Appropriate Antibiotic Prophylaxis for Children with Sickle Cell Disease

Section 1. Basic Measure Information

1.A. Measure Name

Appropriate Antibiotic Prophylaxis for Children with Sickle Cell Disease

1.B. Measure Number

0138

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 between the ages of 3 months and 5 years diagnosed with sickle cell disease (SCD) who receive appropriate antibiotic prophylaxis during the measurement year. Preventive (prophylactic) antibiotics markedly reduce the risk of life-threatening infections for children with SCD in this age group. This measure is implemented with administrative claims data and is calculated as two rates: (1) the percentage of children who received preventive antibiotics for at least 300 days and (2) the percentage who received antibiotics for 350 days or more.

Spleen damage is a common and crucial characteristic of SCD: a damaged spleen cannot effectively clear bacteria from the blood, leaving SCD patients, particularly young children, highly susceptible to infection. Children with SCD experience rates of infection caused by the bacterium *Streptococcus pneumoniae* 30-100 times as frequently as children without SCD. Pneumococcal vaccines are of limited effectiveness in this age group because of lowered antibody response. However, twice-daily doses of an antibiotic sharply reduce the incidence of *S. pneumoniae* disease in children with SCD.

Studies have shown that children with SCD who are enrolled in Medicaid frequently are not dispensed antibiotics soon enough or in sufficient quantities to cover ongoing twice-daily use. Sometimes these children receive no antibiotics at all, even though this simple preventive measure greatly reduces their risk of contracting debilitating and often deadly infections. Clinical guidelines and the results of randomized controlled trials indicate that providers should prescribe appropriate antibiotic prophylaxis to children with SCD who are under 5 years of age. There are no existing quality measures for antibiotic prophylaxis in children with SCD.

1.D. Measure Owner

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

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

NQF ID #3166.

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 Sickle Cell Disease 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 Sickle Cell Disease Administrative Claims 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 between the ages of 3 months and 5 years with SCD who receive appropriate preventive antibiotics during the measurement year. Two rates are reported:

1. The percentage of eligible children who received antibiotics for at least 300 days, as determined by administrative record review.
2. The percentage of eligible children who received antibiotics for at least 350 days, as determined by administrative record review.

Eligible children are 90 days or older on January 1 of the measurement year but younger than 5 years on December 31 of the measurement year. They must be continuously enrolled in Medicaid. To be eligible, a child must have had an appropriate SCD-related ICD-9 code on three or more separate health care encounters during the measurement year (Table 1, see Supporting Documents). The designated ICD-9 codes are for sickle cell anemia, which is the most severe form of SCD. Evidence of antibiotic prophylaxis is determined through administrative records for pharmacy prescriptions filled (Table 2, see Supporting Documents).

1.H. Numerator Exclusions

Claims in the administrative records for any of the SCD variants listed in Table 3 do not count toward the "three or more separate health care encounters" criteria.

1.I. Denominator Statement

The eligible population comprises children aged 90 days or older on January 1 of the measurement year but younger than 5 years on December 31 of the measurement year who were continuously enrolled in Medicaid and received an appropriate SCD-related ICD-9 code on three or more separate health care encounters during the measurement year (Table 1, see Supporting Documents).

1.J. Denominator Exclusions

Claims in the administrative records for any of the SCD variants listed in Table 3 (see Supporting Documents) do not count toward the "three or more separate health care encounters" criteria.

1.K. Data Sources

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

Administrative data (e.g., claims data).

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 the detailed measure specifications, a flowchart for the measure, SAS code, and a full listing of antibiotics.

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).**

Sickle Cell Disease Prevalence and Incidence

SCD is one of the most common genetic disorders in the United States (Kavanagh, Sprinz, Vinci, et al., 2011). The National Heart, Lung and Blood Institute estimates that 2,000 infants are born with SCD in the United States each year (National Heart, Lung, and Blood Institute [NHLBI], 2002). SCD affects 70,000-100,000 children and adults in the United States, predominantly those of African and Hispanic descent (Hassell, 2010).

Sickle Cell Disease Pathology and Severity

Vaso-occlusion (the sudden blockage of a blood vessel caused by the sickle shape of abnormal blood cells) is responsible for most complications of SCD, including pain episodes, sepsis, stroke, acute chest syndrome, priapism, leg ulcers, osteonecrosis and renal insufficiency (Steinberg, 1999). In addition, SCD can have hemolytic and infectious complications that result in morbidity and mortality in children with the condition (Kavanagh, et al., 2011).

Sickle Cell Disease Burden in Daily Life

The effect of SCD on children and families is significant; severe pain episodes and hospitalizations restrict daily activities and reflect negatively on school attendance and performance, as well as on sleep and social activities (Alvim, Viana, Pires, et al., 2005; Lemanek, Ranalli, Lukens, 2009). Although medical management of SCD continues to improve over time, 196 children in the United States died from SCD-related causes between 1999 and 2002 (Yanni, Grosse, Yang, et al., 2009).

Sickle Cell Disease Cost

In a study of health care utilization among low income children with SCD between 2004 and 2007, 27 percent of these children required inpatient hospitalization, and 39 percent used emergency care during a year. Of these children, 63 percent averaged one well-child visit per year, and 10 percent had at least one outpatient visit with a specialist (Raphael, Dietrich, Whitmire, et al., 2009). Patients with SCD use many parts of the health care system, incurring significant costs. In 2009, mean hospital charges for children with SCD and a hospital stay were $23,000 for children with private insurance and $18,200 for children enrolled in Medicaid (Agency for Healthcare Research and Quality [AHRQ], 2012). Kauf and colleagues estimate the lifetime cost of health care per patient with SCD to be approximately $460,000 (Kauf, Coates, Huazhi, et al., 2009).

In a study of health care utilization among low income children with SCD between 2004 and 2007, 27 percent of these children required inpatient hospitalization, and 39 percent used emergency care during a year. Of these children, 63 percent averaged one well-child visit per year, and 10 percent had at least one outpatient visit with a specialist (Raphael, et al., 2009). Patients with SCD use many parts of the health care system, incurring significant costs. In 2009, mean hospital charges for children with SCD and a hospital stay were $23,000 for children with private insurance and $18,200 for children enrolled in Medicaid (AHRQ, 2012). Kauf and colleagues estimate the lifetime cost of health care per patient with SCD to be approximately $460,000 (Kauf, et al., 2009).

Outcomes of Timely and Appropriate Antibiotic Prophylaxis for Children with Sickle Cell Disease

Prompt initiation and consistent use of antibiotics in young children with SCD increases survival rates through the prevention of overwhelming bacterial infections (NHLBI, 2002). Because sickle cells obstruct blood flow to the spleen, splenic function is compromised, leading to susceptibility to bacterial infections (NHLBI, 2002). Meningitis, pneumonia, and sepsis are major causes of death in children with SCD, and pneumococcal sepsis is known to progress from the onset of fever to death in fewer than 12 hours (Gaston, Verter, Woods, et al., 1986). Given

that the highest rate of infection occurs in children with SCD under the age of 3 years (Hirst, Owusu-Ofori, 2010), NHLBI guidelines recommend that infants identified through newborn screening as having SCD should be started on daily prophylactic penicillin as early as possible and remain on preventive antibiotics until age 5 years (NHLBI, 2002). (For children unable to tolerate penicillin, erythromycins may be prescribed.) The Prophylactic Penicillin Study (PROPS), a randomized, double-blind, multicenter trial initiated in 1983 by the NHLBI, demonstrated an 84 percent reduction in the risk of sepsis in children with SCD who took penicillin daily. The trial was ended 8 months early, as 13 of 110 patients in the placebo group developed pneumococcal sepsis compared with 2 of 105 in the treatment arm (Gaston, et al., 1986). Results from PROPS II in 1995 showed no significant increased risk of infection when daily penicillin prophylaxis was ended for children over the age of 5 years (Hirst, Owusu-Ofori, 2010).

This measure indicates appropriate antibiotic prophylaxis to prevent life threatening infections in children between 3 months and 5 years of age. The measure does not change across developmental stages.

Performance Gap – Prophylactic Antibiotics

In one study, children with SCD and enrolled in Medicaid were dispensed, on average, enough prophylactic medication to cover only 40 percent of the study year (Sox, Cooper, Koepsell, et al., 2003). Approximately 22 percent of children received medication to cover more than 270 days, but about 43 percent received 90 days of medication or less, and 10 percent of children received no antibiotics at all. These findings show a clear performance gap in the daily provision of prophylactic antibiotics to children with SCD.

In a study of 248 pediatricians regarding their knowledge and adherence to sickle cell guidelines, 97 percent of pediatricians correctly answered questions about the necessity of antibiotics for children with SCD, yet only 66 percent of pediatricians reported prescribing prophylactic antibiotics for 100 percent of their patients with SCD (Wurst, Sleath, 2004). Although pediatricians understand the necessity of prophylactic antibiotics for children with SCD, they do not always prescribe them as recommended.

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).**

Sickle Cell Disease and Medicaid/CHIP

This measure is relevant to Medicaid because the majority of children with SCD are also enrolled in Medicaid. In 2009, 67 percent of children with SCD discharged from the hospital were enrolled in Medicaid, while 25 percent had private insurance (AHRQ, 2012). Furthermore, several studies have pointed to disparities in prophylactic medication use among patients with public versus private insurance. In a study of children with SCD on Medicaid in Washington State and Tennessee, 10.3 percent of patients with public insurance received no antibiotics during a 365-day period and only 21.5 percent received more than 270 days of medication in a year. Median duration of prescriptions was 10 days (Sox, et al., 2003). In a 10-year retrospective cohort study of 407 infants enrolled in the Tennessee Medicaid program, 60 percent of infants with SCD did not have prophylactic antibiotic prescriptions filled within the recommended period (i.e., the first 12 weeks of life) (Warren, Arbogast, Dudley, et al., 2010). A study assessing compliance with penicillin prophylaxis for SCD found that compliance among patients with public insurance was only 37 percent (Teach, Lillis, Grossi, 1998). This measure would encourage continuous antibiotic prophylaxis for all children with SCD between the ages of 3 months and 5 years, a step that the literature documents is of urgent concern to those covered through Medicaid.

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 are no quality measures for the diagnosis, assessment, or treatment of pediatric SCD.

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:** Yes.
c. **Care Setting – other – please specify:** No.
d. **Service – preventive health, including services to promote healthy birth:** Yes.

e. **Service – care for acute conditions:** No.
f. **Service – care for children with acute 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):** Yes; children ages 90 days to 1 year.
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):** No.
s. **Population – adolescents (11 years through 20 years) (specify age range):** No.
t. **Population – other (specify age range):** No.
u. **Other category (please specify):** 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 a clinical process (appropriate antibiotic prophylaxis), that if followed, results in a desirable clinical outcome (reduced rate of infection among children between 3

months and 5 years of age with SCD). The measure highlights where providers or health systems are falling short in providing this essential element of care.

The body of evidence addresses the effect of appropriate antibiotic prophylaxis in children under 5 years of age with SCD in comparison to no provision of antibiotics. Overall, clinical guidelines and the results of randomized controlled trials indicate that providers should prescribe appropriate antibiotic prophylaxis to children with SCD who are under 5 years of age. Table 4 (see Supporting Documents) summarizes several key sources of evidence for this measure, using the U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted in table; see also https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions).

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.

In patients with SCD, the mortality rate for infection is highest in the first 5 years of life, with the greatest period of risk occurring between 6 months and 1 year. Because compromised splenic function in children with SCD permits bacterial infections to become overwhelming, meningitis, pneumonia, and sepsis can escalate quickly into potentially deadly illnesses. Daily antibiotic prophylaxis, initiated as early as possible in infants with SCD and continued daily until the child is 5 years old, reduces the patient's susceptibility to serious infection (Gaston, et al., 1986; Falletta, Woods, Verter, et al., 1995; Hirst, Owusu-Ofori, 2009; NHLBI, 2002).

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 is based on administrative claims data. Therefore, reliability testing of this measure was conducted from several perspectives, as described below.

Data/Sample

Our sample consisted of six States with a moderate-to-high prevalence of SCD: Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas. Q-METRIC tested this measure using a sample drawn from 5 consecutive years of Medicaid Analytic eXtract (MAX) administrative claims data provided by the Centers for Medicare & Medicaid Services (CMS). The measure was implemented using MAX data for each State to evaluate consistency of results for the most current 5-year period for which MAX data were available. This measure was tested as specified, which requires the assessment among the entire population of children with SCD between the ages of 3 months and 5 years within the measurement year. This measure does not involve sampling within States; all SCD cases are included in the measure specification.

For two States (Michigan and Illinois), additional samples of administrative claims were obtained directly from the respective State Medicaid programs to evaluate the reliability of using MAX administrative data for this measure. In addition, we conducted a medical record review in Michigan to evaluate the coding reliability and accuracy of Medicaid administrative claims for antibiotic prescriptions.

MAX Medicaid Administrative Claims

Results for the measures when tested in the six States are shown in Table 5 (see Supporting Documents). This measure is implemented as two proportions, one for a 300-day period of antibiotic use and another for a 350-day period. For the first proportion (300 days), prescription of antibiotics ranged widely; the highest percentage achieved across all States in the 5-year period was 32.9 percent in Illinois (2007), and the lowest percentage was 4.6 percent in South Carolina (2009). Ranges within States across the 5-year period for the highest and lowest percentages for the 300-day proportion were as follows: Florida (13.2 percent vs.9.7 percent), Illinois (32.9 percent vs. 21.8 percent), Louisiana (27.7 percent vs. 12.2 percent), Michigan (18.9 percent vs. 6.4 percent), South Carolina (20.3 percent vs. 4.6 percent), and Texas (28.3 percent vs. 17.5 percent). In five of the six States, rates for meeting the measure generally declined over the 5-year period (Figure 1; see Supporting Documents), which may suggest concerns about data completeness for MAX prescription data in more recent years.

For the second, more stringent proportion (350 days), the highest and lowest percentages among the six States for the 5-year period were also observed in Illinois (17.1 percent in 2006) and South Carolina (0.0 percent in 2008). Ranges within States for the highest and lowest percentages for the 350- day rate were as follows: Florida (5.2 percent vs.1.5 percent), Illinois (17.1 percent vs. 4.0 percent), Louisiana (13.1 percent vs. 5.1 percent), Michigan (7.6 percent vs. 0.9 percent), South Carolina (8.5 percent vs. 0.0 percent), and Texas (14.1 percent vs. 9.1 percent).

Most States (five) generally trended downward across the 5-year period (Figure 2; see Supporting Documents), which again may be indicative of data completeness issues for MAX prescription data in more recent years.

Claims Acquired Directly from Medicaid Programs

This measure was also tested using administrative claims acquired from Michigan and Illinois directly from their respective Medicaid programs. In Michigan, data were available for the 2007-2009 period corresponding with a subset of the MAX data availability. Figure 3 (see Supporting Documents) illustrates that for the 300 day proportion, the Michigan Medicaid claims results parallel the MAX results and reflect a somewhat higher value for each year observed. The 350-day proportion results for Michigan Medicaid are also higher than the MAX values for each year, and the difference increases over the observed period (Figure 4; see Supporting Documents). Illinois data were available for 2010-2011, although MAX data were not available at the time of testing to evaluate comparability with data acquired directly from the Illinois Medicaid program. Using these data, we were able to demonstrate the feasibility of implementing this measure, although direct comparisons to Illinois MAX data were not made given the different time periods. Using the data acquired directly from the Illinois Medicaid program, for the 300-day measure we found 15.7 percent of children with SCD had an antibiotic prescription, whereas for the 350-day measure the proportion was 7.2 percent.

Medical Record Chart Abstraction

A subset of cases was identified from the Michigan Medicaid claims data, and a chart audit was conducted by trained medical record abstractors to compare administrative data with the corresponding medical record. We conducted a medical chart audit for cases identified in Michigan Medicaid claims for care provided at the three largest centers serving SCD patients in Michigan during 2012: Children's Hospital of Michigan (Detroit), Hurley Medical Center (Flint), and the University of Michigan Hospital and Health System (Ann Arbor).

The reproducibility of our results based on claims data was supported by medical record review. We found that the Medicaid administrative claims have a high degree of agreement for antibiotic prescriptions recorded in medical records. We considered claims within 1 month to accommodate for the difference between the prescription date in the medical record versus the actual prescription fill date recorded in claims. Among the 35 SCD cases eligible for review for this measure, 34 (97 percent) of cases identified through medical record review were successfully matched with Michigan Medicaid administrative claims data; the one case that could not be matched did not have a Medicaid ID. Among the 34 eligible cases, 25 cases (76 percent) had a Medicaid administrative claim for an antibiotic prescription filled within 29 days of the prescription date in the medical record. An additional seven cases (21 percent) had an antibiotic prescription filled between 30 but less than 90 days following the prescription date. One case (3 percent) had an antibiotic prescription claim filled 90 or more days after the prescription date in the medical record.

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 data element 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 advocates for families of children with SCD convened by Q-METRIC. The Q-METRIC expert panel included nationally recognized experts in SCD, representing hematology, pediatrics, and SCD family advocacy. 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 SCD panel included 14 experts, providing a comprehensive perspective on SCD management and the measurement of quality metrics for States and health plans.

The Q-METRIC expert panel concluded that this measure has a very high degree of face validity through a detailed review of concepts and metrics considered to be essential to effective SCD management and treatment. Concepts and draft measures were rated by this group for their relative importance. This measure was among the most highly rated, receiving an average score of 8.5 (with 9 as the highest possible score).

Validity of Coded Data

This measure is based on administrative claims data; therefore, the validity of the coded data reported in Medicaid claims was assessed through a medical record review. A subset of SCD cases was identified from Michigan Medicaid claims data, and a chart audit was conducted by trained medical record abstractors to compare administrative data with the corresponding medical record. We conducted a medical chart audit for cases identified in Michigan Medicaid claims for care provided at the three largest centers serving SCD patients in Michigan during 2012: Children's Hospital of Michigan (CHM, Detroit), Hurley Medical Center (HMC, Flint), and the University of Michigan Hospital and Health System (UMHS, Ann Arbor).

Our review indicates that the Medicaid administrative claims have a high degree of agreement with antibiotic prescriptions recorded in medical records abstracted from CHM, HMC, and UMHS. We considered claims within 1 month of the prescription date to accommodate for lags between the date in the medical record indicating that the antibiotic was prescribed versus the actual prescription fill date recorded in claims. Among the 35 SCD cases eligible for review for this measure, 34 (97 percent) of cases identified through medical record review were successfully matched with Michigan Medicaid administrative claims data (Table 6; see Supporting Documents); the one case that could not be matched was not enrolled in Medicaid (i.e., did not have a Medicaid ID). Sensitivity was high for identifying antibiotic prescription events using Medicaid administrative claims data; 30/34 (88 percent) of antibiotic prescriptions from the medical record review had a Medicaid administrative claim for an antibiotic within 1 month of the prescription date in the medical record. The positive predictive value of a Medicaid claim for an antibiotic prescription event was 100 percent (30/30). All eligible cases identified in the medical records had an antibiotic prescription recorded; consequently, the specificity could not be calculated (i.e., undefined due to division by zero).

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

Q-METRIC summarized demographic data available for children diagnosed with SCD from the six States in which this measure was tested using MAX data (Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas).

SCD is largely concentrated among African Americans. Table 7 (see Supporting Documents) summarizes the distribution in children across race and ethnicity groups in each of the six States included in our testing.

7.B. Special Health Care Needs

The MAX Medicaid administrative claims data do not include indicators of special health care needs.

7.C. Socioeconomic Status

The MAX Medicaid administrative claims data do not include indicators of socioeconomic status.

7.D. Rurality/Urbanicity

The MAX Medicaid administrative claims data do not include indicators of urban/rural residence.

7.E. Limited English Proficiency (LEP) Populations

The MAX Medicaid administrative claims data 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 is implemented with administrative claims data. The primary information needed for this measure includes date of birth, diagnosis codes, and prescription drug records. These data are widely available from CMS via the Research Data Assistance Center (ResDAC; http://www.resdac.org/about-resdac), where MAX data may be secured. For single-State comparisons, data may also be available directly from Medicaid agencies in some States.

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?

This measure was determined to be feasible by Q-METRIC using MAX administrative claims data for six States with moderate to high levels of SCD prevalence. The timeliness of the data needed for this measure will likely improve, as significant initiatives are underway nationally that will greatly increase the use of electronic health record (EHR) systems by the primary care providers and specialists who treat children with SCD. As a result, the timely reporting of antibiotic prescriptions for children with SCD to Medicaid administrative systems will likely improve in the near future.

For example, e-prescribing systems using a controlled terminology for generic and brand name medications will allow easy access to medication prescription orders and fill status from pharmacies. Consequently, prescriptions for antibiotics to children with a diagnosis of SCD will be available electronically in real time. These results can be reported through health information exchange (HIE) technologies that are rapidly becoming operational throughout the United States. HIEs will enable the reporting of e-prescriptions for antibiotics among children with SCD to appropriate State public health departments. In States where this reporting already exists through other methods, the HIE reporting will enable improvements to the timeliness and completeness of these events being reported from physician practices.

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.

This measure is not currently in use in the six States in which Q-METRIC testing was conducted. We do not believe it is being used in any State.

2. If the measure has been used or is in use, what methods, if any, have already been used to collect data for this measure?

Not applicable.

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

Not applicable.

Section 9. Levels of Aggregation

CHIPRA states that data used in quality measures must be collected and reported in a standard format that permits comparison (at minimum) at State, health plan, and provider levels. Use the following table to provide information about this measure's use for reporting at the levels of aggregation in the table.

For the purpose of this section, please refer to the definitions for provider, practice site, medical group, and network in the Glossary of Terms.

If there is no information about whether the measure could be meaningfully reported at a specific level of aggregation, please write "Not available" in the text field before progressing to the next section.

Level of aggregation (Unit) for reporting on the quality of care for children covered by Medicaid/ CHIP†:

State level* Can compare States

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
Yes.

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

Sample Size: **What is the typical sample size available for each unit at this level? What proportion of units at this level of aggregation can achieve an acceptable minimum sample size?**
In each State, all children between the ages of 3 months and 5 years identified in at least three health care encounters as having SCD, according to designated ICD-9 codes.

In Use: **Have measure results been reported at this level previously?**
No.

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

Unintended consequences: **What are the potential unintended consequences of reporting at this level of aggregation?**
None identified; this is the level at which (Medicaid) administrative claims data for SCD are collected and maintained in the United States.

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?**
No.

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

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.

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?**
No.

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

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.

Health plan*: Can compare quality of care among health plans.

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
No.

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

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?**
No.

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

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
Hospital: Can compare hospitals

Intended use: **Is measure intended to support meaningful comparisons at this level? (Yes/No)**
No.

Data Sources: **Are data sources available to support reporting at this level?**
No.

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

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?**
No.

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

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.

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 parents with an intuitive gauge of antibiotic protection among children with SCD. Low rates are easily understood to be unsatisfactory. Likewise, the simplicity of the measure makes it a straightforward guide for providers and plans to assess comprehensive protection against pneumonia and other serious bacterial infections in young children (ages 3 months to 5 years) with SCD.

This measure has not been assessed for comprehension. The primary information needed for this measure comes from Medicaid administrative claims data and includes date of birth, diagnostic codes, and prescription drug records. This information is generally available as demonstrated by Q-METRIC testing using both MAX data and data acquired directly from State Medicaid programs.

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.

It is anticipated that major enhancements will come through the availability of home-based medication management tools that could be used to monitor antibiotic administration to children with SCD. There are numerous mobile device apps now available that record the administration

of medication doses using a controlled terminology for generic and brand medications. As a consequence, these tools will enable a diary for self-reporting the administration of doses and would likely be the most accurate data to use for this measure. Less accurate, though perhaps more feasible today, is the use of prescription fill data from Surescripts or similar prescription relay messaging services (Grossman, Cross, Boukus, et al., 2012; Joseph, Sow, Furukawa, et al., 2013). This system will provide an actual prescribed medication, date, and prescribers' signature; this information will serve as an accurate marker for the timeliness and duration of prescribed medications. However, these data will not furnish information regarding whether the child ever received the medication as prescribed; a proxy for this may be obtained through multiple successive fills, which may be an indicator of medications being used.

Importantly, the accuracy of this measure hinges on the completeness of antibiotic prescriptions for individual patients in a given jurisdiction. The measure was tested at the State level and assumes a complete, centralized source of administrative claims data for children with SCD. Although individual providers will increasingly have access to information within their respective EHR systems for children with SCD, the completeness of prescription/medication fills within their respective EHRs may be limited by interoperability with other providers' EHRs that may likewise capture antibiotic prescription events for these patients. This interoperability will be influenced by HIE technologies that are rapidly becoming operational throughout the United States. HIEs will enable the comprehensive reporting of e-prescription information for antibiotics among children with SCD to appropriate State public health departments. In States where this reporting already exists through other methods, the HIE reporting will enable improvements to the timeliness and completeness of these events being reported from physician practices.

11.B. Health IT Testing

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

Yes.

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

This measure was tested using Medicaid administrative claims data acquired from the MAX data, as well as directly from State Medicaid programs.

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.

The information for this measure is already captured by existing EHR systems. Children with SCD could be identified by patient lists maintained in EHRs for patients with chronic conditions. From this group of cases, the EHR will have data from documented prescriptions that will identify the percentage of patients who were prescribed prophylactic antibiotics. This number will be refined by using fill data to identify the percentage of patients who picked up a prescription for these antibiotics and by home administration data (the most difficult part of this measure) to identify patients who received the antibiotics.

11.D. Health IT Standards

Are the data elements in this measure supported explicitly by the Office of the National Coordinator for Health IT Standards and Certification criteria (see healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_ifr/1195)?

Yes.

If yes, please describe.

The ONC's Health IT Standards explicitly address the receipt of electronic prescribing information into EHRs, which is directly related to the measurement of the timeliness and appropriateness (duration) of antibiotic prescriptions for children with SCD. We have taken into account these electronic prescribing standards and ensured that our standards are consistent with them.

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 will lead to missing cases or calculation errors:

1. Child's date of birth.
2. ICD-9 codes selected to indicate sickle cell anemia.
3. Date of prescription.
4. Type of medication (antibiotic).

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?

Implementation of an order entry system will allow easy access to date and type of antibiotic prescription. Orders will facilitate knowing the medication and dosing regimen prescribed for prophylactic antibiotics; additional technologies, such as receiving RxFILL data and patient-reported medication adherence data using new technologies like personal health records, would greatly enhance measure accuracy.

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 between the ages of 3 months and 5 years with SCD, identified through designated ICD-9 codes, who received appropriate antibiotic prophylaxis during the measurement year.

This measure is implemented with Medicaid administrative claims data. The primary information needed for this measure includes date of birth, diagnosis codes, and prescription drug records. These data are widely available, either from CMS (MAX data) or directly from State Medicaid agencies. However, our testing suggests that data completeness issues may exist for MAX prescription data in more recent years, thereby potentially understating the proportions for this measure. Another possible limitation is that the assignment of ICD-9 codes for SCD is highly variable among institutions. At the State level, community health departments may have the appropriate infrastructure and support to acquire these data directly.

Q-METRIC testing determined that this measure can be addressed using existing administrative claims data systems. It should be noted that at present, some children with SCD may receive antibiotics at no cost; consequently, it is unclear whether the dispensing pharmacies track those events using electronic prescribing mechanisms that result in a claim record being generated.

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, Appropriate Antibiotic Prophylaxis for Children with Sickle Cell Disease, assesses the percentage of children diagnosed with SCD who receive daily preventive (prophylactic) antibiotics between the ages of 3 months and 5 years. Preventive antibiotics reduce the risk of life-threatening infections for children with SCD in this age group. This measure provides an intuitive measure of antibiotic protection and encourages appropriate prescribing for children under the age of 5 years with SCD, a step that the literature documents is of urgent concern for those covered through Medicaid.

Currently, there are no quality measures for the diagnosis, assessment, or treatment of pediatric SCD. Yet SCD is one of the most common genetic disorders in the United States, and its impact among children is great. In patients with SCD, the mortality rate is highest in early childhood, and infancy is a period of especial risk. Splenic damage can occur early in children diagnosed with SCD, affecting their ability to resist infections and leaving them at risk for sudden debilitating illnesses and even death. Prompt initiation of antibiotic prophylaxis in infants and continued use in young children dramatically increases survival rates through the prevention of overwhelming bacterial infections.

The Q-METRIC SCD expert panel established a high degree of face validity for this measure, and reliability was supported by medical record review. In Michigan, Medicaid administrative

claims have a high degree of agreement for antibiotic prescriptions recorded in medical records, with 97 percent of cases identified through medical record review successfully matched with Michigan Medicaid administrative claims data. Validation testing also demonstrated high sensitivity for identifying antibiotic prescription events; 88 percent of antibiotic prescriptions from the Michigan medical record review had a Medicaid administrative claim for an antibiotic within 1 month of the prescription date in the medical record. The positive predictive value of a Medicaid claim for an antibiotic prescription event was 100 percent.

Testing results for the measure, which is implemented as two proportions, varied when calculated using MAX data from Florida, Illinois, Louisiana, Michigan, South Carolina, and Texas. For the 300-day rate, the highest percentage achieved across all States in a 5-year period was 32.9 percent in Illinois (2007); the lowest percentage was 4.6 percent in South Carolina (2009). For the 350-day rate, the highest and lowest percentages were also observed in Illinois (17.1 percent in 2006) and South Carolina (0.0 percent in 2008).

With the exception of Louisiana, rates for both proportions generally declined over the 5-year period. This trend may suggest concerns about data completeness for MAX prescription data in more recent years. And even the best result achieved (32.9 percent) suggests the great majority of young children with SCD are not receiving these simple, but life-saving prescriptions for daily antibiotics.

In general, administrative claims data are widely available, but access may improve further in the short term with the implementation of e-prescribing programs that will routinely route prescription information into the EHR systems of the primary care providers and specialists who treat children with SCD.

This measure is relevant to Medicaid, as the majority of children with SCD are also enrolled in Medicaid. Several studies have pointed to disparities in prophylactic medication use for SCD among young patients with public versus private insurance. Frequently, children with SCD who are enrolled in Medicaid are not dispensed medication soon enough or in sufficient quantities to cover ongoing daily use of an antibiotic; sometimes they receive no antibiotics at all.

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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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