnancy-related problems is discussed in detail in the Importance of the Measure section (Section 3.B) of this report.

Whether occurring prior to conception or affiliated with pregnancy, maternal cardiac disease of any type has the potential for significant morbidity and mortality, representing the largest percentage of pregnancy-related deaths in the United States. Congenital heart diseases require multidisciplinary care for early intervention and close monitoring of maternal and fetal well-being (Dennis, Solnordal, 2012). Discussion regarding the subspecialty services necessary to appropriately care for those OB patients includes the availability of a comprehensive team approach to care comprising a cardiologist, obstetricians, anesthesiologists, pediatricians, clinical nurse specialists, and clinical geneticists (American College of Obstetricians and Gynecologists [ACOG], 1993). All women at risk should have at least one consultative appointment with a subspecialty provider (Pieper, 2008). The principal recommendations focus on: pre-pregnancy counseling and testing (Arendt, Fernandes, Khairy, et al., 2011), specialized care rendered by a multidisciplinary team (Dennis, Solnordal, 2012; John, Gurley, Schaff, et al., 2011), caution with medication management and surgical interventions (Henriquez, Roos-Hesselink, Schali, et al., 2011; McLintock, McCowan, North, 2009), close maternal-fetal monitoring (Dennis, Solnordal, 2012), and evaluation of maternal-fetal risks for decision-making regarding timing of delivery (John, et al., 2011).

Mental illness and substance dependency during pregnancy present a number of challenges for treatment. Decisions about appropriate treatment methods must be cautiously considered with respect to the impact on the health of the mother and the outcomes of the pregnancy (Gentile, 2010). The principal recommendations for treating mental health during pregnancy focus on: screening of all pregnant women for substance abuse, brief interventions (Carson, Cox, Crane, et

al., 2010; Clatworthy, 2012), harm reduction (Carson, et al., 2010), substance abuse withdrawal management (Carson, et al., 2010), multidisciplinary management (Galbally, Roberts, Buist, 2010; Gentile, 2010), individualized pharmacological therapy that considers risks vs. benefits (Anderson, Reti, 2009; Clatworthy, 2012; Einarson, Boskovic, 2009), and careful monitoring of the mother and infant development throughout the pregnancy (Galbally, et al., 2010). It is essential that all high-risk mental health patients have available a consultation and referral to psychiatric and psychological clinicians for management of mood disorders, acute and chronic psychosis, pregnancy loss, unwanted pregnancy, and substance abuse and chronic pain (Dunsis, Smith, 1996). The team approach allows psychiatric consultants to concentrate on psychosocial interventions rather than psychopharmacological interventions when appropriate, thus reducing unintended consequences from pharmacotherapy and increasing positive outcomes.

A great deal of literature suggests the importance of close monitoring by an MFM or a neurologist for pregnant women with epilepsy (Robinson, Cleary-Goldman, 2008). Epilepsy is a significant issue in pregnancy, and specialist care is recommended. Close monitoring of seizure activity, medications, and maternal and fetal well-being require specialist care and collaboration between neurology and obstetrics (Eller, Patterson, Webb, 1997; Dunsis, Smith, 1996). Likewise, data demonstrate that antenatal care and the close monitoring and treatment of pregnant women with HIV can reduce transmission and improve outcomes (Chou, Cantor, Zakher, et al., 2012).

Receipt of prenatal care during the first trimester is a current HEDIS measure. Both timing and adequacy of prenatal care have been the focus of national quality measurement activities in the past. Prenatal care is considered to be an important aspect of quality of care for all pregnancies in this country. Our measure complements this focus. We suggest availability of outpatient specialty care for high-risk pregnant women who are at risk of significant morbidity and mortality for themselves and their infants. This measure has the potential to improve outcomes for both mothers and infants in the setting of high-risk pregnancies. As many high-risk conditions are known prior to delivery, obstetricians and higher level physicians, including MFMs and other specialists, play a crucial and lifesaving role in the surveillance and management of these conditions. Thus, these measures strive to decrease the rate of morbidity and mortality among pregnant women with chronic illness and pregnancy-related problems. Further, our measure also assesses a critical component of safety for this population, as high-risk pregnant women with no prenatal care represent a critical failure of the system.

Section 4. Measure Categories

CHIPRA legislation requires that measures in the initial and improved core set, taken together, cover all settings, services, and topics of health care relevant to children. Moreover, the legislation requires the core set to address the needs of children across all ages, including services to promote healthy birth. Regardless of the eventual use of the measure, we are interested in knowing all settings, services, measure topics, and populations that this measure addresses. These categories are not exclusive of one another, so please indicate "Yes" to all that apply.

Does the measure address this category?

- a. **Care Setting – ambulatory:** Yes.
- b. **Care Setting – inpatient:** No.
- c. **Care Setting – other – please specify:** No.
- d. **Service – preventive health, including services to promote healthy birth:** Yes.
- e. **Service – care for acute conditions:** Yes.
- f. **Service – care for children with special health care needs/chronic conditions:** No.
- g. **Service – other (please specify):** Yes; prenatal.
- h. **Measure Topic – duration of enrollment:** No.
- i. **Measure Topic – clinical quality:** Yes.
- j. **Measure Topic – patient safety:** Yes.
- k. **Measure Topic – family experience with care:** No.
- l. **Measure Topic – care in the most integrated setting:** No.
- m. **Measure Topic other (please specify):** No.
- n. **Population – pregnant women:** Yes.
- o. **Population – neonates (28 days after birth) (specify age range):** No.
- p. **Population – infants (29 days to 1 year) (specify age range):** No.
- q. **Population – pre-school age children (1 year through 5 years) (specify age range):**
No.
- r. **Population – school-aged children (6 years through 10 years) (specify age range):**
No.
- s. **Population – adolescents (11 years through 20 years) (specify age range):** No.
- t. **Population – other (specify age range):** No.
- u. **Other category (please specify):** Not applicable.

Section 5. Evidence or Other Justification for the Focus of the Measure

The evidence base for the focus of the measures will be made explicit and transparent as part of the public release of CHIPRA deliberations; thus, it is critical for submitters to specify the scientific evidence or other basis for the focus of the measure in the following sections.

5.A. Research Evidence

Research evidence should include a brief description of the evidence base for valid relationship(s) among the structure, process, and/or outcome of health care that is the focus of the measure. For example, evidence exists for the relationship between immunizing a child or adolescent (process of care) and improved outcomes for the child and the public. If sufficient evidence existed for the use of immunization registries in practice or at the State level and the provision of immunizations to children and adolescents, such evidence would support the focus of a measure on immunization registries (a structural measure).

Describe the nature of the evidence, including study design, and provide relevant citations for statements made. Evidence may include rigorous systematic reviews of research literature and high-quality research studies.

Evidence is discussed throughout this report. A targeted review of the literature is in the Appendix (see Supporting documents). Further, we interviewed clinicians and engaged clinical societies and accreditors, patient/family groups, New York Medicaid, and others to inform our measure development with the intelligence and experiences of stakeholders as well as the medical literature. The ratings of the panel along with a brief description of methodology are included in the Appendixes (see Supporting Documents). These measures result from careful conduct of a systematic process.

The availability of high-risk obstetric (HROB) services is a challenging concept, and to develop quality measures that assess availability of high-risk obstetrics services we first needed to define: (1) availability of services and (2) high-risk obstetrical services. Specifically we wondered whether the target population optimally should be identified by conditions present in the women, by the clinical services required, or by the clinicians providing the services. Through discussions with our scientific team, Steering Committee, a review of the literature, and in consultation with our Expert Panel, we answered these questions in the following manner. Regarding availability, we expanded on the Anderson and Aday model (Aday, Anderson, 1974), which suggests that utilization of health care is driven by three predisposing characteristics, enabling resources, and need, and that these factors are themselves influenced by the available system of care (Anderson, McCutcheon, Aday, et al., 1983; Kuhlthau, 2011). While their distinction between availability and realized access has blurred over time, we nonetheless chose to respect our assignment by using an availability lens as our framework for these measures.

At a system level, utilization can vary as a result of differences in individual behaviors or system characteristics. The current measures predominantly reflect distribution of system attributes, which may include geography, system design, and/or sufficiency of resources (Kuhlthau, 2011). The definition of HROB specialty physician services for the purposes of these measures is broad and may include services provided by a variety of clinicians if received by a woman who has an identifiable condition that predisposes her or her baby to an increased risk of morbidity and mortality during the assessment period. Our definition of high risk is derived from the literature, Expert Panel ratings, discussions with our Steering Committee, and from insights drawn from clinician interviews.

As described in Section 3, pregnant women with chronic illness and pregnancy complications are at increased risk of maternal and infant morbidity and mortality. Availability of specialty care is particularly important for these women. Evidence suggests access to MFMs, subspecialists, and multidisciplinary care is associated with better outcomes. Professional societies—including ACOG and the Society for Maternal-Fetal Medicine, as well as others—recommend that specialty care be provided for high-risk pregnant women.

5.B. Clinical or Other Rationale Supporting the Focus of the Measure (optional)

Provide documentation of the clinical or other rationale for the focus of this measure, including citations as appropriate and available.

The clinical rationale for this measure is discussed in detail in Section 3, Importance of the Measure. This measure has importance as a descriptor of the higher level physician elements essential for safe maternity care for high-risk women with chronic illness and pregnancy-related conditions. The rationale can be summarized as follows: Our expert panel reinforced and prioritized as highly important several specialty care aspects of high-risk obstetrical care (HROB) that are supported both by the evidence base and by leading clinical societies and other significant actors. There are eight topics (sub-measures) in the availability of specialty physician services for high-risk pregnant women:

- The percentage of high-risk pregnant women who have zero, one, or two or greater outpatient visits with an MFM or an indicated subspecialist during their pregnancy.
- The percentage of pregnant women with HIV disease who have zero, one, or two or greater visits with an MFM or an infectious disease specialist during their pregnancy.
- The percentage of pregnant women with cardiac disease who have zero, one, or two or greater visits with an MFM or a cardiologist during their pregnancy
- The percentage of pregnant women with a mood disorder or mental health disorder complicating pregnancy who have zero, one, or two or greater visits with an MFM or psychiatrist, psychologist, or licensed therapist.
- The percentage of pregnant women with substance dependency who have zero, one, or two or greater visits with an MFM or psychiatrist, psychologist, or licensed therapist during their pregnancy.
- The percentage of pregnant women with specified poor obstetrical history who have zero, one, or two or greater visits with an MFM during their pregnancy.
- The percentage of pregnant women with epilepsy who have zero, one or two, or three or greater visits with an MFM or neurologist during their pregnancy.
- The percentage of high-risk pregnant women who have no outpatient visits with any provider during their pregnancy.

In turn, this measure represents the capacity to provide necessary specialty care. The last sub-measure raises concerns about patient safety. These eight sub-measures are specified so as to be able to identify disparities that arise because of socioeconomic, racial/ethnic, and rural/urban considerations. In this regard, they address five of the six characteristics (Timeliness, Equity, Safety, Patient-Centeredness, and Effectiveness) of quality care described in the Institute of Medicine's (IOM's) *Crossing the Quality Chasm* (IOM, 2001). We have described the importance of the availability to specialty care in our review above. The proposed measures can provide new measures of subspecialty availability with which to assess both the outcomes and the cost-effectiveness of future efforts to enhance the availability of HROB services.

We have operationalized the need for HROB specialty physician services rather broadly, consistent with the guidance provided by our expert panel. Our definitions borrow from the literature and from AHRQ's own clinical classification software, and at the margins, our definitions are defined based upon specific guidance provided by our expert panel. In so doing, we have produced a measure that is more sensitive and less specific, as is desirable for a measure intended to create a gradient at the population level such as we described above. These are not measures designed to assess as good or bad the quality of care for any individual pregnancy. Rather they are designed to provide insight into the availability of HROB subspecialty services to a population of women who may need them. This approach is consistent with the useful IOM definition of quality health care, as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 2001) Thus, each of these measures may be said to specify current professional knowledge in a way that produces an index that describes the degree to which specific HROB services (pertaining to subspecialty care) are available to women who are at risk to need them. All the above notwithstanding, failure to receive any outpatient visits with any provider for pregnancy is typically a major failure and patient safety risk.

The salience and validity of our work has benefited from our use of a formal method, a pragmatic adaptation of the CAPQuaM 360 degree method. The method, as adapted to availability of HROB services, described in the next paragraph was specifically designed to develop valid and reliable measures in the face of pragmatic epistemological uncertainty. That is, recognizing that practice extends well beyond the research base, we designed this method to allow us to develop reliable and valid state of the science measures, in part by explicitly modeling and accounting for uncertainties in the measure development, in part by the conceptualization and implementation of a Boundary Guideline. We have shared and refined this approach in a number of venues including within the Pediatric Quality Measures Program (PQMP), which comprises the various PQMP AHRQ-CMS CHIPRA Centers of Excellence (COEs), the State PQMP participants, and the AHRQ and CMS participants. All presentations invited dialogue and feedback. This work has been similarly presented at a number of Grand Rounds/weekly conferences in the New York-New Jersey area as well as to national/international audiences, including the bioethics and children's health services research communities. These latter venues include:

- 2012 Pediatric Academic Societies State of the Science Plenary (Boston). This presentation is provided as an Appendix (see Supporting Documents).
- 2012 Oxford-Mount Sinai Bioethics Consortium (Amsterdam).
- 2012 Child Health Services Research Interest Group at Academy Health (Orlando).

Feedback from these presentations was extremely positive. The Boundary Guideline construct generated particular enthusiasm. We asked the Bioethics Consortium to extrapolate the *primum non nocere* (First, do no harm) principle to apply regarding this aspect of performance measurement. We received strong feedback that not only is it ethical to measure using systematically developed measures (even in the context of some uncertainty), but that it is ethically preferable to use such measures compared with the alternative of providing care that is not assessed (and perhaps not assessable) because of residual uncertainty.

Fortunately, in the case of this measure, we can present both a systematically developed measure and a variety of evidence to support its use.

Section 6. Scientific Soundness of the Measure

Explain the methods used to determine the scientific soundness of the measure itself. Include results of all tests of validity and reliability, including description(s) of the study sample(s) and methods used to arrive at the results. Note how characteristics of other data systems, data sources, or eligible populations may affect reliability and validity.

6.A. Reliability

Reliability of the measure is the extent to which the measure results are reproducible when conditions remain the same. The method for establishing the reliability of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., the Kappa statistic). Provide appropriate citations to justify methods.

The strengths of this measure derive from its systematic development, meticulous specification, careful conceptualization and articulation, and grounding in existing science and consensus. The data collection and reliability therein depend upon the use of administrative data. These data are used to identify deliveries (our specifications are a slight enhancement of CDC methodologies described in Kuklina and Callaghan (2011); to their work, we added Revenue code 722. This was important for our test because the Medicaid MAX data provided by CMS and in which these schemas were tested do not include DRGs, which are employed in the Kuklina and Callaghan method. We also tested a variation of the approach to identify deliveries employed by HEDIS in its Timing of PreNatal Care measure in the initial CHIPRA core set. We found that these approaches identified substantially the same population of deliveries in a 16-State subset of the national MAX database. We chose the 16 States to include in an attempt to manifest some standardization of approaches across the seven AHRQ-CMS CHIPRA Centers of Excellence—they were recommended to us as a diverse set of States with high data quality by the Children’s Hospital of Pennsylvania COE, which has used them extensively in a number of their validation activities. As the different approaches produced 90 percent or more overlap, we decided to specify the measure based upon the Kuklina-Callaghan/CDC approach as both widely used and relevant for the type of population-based approach to measurement proposed in this measure. We have used this method for all of the CAPQUaM high-risk obstetrical services availability measures.

In determining which women were to be considered potentially in need of HROB services, our specifications further relied on administrative data. One study found that quality measures that could be calculated using administrative data showed higher rates of performance than indicated by a review of the medical record alone, and that claims data are more accurate for identifying services with a high likelihood of documentation due to reimbursement (Diamond, Rask, Kohler, 2001). Further, at the current stage of electronic health record (EHR) development and

implementation, chart review is likely to prove infeasible for population-based measures of this scope. Since this measure is specified to be interpreted at the population and not the individual level, the impact of some of the imperfections of using administrative data will be overcome naturally because of the law of large numbers. We found that of ~119,000 Medicaid deliveries in New York State in 2010, 59,254 were at sufficiently elevated risk to qualify for this measure set (just under 50 percent). Our team had predicted that 40-50 percent of all pregnancies would have elevated risk, and these findings are consistent with the expectations that Medicaid would be at least at the higher end of that range. Use of a mother-only algorithm in MAX data in 16 States indicates the proportion of high-risk pregnancies ranges from 31.50 percent in New Jersey to 63.97 percent in Kentucky. The New York MAX finding was 55,379 HROB pregnancies, almost identical to the 56,465 found using internal data bases on the maternal codes, indicating very high reliability across systems.

Regarding the assessment of the presence or absence of specific provider type visits in this measure, we have specified this measure to use administrative data. We worked with our partners at the New York State Department of Health and investigated New York State Medicaid data to identify outpatient claims for reporting year, July 2011 - June 2012. We determined that these data are available in New York State. In general, provider specialty is assigned by the health plan. For our validation, for the approximately 10 percent of encounters that had more than one provider indicated, one specialty was assigned for each encounter that best described the key provider using a pre-existing Medicaid algorithm. For our final specification, we chose instead to give credit for each specialist seen during one of these encounters. We investigated outpatient visits with cardiologists, infectious disease specialists, neurologists, psychiatrists, psychologists, social workers/therapists, and health educators based on our Expert Panel recommendations and the literature. Health plans typically will credential physicians in an identified specialty. When such is not the case, the approach for specialty assignment should default to any mechanism that is used or recommended by either the State Medicaid program or the State Department of Health.

6.B. Validity

Validity of the measure is the extent to which the measure meaningfully represents the concept being evaluated. The method for establishing the validity of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., R2 for concurrent validity).

The reliability section above also contains information related to validity.

Our definition of high-risk obstetrical services results from a formal RAND/UCLA modified Delphi process conducted with a multidisciplinary panel of national experts that included obstetricians, MFM specialists, and a nurse midwife, anesthesiologist, and family physician. We carefully operationalized the panel's clinical recommendations by fine tuning AHRQ's Clinical Classification Software. We operationalized panel specifications using data elements that are available in typical administrative data sets.

Potential exceptions are elements such as race and ethnicity. Our feasibility work confirmed race/ethnicity information generally is available from clinical charts. The 2009 CHIPRA legislation directs our measures to be capable of identifying disparities, and we have specified it to be so, although we are aware of variability in the manner of assignment of race and ethnicity by health care facilities.

Use of administrative data in performance assessment is common. These data contain consistent elements, are available, inform regarding large numbers of individuals, and are relatively inexpensive. Validity of many administrative datasets has been established, and their strengths and weaknesses relative to data abstracted from medical records and obtained via survey have been documented; in addition, their use is encouraged by Federal agencies (Virnig, McBean, 2001). CMS has made clear to the participating AHRQ-CMS CHIPRA COEs that were funded to develop measures in the PQMP that it places a premium on feasibility.

Expert Panels have been demonstrated to enhance measure development and health care evaluation, including for children (Mangione-Smith, DeCristofaro, Setodji, et al., 2007). Frontline practitioners can assist researchers to create useful measures (Rubio, Berg-Weger, Tebb, et al., 2003). CAPQuaM's 360 degree method is highly engaged with collaborators, partners, and the literature. It targets relevant information and perspective, and measures emerge from the process. Potential measures are tested to the extent that time and resources permit. In developing the HROB availability measures we incorporated:

- Engagement with broadly diverse partnered institutions and senior advisors.
- Detailed literature review.
- Interviews with clinicians from around the country.
- The CAPQuaM scientific team.
- A geographically diverse, multidisciplinary expert panel that participated in a two-round RAND/UCLA modified Delphi process, with enhanced follow up.
- Development of a Boundary Guideline that incorporates simultaneously a variety of gradients, including gradients of importance, relevance, and certainty, as appropriate to the construct being represented.
- Specification and review of measures and approaches to measurement by stakeholders and experts.
- Testing and assessment of measure performance using Medicaid data.

Key Aspects of the Validity of HROB Measures

Availability

The construct of availability is complex and can be muddled in the distinction or lack thereof between availability, access, and utilization (Kuhlthau, 2011). For this PQMP measure set on availability of HROB services, we created an index of the availability of specialty care services. All else equal, we would expect women who live in more medically dense communities to experience greater availability than those in less medically dense communities and those who

live in more isolated communities to have less availability. While these measures are challenging to validate definitively, these predictions give us an opportunity to explore construct validity.

High Risk

We have operationalized a systematic expert process informed by a detailed literature review and incorporating a well-described and frequently utilized system developed by AHRQ. While we have modified this system, it has been done to be consistent with its use in this context and to remain consistent with the guidance of the expert panel. It is transparent and has high face validity. We validated its use in 16 States using MAX data and in 2 separate years of New York State Medicaid data.

Availability of Specialty Care

Provider specialty is typically available for Medicaid and health plan providers as described above. Our validation confirmed that findings varied across geographic areas in the expected directions. For our validation study, we defined the 2-year look back period as the 2 years prior to the delivery date. For our final specifications we defined the 2-year look back period as the 2 calendar years prior to the reporting year and all dates in the reporting year prior to the date of delivery (see Tables 4-6 in the Supporting Documents).

We interpret the findings to suggest that these services become less available with increasing rurality, as we had predicted. We designed the measures to identify reduced availability for any reason, including geographic isolation, and the observed gradient strongly supports the validity of these as population measures of availability. These sub-measures move in similar directions but not in lock step, confirming that they are measuring related concepts and correspond to the fact that certain subspecialists are more available than others. The overall availability of these structural components of high-risk obstetrical services is low compared to the identified need.

Please see sections 3.C, 5.A, and 6.A in this report for additional evidence of validity.

Section 7. Identification of Disparities

CHIPRA requires that quality measures be able to identify disparities by race, ethnicity, socioeconomic status, and special health care needs. Thus, we strongly encourage nominators to have tested measures in diverse populations. Such testing provides evidence for assessing measure's performance for disparities identification. In the sections below, describe the results of efforts to demonstrate the capacity of this measure to produce results that can be stratified by the characteristics noted and retain the scientific soundness (reliability and validity) within and across the relevant subgroups.

7.A. Race/Ethnicity

Our feasibility assessment confirmed that racial and ethnicity data are almost universally available, and that method of assignment of race and ethnicity to the mother varied. It could be based on maternal self-report or assigned by the hospital. National improvement is needed in the methods used to assign race and ethnicity in hospital discharge data. For the purposes of this

measure, we are resigned at this time to the use of existing data as recorded in the mothers' medical records.

Testing sites that participated in the CAPQuaM feasibility assessment were asked to determine if maternal race/ethnicity was documented in the maternal chart. Representatives from institutions were asked to determine whether the data source for maternal race/ethnicity was located in an EHR or a paper format. Institutions were also asked to indicate the difficulty of data abstraction in obtaining maternal race/ethnicity. Responses included: very difficult to collect, difficult to collect, not difficult to collect, or unavailable. Virtually all indicated that this information was not difficult to collect. The data were generally EHRs. The New York State Medicaid Program was able to identify race using their information systems; records for 45 individuals out of nearly 60,000 pregnancies were missing data on race.

We also examined race/ethnicity data in New York State Medicaid files. The following statistics focus on women found to be high risk. Our findings suggest that blacks, Hispanics, and other races/ethnicities are more likely than non-Hispanic white women to have visits with MFMs and specialists. Our data do not give us any indication of severity of illness. There is evidence suggesting that blacks and Hispanics have higher rates of comorbidity and have an increased risk for maternal morbidity and mortality compared with their non-Hispanic white counterparts (Berg, et al., 2010; Callaghan, et al., 2012); see Table 7 in the Supporting Documents.

We found that our measures could identify statistically significant differences in performance across race/ethnicity and poverty and also when stratifying for several of the levels of urbanicity. Consistent with our previous measure specifications, we recommend a minimum stratum size of 250 in order to report stable stratum specific analyses. Many States may not have sufficient numbers to do subpopulation analyses across all conditions.

7.B. Special Health Care Needs

Not assessed.

7.C. Socioeconomic Status

Institutions participating in feasibility assessments were asked to determine whether sources of payment could be found in patient charts. Payment sources were identified as being in the form of an EHR or a paper record. Representatives from the participating institutions were then asked to assess the difficulty of data abstraction of the payment source.

Responses included very difficult to collect, difficult to collect, not difficult to collect, or unavailable. A space was also provided for institutions to provide an explanation and additional comments that might be insightful. Virtually all indicated that this was not difficult to collect; the data generally were in EHRs.

Our feasibility testing demonstrated that we can use Medicaid insurance as a marker for socioeconomic status, and our New York State data demonstrated this to be an important independent predictor of poor maternal outcomes.

We further used the national distribution of percent of individuals in poverty to establish five categories that reflect the county level of poverty. We considered other data, such as county median income or county unemployment, but felt that the percent of individuals in poverty was a more integrative measure. The use of a geographic rather than an individual measure is consistent with recent applications of hierarchical methods to study the impact of poverty and also with data that indicate that local disparities in income can be an independent predictor of outcomes. It also allows this measure to consider issues of socioeconomic status while using publicly available data and requiring only the mother's county of residence, a more reliable data point than self-reported income.

Our analysis of U.S. Department of Agriculture (USDA) data considering 3,142 counties and related geographic units found a mean of 17.2 percent of county residents living in poverty, a standard deviation of 6.5 percent, and an interquartile range of 8.2 percent. The distribution described below, shows meaningful dispersion and supports our plan to build off quartiles of distribution with a finer focus in higher areas of poverty (see Table 8 in the Supporting Documents).

All of New York State lies in the top three quartiles. We would expect to find the largest differences between poorer and other counties and not across the upper end of the spectrum. Nonetheless, we conducted the analysis and found statistically significant differences. High-risk pregnant women living in the top quartile were more likely to have outpatient visits with MFMs or indicated subspecialists than high-risk pregnant women living in the second or third quartiles. There was a gradient with higher income counties having higher availability of MFMs and specialist care (see Table 9 in the Supporting Documents).

7.D. Rurality/Urbanicity

As described in the specifications (see Supporting Documents), we used urban influence codes to describe the level of rurality or urbanicity.

Metropolitan

1. In large metro area of 1+ million residents
2. In small metro area of less than 1 million residents

Non-Metropolitan

3. Micropolitan
4. Non-core adjacent to large metro area
5. Micropolitan adjacent to small metro
6. Non-core adjacent to small metro with own town
7. Non-core adjacent to small metro no own town
8. Micropolitan not adjacent to a metro area
9. Non-core adjacent to micro with own town
10. Non-core adjacent to micro with no own town
11. Non-core not adjacent to metro or micro with own town
12. Non-core not adjacent to metro or micro with no own town

We analyzed 3,143 county equivalents in the United States; results are shown in Table 10 (see Supporting Documents). The population is heavily weighted to metropolitan areas as demonstrated in Table 11 (see Supporting Documents).

As noted, we use Urban Influence Codes (UIC), which have been developed by the USDA based on a number of criteria to describe the levels of urbanicity and rurality. This is intended not only to report within plan differences but also to allow for aggregation as appropriate. While each UIC has its own meaningful definition, some researchers choose to aggregate various codes. Bennett and colleagues at the South Carolina Rural Research Center bring together Codes 1 & 2 as Urban; 3, 5, & 8 as micropolitan rural; 4, 6, & 7 as rural adjacent to a metro area; and 9, 10, 11, & 12 as remote rural (Bennett, Olatosi, Probst, 2008). We observe that UIC 5 might as well be aggregated with 4, 6, & 7 as an adjacent rural area. Further, this approach to rurality does not map exactly to the population density based definition of frontier (fewer than 6 persons per square mile) as articulated in the Affordable Care Act. However, use of such categories is consistent with the ACA's intent that the Secretary ask that data that are collected for racial and ethnic disparities also look at underserved frontier counties. Frontier health care may be approximated by analysis of the remote rural categories (Hart, 2012). Those interested in care specific to large cities may wish to aggregate rural areas and analyze UIC 1 and 2 separately.

The New York State Medicaid data were sensitive to urbanicity. For our validation studies, we chose to group urbanicity by urban, suburban, and rural. We considered UIC 1 (large metropolitan) and UIC 2 (small metropolitan) to be urban; UIC codes 3-6, those areas to adjacent to large and small metropolitan, to be suburban; and UIC codes 7-9 to be rural. New York State does not have counties with UIC codes 10-12. We chose to group urbanicity by urban, suburban, and rural for the purposes of these analyses.

7.E. Limited English Proficiency (LEP) Populations

Not assessed, but there is nothing intrinsic to the measure to inhibit its use in that population so long as the LEP characteristic can be linked to the pregnancy or delivery data.

Section 8. Feasibility

Feasibility is the extent to which the data required for the measure are readily available, retrievable without undue burden, and can be implemented for performance measurement. Using the following sections, explain the methods used to determine the feasibility of implementing the measure.

8.A. Data Availability

1. What is the availability of data in existing data systems? How readily are the data available?

The CAPQuaM HROB measures seek to determine the proportion of high-risk women that have outpatient visits with MFMs or specialists during their pregnancies. As such, the data elements of interest include:

- Outpatient claims data.
- Provider type.
- Documentation of conditions that would classify a woman as “high risk.”
- For stratification purposes:
 - Race and ethnicity.
 - Insurance type (Medicaid, private, uninsured).
 - Managed care insurance – Yes/No (where applicable).
 - Benefit category (for Medicaid- and CHIP-eligible cohorts).
 - Income level (as recorded for Medicaid- and CHIP-eligible cohorts).
 - County equivalent and State or zip code of residence.

Several of these data elements are readily available through hospital administrative data. For example, identification of women with “high-risk” conditions can be achieved through use of the appropriate ICD-9, CCS, and/or revenue codes. Additionally, benefit type is typically recorded in health plan, Medicaid, and CHIP administrative data sets.

As part of our feasibility assessment, CAPQuaM partnered with New York State Medicaid to conduct a variety of analyses using their administrative data set. The findings from these analyses indicated that the afore mentioned administrative data elements are also readily available at the State level and can be abstracted and used for calculating and reporting the CAPQuaM HROB measures. Further, we have specified several variables, for SES and urbanicity, by linking county of residence at the time of delivery to publicly available data sets. The CAPQuaM feasibility assessment received responses from nine of ten sites with obstetrical services around the country. Results from the assessment indicated that in general, the data elements of interest are available in the medical record system and not difficult to abstract, including race, ethnicity, and zip code or State and county of residence, for those administrative systems that may lack them.

Payment source (insurance type) should be available in a health plan database and is also easily obtained from electronic data at the health care facility.

2. If data are not available in existing data systems or would be better collected from future data systems, what is the potential for modifying current data systems or creating new data systems to enhance the feasibility of the measure and facilitate implementation?

The data required for the CAPQuaM HROB structural measures are generally available in the existing data systems. Enhancement of collection of patient reported race-ethnicity data into existing administrative systems would also be valuable.

8.B. Lessons from Use of the Measure

1. Describe the extent to which the measure has been used or is in use, including the types of settings in which it has been used, and purposes for which it has been used.

This is a new measure.

2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?

This measure is not currently in use.

3. What lessons are available from the current or prior use of the measure?

This measure is not currently in use.

Section 9. Levels of Aggregation

CHIPRA states that data used in quality measures must be collected and reported in a standard format that permits comparison (at minimum) at State, health plan, and provider levels. Use the following table to provide information about this measure's use for reporting at the levels of aggregation in the table.

For the purpose of this section, please refer to the definitions for provider, practice site, medical group, and network in the Glossary of Terms.

If there is no information about whether the measure could be meaningfully reported at a specific level of aggregation, please write "Not available" in the text field before progressing to the next section.

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/ CHIP†:

State level Can compare States*

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)

Yes.

Data Sources: Are data sources available to support reporting at this level?

Yes.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

New York State had more than 60,000 eligible pregnancies. We suggest reporting for strata with 250 or more women.

In Use: Have measure results been reported at this level previously?

No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

Limited. Interpretation requires understanding of the measure as a descriptor of a gradient of availability for the defined population. Benchmark data would enhance interpretation. Stratification by urbanicity can be clarifying, depending on the assessment of interest.

Other geographic level: Can compare other geographic regions (e.g., MSA, HRR)

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)

Yes.

Data Sources: Are data sources available to support reporting at this level?

Yes.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not assessed. We recommend a sample size of 250 or more pregnancies for any reporting unit or stratum.

In Use: Have measure results been reported at this level previously?

No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

Limited. Interpretation requires understanding of the measure as a descriptor of a gradient of availability for the defined population. Benchmark data would enhance interpretation.

Medicaid or CHIP Payment model: Can compare payment models (e.g., managed care, primary care case management, FFS, and other models)

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)

Yes.

Data Sources: Are data sources available to support reporting at this level?

Yes.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not assessed. We recommend a sample size of 250 or more pregnancies for any reporting unit or stratum.

***In Use:* Have measure results been reported at this level previously?**

No.

***Reliability & Validity:* Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**

No.

***Unintended consequences:* What are the potential unintended consequences of reporting at this level of aggregation?**

Limited. Interpretation requires understanding of the measure as a descriptor of a gradient of availability for the defined population. Benchmark data would enhance interpretation. Stratification by urbanicity can be clarifying, depending on the assessment of interest.

***Health plan*:* Can compare quality of care among health plans.**

***Intended use:* Is measure intended to support meaningful comparisons at this level?**

(Yes/No)

Yes.

***Data Sources:* Are data sources available to support reporting at this level?**

Yes.

***Sample Size:* What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**

Not assessed. We recommend a sample size of 250 or more pregnancies for any reporting unit or stratum.

***In Use:* Have measure results been reported at this level previously?**

No.

***Reliability & Validity:* Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**

No.

***Unintended consequences:* What are the potential unintended consequences of reporting at this level of aggregation?**

Limited. Interpretation requires understanding of the measure as a descriptor of a gradient of availability for the defined population. Benchmark data would enhance interpretation. Stratification by urbanicity can be clarifying, depending on the assessment of interest.

Provider Level

***Individual practitioner:* Can compare individual health care professionals**

***Intended use:* Is measure intended to support meaningful comparisons at this level?**

(Yes/No)

No.

Data Sources: Are data sources available to support reporting at this level?

Yes.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not recommended for use.

In Use: Have measure results been reported at this level previously?

No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

Not recommended for use.

Provider Level

Hospital: Can compare hospitals

Intended use: Is measure intended to support meaningful comparisons at this level?
(Yes/No)

No.

Data Sources: Are data sources available to support reporting at this level?

No.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

Not recommended for use.

In Use: Have measure results been reported at this level previously?

No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

Not recommended for use.

Provider Level

Practice, group, or facility:** Can compare: (i) practice sites; (ii) medical or other professional groups; or (iii) integrated or other delivery networks

Intended use: Is measure intended to support meaningful comparisons at this level? (Yes/No)

Yes.

Data Sources: Are data sources available to support reporting at this level?

Yes.

Sample Size: What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?

IDNs only; not assessed. We recommend a sample size of 250 or more pregnancies for any reporting unit or stratum.

In Use: Have measure results been reported at this level previously?

No.

Reliability & Validity: Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?

No.

Unintended consequences: What are the potential unintended consequences of reporting at this level of aggregation?

For IDNs only: Interpretation requires understanding of the measure as a descriptor of a gradient of availability for the defined population. Benchmark data would enhance interpretation. Stratification by urbanicity can be clarifying, depending on the assessment of interest

Section 10. Understandability

CHIPRA states that the core set should allow purchasers, families, and health care providers to understand the quality of care for children. Please describe the usefulness of this measure toward achieving this goal. Describe efforts to assess the understandability of this measure (e.g., focus group testing with stakeholders).

The focus of the CAPQuAM measures is on outpatient care for women with chronic illness and pregnancy-related complications. The eight sub-measures—a summary measure that describes the extent to which high-risk pregnant women have outpatient visits with MFMs or subspecialists, six sub-measures that describe the extent of such services for specific subgroups of high-risk women, and a sub-measure that describes the extent to which high-risk pregnant women lack prenatal care—are straightforward and intuitive, as they represent desirable clinical practice. Variations at the population level demonstrate differences in the availability of these services for women with high-risk pregnancies. These measures are intended for use at the population level and not to assess the quality of care or any individual pregnancy.

We have not tested combining these measures into an index but could imagine some States or other entities wanting to do that. Understandability is at the heart of CAPQuaM's measure development process. Throughout development, CAPQuaM brought together diverse stakeholders – clinicians, scientists, payers, purchasers, consumer organizations, and others – to ensure their iterative engagement in advancing quality measures that are understandable, salient and actionable. CAPQuaM employed a 360 degree method, designed to involve key stakeholders in meaningful ways.

Our development process for this measure cultivated formal input from:

- Medical literature (both peer-reviewed and gray, including State Web sites).
- Relevant clinicians.
- Organizational stakeholders (our consortium partners, as well as advisory board members).
- Multi-disciplinary, geographically diverse expert panel, including clinicians and academicians.
- CAPQuaM's scientific team.

Clinical criteria, including consideration of inclusion and exclusion criteria, were developed using a modified version of the RAND/UCLA modified Delphi Panels. CAPQuaM sought recommendations from major clinical societies and other stakeholders to identify academic and clinician expert panel participants with a variety of backgrounds, clinical and regional settings, and expertise. The product of this process was participation by a broad group of experts in the development of clinically detailed scenarios leading to the measures.

CAPQuaM integrated perspectives from a national consortium, Steering Committee, and Senior Advisory Board at each step of the process, in addition to a continuing collaboration with AHRQ. Our team far exceeded the required minimums for expertise outside of the mainstream medical system, ensuring understandability at various levels, and by a variety of audiences.

Alpha testing was performed to assess feasibility, mechanisms of data collection, and operational aspects of collecting and analyzing data for the measure. Beta testing was performed by the New York State Office of Health Insurance Programs (Medicaid) in close collaboration with the CAPQuaM team.

The route to measure specification included development of relevant scenarios and issues for formal processing by our expert panel, whose members participated in a two round RAND/UCLA modified Delphi panel that culminated in a 2-day long in-person meeting hosted at the Joint Commission and moderated by a pediatrician and an obstetrician-gynecologist. The output from that panel meeting was summarized in the form of a boundary guideline that was then used to guide the measure specification and prioritization.

Section 11. Health Information Technology

Please respond to the following questions in terms of any health information technology (health IT) that has been or could be incorporated into the measure calculation.

11.A. Health IT Enhancement

Please describe how health IT may enhance the use of this measure.

As health information systems advance, perhaps the administrative data at the heart of this measure could migrate from billing and management systems to the EHR. We are not yet there.

11.B. Health IT Testing

Has the measure been tested as part of an electronic health record (EHR) or other health IT system?

No.

If so, in what health IT system was it tested and what were the results of testing?

Not at present.

11.C. Health IT Workflow

Please describe how the information needed to calculate the measure may be captured as part of routine clinical or administrative workflow.

Other than perhaps the race/ethnicity data, the clinical data are a part of routine administrative data systems. The migration of diagnosis data from the EHR directly to administrative systems conceivably could improve the accuracy of the data in the future, although that is not clear.

11.D. Health IT Standards

Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

No.

If yes, please describe.

Not applicable.

11.E. Health IT Calculation

Please assess the likelihood that missing or ambiguous information will lead to calculation errors.

Not applicable.

11.F. Health IT Other Functions

If the measure is implemented in an EHR or other health IT system, how might implementation of other health IT functions (e.g., computerized decision support systems in an EHR) enhance performance characteristics on the measure?

Not applicable.

Section 12. Limitations of the Measure

Describe any limitations of the measure related to the attributes included in this CPCF (i.e., availability of measure specifications, importance of the measure, evidence for the focus of the measure, scientific soundness of the measure, identification of disparities, feasibility, levels of aggregation, understandability, health information technology).

The definition of high-risk obstetrical care is based upon a careful, evidence-driven consensus process that was highly engaged and guided by an extraordinary and multidisciplinary panel of national experts. The CAPQuaM team carefully and faithfully operationalized their conclusions and maintained dialogue as they did so. Still there were infinite combinations of qualifying criteria, and we had to specify one. We are confident that the specifications are strong, the conditions meaningful, and the population at increased risk. But these were designed from the outset and explicitly discussed at the expert meeting to be population-based measures. They are intended for the measurement of performance across populations, not for the assessment of the quality of an individual's care. The inevitable noise in the measures was designed to be dwarfed by the signal when applied to large numbers of pregnant women but not for any given individual.

This measure is based on identification of provider types specified in State Medicaid data, health plans, and other administrative data sources. In general, encounter data provider specialty is assigned by the health plan. Our colleagues at the New York State Department of Health and other members of our Steering Committee confirmed that this is a feasible and valid way to assess specialty; each health plan or State Medicaid program would use their own internal algorithm for identifying provider type.

Section 13. Summary Statement

Provide a summary rationale for why the measure should be selected for use, taking into account a balance among desirable attributes and limitations of the measure. Highlight specific advantages that this measure has over alternative measures on the same topic that were considered by the measure developer or specific advantages that this measure has over existing measures. If there is any information about this measure that is important for the review process but has not been addressed above, include it here.

This innovative set of measures addresses a complex and critical idea: How available are important high-risk obstetrical (HROB) services to women who may need them? Specifically, how available are MFMs and specialty physician services to women with chronic illness and pregnancy-related conditions? We set forth specifications to identify pregnancies that constitute high risk and that require specialty care. We assess critical sets of practices or services and pose

specific questions related to their disease or condition and care. The practices for this measure are:

- The percentage of high-risk pregnant women who have zero, one, or two or greater outpatient visits with a maternal fetal medicine specialist or an indicated subspecialist during their pregnancy.
- The percentage of pregnant women with HIV disease who have zero, one, or two or greater visits with a maternal fetal medicine specialist or an infectious disease specialist during their pregnancy.
- The percentage of pregnant women with specified cardiac disease who have zero, one, or two or greater visits with a maternal fetal medicine specialist or a cardiologist during their pregnancy
- The percentage of pregnant women with a mood disorder or mental health disorder complicating pregnancy who have zero, one, or two or greater visits with a maternal fetal medicine specialist or psychiatrist, psychologist, or licensed therapist.
- The percentage of pregnant women with substance dependency who have zero, one, or two or greater visits with a maternal fetal medicine specialist or psychiatrist, psychologist, or licensed therapist during their pregnancy.
- The percentage of pregnant women with specified poor obstetrical history who have zero, one, or two or greater visits with a maternal fetal medicine specialist during their pregnancy
- The percentage of pregnant women with epilepsy who have zero, one or two, or three or greater visits with a maternal fetal medicine specialist or neurologist during their pregnancy
- The percentage of high-risk pregnant women who have no outpatient visits with any provider during their pregnancy.

These measures respond to the assignment of the topic of availability of high-risk obstetrical services to CAPQuaM, an AHRQ-CMS CHIPRA Center of Excellence in the Pediatric Quality Measures Program. We have used a rigorous and systematic process that was highly engaged with clinicians, stakeholders, and experts to develop these measures. We began with the evidence base and the literature.

Childbirth accounts for a plurality of hospital admissions for Medicaid programs; our data show that between one- and two-thirds of pregnancies insured by Medicaid across the country are high risk, according to our algorithms. Hospital costs for childbirth are large. High-risk women suffer increased rates of maternal or infant morbidity and mortality compared with women not at high risk.

Maternal deaths and near misses are often preventable through improved quality and safety of maternity care. The rapidly rising rate of chronic illness and associated complications illustrate the need for increased availability of maternal fetal medicine specialists and subspecialty care. These measures are important for quality and patient safety. Racial/ethnic disparities in practice are well documented; the proposed availability of specialty physician services measures address

important gaps in quality and safety for minority women who often suffer higher rates of comorbidity.

These measures were designed to be population measures, and we have tested them in that regard. As intended, our validation tests found that more geographically isolated areas show less availability than areas with more dense medical services. We found the measures to be complementary and not duplicative. They were sensitive to differences in socioeconomic status, race, and urbanicity. We found they could be implemented in New York State Medicaid data. The measures performed well.

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The CHIPRA Pediatric Quality Measures Program (PQMP) Candidate Measure Submission Form (CPCF) was approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act.

The OMB Control Number is 0935-0205 and the Expiration Date is December 31, 2015.

Public Disclosure Requirements

Each submission must include a written statement agreeing that, should U.S. Department of Health and Human Services accept the measure for the 2014 and/or 2015 Improved Core Measure Sets, full measure specifications for the accepted measure will be subject to public disclosure (e.g., on the Agency for Healthcare Research and Quality [AHRQ] and/or Centers for Medicare & Medicaid Services [CMS] websites), except that potential measure users will not be permitted to use the measure for commercial use. In addition, AHRQ expects that measures and full measure specifications will be made reasonably available to all interested parties. "Full measure specifications" is defined as all information that any potential measure implementer will need to use and analyze the measure, including use and analysis within an electronic health record or other health information technology. As used herein, "commercial use" refers to any sale, license or distribution of a measure for commercial gain, or incorporation of a measure into any product or service that is sold, licensed or distributed for commercial gain, even if there is no actual charge for inclusion of the measure. This statement must be signed by an individual authorized to act for any holder of copyright on each submitted measure or instrument. The authority of the signatory to provide such authorization should be described in the letter.

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