

# Inhaled Corticosteroids for Children with Persistent Asthma Prescribed at Time of Discharge from the Emergency Department

## Section 1. Basic Measure Information

### 1.A. Measure Name

Inhaled Corticosteroids for Children with Persistent Asthma Prescribed at Time of Discharge from the Emergency Department

### 1.B. Measure Number

0212

### 1.C. Measure Description

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

This measure assesses the percentage of children, ages 1 through 17 years, with persistent asthma who, during the measurement year, presented to a hospital emergency department (ED) for an asthma exacerbation and were prescribed an inhaled corticosteroid (ICS) at the time of discharge. A higher proportion indicates better performance, as reflected by children with persistent asthma being prescribed an appropriate medication. Children with persistent asthma are restricted to those who meet at least one of the following criteria during both the measurement year and the year prior: at least one ED visit with a principal diagnosis of asthma; at least one acute inpatient encounter with a principal diagnosis of asthma; at least three outpatient visits with an asthma diagnosis on different dates; or at least four asthma medication dispensing events. Criteria need not be the same across both years.

Asthma is a chronic respiratory disease characterized by exacerbations that lead to symptoms of coughing, wheezing, and difficulties breathing. Pediatric asthma is the most common chronic disease of childhood and is on the rise, with over 7 million U.S. children currently living with asthma (Centers for Disease Control and Prevention [CDC], 2012; National Heart, Lung, and Blood Institute [NHLBI], 2007). Asthma is also a leading cause of hospitalization for children in the United States, responsible for approximately \$56 billion in medical costs, lost days from school and work, and early deaths (CDC, 2011).

Clinical practice guidelines for asthma have been developed to direct providers to evidence-based medications and care to improve the quality of care for patients with asthma, while decreasing morbidity and mortality. ICS are the gold-standard of asthma care and have been shown to reduce the number of asthma exacerbations and decrease acute care visits for asthma (Andrews, Teufel, Basco, 2012). Regularly scheduled medical visits to evaluate asthma control

and check medication adherence and device technique are recommended, as underlying asthma can change over time, and treatment needs to be adjusted accordingly (NHLBI, 2007). However, many children receive care on an episodic basis in their local ED rather than at regular outpatient visits. Primary care providers infrequently add controller medication (e.g., an ICS) after an ED visit (Schuh, Zemek, Plint, et al., 2012); and even when providers do prescribe ICS, only 65 percent of patients in a study by Lehman and colleagues subsequently filled their prescriptions at a pharmacy (Lehman, Lillis, Shaha, et al., 2006). In a study by Andrews and colleagues (2012), children with asthma and an ED visit also demonstrated low rates of corticosteroid use and outpatient follow-up.

These findings, paired with the difficulties that minority populations have accessing primary care (Singer, Carmago, Lampell, et al., 2005), highlight the opportunity emergency physicians have to prescribe ICS in the ED to improve asthma management for all children, especially those at highest risk (Self, Twilla, Rogers, et al., 2009).

This measure uses administrative claims and medical record data and is calculated as the percentage of eligible children who were prescribed an ICS at the time of discharge from the ED.

#### **1.D. Measure Owner**

The Quality Measurement, Evaluation, Testing, Review, and Implementation Consortium (Q-METRIC).

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

Not applicable.

#### **1.F. Measure Hierarchy**

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

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

This measure is part of the Q-METRIC Pediatric Asthma Measures Collection.

- 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.**

This measure is part of the Q-METRIC Asthma Chronic Care Management 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.**

Not applicable.

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**

The numerator is the number of children, ages 1 through 17 years, with persistent asthma who, during the measurement year, presented to a hospital ED for an asthma exacerbation and were prescribed an ICS at the time of discharge.

## **1.H. Numerator Exclusions**

None.

## **1.I. Denominator Statement**

The denominator is the number of children, ages 1 through 17 years, with persistent asthma who, during the measurement year, presented to a hospital ED for an asthma exacerbation. The eligible population includes children who are 1 year or older on January 1 of the measurement year but younger than 18 years on December 31 of that year. Children must be continuously enrolled in their insurance plan during both the measurement year and the year prior.

Children with persistent asthma are restricted to those who meet at least one of the following criteria during both the measurement year and the year prior to the measurement year. Criteria are drawn from the Healthcare Effectiveness Data and Information Set (HEDIS, 2014) and need not be the same across both years (see Supporting Documents for Tables 1 and 2).

- At least one ED visit with a principal diagnosis of asthma.
- At least one acute inpatient encounter with a principal diagnosis of asthma.
- At least three outpatient visits with an asthma diagnosis on different dates.
- At least four asthma medication dispensing events (Appendix 1 - Asthma Drug and Device List, see Supporting Documents).

ED visits were defined using CPT and Revenue Codes (Table 1, see Supporting Documents); ED visits related to asthma were defined as an ED visit with at least one asthma diagnosis related to such visit (Table 2, see Supporting Documents).

ICS are anti-inflammatory medications that help control inflammation in the bronchial tubes, which causes airway narrowing in asthma (Appendix 2 - Inhaled Corticosteroids, see Supporting Documents). Prescription of an ICS upon ED discharge was based on medical record review.

## 1.J. Denominator Exclusions

- Children with claims-based evidence of current ICS use (Appendix 2 – Inhaled Corticosteroids, see Supporting Documents).
- Children with claims-based evidence of current controller medication use (Appendix 3 – Controller Medications, see Supporting Documents).
- Children seen in the ED who are admitted to the hospital.
- Children with a diagnosis during the measurement year or the year prior to the measurement year indicating cystic fibrosis or bronchiectasis (Table 3, see Supporting Documents).
- Children younger than 6 years with a diagnosis during the measurement year or the year prior to the measurement year indicating bronchopulmonary dysplasia, tracheomalacia, or bronchomalacia (Table 3, see Supporting Documents).
- Children 6 years or older with a diagnosis during the measurement year or the year prior to the measurement year indicating bronchopulmonary dysplasia, tracheomalacia, or bronchomalacia (Table 3, see Supporting Documents), unless there is also a diagnosis for persistent asthma (Table 2, see Supporting Documents).
- Children with a diagnosis indicating “exercise induced bronchospasm” (ICD-9 code 493.81 in Table 3), unless there is also a diagnosis for persistent asthma (Table 2, see Supporting Documents).

## 1.K. Data Sources

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

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

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

Not applicable.

## Section 2: Detailed Measure Specifications

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

Please see the Supporting Documents for detailed measure specifications.

## **Section 3. Importance of the Measure**

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

### **3.A. Evidence for General Importance of the Measure**

**Provide evidence for all applicable aspects of general importance:**

- **Addresses a known or suspected quality gap and/or disparity in quality (e.g., addresses a socioeconomic disparity, a racial/ethnic disparity, a disparity for Children with Special Health Care Needs (CSHCN), a disparity for limited English proficient (LEP) populations).**
- **Potential for quality improvement (i.e., there are effective approaches to reducing the quality gap or disparity in quality).**
- **Prevalence of condition among children under age 21 and/or among pregnant women.**
- **Severity of condition and burden of condition on children, family, and society (unrelated to cost).**
- **Fiscal burden of measure focus (e.g., clinical condition) on patients, families, public and private payers, or society more generally, currently and over the life span of the child.**
- **Association of measure topic with children’s future health – for example, a measure addressing childhood obesity may have implications for the subsequent development of cardiovascular diseases.**
- **The extent to which the measure is applicable to changes across developmental stages (e.g., infancy, early childhood, middle childhood, adolescence, young adulthood).**

#### **Pediatric Asthma Disease Prevalence and Incidence**

Pediatric asthma is the most common chronic disease of childhood and is the leading cause of childhood school absences, ED visits, and hospitalizations due to chronic illness (Pedersen, Hurd, Lemanske Jr, et al., 2011). The prevalence of pediatric asthma is increasing, with approximately 7 million U.S. children under age 18 years currently living with asthma (CDC, 2012). Of these 7 million children, 4.1 million have suffered from an asthma attack in the previous 12 months (CDC, 2011).

#### **Pediatric Asthma Pathology and Severity**

Asthma is a chronic disease of the small airways characterized by inflammation and airway hyper-responsiveness, which together lead to bronchoconstriction and mucus plugging

(Pedersen, et al., 2011). Symptoms of asthma include recurring episodes of wheezing, shortness of breath, chest tightness, and coughing. These episodes, or exacerbations, are typically associated with at least partially reversible airflow obstruction (NHLBI, 2007) and may range in severity from mild to life-threatening (CDC, 2013). The causes of asthma are not fully understood (NHLBI, 2007), but it is thought that multiple host and environmental factors may be involved at critical times in immune development (CDC, 2013). Environmental factors that are common triggers include respiratory viral infections; airborne allergens such as pollens, mold, animal dander, and dust mites; and air pollution, including tobacco smoke. There is no cure for asthma, but it can be controlled with appropriate medical care, medications, and avoidance of triggers (NHLBI, 2007).

### **Pediatric Asthma Burden in Daily Life**

The burden of pediatric asthma on children and families is significant. In 2008, the disease resulted in 14 million missed school days and an estimated \$3.8 billion in lost productivity (CDC, 2013). Poorly controlled asthma can affect children's quality of sleep, school performance, and ability to participate in sports and social activities. Asthma deaths are rare, particularly among children and young adults, with the majority of deaths due to asthma occurring in individuals aged 65 years and older. However, children do die from asthma. The CDC has reported that in 2011, 169 children under 15 years of age died from the disease (CDC, 2014). Asthma deaths are thought to be largely preventable through appropriate care and management.

### **Pediatric Asthma Disease Cost**

Pediatric asthma is one of the most common causes of preventable hospitalization (Kenyon, Rubin, Zorc, et al., 2015). Although only a small percentage of the nearly 7 million US children with asthma are admitted to the hospital in a given year, asthma is the third leading cause of child hospitalization and accounts for nearly one-third of national pediatric asthma costs (Kenyon, Melvin, Chiang, et al., 2014). Pediatric patients with asthma are seen across the health care spectrum. They account for almost 5 million physician visits (Akinbami, 2006), and their average annual prescription drug expenditures have nearly doubled since the 1990s (Sarpong, 2011).

### **Outcomes of Inhaled Corticosteroids Prescribed in the Emergency Department**

Asthma is a chronic disease that cannot be cured, but it can be controlled through appropriate management (van der Molen, Ostrem, Stallber, et al., 2006). ICS are considered the gold standard for the treatment of persistent asthma and are associated with a significant protective effect against future hospitalizations and ED visits (Adams, Fuhlbrigge, Finkelstein, et al., 2001). Despite the well-established efficacy of ICS, these anti-inflammatory medications are often under-used. Non-adherence in children and adolescents is particularly high, leading to poor asthma control and subsequent decreased quality of life, increased health care utilization, and even risk of death (Desai, Oppenheimer, 2011). Pediatric asthma patients seen in the ED are at high risk for future exacerbations, making it important that they receive appropriate preventive care (Andrews, et al., 2012). Initiating maintenance ICS in the ED, at the time of an acute exacerbation, is one important strategy to increase ICS coverage and decrease risk of future exacerbations for pediatric asthma patients.

Asthma is the third leading cause of hospitalization in children under the age of 15 years and is associated with increased frequency of ED visits (Pearson, Goates, Harrykisson, et al., 2014). The appropriate use of controller medications has been shown to reduce asthma exacerbations and related acute care visits for asthma (Andrews, et al., 2012). However, under-utilization of controller medications is common. An analysis of an integrated managed care database found that asthma patients seen in the ED were more dependent on rescue medications, such as short-acting beta-agonists and oral corticosteroids, than on long-term controllers, such as ICS, in the month prior to the ED visit (Ornato, 2007). Garro and colleagues found ample opportunity (over 2.2 million asthma-related visits in the 2 year study period, from 2005 to 2007 at U.S. EDs) to prescribe an ICS in this setting (Garro, Asnis, Merchant, et al., 2011). Yet Andrews and colleagues (2012) demonstrated that less than 20 percent of patients seen in the ED for asthma had filled a prescription for a controller medication in the month of or the month after the urgent visit, and only 12 percent had followed up with their primary care provider. Another study showed that prescribing or dispensing ICS at the time of discharge from the ED led to fewer return visits to the ED and fewer hospitalizations in the subsequent 30-day period (Andrews, Russell, Titus, et al., 2014). Experts have urged that standards of care should change in order to reflect evidence and international guidelines regarding initiation of ICS maintenance therapy (Self, et al., 2009).

As mentioned, both national and international asthma guidelines support the initiation of ICS prior to discharge from the ED. The National Asthma Education and Prevention Program's Expert Panel Report-3: Guideline for the Diagnosis and Management of Asthma supports the practice of prescribing ICS at all levels of care and notes that initiating ICS at discharge from the ED (for example, providing a 1–2 month supply) should be considered for many reasons: the potential for ICS is to reduce subsequent ED visits, the clear evidence that long-term-control ICS therapy reduces exacerbations in patients with persistent asthma, and the opinion of the Expert Panel that initiation and continuation of ICS therapy at ED discharge can be an important effort to bridge the gap between emergency and primary care for asthma (NHLBI, 2007). The Global Initiative for Asthma (GINA): Global Strategy for Asthma Management and Prevention (GINA, 2014) likewise recommends that the majority of patients should be prescribed regular ongoing ICS treatment at discharge, given that the occurrence of a severe exacerbation is a risk factor for future exacerbation and that ICS medications significantly reduce the risk of asthma-related death or hospitalization.

This measure assesses the percentage of children, ages 1 year through 17 years, with persistent asthma who, during the measurement year, presented to a hospital ED for an asthma exacerbation and were prescribed an ICS at the time of discharge. A higher proportion indicates better performance, as reflected by children with persistent asthma being prescribed an appropriate medication. The measure does not change across developmental stages.

### **Performance Gap**

ICS are considered the best treatment for persistent asthma and are associated with a significant protective effect against future hospitalizations and ED visits (Adams, et al., 2001). However, most children with asthma presenting to the ED have poorly controlled asthma (Singer, et al.,

2005), and only 4 percent of children with asthma discharged from the ED with persistent asthma were prescribed ICS at discharge (Garro, et al., 2011).

Warman, Silver, and Stein (2001) found that only 35 percent of children who had been hospitalized with asthma were receiving ICS, and Lehman and colleagues (2006) reported that only 65 percent of patients with an ICS prescription from their primary care provider filled that prescription at their pharmacy. These statistics, paired with the difficulties many minority populations face accessing primary care (Singer, et al., 2005), highlight the current gap in care for children with asthma. Prescribing or dispensing an ICS at ED discharge to all children with persistent asthma who present with an asthma exacerbation would help decrease the number of children with poorly controlled asthma. This, in turn, would decrease the number of costly ED visits.

There currently is no quality measure assessing the rate at which ICS are prescribed at ED discharge for children, ages 1 through 17 years, with persistent asthma who presented with an asthma exacerbation. This measure, in providing an accurate assessment of dispensing and prescribing rates, would be a first step in filling this gap. Providing appropriate anti-inflammatory medications to children with persistent asthma is likely to improve patient outcomes by reducing the frequency of urgent care and ED visits and the number of hospitalizations, while improving perceived quality of life.

### **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).**

#### **Pediatric Asthma and Medicaid/CHIP**

Medicaid and CHIP provide health care coverage for 44 million children and are critically important for population sub-groups who have disproportionately lower incomes, including racial and ethnic minority groups (Burwell, 2014). The burden of pediatric asthma is not uniform across all populations. It is well known that asthma disproportionately affects racial and ethnic minorities and those of low socioeconomic status (GIP, 2008). The CDC's Morbidity and Mortality Weekly Report (MMWR) on asthma prevalence (Moorman, Zahran, Truman, et al., 2011) describes pediatric asthma disparities with surveillance data showing that Puerto Rican Hispanics have the highest asthma prevalence rates (18.4 percent) compared with non-Hispanic blacks (14.6 percent), multiracial individuals (13.6 percent), and non-Hispanic whites (8.2 percent). Children enrolled in Medicaid are at a higher risk for asthma hospitalization, and many do not receive appropriate outpatient care (Lieu, Finkelstein, Lozano, et al., 2004). Kim and colleagues conclude that minority children from socioeconomically disadvantaged families



depend more on urgent and emergency care, and less on preventive care, to deal with asthma. Black children, in particular, had the lowest level of office visits and highest level of ED utilization (Kim, Kieckhefer, Greek, et al., 2009).

These national disparities are also observed in many local jurisdictions. For example, The Bureau of Epidemiology at the Michigan Department of Community Health reported that the prevalence of persistent asthma among the pediatric Medicaid population increased from 5.1 percent in 2005 to 5.5 percent in 2010. In 2010, black children insured by Medicaid experienced higher asthma prevalence compared with white children (6 percent vs. 5 percent) (Garcia, Lyon-Callo, 2012).

Children with asthma enrolled in Medicaid pose an important challenge to the health care system. Children in low-income families have the lowest rates of outpatient visits, prescription fills, and ICS adherence, and they have the highest rates of urgent care use; one study found that 65 percent of the children with persistent asthma underuse preventive medication (American Lung Association, 2010; Kim, et al., 2009; Lieu, et al., 2004). Overall, children enrolled in Medicaid may receive worse care than those who are privately insured, even when they are participating in the same health plans (Lieu, et al., 2004). Mehta, Nagar, and Aparasu (2009) illustrate that African-American race and poverty were associated with unmet prescription medication needs (UPMN) due to any reason. Furthermore, children with asthma were 3.15 times as likely to have UPMN as children without asthma, and children with asthma experienced UPMN related to medication costs. Employing guideline-based care will increase the number of children receiving appropriate medication, leading to better controlled asthma, fewer urgent care and ED visits, fewer hospitalizations, and improved quality of life.

### **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).**

Currently, there is no quality measure assessing whether children with persistent asthma who present to the ED for an asthma exacerbation are prescribed an ICS at the time of discharge from the ED. This measure does, however, complement already existing measures that assess ICS rates for those with persistent asthma.

## **Section 4. Measure Categories**

**CHIPRA legislation requires that measures in the initial and improved core set, taken together, cover all settings, services, and topics of health care relevant to children. Moreover, the legislation requires the core set to address the needs of children across all ages, including services to promote healthy birth. Regardless of the eventual use of the measure, we are interested in knowing all settings, services, measure topics, and**

populations that this measure addresses. These categories are not exclusive of one another, so please indicate "Yes" to all that apply.

Does the measure address this category?

- a. Care Setting – ambulatory: Yes.
- b. Care Setting – inpatient: No.
- c. Care Setting – other – please specify: No.
- d. Service – preventive health, including services to promote healthy birth: No.
- e. Service – care for acute conditions: Yes.
- f. Service – care for children with special health care needs/chronic conditions: Yes.
- g. Service – other (please specify): No.
- h. Measure Topic – duration of enrollment: No.
- 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): No.
- 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): Yes; all ages in this range.
- r. Population – school-aged children (6 years through 10 years) (specify age range): Yes; all ages in this range.
- s. Population – adolescents (11 years through 20 years) (specify age range): Yes; adolescents 11-17 years.
- t. Population – other (specify age range): Not applicable.
- u. Other category (please specify): Not applicable.

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

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

### **5.A. Research Evidence**

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

**level and the provision of immunizations to children and adolescents, such evidence would support the focus of a measure on immunization registries (a structural measure).**

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

This measure focuses on assessing whether children, ages 1 through 17 years with persistent asthma, have an ICS prescribed at discharge after presenting to a hospital ED for an asthma exacerbation.

Underuse of controller medications results in more acute episodes, greater use of EDs, and increased treatment costs. Patients seen in the ED for asthma exacerbations are at an increased risk for future exacerbations requiring ED care (Andrews et al., 2012). Appropriate use of ICS can help prevent these relapses. Table 4 (see Supporting Documents) summarizes national and international guidelines as evidence for this measure, using U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted in a note to Table 4). Both national and international asthma guidelines support the initiation of ICS prior to discharge from the ED (GINA, 2014; NHLBI, 2007; Self, et al., 2009). The National Asthma Education and Prevention Program's Expert Panel Report-3: Guideline for the Diagnosis and Management of Asthma (NHLBI, 2007) notes that initiating ICS at discharge from the ED with a 1–2 month supply should be considered for many reasons, including reducing subsequent ED visits and exacerbations in patients with persistent asthma and bridging the gap between emergency and primary care for asthma. The Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention (GINA, 2014) likewise recommends that on discharge the majority of patients should be prescribed regular, ongoing ICS treatment, as having a severe exacerbation is a risk factor for recurrence; furthermore, the use of ICS significantly reduces the risk of asthma-related death or hospitalization.

## **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.**

Not applicable.

## **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.**

This measure was tested using inter-rater reliability (IRR) of medical record data, as described below.

### **Medical Record Abstraction**

Medical record data were obtained through HealthCore, Inc., for the 2013 measurement year. HealthCore is an independent subsidiary of Anthem, Inc., the largest health benefits company/insurer in the United States. HealthCore owns and operates the HealthCore Integrated Research Database (HIRD), a longitudinal database of medical and pharmacy claims and enrollment information for members from 14 geographically diverse Blue Cross/Blue Shield health plans in the Northeast, South, West and Central regions of the United States, with members living in all 50 States. In total, the HIRD includes data for approximately 60 million insured individuals between January 2006 and June 2014.

Approximately 205,000 children, ages 0 through 17 years, with an asthma diagnosis/symptoms were identified in the HIRD in 2012 (the year prior to the measurement year, per measure specification). Of these, a cohort of 10,156 (5.0 percent) children meeting the criteria for persistent asthma was identified. Among this set of children, 376 (3.7 percent) presented to a hospital ED for an asthma exacerbation during the measurement year and met inclusion/exclusion criteria (e.g., had no evidence of current ICS or daily controller medication use) for this measure. A stratified random sample of charts was requested from provider offices and health care facilities, with a target of obtaining at least 135 completed records.

Patient medical records were sent to a centralized location for data abstraction. Trained medical record abstractors collected and entered information from paper copies of both electronic and paper medical records into a password-protected database. To help ensure consistency of data collection, the medical record abstractors were trained on the study's design and presented with a standardized data collection form developed to minimize the need for abstractors to make subjective judgments during the abstraction process. In addition, data entered onto a scanner form and subsequently scanned were reviewed through a series of quality checks.

In total, 160 charts were reviewed and met all inclusion/exclusion criteria. Nine children (5.6 percent) were excluded, as they turned 18 years old within the measurement year, resulting in a final denominator of 151 (94.4 percent). Chart review indicated that among these 151 children with persistent asthma who presented to the ED for an asthma exacerbation, 14 (9.3 percent) were prescribed an ICS at the time of discharge.

### **Inter-Rater Reliability**

Reliability of medical record data was determined through re-abstraction of patient record data to calculate the IRR between abstractors. Broadly, IRR is the extent to which the abstracted information is collected in a consistent manner. Low IRR may be a sign of poorly executed abstraction procedures, such as ambiguous wording in the data collection tool, inadequate abstractor training, or abstractor fatigue. IRR was determined by calculating percent agreement. Any differences were remedied by review of the chart. IRR was determined by calculating both percent agreement and Cohen's kappa statistic.

## **IRR Results**

Of the 160 records abstracted for this measure, seven (4 percent) were reviewed for the IRR. IRR was assessed by comparing abstractor agreement with a senior abstractor on data elements that could be abstracted for this measure. Overall, abstractor agreement was 100 percent; the kappa statistic was 1.0, indicating that a perfect level of IRR was achieved. Given this evidence, the data elements needed for calculation of the measure can be abstracted from medical records with a high degree of accuracy.

## **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 validity of this measure was determined from two perspectives: face validity and validity of the medical record data.

### **Face Validity**

Face validity is the degree to which the measure construct characterizes the concept being assessed. The face validity of this measure was established by a national panel of experts and parent representatives for families of children with asthma convened by Q-METRIC. The Q-METRIC expert panel included nationally recognized experts in asthma, representing the areas of general pediatrics, family practice, pediatric pulmonology, allergy, asthma education (including certified asthma educators), and general and pediatric emergency medicine, as well as a pediatric hospitalist. In addition, measure validity was considered by experts in State Medicaid program operations, health plan quality measurement, health informatics, and health care quality measurement. In total, the Q-METRIC asthma panel included 16 experts, providing a comprehensive perspective on asthma care and the measurement of quality metrics for States and health plans.

The Q-METRIC expert panel concluded that this measure has a high degree of face validity through a detailed review of concepts and metrics considered to be essential to effective asthma management and treatment. Concepts and draft measures were rated by this group for their relative importance. This measure was highly rated, receiving an average score of 7.1 (with 9 as the highest possible score).

## **Importance of Abstracted Medical Record Data**

This measure is specified using medical record data after administrative claims were used to identify the eligible population. Medical records are considered the gold standard for clinical information; our findings indicate that these data have a high degree of face validity and reliability, as summarized above. As the prescription of an ISC upon discharge from the ED cannot be identified using claims, it is necessary to identify this criterion within medical records in order to accurately assess this measure. As a consequence, implementing this measure solely upon administrative claims data would not be possible, and abstraction of medical records is necessary.

## **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**

Patient-level demographic and socioeconomic characteristics were generally unavailable from the medical records reviewed for measure testing. Therefore, we used zip-code level information on race and ethnicity, median household income, and urbanicity, collected for the 2010 United States Census and the 2011 American Community Survey (ACS), as proxy variables to characterize the population (U.S. Census Bureau, 2011). The small numbers of eligible denominator and numerator cases (n=151 and n=14, respectively) do not allow for meaningful comparisons across different socio-demographic groups.

#### **Race and Ethnicity Census Characteristics**

On average, children within the denominator and numerator resided in zip codes reporting primarily white race (77.6 percent and 78.9 percent, respectively) and modest levels of Hispanic ethnicity (12.6 percent and 13.7 percent, respectively). These demographic characteristics differ from the population of the United States as a whole, as the 2010 U.S. Census data indicate that approximately 72.4 percent of the population was white, 13.2 percent was black, and 16.3 percent was of Hispanic ethnicity (U.S. Census Bureau, 2010). The summary statistics for race and ethnicity within zip code across the sampled subgroups of children with valid zip codes are reported in Tables 5 and 6 (see Supporting Documents).

### **7.B. Special Health Care Needs**

The data obtained for this study do not include indicators of special health care needs.

## **7.C. Socioeconomic Status**

### **Census Characteristics**

On average, the zip code-level median household income was similar for children in both the denominator and numerator groups (\$62,689 and \$59,145, respectively). The median household income for the zip codes in which these children resided was somewhat higher than the median household income of the population of the entire United States, as reported in the ACS in 2011, which was \$50,502. Summary statistics for distribution of the zip-code level median household income for sampled groups of children with valid zip codes and complete census data are reported in Table 7 (see Supporting Documents).

## **7.D. Rurality/Urbanicity**

### **Census Characteristics**

Children within the denominator and numerator groups primarily reside in urban zip codes (80.8 percent and 63.4 percent, respectively). In the United States, approximately 79 percent of the population resides in an urban area. The summary statistics for urbanicity within zip code for sampled groups of children with valid zip codes are reported in Table 8 (see Supporting Documents).

## **7.E. Limited English Proficiency (LEP) Populations**

The data obtained for this study do not include indicators of LEP.

# **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?**

This measure was tested using medical record data after administrative claims were used to identify the population to sample for chart review. Administrative data needed for this measure include date of birth, diagnosis codes, and procedure codes and dates. These data are generally available, although obtaining them may require a restricted-use data agreement and Institutional Review Board (IRB) approval.

Testing this measure using medical record data required the development of an abstraction tool and the use of qualified nurse abstractors. Review of clinical documentation was required to ensure that the numerator was appropriately captured.

**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?**

Continuing advances in the development and implementation of electronic health records (EHRs) may prompt providers to document key elements needed for application of inclusion and exclusion criteria necessary for this measure.

## **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.**

To our knowledge, this measure is not currently in use anywhere in the United States.

**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)**

No.

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

Not applicable.



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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

**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)

No.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

**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)

No.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

**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?**

This measure requires medical record abstraction; medical records are maintained by all health services providers. Target population for sampling requires administrative claims data to identify subgroups of potentially eligible cases for medical record review.

**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?**

To accurately identify a difference of 5 to 15 percent among health plans, a minimum of 200 charts per plan would be necessary. Our results indicate that approximately 0.2 percent (376/205,000) of children with a diagnosis of asthma met the criteria for chart extraction for this measure. Therefore, approximately 100,000 children (200/0.002) with an asthma diagnosis would be necessary within the health plan to accurately identify this 10 percent difference.

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

Not applicable.

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

Not applicable.

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

Not applicable.

***Provider Level***

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

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

(Yes/No)

No.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

***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?

This measure requires medical record abstraction; medical records are maintained by all health services providers.

***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 measure has not been tested at the hospital level; consequently, the minimum number of patients per hospital has not been determined.

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

Not applicable.

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

Not applicable.

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

Not applicable.

***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)

No.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

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

Not applicable.

## **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).**

This measure offers guidelines to ED providers and gives families a standard of care in the ED for pediatric persistent asthma. Low rates for prescribing an ICS in the ED for children with

persistent asthma are easily understood to be unsatisfactory. The simplicity of the measure likewise makes it a straightforward guide for providers and purchasers to assess how well comprehensive care is managed for children with asthma.

This measure has not been formally assessed for comprehension. The primary information needed for this measure comes from medical record data and includes basic demographics, diagnostic codes, and procedure codes, all of which are widely available and understood by those working in the health care field.

## **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.**

This measure, which assesses whether ICS medications are prescribed at ED discharge to children with persistent asthma, relates to the process of asthma care in acute settings; thus, it is amenable to alerts and reminders. Such prompts could provide real-time feedback when suggested care is not followed. In addition, engineering of the system through the use of process control dashboards that outline what has and has not been completed for patients with asthma exacerbations would enhance use of this measure.

### **11.B. Health IT Testing**

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

No.

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

Not applicable.

### **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.**

For this measure regarding whether ICS medications are prescribed at ED discharge to children with persistent asthma, information will need to come from submitted claims for visits (using ICD or CPT codes), from reviewing visit notes in search of terms that describe asthma diagnoses or treatments, from the problem list, or indirectly from prescribed medications. Information may be extracted from the medications list, the medications section of a note, or the plan section of a note. Information may be difficult to obtain about medications dispensed in an ED, as most dispensing occurs in pharmacies. However, it is possible that the visit note will explicitly state

what was dispensed by the clinic or that the e-prescribing tool documents medications and devices that are dispensed locally.

## **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 (ONC) criteria (see [healthit.hhs.gov/portal/server.pt/community/healthit\\_hhs\\_gov\\_\\_standards\\_ifr/1195](http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195))?**

Yes.

**If yes, please describe.**

The ONC's Health IT Standards explicitly address the receipt of laboratory results and other diagnostic tests into EHRs. In addition, these standards indicate the requirement for EHRs to track specific patient conditions, such as asthma. The ONC standards include the following specific requirements in the Certification criteria (ONC, 2010) pertaining to Stage 2 Meaningful Use requirements:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care. In addition, the exchange of information in the most structured format possible is encouraged. This can be accomplished through mechanisms such as the electronic transmission of orders entered using computerized provider order entry (CPOE). The generation of lists of patients by specific conditions to use for quality improvement and reduction of disparities outreach is specifically addressed (ONC, 2010).

## **11.E. Health IT Calculation**

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

Missing or ambiguous information in the following areas could lead to missing cases or calculation errors:

1. Child's date of birth.
2. ICD-9 or ICD-10 codes selected to indicate asthma diagnosis or exclusions.
3. Type of asthma medication.
4. CPT codes to identify visit type.
5. Date and time of treatment.
6. Dates of insurance coverage.
7. Documentation in medical record indicating prescription of an ICS on ED discharge.
8. Exclusion diagnoses.

## **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?**

Please see the answer above regarding health IT enhancement. In this case, the collection of information and the use of the measure are both equally enhanced by the availability of health IT functions, such as decision support, process control, and order sets.

## **Section 12. Limitations of the Measure**

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

This measure assesses the percentage of children 1 through 17 years of age with persistent asthma, who, during the measurement year, presented to a hospital ED for an asthma exacerbation and were prescribed an ICS at the time of discharge. A higher proportion indicates better performance, as reflected by children with persistent asthma being prescribed an appropriate medication.

Limitations to this measure exist. First, children with less than a 1-year history of persistent asthma and those with intermittent asthma are not likely to be included in this measure, given the definition of the denominator. However, these children would still likely benefit from receipt of an ICS prescription at time of discharge from the ED after an asthma exacerbation (Andrews, et al., 2012; 2014). In addition, the presence of a prescription for an ICS at time of discharge does not evaluate if the prescription was filled, nor if the ICS was used by the appropriate child. This measure does not address the appropriateness of a prescribed medication delivery device for a particular patient (e.g., dry powder inhalers are not recommended for patients under the age of 4 years or for older children incapable of generating the necessary inspiratory flow rate to trigger the release of medication). This measure also does not assess other aspects of care that are a necessary part of ICS delivery, such as education on the appropriate inhalation technique. Lack of standardization in medical record documentation between health care providers could result in missing or incorrect information.

## **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 assesses the percentage of children, ages 1 through 17 years with persistent asthma, who, during the measurement year, presented to a hospital ED for an asthma exacerbation and were prescribed an ICS at the time of discharge. This measure requires both administrative claims and medical record data. There currently is no quality measure assessing whether children with persistent asthma who present to an ED for an asthma exacerbation are prescribed an ICS at the time of discharge. This measure does, however, complement already existing measures that assess ICS rates for those with persistent asthma.

Pediatric asthma is the most common chronic disease of childhood and is a leading cause of childhood school absences, ED visits, and hospitalizations due to chronic illness. Asthma cannot be cured, but it can be controlled through appropriate management; inhaled asthma medications are an important aspect of this management. ICS are the gold-standard of asthma care and have been shown to reduce asthma exacerbations and decrease acute care visits for asthma. Regularly scheduled medical visits to evaluate asthma control and check medication adherence and device technique are recommended. However, many children receive care on an episodic basis in their local ED, rather than at regular outpatient visits. Research shows that controller medications are infrequently prescribed in the primary care setting after an ED visit; even then, many patients fail to fill these prescriptions. Considering, too, the difficulties that minority populations have accessing primary care, emergency physicians can improve asthma management for children by prescribing ICS in the ED before discharge.

This measure was tested among a total of 151 children, ages 1 through 17 years with persistent asthma, to determine the percentage of children who, during the measurement year, presented to a hospital ED for an asthma exacerbation and were prescribed an ICS at the time of discharge. Our analysis shows that 14 children (9.3 percent) were prescribed an ICS medication during that timeframe.

This measure provides families with a minimum standard of care for pediatric asthma. The primary information needed for this measure includes basic demographic data, dates, diagnostic codes, and procedure codes, all of which are widely available. Limitations to the measure include possible exclusion of children with intermittent or recent-onset asthma, an inability to assess whether a prescription was filled, and lack of detail on the appropriateness of the medication prescribed.

Continuing advances in the development and implementation of health information technology may establish the feasibility of referencing implemented care for patients to guide prescribing practices.

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## **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.**

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