Education in Proper Use of New Asthma Medication Delivery Device for Children with Asthma

Section 1. Basic Measure Information

1.A. Measure Name

Education in Proper Use of New Asthma Medication Delivery Device for Children with Asthma

1.B. Measure Number

0201

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, identified as having asthma, regardless of severity, who are prescribed and dispensed a new medication delivery device and have documentation of the child or caregiver receiving education in the proper use of the device. Children of different ages require these devices to facilitate effective delivery of medication to their lungs. For the purposes of this measure, education in proper use is defined as documentation of verbal instruction, education, and/or demonstration. Asthma may be of any severity; examples of devices include metered-dose inhalers (MDI), dry-powder inhalers (DPI), nebulizers, chambers, and masks. Children must be continuously enrolled in their insurance plan during the measurement year (January through December) and the year prior. A higher proportion indicates better performance, as reflected by appropriate education.

Asthma is a chronic respiratory disease characterized by exacerbations that lead to symptoms of coughing, wheezing, and difficulty breathing. Pediatric asthma is the most common chronic disease of childhood and is on the rise, with over 7 million American 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. In 2007, the disease was responsible for approximately $56 billion in medical costs, as well as days lost from school and work and early deaths (CDC, 2011a).

Clinical practice guidelines for asthma presented in the National Asthma Education and Prevention Plan's Expert Panel Report 3 (NHLBI, 2008) have been developed to direct providers to evidence-based care in an effort to address and improve the quality of care for patients with asthma and to decrease morbidity and mortality in this population. Providing and documenting instruction on the proper use of delivery devices for inhaled medications and making sure patients and providers can demonstrate appropriate technique is a crucial part of guideline-driven asthma self-management education (NHLBI, 2008).

This measure requires administrative claims and medical record data.

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 Pediatric 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, identified as having asthma, regardless of severity, who are prescribed and dispensed a new medication delivery device and have documentation of the patient or the caregiver(s) receiving education in the proper use of a new medication delivery device in the measurement year. Education on proper use may include notes indicating verbal instruction, education, and/or demonstration.

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

The denominator is the number of children, ages 1 through 17 years, identified as having asthma, regardless of severity, who are prescribed and dispensed a new medication delivery device in the measurement year. The eligible population includes children who are 1 year old 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 asthma of any severity are identified using the asthma diagnosis codes listed in Table 1 (see Supporting Documents). The asthma diagnosis must occur within the year prior to the measurement year.

For inhaled medications (see Appendix in the Supporting Documents), a new medication delivery device is considered to be any device that is prescribed and dispensed within the measurement year that was neither dispensed earlier in the measurement year nor in the year prior to the measurement year. Dispensed delivery devices are identified using pharmacy administrative claims. The devices are verified as newly prescribed in the measurement year using medical records. A first-time prescribed and dispensed MDI is one example; another would be changing from a nebulizer to a DPI delivery format.

1.J. Denominator Exclusions

There are several denominator exclusions:

- Children with a diagnosis during the measurement year or the year prior to the measurement year indicating cystic fibrosis or bronchiectasis (Table 2; see Supporting Documents).

- Children who are younger than 6 years of age and have a diagnosis during the measurement year or the year prior to the measurement year indicating bronchopulmonary dysplasia, tracheomalacia, or bronchomalacia (Table 2; see Supporting Documents).

- Children who are 6 years of age or older and have a diagnosis during the measurement year or the year prior to the measurement year indicating bronchopulmonary dysplasia, tracheomalacia, or bronchomalacia (Table 2; see Supporting Documents), unless there is also a diagnosis for an asthma variant listed in Table 1 (see Supporting documents).

- Children with a diagnosis indicating "Exercise induced bronchospasm" (Table 2; see Supporting Documents), unless there is also a diagnosis for an asthma variant listed in Table 1 (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 the leading cause of childhood school absences, emergency department visits, and hospitalizations due to chronic illness (Pedersen, Hurd, Lemanske Jr, et al., 2011). The prevalence of pediatric asthma is currently plateaued (Akinbami, Simon, Rossen, 2016), with approximately 7 million U.S. children under the age of 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, 2011b).

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; the majority of deaths due to asthma occur in individuals aged 65 years and older. However, children do die from asthma. The CDC reported that in 2011, 169 children younger than 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 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 Appropriate Education for Proper Use of New Asthma Medication Delivery Devices

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). Clinical guidelines outlined in the National Asthma Education and Prevention Program's Expert Panel Report-3: Guideline for the Diagnosis and Management of Asthma (NHLBI, 2008) clearly detail steps for diagnosis, classification of disease severity, and appropriate medication management across the lifespan. Inhaled asthma medications are an important aspect of asthma management. The administration of asthma medications through inhalation is advantageous because it allows for direct delivery of medication to the lungs and rapid onset of action, maximizing the desired effects and minimizing potential problems associated with systemic administration (Giraud, Allaert, Roche, 2011). Inhalers are the most common type of medication devices used in asthma treatment; however, there are many asthma medication delivery devices, each requiring different handling and inhalation techniques.

Children have anatomic and physiologic differences that may alter deposition of the medication into the lungs. These characteristics include lower tidal volume (the volume of air inhaled and exhaled during a normal breath) and highly variable breathing patterns (Kwok, Chan, 2014). Asthma medication delivery can be further complicated in the pediatric population when medication has to be administered to uncooperative children (Goralski, Davis, 2014). These difficulties make correct inhalation technique vital, as decreased medication delivery to the lungs results in little or no therapeutic benefit from the treatment. Poor inhalation technique leads to poor asthma control, followed by an increased risk of exacerbations and adverse effects. It is estimated that between 70 and 80 percent of patients do not use their inhalers correctly (Global Initiative for Asthma [GINA], 2014). Understanding device technique is particularly important for young children and their caregivers, as younger patients often need adult help administering their asthma treatments (Reznik, Silver, Cao, 2014).

Instructing patients and caregivers on the proper use of a newly prescribed asthma delivery device is a crucial part of the guideline-based asthma self-management education recommendations that support appropriate care (GINA, 2014; NHLBI, 2008); having patients or caregivers demonstrate appropriate device technique is also important. Guidelines recommend that clinicians demonstrate, review, evaluate, and correct inhalation technique at each visit, because the skills necessary to take asthma medication appropriately deteriorate quickly (GIBA, 2014; NHLBI, 2008). If followed, this teaching process leads to improved control and decreased risk of exacerbations and adverse effects (GINA, 2014), as well as fewer urgent care visits and hospitalizations, reduced asthma-related health care costs, and improved health (NHLBI, 2008). In particular, correct use of inhalation devices by children and adolescents is associated with

improved lung function, reduced school absenteeism, decreased number of days with restricted activities, and fewer visits to emergency departments (Inhaler Error Steering Committee, 2013).

This measure assesses the percentage of children, ages 1 through 17 years, identified as having asthma, regardless of severity, who are prescribed a new medication delivery device and have documentation of the patient or caregiver(s) receiving instruction or demonstration in the proper use of that device. A higher proportion indicates better performance, as reflected by appropriate instruction and use.

Performance Gap

Despite the availability of a wide range of controller medications, many patients have asthma that is poorly controlled (Wechsler, 2014). Factors affecting asthma control include patient adherence issues, health care disparities, and provider prescribing practices. However, even when the medication is in the hands of the patient, there are still barriers to getting it to the lungs. Having an appropriate mechanism for the effective delivery of medication is crucial, regardless of the age of a child. Using an inhaler is a skill that must be learned and maintained in order for medication to be delivered effectively (GINA, 2014). Additionally, inhaled asthma medicines are available in a variety of formats (MDI, DPI, nebulizer) that involve different delivery devices and differing inhalation techniques, which can be confusing for patients. Confusion leads to incorrect use; bad technique results in poorly controlled asthma and higher costs, either as a result of increased morbidity or increased use of relief medication (Inhaler Error Steering Committee, 2013).

Despite tremendous advancements in aerosolized medication technology that have permitted the introduction of more user-friendly devices, studies have shown that inhaler mishandling remains a serious issue for products currently available (Melani, Bonavia, Cilenti, et al., 2011). Technique failure occurs at both the patient and provider levels. Sleath and colleagues demonstrated that only 8.1 percent of children performed all of the metered dose inhaler steps correctly, only 22 percent performed all of the Diskus® (one type of DPI device) steps correctly, and only 15.6 percent performed all of the Turbuhaler® (a different type of DPI device) steps correctly (Sleath, Ayala, Gillette, et al., 2011). The perceived complexity of inhaled medications may lead to discontinuation of the medication, which will further erode asthma control (Chorão, Pereira, Fonesca, 2014).

As for providers, research has shown that clinicians often do not demonstrate or assess inhaler use during pediatric asthma visits (Sleath, et al., 2011). Only 15 percent to 69 percent of health care professionals (across all disciplines) are able to demonstrate correct inhaler use, and the proportion who review inhaler technique over time is even smaller (Inhaler Error Steering Committee, 2013). In a study by Reznik and colleagues (2014), 85 percent of caregivers of children with asthma recalled a physician or nurse demonstrating MDI-spacer technique, but only 54 percent said the provider asked them to show back how they would use the device.

Poor asthma control, whether from adherence issues or improper device technique, leads to increased rates of emergency department visits and hospitalizations, greater health care utilization, and decreased quality of life (Reznik, Jaramillo, Wylie-Rosett, 2014). Assessing whether children with asthma receive instruction in proper use of their asthma medication

devices and whether they can demonstrate correct use will support efforts to improve asthma control in the pediatric population.

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

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 (NHLBI, 2008). 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 care and less on preventive care to deal with asthma (Kim, Kieckhefer, Greek et al., 2009). 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 inhaled corticosteroid (ICS) adherence, as well as high rates of urgent care use; one study found that 65 percent of the children with persistent asthma underuse preventive medication (American Lung Association [ALA}, 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).

Consistently employing guideline-based self-management education, including instruction in and demonstration of asthma medication delivery devices, will increase the number of children receiving appropriate care. This should lead to better controlled asthma, fewer urgent care and emergency department 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).

There currently are no quality measures related to documentation of the patient with asthma or a caregiver being instructed in the proper use of asthma medication delivery devices or documentation of the patient or caregiver demonstrating proper use of that device. This measure does, however, complement already existing measures that require particular activities or educational components to be performed or taught.

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; ages 11 through 17 years.
t. **Population – other (specify age range):** No.
u. **Other category (please specify):** Not applicable.

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

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

5.A. Research Evidence

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

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

This measure focuses on assessing documentation of education in the proper use of a new asthma medication delivery device. Guideline-based care recommends that clinicians demonstrate, review, evaluate, and correct inhaler technique at each visit because these skills can deteriorate rapidly (NHLBI, 2007). Effective asthma medication delivery device technique can improve patient outcomes, including fewer urgent care and emergency department visits, fewer hospitalizations, and better perceived quality of life (NHLBI, 2007). This measure highlights where providers are falling short in offering guideline-based care for children with a diagnosis of asthma. Table 3 (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 the table). The evidence supports initial instruction of appropriate inhalation technique, with repeated checking and instruction at subsequent visits. While reinforcement of education at follow-up visits is very important, this measure focuses on the first prescribing event as a minimum standard. The initial prescription of a new medication device is an important clinical event and is often more in-depth than subsequent checks; thus, it is more likely to trigger documentation.

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 here.

Medical Record Abstraction

Medical record data were obtained through HealthCore, Inc., for the measurement year of 2013. 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 and/or 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 information for approximately 60 million insured individuals between January 2006 and June 2014.

Approximately 205,000 children, newborn through 17 years of age, with an asthma diagnosis and/or symptoms were identified in the HIRD in 2012 (the year prior to the measurement year, per measure specification). Of these, a cohort of 649 children were identified who had a new medication delivery device dispensed in 2013 and met the additional inclusion/exclusion criteria for this measure. A stratified random sample (SRS) 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 designed to minimize the need to make subjective judgments during the abstraction process. In addition, data entered onto a scanner form and subsequently scanned was reviewed through a series of quality checks.

In total, 177 charts were reviewed. Chart review indicated that among these 177 children who were dispensed a new medication delivery device, evidence of prescription of the new

medication delivery device was present in 118 charts. Furthermore, children who turned 18 years of age during the measurement year were excluded, resulting in a final chart population of 116 children with asthma who were prescribed and dispensed a new medication delivery device.

Among the 116 children eligible for the denominator, 94 (81 percent) had a diagnosis of asthma recorded in the medical record for the measurement year. A total of 28 (24.1 percent) children had documentation of either the child or caregiver(s) receiving education in proper use of the device.

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 118 records abstracted for this measure, seven (4 percent) were reviewed for IRR. IRR was assessed by comparing abstractor agreement with a senior abstractor on data elements that could be abstracted for the 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 the 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).

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 panel included nationally recognized experts in asthma, representing the areas of general pediatrics, family practice, pediatric pulmonology, allergy, pediatric hospitalist, asthma education (including Certified Asthma Educators), and general and pediatric emergency medicine. 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 very highly rated, receiving an average score of 7.8 (with 9 as the highest possible score).

Importance of Abstracted Medical Record Data

This measure was 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 both the prescription of a new medication delivery device and education in the proper use of a new medication delivery device cannot be identified using claims, it is necessary to identify these criteria within medical records in order to accurately assess the proportion of children with asthma and a new delivery device who are receiving this integral education. 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.

Patient-Level Sociodemographic Variables

Patient-level demographic and socioeconomic characteristics were generally unavailable from the medical records reviewed for measure testing. Therefore, we used zip code-level 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. The small numbers of eligible denominator and numerator cases (n=116 and n=28, respectively) do not allow for meaningful comparisons across different socio-demographic groups among children identified as having asthma, regardless of severity, who were dispensed a daily controller medication yearly.

7.A. Race/Ethnicity

Race and Ethnicity Census Characteristics

On average, children within the denominator and numerator resided in zip codes reporting primarily white race (77.5 percent and 86.0 percent, respectively) and modest levels of Hispanic ethnicity (12.5 percent and 9.9 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 black, and 16.3 percent was of Hispanic ethnicity at that time. The summary statistics for race and ethnicity within zip codes across the sampled subgroups of children with valid zip codes are reported in Tables 4 and 5 (see Supporting Documents).

7.B. Special Health Care Needs

The medical records data abstracted 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 group and numerator group ($74,544 and $80,199, respectively). The median household income for the zip codes in which these children resided was substantially higher than the median household income of the population of the entire United States, as reported in the 2011 ACS, which was $50,502. The 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 6 (see Supporting Documents).

7.D. Rurality/Urbanicity

Census Characteristics

Children within the denominator and numerator groups primarily reside in urban zip codes (83.3 percent and 70.2 percent, respectively). The proportion of children in this sample who resided in urban zip codes is similar to the rest of the United States, where 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 7 (see Supporting Documents).

7.E. Limited English Proficiency (LEP) Populations

The medical records data abstracted 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 the inclusion and exclusion criteria necessary for this measure. One key element may be as simple as documentation that training was provided with every newly prescribed asthma device.

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 in use currently 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?**
Yes; this measure requires medical record abstraction; medical records are maintained by all health services providers. The target population for sampling requires administrative claims data to identify subgroups of potentially eligible case 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 3 percent of children with a diagnosis of asthma met the criteria for chart abstraction for this measure. Therefore, approximately 6,500 children (200/0.03) 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?**
No

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Not 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?**
No.

Reliability & Validity: **Is there published evidence about the reliability and validity of the measure when reported at this level of aggregation?**
No.

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
Not 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 provides families with a minimum standard of care for pediatric asthma. Low rates for documentation of the patient or caregiver receiving education in the proper use of asthma medication delivery devices 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 in 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 the percentage of children ages 1 through 17 years identified as having asthma, regardless of severity, who are prescribed a new medication delivery device and have documentation of the child or caregiver receiving education in the proper use of the device, relates to the process of asthma care in health maintenance settings and is amenable to alerts and

reminders. Such prompts could provide real-time feedback (at appropriate points in the clinic or home workflow) 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 or symptoms suggestive of asthma 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 education in the proper use of new asthma medication delivery devices for children, information will need to come from submitted claims for visits (using ICD and drug device 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 about education in proper use of these devices will be documented in many different settings. Most often, nursing or respiratory therapist notes might document this education. Occasionally, this instruction will be documented by the primary care provider in his or her note. There are Current Procedural Technology (CPT) codes for instruction, but they are seldom used and virtually never reimbursed.

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)?

Yes.

If yes, please describe.

The ONC's Health IT Standards explicitly address the receipt of laboratory results and other diagnostic tests into EHRs, which are directly relevant to this measure. 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:

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 reduction of disparities outreach is specifically addressed:

"Enable a user to electronically select, sort, retrieve, and output a list of patients and patients' clinical information, based on user-defined demographic data, medication list, and specific conditions."

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:

- Child's date of birth.
- ICD-9-CM or ICD-10-CM codes selected to indicate an asthma diagnosis.
- Type of asthma medication and associated delivery device.
- Charting to indicate a device was not prescribed in the year prior to the measurement year.
- CPT codes to identify visit type.
- Date and time of treatment.
- Dates of insurance coverage.
- Documentation in the medical record indicating instruction and demonstration of device use occurred during outpatient visit.
- 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?

See item 11.A, 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, ages 1 through 17 years with asthma, regardless of severity, who are prescribed and dispensed a new medication delivery device and have documentation of the child or caregiver receiving education in proper use of the device. For the purposes of this measure, education in proper use is defined as verbal instruction, education, and/or demonstration. A higher proportion indicates better performance, as reflected by appropriate education.

Limitations to this measure exist. First, although the specification required documentation of education, there is no information on the quality of education provided to the caregiver and/or child. In addition, this measure did not cover repeated education to the caregiver and/or child, which is a more ideal behavior recommended in national and international guidelines. Eligible cases are identified based on dispensing events through pharmacy claims. This specification will miss dispensing events that occur in the inpatient setting or in the outpatient setting in the absence of an insurance claim (e.g., donated or sample medications or devices). This measure does not address the appropriateness of a prescribed medication delivery device for a particular patient (e.g., DPIs 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).

Lack of standardization in medical record documentation between health care providers could have resulted 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.

Pediatric asthma is the most common chronic disease of childhood and the leading cause of childhood school absences, emergency department 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 process. However, correct inhalation technique is vital, as decreased medication delivery to the lungs results in little or no therapeutic benefit from the treatment. This leads to poor asthma control and an increased risk of exacerbations and adverse effects. The number of patients with correct inhalation technique is suboptimal; therefore, guidelines recommend that clinicians demonstrate, review, evaluate, and correct inhaler technique at each visit, as the skills necessary to take asthma medication appropriately deteriorate quickly. Assessing whether children with asthma or their caregivers receive education in proper use of their asthma medication devices and can demonstrate correct use will support efforts to improve asthma control in the pediatric population.

This measure was tested among a total of 116 children, ages 1 through 17 years, with a diagnosis of asthma, who were prescribed and dispensed a new medication delivery device. Among these children, 28 (24.1 percent) had documentation of the child or caregiver receiving education in the proper use of the device. This measure provides families, providers, and purchasers with a minimum standard of care to assess how well comprehensive care is managed in children with asthma. The primary information needed for this measure includes basic demographics, dates, diagnostic codes, and drug device codes, all of which are widely available. Continuing advances in the development and implementation of health IT may establish the feasibility of regularly implementing this measure with data supplied by electronic medical records.

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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.