

# Cesarean Birth (PC-02) Measure Public Comment Summary Report

## ***Project Title:***

Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance

## ***Dates:***

- The call for public comment ran from Monday, September 14, 2015, to Monday, October 12, 2015.
- The public comment summary was submitted to the Centers for Medicare & Medicaid Services (CMS) on Monday, October 26, 2015.

## ***Project Overview:***

CMS has contracted with Mathematica Policy Research and its partners to develop, electronically specify, and maintain process and structural clinical quality measures for five CMS hospital quality programs. These programs are the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program, and Electronic Health Record (EHR) Incentive Program for Eligible Hospitals. The name of the contract is Hospital Inpatient and Outpatient Process and Structural Measure Development and Maintenance (Hospital-MDM). The contract number is HHSM-500-2013-13011I/HHSM-500-T0003. As part of its measure development process, CMS has asked interested parties to submit comments on the PC-02 (Cesarean Birth) measure.

## ***Project Objectives:***

The project's primary objectives include:

- Conducting an environmental scan to identify gaps in existing hospital quality reporting programs where new measures will be useful and important;
- Developing, specifying, and testing new hospital electronic clinical quality measures (eCQMs) for implementation in CMS's quality reporting programs in the areas identified during the environmental scan;
- Retooling existing measures to facilitate reporting using data extracted from an EHR; and
- Maintaining previously-developed hospital measures currently in the five CMS

programs named above by monitoring their validity and effectiveness and recommending improvements as needed.

### ***Information About the Comments Received:***

The project team used extensive outreach methods to notify stakeholders and the general public about the comment period:

- Email sent to CMS listserv groups, including the eHealth provider and vendor workgroups
- Email sent to hospitals currently reporting Perinatal Care (PC) measures to The Joint Commission
- Email sent to stakeholders and stakeholder organizations, including:
  - American Academy of Family Physicians
  - American Academy of Physician Assistants
  - American Association of Nurse Practitioners
  - American Board of Internal Medicine
  - American Board of Obstetrics and Gynecology
  - American Board of Surgery
  - American College of Nurse Midwives
  - American College of Physicians
  - American College of Surgeons Advisory Council for Gynecology and Obstetrics
  - American Congress of Obstetricians and Gynecologists
  - American Gynecological and Obstetrical Society
  - American Hospital Association
  - American Medical Association
  - American Medical Group Association
  - Association of Physician Assistants in Obstetrics and Gynecology
  - Association of Professors of Gynecology and Obstetrics
  - Association of Women's Health, Obstetric, and Neonatal Nurses
  - Health IT Policy Committee Quality Measures Work Group
  - Healthcare Information and Management Systems Society (HIMSS) Electronic Health Record Association
  - HIMSS Clinical Quality Collaboration Center
  - Institute for Healthcare Improvement
  - Maternal Health Information Initiative
  - National Quality Forum eMeasure Contacts
  - Society for Academic Specialists in General Obstetrics and Gynecology
  - Society for Maternal-Fetal Medicine
  - Society of OB/GYN Hospitalists

- The Joint Commission’s PC Measure Maintenance Technical Advisory Panel (TAP)
- Facilitators of the following groups were asked to announce the public comment period during periodic meetings:
  - C3 Forum
  - eMeasures Issue Group Work Group
  - Medicare Learning Network Connects national provider calls
  - Weekly governance call for measure developers
- Announcement on the eCQI Resource Center website
- Announcement through the IQR Support Contractor Listserv
- Posting on the CMS Public Comment website

We received 21 comments from the following during the public comment period:

- Nine hospital/health systems (Baylor Scott & White, The Johns Hopkins Hospital, Valley View Hospital, Oconee Regional Medical Center, St. Luke’s Cornwall Hospital, Blount Memorial Hospital, Tufts Medical Center, Union Hospital, Overlake Hospital)
- Two EHR vendors (Epic and Cerner)
- One professional society (Association of Women’s Health, Obstetric and Neonatal Nurses [AWHONN])
- Two individuals (organizations not provided)

We received one comment after the close of the period on October 12, 2015. That comment is not included in this summary report and will be reviewed by the project team separately.

### ***Stakeholder Comments—General and Measure-Specific***

#### General comments

*One commenter* supported the measure overall.

**Response:** Thank you for your support for the current approach.

*One commenter* stated that this measure would only be useful if it’s not sampled.

**Response:** Please note that electronic clinical quality measures are not sampled.

#### Measure specifications

*Five commenters* expressed a desire to add exclusions to the measure, including exclusions for medical conditions that would justify a cesarean birth, induced labor, and mother’s preferences or other social situations.

**Response:** Thank you for your comments. The PC-02 electronic clinical quality measure was

developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference. However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.

We appreciate concerns raised regarding unintended consequences of the measure—specifically, that hospitals will delay or not perform necessary cesareans due to concerns over measure performance. The measure is intended to be an accurate way for leaders to identify whether a hospital's rate of cesarean births for women in this select population is consistent with the rates of this same population at another hospital. Hospitals whose measure rates are higher than rates at other hospitals are encouraged to explore and evaluate differences in the medical and nursing management of women in labor. The measure is not intended to discourage providers from performing cesareans that have been deemed appropriate and necessary. According to measure specifications, each numerator case should be evaluated to determine if care could have been provided differently so as to have precluded the procedure. We will discuss these concerns and strategies for response with CMS and our technical advisory panel.

Additional resources:

Main EK, Morton EH, Hopkins D, Giuliani G, Melsop K, Gould JB. "CMQCC White Paper: Cesarean Deliveries, Outcomes, and Opportunities for Change in California." 2011. Available at [http://www.cmqcc.org/white\\_paper](http://www.cmqcc.org/white_paper). Accessed October 21, 2015.

The American College of Obstetricians and Gynecologists. "Safe Prevention of the Primary Cesarean Delivery." 2014. Available at [http://www.acog.org/Resources\\_And\\_Publications/Obstetric\\_Care\\_Consensus\\_Series/Safe\\_Prevention\\_of\\_the\\_Primary\\_Cesarean\\_Delivery](http://www.acog.org/Resources_And_Publications/Obstetric_Care_Consensus_Series/Safe_Prevention_of_the_Primary_Cesarean_Delivery). Accessed October 21, 2015.

*One commenter* suggested clarifying the guidance section of the measure specifications that describes the denominator as "capturing the patient's number of live births."

**Response:** Thank you for the recommendation. We will revise the guidance to more clearly indicate that the number of previous live births is represented as either parity (number of >20 week births), gravidity (number of times a woman has been pregnant), or as count of zero term or pre-term births.

## Value sets

*Five commenters* asked questions related to the measure's value sets. Specifically:

*One commenter* asked how to access the value sets.

**Response:** To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at this link: <https://vsac.nlm.nih.gov/>. You can search the VSAC by value set ID or OID number (e.g., 2.16.840.1.113883.3.117.1.7.1.282), text (e.g., "cesarean birth"), or code (e.g., Z37.0).

*One commenter* asked how parity and gestational age are coded.

**Response:** CMS will make complete measure specifications available after the measure has completed testing. Please also note that value sets for "Estimated Gestational Age at Delivery" and "Parity" are coded using SNOMED-CT value sets. To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at this link: <https://vsac.nlm.nih.gov/>. You can search the VSAC by value set ID or OID number (e.g., 2.16.840.1.113883.3.117.1.7.1.282), text (e.g., "cesarean birth"), or code (e.g., Z37.0).

*One commenter* noted that the list of codes was prohibitively long.

**Response:** Thank you for your comment. The value sets used in the electronic clinical quality measure to represent the denominator population and excluded populations are aligned with the code tables reviewed and approved by our technical advisory panel for use in the chart-abstracted measure.

*One commenter* asked why the "Normal Delivery and Other Indications of Care" value set included codes indicating an abnormal presentation of the fetus.

**Response:** Thank you for your comment. The "Normal Delivery and Other Indications for Care" value set is an ICD-9 value set. In ICD-9, the concept of delivery is captured in the fifth digit of maternal diagnosis codes. In order to define the entire population of deliveries, this value set includes all patients who deliver, including patients who have deliveries with abnormal presentations. These patients are later removed in the denominator exclusion for abnormal presentation. In ICD-10 and SNOMED, delivery is represented as a procedure, and thus the initial patient population will include all patients who deliver when these data are captured in ICD-10 or SNOMED.

*One commenter* asked why the "Abnormal Presentation" value set includes codes for multiple fetuses.

**Response:** Although the measure does constrain the denominator to patients who deliver a singleton, the value sets for the abnormal presentation and multiple gestation denominator exclusions provide a second check to remove these patients from the measure. This is modeled like the chart-abstracted measure, which similarly defines the population as single deliveries but also excludes multiple gestations.

*One commenter* asked if the ICD-9 codes in the “Initial Population” value set would be updated to ICD-10.

**Response:** The initial population (IP) is currently defined using ICD-9, ICD-10 and SNOMED codes. We will review potential coding updates with CMS and our measure development team.

*One commenter* asked why the “Delivery of Singleton” value set was used in this measure instead of the “Single Live Birth” value set used in the PC-05 measure. The “Delivery of Singleton” value set contains an ICD-9 and ICD-10 code in addition to the same SNOMED code that is used in the “Single Live Birth” value set.

**Response:** PC-02 assesses care delivered in the maternal encounter, whereas PC-05 (“Exclusive Breastmilk Feeding”) addresses the newborn and newborn encounter. Although we would expect a “Single Live Birth” code to be present in the newborn’s record, we would not expect to find this information in the mother’s record. This is why the more extensive “Delivery of Singleton” value set is used for this measure. Thank you for your comment about the overlap in the SNOMED code used in both value sets. We will review this comment with CMS and our measure development team.

### Measure logic

*Six commenters* asked for clarity or recommended changes to the measure logic. Specifically:

*One commenter* asked why the codes that define the IP must start during the inpatient encounter.

**Response:** Thank you for your comment. The value sets included in the IP are intended to identify patients who deliver during the inpatient encounter. We do not intend to include patients who deliver outside of the inpatient setting and are subsequently admitted. Thus, we are only including patients who have a delivery diagnosis start during the encounter. In ICD-9, the concept of delivery is represented in the fifth digit of a diagnosis code, which may be why it’s not apparent that all codes in the IP are intended to represent delivery.

*One commenter* suggested changing the unit of measure from months to weeks.

**Response:** Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.

*One commenter* suggested adding occurrences to constrain the preterm and term newborn data elements to the current time of delivery.

**Response:** Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.

*One commenter* asked for clarification as to why the “Physical Exam Performed: Abnormal Presentation” data element has to start during the inpatient encounter. The commenter felt this was restrictive because the abnormal presentation could have been identified before the inpatient encounter and either persisted or corrected to a vertex position later.

**Response:** Thank you for your comment. Our intent is to not exclude those patients who have

a breech presentation that corrects to a vertex presentation. We will review this suggestion with CMS and our measure development team.

*One commenter* suggested that it's too restrictive to require that the "Physical Exam, Performed: Estimated Gestational Age at Delivery" data element start within one day of delivery.

**Response:** Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.

*One commenter* said it's uncommon to document a single delivery as "Diagnosis, Active."

**Response:** Thank you for your comment. We will review this comment with CMS and our measure development team.

### Interoperability challenges

*Six commenters* submitted comments on whether the measure's data elements are available in an enterprise or specialty obstetric EHR or in a fetal monitoring system, as well as the method of data transfer between these systems. Specifically:

*Four commenters* said their fetal monitoring systems or specialty obstetric EHRs do not interact with their enterprise EHRs.

*Two commenters* said a fetal monitoring system would not be needed to calculate the measure.

*One commenter* said all measure data elements are located in the enterprise EHR.

*One commenter* said her fetal monitoring system can record nulliparous term singleton deliveries in a vertex position.

**Response:** Thank you for your comment. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.

### ***Preliminary Recommendations***

We will review the following commenter suggestions with CMS and our measure development team:

- Revising the guidance to more clearly indicate that the number of previous live births is represented as either parity (number of >20 week births), gravidity (number of times a woman has been pregnant), or as count of zero term or pre-term births.
- Excluding diagnoses of abnormal presentation that were identified before the

- encounter, while not excluding patients for whom presentation corrected.
- Adding “occurring” to the denominator logic representing preterm and term births.
  - Changing the temporal calculation method from months to weeks to provide greater control over data elements, with a lookback period of 10 months before delivery.
  - Examining SNOMED for the availability of a concept of “Newborn Delivery” and removing the concept of “Newborn Birth.”
  - Examining whether the quality data model (QDM) supports calculation of gestational age similar to the calculation of age based on date of birth.

Any updates to the measure specifications will be disseminated to the public when the measure has completed testing.

### ***Overall Analysis of the Comments and Recommendations***

Feedback received on the PC-02 measure was highly constructive. Many commenters raised valid concerns about potential reasons why a patient would undergo a cesarean and the impact that reporting the measure may have on provider behavior. We also received specific comments on the rationale for using or including certain codes in the measure’s value sets. Comments on measure logic focused on the timing of certain data elements. Commenters also provided important feedback on the current EHR landscape as it pertains to this measure, including specific remarks on the feasibility of communication between the various record systems that may be needed to calculate the measure. We thank commenters for providing their unique perspectives on this measure.

### Public Comment Verbatim Report

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
10/12/2015	<p>On behalf of Baylor Scott &amp; White Health (BSWH), its 18 acute care hospitals, and the Office of the Chief Quality Officer, BSWH welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS's) data collection specifications using the EHR for the Cesarean Section (PC-02) measure.</p> <p>BSWH is based in Dallas and Temple, Texas, representing 43 hospitals, more than 500 patient care sites, more than 6,000 affiliated physicians, 34,000 employees, the Scott &amp; White Health Plan, and the Health Texas Provider Network (HTPN), a physician provider organization. BSWH thanks CMS for requesting feedback on the Cesarean Section (PC-02) measure.</p> <p>The following comments are being submitted on behalf of BSWH:</p> <p>Whether the data elements are available in an enterprise EHR (a standard inpatient EHR or an EHR with a maternity-specific component, such as Epic Stork or Cerner Maternity) or a fetal monitoring system (such as Centricity Perinatal or OBTV)</p> <ul style="list-style-type: none"> <li>- All data elements for this measure are contained within Allscripts.</li> <li>- Fetal monitoring system will not be a source for any data elements for this measure.</li> </ul> <p>The method of data transfer from a fetal monitoring system to an enterprise EHR system, if applicable</p> <ul style="list-style-type: none"> <li>-Not available at this time. There will be no interface until 2017.</li> </ul> <p>The feasibility of collecting and submitting data on the PC-02 measure as part of CMS's quality reporting programs</p> <p>Feasible – all data elements are available in Allscripts</p> <p>-“Live Birth” proxy will be “Living Children”</p>	Karen Collins, Baylor Scott & White	<a href="mailto:karen.collins@baylorhealth.edu">karen.collins@baylorhealth.edu</a>	Hospital/health system	<p>Thank you for your comments. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.</p> <p>We appreciate your comments on the potential use of this measure in CMS's quality reporting programs. We will review this suggestion with CMS and our technical advisory panel.</p> <p>The PC-02 electronic clinical quality measure was developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference. However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.</p>

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	<p>- Will rely on HIM discharge diagnosis (ICD-10)  - Fields available in 86 OB Delivery Summary</p> <ul style="list-style-type: none"> <li>• Live birth</li> <li>• Singleton (Baby A only)</li> <li>• Vertex presentation</li> </ul> <p>Additional Comments  BSWH recognizes that PC-2 Cesarean Birth is an important metric for hospitals in improving the quality of perinatal care and an important public health metric for assessing overall quality of perinatal care. Hospitals should implement best practices to reduce rates of cesarean birth in nulliparous mothers and evaluate their progress by monitoring performance on this metric.</p> <p>However, we feel it is neither useful nor appropriate for use in the CMS quality reporting programs. The Joint Commission (TJC) ORYX quality reporting program is designed to encourage hospitals to evaluate and strive to continuously improve their own performance over time on evidence-based quality measures. Unlike TJC, the CMS quality reporting programs subject individual hospitals to public comparison and financial rewards or penalties for performance relative to one another. While CMS must use all quality reporting metrics in this fashion, TJC only subjects a subset of ORYX measures, the Accountability Measures, to this level of scrutiny and potential penalty. PC-2 Cesarean Birth is not publicly reported or held to minimum performance standards because it does not meet all Accountability Measure requirements:</p> <ul style="list-style-type: none"> <li>• Research: Strong scientific evidence exists demonstrating that compliance with a given process of care improves health care outcomes (either directly or by reducing the risk of adverse outcomes).</li> <li>• Proximity: The process being measured is closely connected to the outcome it impacts; there are relatively few clinical processes that occur after the one that is measured and before the improved outcome occurs.</li> </ul>				<p>We appreciate the concerns raised regarding unintended consequences of the measure—specifically, that hospitals will delay or not perform necessary cesareans due to concerns over measure performance. The measure is intended to be an accurate way for leaders to identify whether a hospital’s rate of cesarean births for women in this select population is consistent with the rates of this same population at another hospital. Hospitals whose measure rates are higher than rates at other hospitals are encouraged to explore and evaluate differences in the medical and nursing management of women in labor. The measure is not intended to discourage providers from performing cesareans that have been deemed appropriate and necessary. According to the measure specifications, each numerator case should be evaluated to determine if care could have been provided differently so as to have precluded the procedure. We will discuss these concerns and strategies for response with CMS and our technical advisory panel.</p>

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	<ul style="list-style-type: none"> <li>• Accuracy: The measure accurately assesses whether the evidence-based process has actually been provided. That is, the measure should be capable of judging whether the process has been delivered with sufficient effectiveness to make improved outcomes likely. If it is not, then the measure is a poor measure of quality, likely to be subject to workarounds that induce unproductive work instead of work that directly improves quality of care.</li> <li>• Adverse effects: The measure construct is designed to minimize or eliminate unintended adverse effects.</li> </ul> <p>BSWH believes that, because this metric does not exclude many situations in which it is clinically appropriate to perform a cesarean birth, it is not appropriate to include it in a program which requires hospitals to strive to achieve perfect performance through public use of comparative data and penalizes hospitals who are not in the top 10 percent of national performance. Additionally, we believe that there is significant risk of adverse effects by including it in the CMS quality reporting programs, as some organizations may implement unsafe processes and policies in an effort to achieve top comparative performance and avoid financial penalty, such as:</p> <ul style="list-style-type: none"> <li>• Requiring physicians to get department chair or council permission before performing cesarean births, delaying needed care</li> <li>• Allowing patients to labor to the point of risk of maternal injury or neonatal damage</li> </ul> <p><b>CONCLUSION</b> The preceding responses represent general concerns from Baylor Scott &amp; White Health. Thank you for the opportunity to present our views. If you have any questions or issues regarding our feedback, please feel free to contact me at the information provided below.</p>				

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
10/12/2015	Where are the ICD-10 codes? Need to understand how to get to the coding value sets. Where do you get the QDM value sets you are referencing?	Linda Daniel		Unknown	To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at this link: <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a> . You can search the VSAC by value set ID or OID number (e.g., 2.16.840.1.113883.3.117.1.7.1.282), text (e.g., "cesarean birth"), or code (e.g., Z37.0).
10/9/2015	<p>Johns Hopkins Hospital had a 19% rate for Primary Cesarean Sections for 2014, without applying the exclusion criteria for PC02. Every Cesarean Section gets discussed, and elective Cesareans are not done without a medical reason. We began submitting data for PC02 in CY2013 Q1. We started looking into the reasons for failures and found they were medically justified and met the standard of care. ACOG (American College of Obstetrics &amp; Gynecology) and March of Dimes state the following are acceptable reasons for Cesarean Sections: Cephalopelvic Disproportion, Umbilical Cord Prolapse, Failure to Descend, Arrest of Dilation/Failure to Progress, Non-Reassuring Fetal Heart Tracing, HIV with elevated vial load, Maternal Herpes, and problems with the Placenta (ACOG FAQ 2006 Labor, Delivery, and Postpartum Care). When we sent an email to ORYX inquiring if these medical indications could be considered for exclusions, the reply was that these medical indications are not being considered for exclusions as "the measure is designed to identify complications that largely arise during labor and not exclude them."</p> <p>Our goal is to deliver as many babies vaginally as possible when clinically indicated. "Medical Practices" during labor have no effect on whether the mother has HIV, Maternal Herpes, Placenta Problems, Cephalopelvic Disproportion, or Prolapsed Umbilical Cord. We do see that the complications listed above from ACOG and March of Dimes are within acceptable exclusions noted on Appendix A 11.09 'Early Onset Deliveries' and applying this code would drive our Cesarean Rate down to zero but when our hospital's coding expert looked at the specifics of this code it is</p>	Karen McMorro, The Johns Hopkins Hospital	<a href="mailto:kmcmorr1@jhmi.edu">kmcmorr1@jhmi.edu</a>	Hospital/health system	<p>Thank you for your comments. The PC-02 electronic clinical quality measure was developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference. However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.</p> <p>According to the measure specifications, each numerator case should be evaluated to determine if care could have been provided differently so as to have precluded the procedure.</p> <p>With regard to your quote from the ORYX helpdesk stating that "the measure is designed to identify complications that largely arise during labor and not exclude them," this statement is correct for the eCQM version of the measure.</p>

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
	<p>only applicable for babies &lt;37 weeks. It is hard to understand the logic that if a pregnant woman has one of the medical issues listed above at 36 weeks gestation, like prolapsed umbilical cord, the Joint Commission will exclude the case from this measure but one week later in gestation, and hospitals are penalized for the Cesarean delivery.</p> <p>Our strong suggestion would be to add additional C-Section exclusions for all gestational ages that are recognized by ACOG/March of Dimes like Cephalopelvic Disproportion, Umbilical Cord Prolapse, Failure to Descend, Arrest of Dilation/ Failure to Progress, Non-Reassuring Fetal Heart Tracing, HIV with elevated viral load, Maternal Herpes, and problems with the Placenta. By doing this you could set a defined benchmark of 0% and have a more robust comparison. This would highlight hospitals that electively doing C-Sections. On rare occasion, there are women that opt for C-Section despite counseling and education.</p>				<p>Complications such as prolapsed umbilical cord are not acceptable exclusions and are not listed on Appendix A, Table 11.09. Thus, we have not included these conditions in the eCQM specification.</p> <p>As of the implementation of ICD-10 on October 1, 2015, ICD-9 codes, including “Early Onset Delivery” are no longer listed on Table 11.09. For the most recent version of <i>The Specifications Manual for Joint Commission National Quality Core Measures (version 2015B1)</i> please refer to <a href="https://manual.jointcommission.org">https://manual.jointcommission.org</a>.</p> <p>For the eCQM specification, the value sets “Abnormal Presentation” and Multiple Gestation” include the codes in Table 11.09. To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at this link: <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a>. You can search the VSAC by value set ID or OID number (e.g., 2.16.840.1.113883.3.117.1.7.1.282), text (e.g., “cesarean birth”), or code (e.g., Z37.0).</p> <p>The ICD-9 code 644.21 “Early Onset Delivery” was not included in the eCQM as it does not specifically indicate a multiple gestation or abnormal presentation, which is in line with the current version of the chart-abstracted measure, where these concepts are represented with improved granularity in ICD-10.</p> <p>We will discuss these concerns and strategies for response with CMS and our technical advisory panel.</p>
10/9/2015	<p>AWHONN supports the draft and urges CMS to maintain the measure specifications to match The Joint Commission’s specifications for its related measure.</p>	<p>Kerri Wade, Association of Women’s Health, Obstetric and Neonatal Nurses (AWHONN)</p>	<p><a href="mailto:kwade@awhonn.org">kwade@awhonn.org</a></p>	<p>Professional society</p>	<p>Thank you for your support for the current approach.</p>

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
10/7/2015	The guidance section describes the denominator as "...capturing the patient's number of live births." Nothing in the denominator logic counts look to living status. We would recommend considering alternate wording such as "prior para" or "nulliparous."	Alex Liu		Unknown	Thank you for the recommendation. We will revise the guidance to more clearly indicate that the number of previous live births is represented as either parity (number of >20 week births), gravidity (number of times a woman has been pregnant), or as count of zero term or pre-term births.
10/7/2015	Given the QDM temporal calculation method for determining months, switching to units of weeks would provide greater control of these data criteria in not including documentation up to 11 months prior to Time of Delivery.	Alex Liu		Unknown	Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.
10/7/2015	The Physical Exam Performed data elements for Preterm and Ter[m] Newborn are missing temporal fixing to Time of Delivery. There needs to be an Occurrence statement to pair the two statements. Parity and Gravida have the appropriate occurrence statements.	Alex Liu		Unknown	Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.
10/5/2015	<p>PCO2 measure as adopted by the Joint Commission raises several concerns about waiting too long to do a cesarean section when there may be fetal intolerance to labor. Have you considered this as an exclusion? Concern over harm to an infant if a C-section is delayed due to the concern of the rate of nulliparous cesarean deliveries.</p> <p>The focus of the measure should be if an induction of labor occurred prior to the cesarean section. Looking at this from an ECQM standpoint, a bishop score as a discrete field could be a determining factor to justify if the induction was indicated.</p>	Michele Zywiec, Valley View Hospital	<a href="mailto:michele.zywiec@vvh.org">michele.zywiec@vvh.org</a>	Hospital/health system	Thank you for your comments. We appreciate concerns raised regarding unintended consequences of the measure—specifically, that hospitals will delay or not perform necessary cesareans due to concerns over measure performance. The measure is intended to be an accurate way for leaders to identify whether a hospital's rate of cesarean births for women in this select population is consistent with the rates of this same population at another hospital. Hospitals whose measure rates are higher than rates at other hospitals are encouraged to explore and evaluate differences in the medical and nursing management of women in labor. The measure is not intended to discourage providers from performing cesareans that have been deemed appropriate and necessary. According to the measure specifications, each numerator case should be evaluated to determine if care could have been provided differently so as to have precluded the procedure.

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
					<p>The PC-02 electronic clinical quality measure was developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference. However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.</p> <p>We will discuss these concerns and strategies for response with CMS and our technical advisory panel.</p>

Date posted	Text of comment	Name and organization of commenter	E-mail address	Type of organization	Final response
10/2/2015	<p>Value Sets:</p> <p>1) Abnormal Presentation Grouping value set—why are there codes for multiple fetus[es] if the measure is related to single births?</p> <p>2) All codes in the IPP value sets are ICD9. Assume these will be updated [t]o ICD10?</p> <p>3) What is the thought for using Delivery of Singleton value set vs. Single Live Birth value set, as in PC-05 eCQM (also Diagnosis, Active)? It appears that Delivery of Singleton contains an ICD9 and ICD10 in addition to the same SNOMED code that is in Single Live Birth.</p> <p>Logic:</p> <p>1) With our (Cerner’s) Maternity module, and even without, it would be very uncommon to document a single delivery as Diagnosis, Active. With the Maternity module, a “Histories” section stores single delivery, gravida, parity, etc. Without the Maternity module, these are all documented as clinical events within the chart.</p> <p>2) We do not see where Fetal Link data would be used within this measure as it is currently defined. Fetal Link data is more like fetal vital signs, etc.</p>	Lynn Baldwin, Cerner	<a href="mailto:lbaldwin@cerner.com">lbaldwin@cerner.com</a>	EHR vendor	<p>Thank you for your comments. Please see our replies below:</p> <p>Value Sets:</p> <ol style="list-style-type: none"> <li>1. Although the measure does constrain the denominator to patients who deliver a singleton, the value sets for the abnormal presentation and multiple gestation denominator exclusions provide a second check to remove these patients from the measure. This is modeled like the chart-abstracted measure, which similarly defines the population as single deliveries but also excludes multiple gestations.</li> <li>2. The initial population (IP) is currently defined using ICD-9, ICD-10 and SNOMED codes. We will review potential coding updates with CMS and our measure development team.</li> <li>3. PC-02 assesses care delivered in the maternal encounter, whereas PC-05 (Exclusive Breastmilk Feeding) addresses the newborn and newborn encounter. Although we would expect a “Single Live Birth” code to be present in the newborn’s record, we would not expect to find this information in the mother’s record. This is why the more extensive “Delivery of Singleton” value set is used for this measure. Thank you for your comment about the overlap in the SNOMED code used in both value sets. We will review this comment with CMS and our measure development team.</li> </ol>

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					<p>Logic:</p> <p>4. Thank you for your comment. We will review this comment with CMS and our measure development team.</p> <p>5. Thank you for your comment. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.</p>
10/2/2015	<p>The request for comment asks us to comment on the availability of data elements in a fetal monitoring system and transfer of data from the monitoring system to an EHR. Also, several other commenters have mentioned the difficulty of reporting on data from a monitoring system.</p> <p>We are unaware of any data elements that would depend on a fetal monitoring system at all or why that would be a consideration. If other commenters know of how this is relevant, perhaps they can add comments to this ticket.</p>	Howard Bregman, Epic		EHR vendor	Thank you for your comment. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.

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9/30/2015	<p>Reducing primary c-sections is a goal all providers/facilities for OB should have. However, that should be done as an internal peer review process following the current ACOG/AWHONN guidelines. Forcing a provider to place themselves and their patients at risk after labor begins is not in anyone's best interest. EFM, while not shown to prevent cerebral palsy, does provide information about the fetal status—the interpretation of that information falls on the providers and perhaps deciding not to section a patient for fear of not meeting CMS core measures—won't make a bit of difference to a mother who has a child that is less than perfect. The fact that this measure has no exceptions for this situation and others—is ludicrous! ACOG has a position statement for maternal request for C-section—not honoring this request (albeit rare perhaps) is potentially committing battery if she is forced to undergo labor against her will. I certainly will agree that inductions of labor are done without hard medical indications; however, ACOG has a list of acceptable social situations, but none of these are included as an exclusion. There is literature coming from ACOG that setting some different definitions for active labor (6 cms), time allowed for failure to progress (4 hours) that if/when adopted by providers will move the primary rate in a different direction. Before any of this can be accomplished—the legal community will have to be involved as well as more education for the consumers. I would strongly suggest a re-thinking of this measure—simply stating that any primipara delivered greater than 37 weeks by c-section with no exclusions isn't good science, policy, or safety.</p>	Deborah Block, Oconee Regional Medical Center	<a href="mailto:dblock@ormcinc.org">dblock@ormcinc.org</a>	Hospital/health system	<p>Thank you for your comments.</p> <p>We appreciate concerns raised regarding unintended consequences of the measure—specifically, that hospitals will delay or not perform necessary cesareans due to concerns over measure performance. The measure is intended to be an accurate way for leaders to identify whether a hospital's rate of cesarean births for women in this select population is consistent with the rates of this same population at another hospital. Hospitals whose measure rates are higher than rates at other hospitals are encouraged to explore and evaluate differences in the medical and nursing management of women in labor. The measure is not intended to discourage providers from performing cesareans that have been deemed appropriate and necessary or are requested by the mother. According to the measure specifications, each numerator case should be evaluated to determine if care could have been provided differently so as to have precluded the procedure.</p> <p>The PC-02 electronic clinical quality measure was developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference.</p>

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					<p>However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.</p> <p>We will discuss these concerns and strategies for response with CMS and our technical advisory panel.</p>
9/30/2015	<p>Regarding feasibility: The list of codes for exclusions is way too extensive to list, never mind have physicians scroll through to find the correct code. In addition, our EMR is dated, and our IT resources are extremely limited.</p> <p>Based on the codes, it does not seem you will be getting the true clinical picture.</p>	Jeanne Boydston, St. Luke's Cornwall Hospital	<a href="mailto:jboydston@slchospital.org">jboydston@slchospital.org</a>	Hospital/health system	Thank you for your comment. The value sets used in the electronic clinical quality measure to represent the denominator population and excluded populations are aligned with the code tables reviewed and approved by our technical advisory panel for use in the chart-abstracted measure.
9/28/2015	Our current EMR does not have an OB component; the OB EMR is a standalone system. All data entered into the OB EMR is not able to [be] extracted for customizable reports. As a small facility, the cost to upgrade to a customizable OB EMR is prohibitive. This data would need to be extracted by hand, or the hospital would have to pay for customized reporting from the OB EMR system.	Lora Irwin, Blount Memorial Hospital	<a href="mailto:loirwin@bmnet.com">loirwin@bmnet.com</a>	Hospital/health system	Thank you for your comment. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.
9/28/2015	It's not clear why the Physical Exam, Performed: Abnormal Presentation has to start during the inpatient encounter. The presentation could have been identified prior to the encounter and might persist into the encounter. Yes, the baby could have corrected to a vertex position, but still requiring this to start during the encounter will lead to false positives—pregnancies which are breech but are not recognized as such by the measure.	Howard Bregman, Epic		EHR vendor	Thank you for your comment. Our intent is to not exclude those patients who have a breech presentation that corrects to a vertex presentation. We will review this suggestion with CMS and our measure development team.

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9/28/2015	It is not clear why the diagnoses that qualify the patient for the IPP must start during the inpatient encounter. If they were just required to be active during the encounter, they would satisfy the clinical need, especially since many of the conditions could clearly have started earlier in the pregnancy. Yes, these specific codes refer to the pregnancy having been delivered, but still it is not clear why this requirement is there, especially since the multiple gestation criterion is much more liberal.	Howard Bregman, Epic		EHR vendor	Thank you for your comment. The value sets included in the IP are intended to identify patients who deliver during the inpatient encounter. We do not intend to include patients who deliver outside of the inpatient setting and are subsequently admitted. Thus, we are only including patients who have a delivery diagnosis start during the encounter. In ICD-9, the concept of delivery is represented in the fifth digit of a diagnosis code, which may be why it's not apparent that all codes in the IP are intended to represent delivery.
9/28/2015	The value set "Normal Delivery and Other Indications for Care" includes a number of codes that indicate an abnormal presentation of the fetus (specifically breech presentation). These codes should be used to define a denominator exclusion that indicates abnormal presentation. You have this data in the record—you are using it to define the IPP. It should be sufficient to define the exclusion population.	Howard Bregman, Epic		EHR vendor	Thank you for your comment. The "Normal Delivery and Other Indications for Care" value set is an ICD-9 value set. In ICD-9, the concept of delivery is captured in the fifth digit of maternal diagnosis codes. To define the entire population of deliveries, this value set includes all patients who deliver, including patients who have deliveries with abnormal presentations. These patients are later removed in the denominator exclusion for "Abnormal Presentation." In ICD-10 and SNOMED, delivery is represented as a procedure, and thus the initial patient population will include all patients who deliver when these data are captured in ICD-10 or SNOMED.
9/28/2015	The modeling of gestational age as a physical exam result that must start within one day of delivery is unnecessarily restrictive. The gestational age is a patient-level data element (as opposed to an encounter-level element) that is associated with the pregnancy. It is recorded and updated at various times during the pregnancy. It does not need to "start" within a restrictive time frame of the beginning of the admission. Instead, it should just be a certain value at the time of the delivery. It's not obvious how to model this in a more flexible way, but an alternative should be found.	Howard Bregman, Epic		EHR vendor	Thank you for the recommendation. We will review this suggestion with CMS and our measure development team.

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9/21/2015	<ol style="list-style-type: none"> <li>1. Data elements for this measure are available in OBTV at our institution; however, OBTV is a standalone EHR that doesn't interface with our enterprise EHR (Soarian)</li> <li>2. We are able to identify NTSV-CS and NTSV Vag patients from our OBTV reports</li> <li>3. The usefulness of this measure is limited as it does not ask questions about medical induction versus augmentation and what led to a CS (example: arrest of labor, arrest of descent) - some of these are not coded - so would need to be a manual entry (indications for CS)</li> <li>4. Agree this is an important measure but only useful if NOT SAMPLED (we're a Massachusetts hospital - and we are seeing a difference between our 100% sample versus PC-02 and MAT 4 results - which are both sampled! Not accurate)</li> </ol>	Shelly Bazes, Tufts Medical Center	<a href="mailto:sbazes@tuftsmedicalcenter.org">sbazes@tuftsmedicalcenter.org</a>	Hospital/health system	<p>Thank you for your comments.</p> <ol style="list-style-type: none"> <li>1. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.</li> <li>2. Please see the response above.</li> <li>3. The PC-02 electronic clinical quality measure was developed to align as closely as possible with the chart-abstracted version of the measure. This includes alignment of the measure exclusions, which currently include multiple gestations and presentations other than a vertex presentation. Like its chart-abstracted predecessor, the intent of the measure is to evaluate the cesarean birth rate among a lower-risk population of women. This is a population that we would expect to have mostly vaginal births. There are a number of reasons why a woman in this population may have a cesarean birth. These reasons include, but are not limited to, maternal and fetal medical complications, labor induction, and the mother's preference. However, extensive testing of the chart-abstracted measure has shown that including a comprehensive set of maternal and fetal medical exclusions would add to providers' data collection burden without commensurate benefit. This is because the majority of these reasons are rare in this population, and excluding them does not significantly increase a hospital's adjusted cesarean rates.</li> <li>4. Please note that electronic clinical quality measures are not sampled.</li> </ol>

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9/18/2015	We use the Meditech EMR. Our OB patient record is OB Traceview. They are not able to interface at this time, and we would not be able to electronically report the PC02 measure without great expense.	Carol Murphy, Union Hospital	<a href="mailto:carolm@unionhospital.org">carolm@unionhospital.org</a>	Hospital/health system	Thank you for your comment. Part of assessing the feasibility of this measure includes obtaining feedback on the extent to which a hospital's enterprise EHR system and obstetric-specific record systems, such as fetal monitoring systems, interact. We will review your comments with CMS and our measure development team when discussing challenges and opportunities associated with future measure implementation.
9/17/2015	To have this be a fully electronic measure, we would need specifications and time to build into our system to meet requirements for anything that is not captured in coding. PC-02 still has manual abstraction that is required: parity and gestational age are not coded [unless they will be in ICD-10?]	Elizabeth Anne Pesek, Overlake Hospital	<a href="mailto:elizabeth.pesek@overlakehospital.org">elizabeth.pesek@overlakehospital.org</a>	Hospital/health system	Thank you for your comment. CMS will make complete measure specifications available after the measure has completed testing. Please also note that value sets for "Estimated Gestational Age at Delivery" and "Parity" are coded using SNOMED-CT value sets. To access the value sets for the measure, please visit the Value Set Authority Center (VSAC), sponsored by the National Library of Medicine, at this link: <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a> . You can search the VSAC by value set ID or OID number (e.g., 2.16.840.1.113883.3.117.1.7.1.282), text (e.g., "cesarean birth"), or code (e.g., Z37.0).