

Cesarean Delivery for Nulliparous (NTSV) Women (Appropriate Use)

Section 1. Basic Measure Information

1.A. Measure Name

Cesarean Delivery for Nulliparous (NTSV) Women (Appropriate Use)

1.B. Measure Number

0082

1.C. Measure Description

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

This measure is aimed at assessing the number of cesarean deliveries at 37 weeks or after, for women with their first pregnancy, with a baby in vertex (not breach) position. These patients typically are considered low-risk patients and generally are not candidates for cesarean deliveries.

"Percentage of nulliparous patients, regardless of age, who gave birth during a 12-month period to a live singleton in vertex presentation at or beyond 37 weeks of gestation who had a cesarean delivery."

This measure was developed by the American Medical Association-Physician Consortium for Performance Improvement (AMA-PCPI), which is a key member of the Pediatric Measurement Center of Excellence (PMCoE) consortium. The PMCoE is funded by the Agency for Healthcare Research and Quality (AHRQ) and includes the following consortium members: American Academy of Pediatrics; American Board of Pediatrics; American Board of Medical Specialties; Northwestern University; Truven Health Analytics (formerly Thomson Reuters); Children's Hospital and Health System, Milwaukee; Medical College of Wisconsin; and the American Medical Association (AMA).

1.D. Measure Owner

The AMA-convened Physician Consortium for Performance Improvement[®] (PCPI[™]) is the measure owner. The AMA holds copyright on the measure set.

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.**

None.

- 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.**

Prenatal/Perinatal Performance Measurement Set.

- 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.**

None.

- 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

Patients who had a cesarean delivery.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

All nulliparous patients, regardless of age, who gave birth during a 12-month period to a live singleton in vertex presentation at or beyond 37 weeks of gestation.

1.J. Denominator Exclusions

None.

1.K. Data Sources

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

Electronic Medical Record, Other (Please list all other data sources in the field below).

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

None.

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 attachments for full eSpecifications and coding spreadsheets. Below is an overview of our technical specifications process.

The PMCoE Center of Excellence adopted the PCPI specification process, which places emphasis on developing comprehensive measure specifications for electronic health records (EHRs), provides relevant clinical data on patients, and provides actionable feedback to providers. There are several data sources available for collecting performance measures; generally, different data sources require different sets of measure specifications due to the structure of the systems storing the data. The PCPI recognizes that EHRs are the state of the art for clinical encounters and is focusing significant resources and expertise toward specifying and testing measures within EHRs, as they hold the promise of providing the relevant clinical data for measures and for providing feedback to physicians and other health care providers that is timely and actionable.

The type of specifications developed for this measurement set are aligned with the PCPI approach to focus on the development of EHR specifications for new measure development projects. While the PCPI values prospective claims reporting programs and the data these programs can provide, the PCPI is looking to leverage the data in EHRs. This new focus will align the PCPI with national initiatives that highlight the benefits and wealth of data that EHRs bring to health care.

The measure specifications attached with this submission form include the following components:

1. A text description of the measure.
2. The Data Requirements Table, which outlines the data elements that are required for the measure, including the identification of the clinical vocabularies applicable to a given data element, the NQF Quality Data Model category and State, and the timing parameters for each data element.
3. A visual flow diagram that uses Boolean logic to identify the Initial Patient Population, Exclusions, Denominator, Numerator, and Exceptions included in the measure.
4. Measure Calculation.
5. Value sets for each of the data elements.

The measure specification provides the required information to collect the data needed to calculate the quality measure. The AMA-PCPI, through PMCoE, has made full measure specifications for the measure available for public use in accordance with the terms detailed in the Notice of Grant Award.

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).**

This measure was developed by the AMA-PCPI, which is a key member of the Pediatric Measurement Center of Excellence (PMCoE) consortium. The AMA-convened PCPI™ is a national, physician-led initiative dedicated to improving patient health and safety through the identification and development of evidence-based clinical performance measures and measurement resources that enhance the quality of patient care and foster accountability. The PCPI is nationally recognized for measure development, specification and testing of measures, and enabling use of measures in EHRs. The PCPI’s measure development resources include a measure testing protocol, a position statement on the evidence base required for measure development, a composite framework, specification and categorization of measure exceptions, and an outcomes measure framework. The PCPI is made up of over 170 member organizations and individuals, including national medical specialty societies, State medical societies, health care professional organizations, Federal agencies, individual members, and other groups interested in improving the quality of health care. Today, the PCPI portfolio includes measures in more than 46 clinical areas with over 280 individual measures.

The current quality gap in the number of women undergoing cesarean delivery is well documented and provides a significant area for quality improvement that has implications for mothers, babies, and providers, such as pediatricians.

Cesarean sections are now the most common operating room procedure in the United States, and expenses related to these births account for 45 percent of the more than \$79 billion in annual hospital charges related to childbirth in the United States. C-sections cost about \$13,000 for privately insured patients. C-section is an expensive intervention, with an average cost in 2003 of \$12,468—twice the cost of the average vaginal birth (\$6,240). The incidence of cesarean delivery without medical or obstetric indications is increasing in the United States (Health Affairs 2006; 25:w355–w367; 10.1377/hlthaff.25.w355]). There is also evidence that women undergoing a cesarean delivery are at much higher risk for rehospitalization for uterine infection and obstetrical surgical wound complications (Lydon-Rochelle M, Holt VL, Martin DP, et al.

Association between method of delivery and maternal rehospitalization. *JAMA* 2000; 283(18):2411-6. doi: 10.1001/jama.283.18.2411).

Data from the 2009 National Vital Statistics Report highlights that the overall U.S. cesarean delivery rate rose to 32.9 percent of all births, up from the all-time high rate of 31.1 in 2006 (Martin JA, Hamilton BE, Ventura SJ, et al. Births: final data for 2009. National Vital Statistics Reports. Hyattsville, MD: Centers for Disease Control and Prevention, National Center for Health Statistics; 2011:60). The cesarean rate has climbed 50 percent since 1996. Rates for primary cesareans were up and vaginal births after previous cesarean were down for both revised and unrevised reporting areas. Cesarean rates have risen at all gestational ages over the last decade.

Elective repeat cesarean delivery before 39 weeks of gestation is common and is associated with respiratory and other adverse neonatal outcomes.(Tita AT, Landon MB, Spong CY, et al. Timing of elective repeat cesarean delivery at term and neonatal outcomes. *NEJM* 2009;306:111-20). Inappropriate C-sections may result in increased risk or harm to both mother and baby. Higher procedure rates might even be associated with iatrogenic harm, stemming from surgical complications that are not offset by therapeutic benefit. Many cesarean births occur for non-clinical factors, such as provider supply, malpractice liability, and patient preference (Martin JA, Hamilton BE, Ventura SJ, et al. Births: final data for 2009. National Vital Statistics Reports. Hyattsville, MD: Centers for Disease Control and Prevention, National Center for Health Statistics; November 3, 2011: 60(1)).

A 2009 *NEJM* article examined a C-section registry from 19 academic medical centers and found that more than one-third did not follow American Congress of Obstetricians and Gynecologists (ACOG) guidelines; infants delivered at 37 weeks to mothers who had elective repeat C-sections were about twice as likely as newborns delivered at the recommended 39 weeks to experience breathing problems, bloodstream infections, and other complications. Of 24,077 repeat cesarean deliveries at term, 13,258 were performed electively; of these, 35.8 percent were performed before 39 completed weeks of gestation (6.3 percent at 37 weeks and 29.5 percent at 38 weeks) and 49.1 percent at 39 weeks of gestation (NIH State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request. *NIH Consens State Sci Statements* 2006 Mar 27-29;23(1):1-29).

There is enormous geographic variation in the use of cesarean delivery. Higher cesarean rates are only partially explained by patient characteristics but are greatly influenced by nonmedical factors such as provider density, the capacity of the local health care system, and malpractice pressure. Areas with higher usage rates perform the intervention in medically less appropriate populations—that is, relatively healthier births—and do not see improvements in maternal or neonatal mortality (*Health Affairs* 2006; 25:w355–w367; 10.1377/hlthaff.25.w355).

A 2006 *Health Affairs* report looked at geographical variation in cesarean sections; great geographic variation in the use of cesarean delivery was found. For births over 2,500 grams, adjusted cesarean rates vary fourfold between low- and high-use areas. Even for births under 2,500 grams, high-use counties had rates that are double those of low-use ones.

There are also significant disparities in relation to the appropriate use of C-section, both in terms of age and race. To assist the PMCoE Prenatal/Perinatal work group in evaluating Cesarean Delivery for Nulliparous (NTSV) Women for overall performance rates and variation by maternal age and maternal race/ethnicity, 2008 data from the Centers for Disease Control and Prevention, National Center for Health Statistics Birth Data File were analyzed. The data were analyzed for frequency of cesarean delivery in nulliparous women with a singleton in vertex presentation at or beyond 37 weeks of gestation. Of the 4,255,156 records, there were 1,185,890 births that met the criteria for inclusion. Among these 1,185,890 births, 321,459 newborns were delivered by cesarean, representing 27.1 percent (321,459 / 1,185,890) of eligible births. Based on maternal age at delivery, the average cesarean rate increases with maternal age. The rate varied from 17.6 percent for mothers less than 18 years of age, to 23.5 percent for mothers aged 18-24 years, to 30.8 percent for mothers 25-35 years old, to 46.1 percent for mothers older than age 35. Non-Hispanic white women had a rate (26.9/hlthaff.25.w355 percent) that was slightly below the overall average, while Non-Hispanic black women had a rate that was above the overall average (30.0 percent) and Mexican women had a rate that was below the overall average (24.3 percent). These disparities and quality gaps illustrate the critical need for this measure in the CHIPRA program.

References

Health Affairs 2006; 25:w355-67; 10.1377/hlthaff.25.w355.

NIH State-of-the-Science Conference Statement on Cesarean Delivery on Maternal Request. NIH Consens State Sci Statements 2006 Mar 27-29; 23(1):1-29.

Lydon-Rochelle M, Holt VL, Martin DP, et al. Association between method of delivery and maternal rehospitalization. JAMA 2000; 283(18):2411-6. doi: 10.1001/jama.283.18.2411.

Martin JA, Hamilton BE, Ventura SJ, et al. Births: final data for 2009. National Vital Statistics Reports. Hyattsville, MD: Centers for Disease Control and Prevention, National Center for Health Statistics; November 3, 2011; 60(1).

Tita AT, Landon MB, Spong CY, et al. Timing of elective repeat cesarean delivery at term and neonatal outcomes. N Engl J Med 2009; 306:111-20.

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).**

This measure would fill a gap in the Medicaid and CHIP programs core set of children’s health care quality measures aimed at providing services and treatment to promote healthy birth and prevent premature birth. The measure will provide a mechanism to help assess the appropriateness of deliveries and prevent adverse neonatal outcomes. This measure is of particular importance for CHIPRA in that it is high impact with Medicaid patients and addresses concerns related to both mother and baby. Additionally, there are disparities in the number of cesarean sections among minority patients, which is costly to Medicaid and increases the risk of undesirable outcomes.

We encourage the use of this measure by physicians, other health care professionals, and health care systems/health plans, where appropriate. This clinical performance measure is designed for practitioner and/or system level quality improvement to achieve better outcomes for maternity care patients and their babies.

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).

This measure is harmonized with the National Quality Forum (NQF)-endorsed Joint Commission cesarean delivery measure, PC-02. The measures are harmonized in the measure language, specifications, and measure intent. The Joint Commission measure is a facility-level measure while this measure is a provider-level measure.

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?

- Care Setting – ambulatory: No.**
- Care Setting – inpatient: Yes.**
- Care Setting – other – please specify: No.**

- d. Service – preventive health, including services to promote healthy birth: No.
- e. Service – care for acute conditions: No.
- f. Service – care for children with acute conditions: No.
- g. Service – other (please specify): No.
- h. Measure Topic – duration of enrollment: Yes.
- i. Measure Topic – clinical quality: Yes.
- j. Measure Topic – patient safety: No.
- k. Measure Topic – family experience with care: No.
- l. Measure Topic – care in the most integrated setting: No.
- m. Measure Topic other (please specify): Yes.
- n. Population – pregnant women: No.
- 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): No.

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.

The evidence behind the inappropriate use of cesarean delivery and its link to increased risk of adverse outcomes for mothers and babies is well established and very comprehensive. Research evidence includes clinical practice guidelines, numerous research studies on the increase in cesareans and their inappropriate use, data from the Centers for Disease Control and Prevention (CDC) on disparities and quality gaps, as well as systematic evidence reviews that highlight the growing inappropriate use of cesarean sections.

Clinical Evidence Base Available for Measure: Evidence-based clinical practice guidelines that were reviewed for this project:

- American College of Obstetricians and Gynecologists.
- American Academy of Family Physicians.
- Centers for Disease Control and Prevention.
- United States Preventive Services Task Force.
- Veterans Administration/Department of Defense Clinical Practice Guideline for Pregnancy Management.
- Society of Obstetricians and Gynecologists of Canada.

Data from the 2009 National Vital Statistics Report show that the overall U.S. cesarean delivery rate rose to 32.9 percent of all births, up from the all-time high rate of 31.1 percent in 2006. The cesarean rate has climbed 50 percent since 1996. Rates for primary cesareans were up, and vaginal births after previous cesarean were down for both revised and unrevised reporting areas. Cesarean rates have risen at all gestational ages over the last decade.

Elective repeat cesarean delivery before 39 weeks of gestation is common and is associated with respiratory and other adverse neonatal outcomes. Inappropriate cesarean sections may result in increased risk of harm to both mother and baby. Higher procedure rates might even be associated with iatrogenic harm, stemming from surgical complications that are not offset by therapeutic benefit. Many cesarean births occur for non-clinical factors, such as provider supply, malpractice liability, and patient preference.

A 2009 article in the New England Journal of Medicine examined a C-section registry from 19 academic medical centers and found more than one-third did not follow ACOG guidelines; infants delivered at 37 weeks to mothers who had elective repeat C-sections were about twice as likely as newborns delivered at the recommended 39 weeks to experience breathing problems, bloodstream infections, and other complications. Of 24,077 repeat cesarean deliveries at term, 13,258 were performed electively; of these, 35.8 percent were performed before 39 completed weeks of gestation (6.3 percent at 37 weeks and 29.5 percent at 38 weeks) and 49.1 percent at 39 weeks of gestation.

A systematic review was also conducted, analyzing the evidence related to cesarean deliveries for women in whom cesarean delivery is not indicated. The following review was assessed: Childbirth Connection. Comparing risks of cesarean and vaginal birth to mothers, babies, and

future reproductive capacity: a systematic review. New York: Childbirth Connection; April 2004. (The following study documents are available as PDF files from the Childbirth Connection Web site at <http://www.childbirthconnection.org/>: description of methods and sources, including full bibliography; list of main questions and outcomes, including a table of contents for evidence tables; first file of evidence tables; and second file of evidence tables.)

The review further highlighted the need for reducing cesarean sections and was in concordance with the measure that is being submitted. The Childbirth Connection systematic review found the following:

- Thirty-three areas where cesarean section was found to involve more risk than vaginal birth.
- Four areas where vaginal birth was found to involve more risk than cesarean section.
- Extra risks associated with cesarean section.

Current research suggests that cesarean section has the following disadvantages in comparison with vaginal birth:

- Physical problems in mothers: Compared with vaginal birth, cesarean section increases a woman's risk for a number of physical problems. These problems range from less common but potentially life-threatening problems, including hemorrhage (severe bleeding), blood clots, and bowel obstruction, to much more common concerns such as longer-lasting and more severe pain and infection. Even after recovery from surgery, scarring and scar tissue increase risk for ongoing pelvic pain and for twisted bowel.
- Hospitalization of mothers: If a woman has a cesarean, she is more likely to stay in the hospital longer and is at greater risk of being re-hospitalized.
- Emotional well-being of mothers: A woman who has a cesarean section may be at greater risk for poorer overall mental health and some emotional problems. She is also more likely to rate her birth experience poorer than a woman who has a vaginal birth.
- Early contact with and feelings toward babies: A woman who has a cesarean usually has less early contact with her baby and is more likely to have initial negative feelings about her baby.
- Breastfeeding: Recovery from surgery poses challenges for getting breastfeeding underway, and a baby who is born by cesarean is less likely to be breastfed and experience the benefits of breastfeeding.
- Health of babies: Babies born by cesarean are more likely to:
 - Be cut during the surgery (usually minor).
 - Have breathing difficulties around the time of birth.
 - Experience asthma in childhood and in adulthood.
- Future reproductive problems for mothers: A cesarean section puts a woman at risk for future reproductive problems in comparison with a woman who has a vaginal birth. These

problems may involve serious complications and medical emergencies. The likelihood of experiencing some of these conditions goes up sharply as the number of previous cesareans increases. These problems include:

- Ectopic pregnancy: pregnancies that develop outside the uterus or within the scar.
- Reduced fertility, due to either less ability to become pregnant again or less desire to do so.
- Placenta previa: the placenta attaches near or over the opening to the cervix.
- Placenta accreta: the placenta grows through the lining of the uterus and into or through the muscle of the uterus.
- Placental abruption: the placenta detaches from the uterus before the baby is born.
- Rupture of the uterus: the uterine scar gives way during pregnancy or labor.
- Concerns about babies in future pregnancies: A cesarean section in one pregnancy can affect the babies in future pregnancies. Research has shown that they are more likely to:
 - Be born too early (preterm).
 - Weigh less than they should (low birthweight).
 - Have a physical abnormality or injury to their brain or spinal cord.
 - Die before or shortly after birth.
- Planned cesarean compared with unplanned cesarean: A planned cesarean offers some advantages over an unplanned cesarean (a cesarean that occurs after labor is underway). For example, there may be fewer surgical injuries and fewer infections. The emotional impact of a cesarean that is planned in advance appears to be similar to or somewhat worse than a vaginal birth. By contrast, unplanned cesareans can take a greater emotional toll.
- Planned cesarean compared with vaginal birth: A planned cesarean still involves the risks associated with major surgery. Also, both planned and unplanned cesareans result in a uterine scar and internal scarring and adhesions. This means women with planned and unplanned cesareans face similar risks in future pregnancies and for problems related to scarring and adhesions at any time.

Extra risks associated with vaginal birth: In a few areas, mothers and/or babies experience poorer outcomes following a vaginal birth in comparison with cesarean birth, including:

- Perineal pain: While a woman with a cesarean birth is more likely to experience more intense and longer-lasting pain overall, a woman with a vaginal birth is more likely to experience pain in the vaginal area in the weeks and months after birth.
- Incontinence: A woman with a vaginal birth is more likely to leak urine (urinary incontinence) and to leak gas or, more rarely, feces (bowel incontinence). Pregnancy itself and other factors such as the woman's weight play a role in these problems. Few

women experience troubling symptoms beyond the recovery period in the weeks and months after birth.

- Nerve injury in babies: In comparison with a baby born by cesarean section, a baby who is born vaginally is more likely to have a nerve injury that affects the shoulder, arm, or hand.

References

American College of Obstetricians and Gynecologists (ACOG). Committee Opinion No. 394. Cesarean delivery on maternal request. *Obstet Gynecol* 2007 Dec; 110(6):1501.

Childbirth Connection. Comparing risks of cesarean and vaginal birth to mothers, babies, and future reproductive capacity: a systematic review. New York: Childbirth Connection; 2004 April.

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.

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.

Analytic Method

The study sample for reliability testing was derived from the urban, tertiary-care hospital with an EHR system integrating inpatient and outpatient data. The EHR system is certified for the Medicare and Medicaid EHR Incentive Programs. Data used in the analysis are from a patient population of 12,108 for 2010. We carried out an assessment of measure reliability applying a reliability coefficient in the form of the signal to noise ratio (SNR). In SNR analysis, reliability is

the measure of confidence in differentiating performance between physicians or other providers.¹ The signal is the variability in measured performance that can be explained by real differences in physician performance, and the noise is the total variability in measured performance. Reliability is then the ratio of the physician-to-physician variance to the sum of the physician-to-physician variance plus the error variance specific to a physician:

$$\text{Reliability} = \text{Variance (physician-to-physician)} / [\text{Variance (physician-to-physician)} + \text{Variance (physician-specific-error)}].$$

Reliability equal to zero implies that all the variability in a measure is attributable to measurement error. Reliability equal to one implies that all the variability is attributable to real differences in physician performance. Reliability of 0.70 is generally considered to be a minimum threshold for reliability, and 0.80 is considered very good reliability.²

The SNR reliability testing was performed using a beta-binomial model. The beta-binomial model assumes the physician performance score is a binomial random variable conditional on the physician's true value that comes from the beta distribution. The beta distribution is usually defined by two parameters, alpha and beta. Alpha and beta can be thought of as intermediate calculations to get to the needed variance estimates.

Reliability can be estimated at different points. The convention is to estimate reliability at two points: (1) at a minimum number of quality reporting events per physician and (2) at the average number of quality reporting events per physician. We set the minimum number required as 10 events. Limiting the reliability analysis to only those physicians with a minimum number of events reduces the bias introduced by the inclusion of physicians without a significant number of events. Reliability testing results from SNR analysis have been included in support of AMA-PCPI measures submitted for NQF endorsement.³

A second phase of reliability testing on the measure is ongoing at the same sites where feasibility testing was conducted. This approach utilizes parallel forms reliability where measure data elements and performance from an automated report from the EHR are compared to those data from a manual review of the EHR—that is, comparison to the gold standard. (See Measure Testing Protocol for PCPI Performance Measures, ama-assn.org/resources/doc/cqi/pcpi-testing-protocol.pdf.)

Reliability Testing Results

A total of 116 physicians had all the required data elements and met the minimum number of 10 quality reporting events for inclusion in the reliability analysis. The average number of quality reporting events for physicians included is 40.08 for a total of 4,649 events. The number of quality reporting events for physicians included ranges from 10 to 100.

This measure has high reliability at the average number of quality events and moderate reliability when evaluated at the minimum number of quality reporting events. Reliability at the average number of quality reporting events and at the minimum number of quality reporting events were 0.73 and 0.41, respectively.

Data analyses were conducted using SAS/STAT software, version 8.2 (SAS Institute, Cary, NC).

1. Adams JL, Mehrotra A, McGlynn EA. Estimating reliability and misclassification in physician profiling. Santa Monica, CA: RAND Corporation; 2010.
http://www.rand.org/pubs/technical_reports/TR863; Adams JL, Mehrotra A, Thomas JW, et al. Physician cost profiling—reliability and risk of misclassification. *N Engl J Med* 2010 Mar 18; 362(11):1014-21. <http://www.nejm.org/doi/pdf/10.1056/NEJMsa0906323>; and Scholle SH, Roski J, Adams JL, et al. Benchmarking physician performance: reliability of individual and composite measures. *Am J Manag Care* 2008; 14:833-8.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2667340/pdf/nihms-99203.pdf>.
2. Nunnally J, Bernstein I. Psychometric theory. 3rd ed. New York, NY: McGraw-Hill; 1994.
3. National Quality Forum. Press release; 2012.
http://www.qualityforum.org/News_And_Resources/Press_Releases/2012/NQF_Removes_Time-Limited_Endorsement_for_21_Measures;_Measures_Now_Have_Endorsed_Status.aspx.

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 measure was assessed for content validity and face validity. Evidence of content validity is provided by looking for agreement among subject matter experts. The performance measure was assessed for content validity by a panel of expert workgroup members during the development process. This expert panel consisted of 24 members, with representation from measure methodologists, patient advocacy groups, and the following clinical specialties: anesthesiology, family practice, geriatric medicine, maternal fetal medicine, neonatology, nurse midwife, obstetrics and gynecology, and perinatal nursing. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and also by soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All comments received are reviewed by the expert workgroup, and the measures are adjusted as needed. Other external review groups (e.g., focus groups) may be convened if there are any remaining concerns related to the content validity of the measures.

The expert panel members also assessed the measure's face validity through an online survey. The survey introduction provided the following definition of face validity: Face validity is the extent to which an empirical measurement appears to reflect that which it is supposed to "at face value." Face validity of an individual measure poses the question of how well the definition and specifications of an individual measure appear to capture the single aspect of care or health care quality as intended. The expert panel was asked to rate their agreement with the following

statement: The scores obtained from the measure as specified will accurately differentiate quality across providers. A 5-point Likert scale was used in the survey (1=Strongly Disagree; 2= Disagree; 3=Neither Disagree nor Agree; 4 = Agree 5=Strongly Agree).

The survey results show that for the Cesarean Delivery for Low-Risk Nulliparous Women measure, the mean score was 4.85; 100 percent (13/13) of respondents agree or strongly agree that the scores obtained from the measure as specified will accurately differentiate quality across providers; and no respondents disagree or strongly disagree that the scores obtained from the measure as specified will accurately differentiate quality across providers.

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

We include race and ethnicity as Supplemental Data Elements to collect for each measure to allow for the stratification of measure results by these variables to assess disparities and initiate subsequent quality improvement activities.

The CDC value sets for race and ethnicity are referenced in the measure specifications to collect race and ethnicity information, which is the requirement for race and ethnicity outlined in the CMS Blueprint.

Also see Section 8.B.1 and Section 8.B.2.

7.B. Special Health Care Needs

Not applicable for this measure.

7.C. Socioeconomic Status

We include payer as a Supplemental Data Element to collect for each measure to allow for the stratification of measure results by this variable to assess disparities and initiate subsequent quality improvement activities.

The Payment Typology value set is referenced in the measure specifications to collect payer information, which is the requirement for payer outlined the CMS Blueprint.

Also see Section 8.B.1 and Section 8.B.2.

7.D. Rurality/Urbanicity

Future measure testing and implementation will collect data on the location of the patient and provider populations in order to stratify performance and test for variation by location.

7.E. Limited English Proficiency (LEP) Populations

We include preferred language as a Supplemental Data Elements to collect for each measure to allow for the stratification of measure results by this variable to assess disparities and initiate subsequent quality improvement activities.

The CDC value set is referenced in the measure specifications to collect preferred language information, which is the requirement for preferred language outlined in the CMS Blueprint.

Also see Section 8.B.1 and Section 8.B.2.

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?

Data Element Table Tool

The PMCoE Center of Excellence adopted the AMA-PCPI testing methodology which uses the Data Element Table (DET) tool to assess the availability of the data and the technical feasibility and implementation feasibility of the measures. The DET is an Excel workbook designed to capture information that will determine whether or not each site can feasibly collect the data for the measures. It is structured to collect meta-data about each data element necessary to construct each measure stored in the EHR. It will also collect information related to integrity and validity of data collection. Specifically, the DET is designed to capture the following information:

- **Data element information:** Whether or not the data element is captured in the EHR, the data source application, primary user interface data location, data type, coding system, unit of measure, frequency of collection, and calculability within the measure context.

- **Measure integrity information:** An assessment by the testing site as to what degree the measure, as specified, retains the originally stated intention of the measure.
- **Measure validity information:** An assessment by the testing site as to what degree the scores obtained from the measure, as specified, will accurately differentiate quality performance across providers.

The DETs collected responses used to assess technical and implementation feasibility for each measure. Measure technical feasibility was defined as “Can my EHR do this?” and measure implementation feasibility was defined as “Will workflow be used consistently?” The responses were captured in the form of a rating using the following responses:

- “Feasible. Can do today.”
- “Feasible with workflow mod/changes to EHR.”
- “Non-feasible. Unable to do today.”

This information was entered from drop-down options pertaining to the specific criteria and in free text fields for questions related to specific workflow and EHR configurations. The free text fields and specific narrative questions provide qualitative feedback from the sites, which can be factored into the overall feasibility grade for the measure.

The DET is completed by staff at each testing site. After the completion of the DET by the testing sites, a determination can be made as to which of the measures are relevant for each specific site. For some sites, all of the measures in the Perinatal/Prenatal Measurement Set may be collected, for others it may be only a few.

Once the completed DETs were submitted by the test sites, the PMCoE project team conducted quality assurance (QA) of the DETs to ensure the data were complete and ready for analysis. A series of analyses were subsequently performed in order to characterize the feasibility, integrity, and face validity of the measures being tested.

Feasibility testing was conducted at two sites: an urban tertiary care hospital and a suburban community hospital.

One test site reported that their EHR could capture all eight data elements in code, text, or Boolean format. The second test site reported that six of the eight data elements are available in their EHR. Of the two data elements that this site currently does not capture, one was a measure exclusion (clinical trial status).

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?

Measure Technical Feasibility and Implementation Feasibility

The measure technical feasibility assessment determined how many of the total measure data elements are feasible data elements. A “feasible data element” is one that can be captured by the test site EHR system. The sites assessed technical feasibility for the measure based on the following rating scale:

- “Feasible. Can do today.”
- “Feasible with workflow mod/changes to EHR.”
- “Nonfeasible. Unable to do today.”

The sites also used this scale to assess measure implementation feasibility. Implementation feasibility represents the site’s ability to implement the measure using current workflows and EHRs and addresses issues of projected data reliability related to the consistency with which providers document and capture the data elements needed to implement the measure.

The technical feasibility and implementation feasibility were rated the same for each of the measures. For example, if the technical feasibility of a measure was rated as “Feasible. Can do today,” and its implementation feasibility was also rated as “Feasible. Can do today.”

Both of the sites that evaluated the technical and implementation feasibility for this measure selected the highest rating of “Feasible. Can do today.” Although two of the eight data elements were not available at one site, the information provided by the sites indicates that only minimal changes would be required and that they would be able to calculate the measure with their current technical configuration.

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.

Measure development was completed early in 2012, but there have been limited opportunities to have the measure adopted and implemented. Feasibility and reliability testing of the measures has been conducted in EHRs in a variety of settings, including an urban, tertiary care hospital; an urban, public hospital; and a suburban community hospital. The testing results provide a description of means of data collection, methods, and insights into lessons learned. See results presented in Section 6.A. Reliability and Section 8. Feasibility.

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?

Not applicable.

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

Not applicable.

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?

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?

This information is not available.

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?

This information is not available.

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?

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?

This information is not available.

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?

This information is not available.

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?

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?

This information is not available.

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?

This information is not available.

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?

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?

This information is not available.

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?

This information is not available.

Provider Level

Individual practitioner: *Can compare individual health care professionals*

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?

This information is not available.

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?

This information is not available.

Provider Level

Hospital: Can compare hospitals

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?

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?

This information is not available.

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?

This information is not available.

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?

This information is not available.

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?

This information is not available.

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 AMA-PCPI has worked collaboratively on this measure set with the AMA-PCPI-Consumer Purchaser Panel (CPP), which comprises representatives from the patient, consumer, and purchaser communities. The panel strongly supports this measure and applauds the inclusion of it at the level of the individual clinician. The CPP states that this important measure of appropriateness can help to reduce c-section rates. Inappropriate c-sections can be harmful to mother and child and are a source of rising medical costs. In addition, the workgroup included member representatives from consumer groups, patient advocacy groups, and a health plan.

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.

The use of health IT in the collection and calculation of this measure allows for the clinical data to be used to assess measure results. The use of clinical data is more desirable compared to administrative data due to the increased granularity of information that can be collected.

11.B. Health IT Testing

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

Yes.

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

A second phase of reliability testing on the measure is ongoing at the same sites where feasibility testing was conducted. This approach utilizes parallel forms reliability where measure data elements and performance from an automated report from the EHR are compared to those data from a manual review of the EHR—that is, comparison to the gold standard. (See Measure Testing Protocol for PCPI Performance Measures, ama-assn.org/resources/doc/cqi/pcpi-testing-protocol.pdf.)

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.

See Section 8.A/Issues in Implementation for workflow discussion.

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)?

Yes.

If yes, please describe.

We use the following standards in the development of our EHR specifications: The Quality Data Model (QDM), developed by the National Quality Forum, the vocabulary recommendations named by the Health IT Standards Committee (of the Office of the National Coordinator for Health IT), (e.g., SNOMED, RxNorm, LOINC), and also referenced in the CMS Blueprint. The vocabulary standards used in the specifications are consistent with those recommendations proposed for Stage II of the CMS EHR incentive program (Meaningful Use). Another available standard is the HL7 Health Quality Measure Format (HQMF), an XML-based structured document to express a quality measure specification. The HQMF is used for specifications included in the Meaningful Use program and also references the QDM. The specifications provided with this submission form have not been incorporated into the HQMF eMeasure format, however the information included in the specifications serve as the foundation for the HQMF—that is, the PCPI electronic specification outlines the requirements to develop the HQMF.

11.E. Health IT Calculation

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

It is highly likely that missing data or ambiguous information stored in the EHR will lead to calculation errors. The specifications provided for this measure are designed to query the EHR in order to obtain the data required for the measure calculation.

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?

These IT functions could make measure recording in the EHR more feasible and reliable, as well as improve performance on the measure and patient outcomes. For example, computerized decision support with menu drop downs or reminders could be programmed to give providers prompts to provide the appropriate services to patients.

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 measure may have limited utilization due to the limited adoption of EHRs, particularly among practices treating the Medicaid population. However, the vocabulary standards used in the specifications are as proposed for Stage II of the CMS EHR incentive program (Meaningful Use), so its usability is expected to be enhanced by increased participation in this program. As adoption of EHRs increases, utilization of this measure should also increase.

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 measure should be selected because it expands the core set of measures beyond their current use. The measure will provide a mechanism to help assess the appropriateness of cesarean deliveries and prevent adverse neonatal outcomes. This measure is of particular importance for CHIPRA in that it is high impact with Medicaid patients and addresses concerns related to both mother and baby. Additionally, since this measure has full eSpecifications, it can be a candidate for future inclusion in the EHR Incentive Program for Meaningful Use.

Our EHR specifications follow the standards in the Quality Data Model (QDM), developed by the National Quality Forum, the vocabulary recommendations named by the Health IT Standards Committee (of the Office of the National Coordinator for Health IT), (e.g., SNOMED, RxNorm, LOINC), and also referenced in the CMS Blueprint. The vocabulary standards used in the specifications are a part of Stage II of the CMS EHR incentive program (Meaningful Use).

Section 14: Identifying Information for the Measure Submitter

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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.

The signed written statement was submitted.

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