High-Risk Deliveries at Facilities with 24/7 In-House Physician Capable of Safely Managing Labor and Delivery and Performing a Cesarean Section, Including an Emergent Cesarean Section

Section 1. Basic Measure Information

1.A. Measure Name

HROB1: High-Risk Deliveries at Facilities with 24/7 In-House Physician Capable of Safely Managing Labor and Delivery and Performing a Cesarean Section, Including an Emergent Cesarean Section

1.B. Measure Number

0120

1.C. Measure Description

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

Percent of high-risk deliveries that are delivered at a facility with 24/7 in

This measure belongs to the Pediatric Quality Measures Program (PQMP) 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.

   High-risk obstetrical deliveries at facilities with appropriate high-risk facilities.

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.

   Structural 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

Number of eligible deliveries that occur in facilities with 24/7 in-house physician coverage that is dedicated to obstetrics, and includes a physician capable of safely managing labor and delivery, and performing a cesarean section, including an emergent cesarean section.

Numerator Elements:

- Number of deliveries.
- Maternal and infant ICD-9-CM codes.
- Response to survey question identified on technical specifications.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

Overall number of eligible deliveries. Eligible deliveries are identified in two distinct ways. Maternal and infant ICD-9-CM codes are specified in Section 2 Detailed Measure Specifications (see Supporting Documents).

1. Class A: Maternal Diagnoses and Comorbidities
2. Class B: Delivery Complications, Fetal Injury or Compromise, or Suboptimal Infant Diagnoses

a. Maternal Delivery Complication Codes (ICD-9-CM).

b. Maternal Stillbirth or Birth Hypoxia/Asphyxia Codes.
c. Premature or small infant. (Infant codes).

3. Either Class A or Class B

Denominator Elements:

- Number of deliveries.
- Maternal and infant ICD-9-CM codes.
- Maternal DRG, CPT codes, and revenue codes when available.

1.J. Denominator Exclusions

None.

1.K. Data Sources

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

Administrative Data (e.g., claims data); Survey – Health care professional report.

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

Health care professional can be representing a health care facility that delivers babies.

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

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).

The proposed availability measures address important gaps in quality and safety and also have the potential to narrow disparities in maternal and neonatal outcomes. These four structural attributes (24-hour in-house physicians covering obstetrics and capable of managing labor and delivery, including performing emergent cesarean sections; 24-hour in house physicians available and capable of providing obstetric anesthesia; 24-hour availability of blood bank/transfusion services; and delivery at a facility with a Level 3 or higher neonatal intensive care unit [NICU]) have the potential to improve both maternal and infant outcomes in the setting of high-risk deliveries. They were chosen to represent a prioritized selection of key structural attributes that impact the timeliness with which a potentially urgent service may be available to women who are delivering in the context of a pregnancy that manifests higher than typical risk. The prioritization process involved our team of stakeholders as well as an expert panel; the clinical and health services judgment of these team members guided the process.

Delivery care provided to pregnant women is critical for the health and well-being of mothers and babies. The burden of chronic illness and risk factors for pregnancy complications (e.g., hypertension, diabetes, advancing maternal age, previous cesarean section) are all rising among women, increasing their risk for morbidity and mortality (Hankins, 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, Ke0 Trr-6(g)eedw 2.9hacil(is)1 Td [(be)4

concept of regionalization of care. The panel specifically endorsed the importance of certain services being available 24/7 in the hospital of delivery, among those a qualified obstetrical physician, an obstetrical anesthesiologist, blood banking/transfusion services, and a Level 3 or higher NICU. A working draft of the Panel Summary after the second round of voting can be found in the 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 availability measures should be 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 also 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.

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Examination of neighboring States (e.g., Arizona and New Mexico) showed similar performance, (35.76 percent and 35.47 percent, respectively), adding face validity to our analysis.

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).

We have developed four related measures based on 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:

1. Coverage of the obstetrical service by a physician dedicated to the OB service and capable of safely managing labor and delivery, performing a cesarean section, including an emergent cesarean section.
2. In-house coverage dedicated to the obstetrical service by an anesthesiologist who is qualified to provide obstetrical anesthesia.
3. On-site b

percent of Class A deliveries, 27.98

early recognition, proper management to achieve rapid hemostasis, and prompt and sometimes repeated transfusion. Key data from CMQCC are shown in Table 5 (see Supporting Documents).

For our New York State Medicaid data analysis, we used regional perinatal centers (RPC) as a proxy for round-the-clock transfusion services; RPC are required to have these services always available. Considering the three specific phe atrwacns tCre m304 Tc 0.06 315 5-2(4(pe)4()]T46us)-1(i)-2(on. K)-

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The availability of high-risk obstetric (HROB) services is a challenging concept, and to develop quality measures that assess the availability of high-risk obstetric services we first needed to define the availability of services and high risk obstetrical services. Specifically we wondered

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,

clinical classification software, and at the margins are defined based upon specific guidance provided by our expert panel.

In so doing, we produce 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 services to a population of women who may need them. This approach is consistent with the useful Institute of Medicine 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 delivery) are available to women who are at risk to need them.

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 (see below). We have shared and refined this approach in a number of venues including within the PQMP, which comprises the various PQMP AHRQ-CMS CHIPRA Centers of Excellence, the State PQMP participants, and AHRQ and CMS participants. All presentations have 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 communities. These latter venues include:

- 2012 Pediatric Academic Societies State of the Science Plenary (Boston). This presentation is included as an Appendix (see Supporting Documents).
- 2012 Oxford-Mount Sinai Bioethics Consortium-2(e2(t S)-2t.002 T.)Tj ( )rwaa hetmd (.)Tj0 Td [(he)49.

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

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.

As an illustration of our approach, we provide a case example of our decision to exclude two diagnoses from the inclusion criteria. The expert panel rated valvular heart disease as significant and an indication of the need for HROB. In its deliberations, the panel made clear that conditions such as murmurs or simple mitral valve prolapse, which often are trivial,

pregnancies) were identified only using Class B. We expected a substantial “voltage drop” between a condition of elevated risk and a complication or an undesirable outcome. Hence, maternal diagnoses codes of Class A will predictably be orders of magnitude larger than the delivery and neonatal codes of Class B. These findings are consistent with our predictions and

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 whose members participated in a two-round RAND/UCLA modified Delphi process, with enhanced follow-up.
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high-risk pregnancy, since premature labor and growth retardation are within our definition of risk. While

measure, we are resigned at this time to using the 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, the infant chart, or in both charts. Sites were also asked if infant race/ethnicity was documented in the maternal chart, the infant chart, or both charts. Representatives from institutions were asked to determine whether the data source for maternal race/ethnicity was located in an EHR format 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 was not difficult to collect. The data generally were in the EHR. The New York State Medicaid Program was able to identify race using their information systems; 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 by at least one of our two approaches identifying high-risk women. Although the scarcity of black women having babies in rural counties limited the scope of our analyses, we were able to see racial differences in the more urban counties. Among women in large metropolitan areas who met our criteria for high-risk deliveries, 44.76 percent of black women, 40.11 percent of Hispanic women, and 30.04 percent of white women with Medicaid delivered in hospitals with Level 3 or higher NICUs. This may reflect housing patterns with increased numbers of minorities in inner cities, more proximate to hospitals with these services. This hypothesis is supported because those living in smaller metropolitan areas (under 250,000), show both lower rates and a different distribution: black women at 33.54 percent, white women at 20.04 percent, and Hispanic women at 13.89 percent.

A different pattern is seen with regional perinatal centers, our proxy for 24/7 blood banking/transfusion centers. For large metro areas among women who met our criteria for high-risk deliveries, 19.25 percent of white women, 13.92 percent of black women, and 13.82 percent of Hispanic women delivered at these institutions. Still a slightly different pattern (black>Hispanic>white) is seen in large metro areas for our OB proxy measure.

We found that our measures are able to identify statistically significant differences in performance across race/ethnicity and poverty and also when stratifying for several of the levels of urbanicity.

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 information was not difficult to collect. The data were generally in the EHRs.

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, and the results are shown in Table 9 (see Supporting Documents). The population is heavily weighted to metropolitan areas as demonstrated in Table 10 (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 to allow for aggregation as appropriate. While each UIC has its own meaningful definition, some researchers choose to aggregate various codes. We recommend consideration of the aggregation schema of Bennett and colleagues at the South Carolina Rural Research Center (Bennett, Olatosi, Probst, 2008). Their aggregation scheme brings together Codes 1 & 2 as Urban; 3,5, & 8 as micropolitan rural; 4,6, & 7 as rural adjacent t

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

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†:

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?
Minimum size specified for analysis is 250. Study of HROB deliveries in MAX data in 18 States using slightly less sensitive criteria than those specified herein found a range from 1637 (VT) to 55,382 (NY). The Median is 14,500, with 25 percent less than 4,000 deliveries. We specify using urban influence codes which allows for a variety of analyses.

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?
None anticipated.

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

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?
None anticipated.

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 sourceverat te tsa is levedl of Yes.
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Not specified for this purpose.

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 specified for this purpose.

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 specified for this purpose.

In Use: Have measure results been reported at this level previously?
No. at(/1(Yea)4(n-)J/

No.

Sample Size: What is the typical samplesize available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?
Not specified for this purpose.

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 specified for this purpose.

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 HROB measures describe the percent of high-risk deliveries that occur in hospitals with the appropriate structural facilities. This measure is straightforward and intuitive, as this represents a desirable clinical practice. Variations at the population level demonstrate differences in the availability of these services for women with high-risk pregnancies and deliveries. 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 as a 0-4 measure but could envision some States or other entities wanting to do that. We will consider that for our future development work.

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° method, designed to involve key stakeholders in meaningful ways.

Our development process for this measure cultivated formal input from:

- The medical literature (both peer reviewed and gray, including State Web sites).

- Relevant clinicians.
- Organizational stakeholders (our consortium partners, as well as advisory board members,
- see below).
- A multidisciplinary, 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

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 r0 Td [illegible]

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).

This measure is based on the self-reported presence of a key structural aspect of hospital care. That is the current state of the art for broad structural measures, absent mechanisms like Accreditation Audits. As these data re not to be collected anonymously, as they are verifiable, as the health care facility has no specific incentive to deceive, and as deception related to performance measurement could be considered fraud, we are confident that this is a mild limitation.

The definition of high-risk obstetrical care is based on 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 we 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 measures 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.

Section 13. Summary Statement

s a Provide a summary rationale for why the measure should be selected for use, taking into

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