

Protocol for Identifying and Treating Children with Sepsis Syndrome in the Emergency Department

Section 1. Basic Measure Information

1.A. Measure Name

Protocol for Identifying and Treating Children with Sepsis Syndrome in the Emergency Department

1.B. Measure Number

0228

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 proportion of hospitals with a specific written protocol to identify and treat children with sepsis syndrome in the emergency department (ED).

Sepsis is a potentially catastrophic condition that can escalate from infection to organ failure and death within hours. While mortality rates for pediatric sepsis have decreased over time, 4 percent-10 percent of hospitalized children with sepsis in the United States die (Odetola, Gebremariam, Freed, 2007; Watson, Carcillo, Linde-Zwirble, et al., 2003). Also, annual hospital treatment costs are significant, at nearly \$2 billion (Watson, et al., 2003). Clinical practice parameters and clinical guidelines for the treatment of children with sepsis syndrome emphasize the critical importance of early recognition and aggressive treatment for all suspected cases (Carcillo, Fields, et al., 2002; Dellinger, Levy, Rhodes, et al., 2013). Improved survival has been associated with adherence to guidelines that emphasize time-sensitive resuscitation of children with sepsis syndrome (Han, Carcillo, Dragotta, et al, 2003). Whether a child presents to an academic medical center or to a community hospital, clinicians must be ready to rapidly deploy a set of time-sensitive, goal-directed, step-wise procedures to hinder or reverse the cascade of events in sepsis that lead to organ failure and death.

One fundamental element of timely and appropriate treatment is a sepsis management protocol. Based on clinical guidelines and research-driven data, instructions within the protocol provide a set of consistent steps to help clinicians in the ED recognize sepsis syndrome in pediatric patients and promptly initiate evidence-based interventions—such as fluid resuscitation and antibiotics—that are likely to hinder the occurrence of, or reverse progression to, septic shock. Protocols support immediate, consistent, and appropriate treatment, regardless of care setting. They also help institutions centralize resources for very sick patients, foster acceptable levels of competence for the skills necessary to provide successful treatment, and produce uniform data amenable to useful comparison and analysis (Cruz, Perry, Williams, et al., 2011; Dellinger, et al., 2013; Larsen, Mecham, Greenberg, 2011; Rivers, Ahrens, 2008). Despite the clear value of such

protocols, however, many hospitals lack them, undermining the ability of ED staff to quickly identify and effectively treat children with sepsis syndrome.

This measure uses facility survey data to calculate the proportion of hospitals with a specific written protocol to identify and treat children with sepsis syndrome in the ED.

1.D. Measure Owner

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

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

Not applicable.

1.F. Measure Hierarchy

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

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

This measure is part of the Q-METRIC Sepsis 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.**

Not applicable.

- 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 represents the number of hospitals with a specific written protocol to identify and treat children with sepsis syndrome in the ED. A written protocol is defined as any paper or electronic protocol with any mention of “sepsis” and either “children” or individuals younger than 19 years of age. Sepsis syndrome is defined in Table 1 (see Supporting Documents). Codes to identify sepsis syndrome diagnoses are documented in Table 2 (see Supporting Documents).

1.H. Numerator Exclusions

None.

1.I. Denominator Statement

The eligible population for the denominator is all hospitals with an ED.

1.J. Denominator Exclusions

None.

1.K. Data Sources

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

Health care professional report.

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.

Detailed measure specifications are available; see Supporting Documents.

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).**

Importance

Sepsis is a complex, systemic response to invasion by a pathogen that can progress to impaired blood flow and organ dysfunction (Skippen, Kisson, Waller, et al., 2008). Septic shock in children is a life-threatening illness that requires immediate recognition and rapid treatment (Han, et al., 2003).

Sepsis Prevalence and Incidence

While sepsis-associated mortality in children has declined in recent years, from 97 percent in infants in 1966 to 9 percent in the early 1990s, it remains a major cause of morbidity and mortality among children (Watson, Carcillo, Linde-Zwirble, et al., 2003). The incidence of pediatric sepsis was estimated in 1995 to be 0.56/1,000 children, with the highest prevalence in infancy at 5.6/1,000 children; boys had a higher incidence compared with girls (0.60 vs. 0.52 per 1,000 infants) (Watson, et al., 2003). Sepsis prevalence tends to have two peaks during childhood. The first peak occurs during infancy, as reported by Angus, Linde-Zwirble, Lidicker, et al. in 2001 (5.3/1,000 infants) and Watson, et al. (5.16/1,000 infants) in 2003. Odetola and colleagues (2007) reported a second age-specific peak in hospitalization rates: in 2003, children

15 to 19 years of age made up 18 percent of the pediatric population hospitalized nationally for sepsis.

Mortality among hospitalized children with severe sepsis has been reported to be between 4 percent and 10 percent (Odetola, et al., 2007; Watson, et al., 2003). Mortality is strongly associated with multiple organ dysfunction syndrome, occurring in 7 percent of children with one failing organ, increasing to 53 percent in those with at least four failing organs (Watson, et al., 2003). Comorbid illness is also associated with mortality from sepsis, with mortality rates of 8 percent in children with comorbid illness versus 2 percent among previously healthy children (Odetola, et al. 2007).

In addition, there are reports of age-specific differences in mortality from pediatric sepsis. Higher mortality rates among children over the age of 2 years may be attributable to the presence of chronic and severe underlying disease and to improved survival of immune-compromised and immune-suppressed children (Oliveira, Nogueira, Oliveira, et al., 2008). Also, older pediatric patients may have been sick longer than younger patients and may also have experienced more hospital admissions and treatments, such as transplantation or chemotherapy, making them more vulnerable to sepsis syndrome (Oliveira, et al., 2008).

Sepsis Cost

Estimated annual total cost of pediatric sepsis in the United States is \$1.97 billion (Watson et al., 2003). The average (mean) charge per hospitalization for sepsis is \$47,126 (Odetola, et al., 2007). Children who died from sepsis had total hospital charges that were 2.5-fold as high as those who survived. Higher charges were also associated with higher severity of illness. Longer length of stay for children hospitalized with sepsis was associated with multiple comorbidities, multiple organ dysfunction, and higher illness severity (Odetola, et al., 2007).

Sepsis Pathology and Severity

Sepsis syndrome comprises three stages of illness:

1. Sepsis is defined as systemic inflammatory response syndrome (SIRS) occurring in the presence of a suspected or proven infection (bacterial, viral, fungal, or rickettsial) (Goldstein, Giroir, Randolph, et al., 2005; Melendez, Bachur, 2006). Diagnosis of SIRS requires at least two of the following criteria, one of which must be abnormal temperature or leukocyte count: abnormal temperature (greater than 38.5°C [hyperthermia] or less than 36°C [hypothermia]); abnormal leukocyte count (elevated or depressed); accelerated heart rate (tachycardia); or accelerated respiratory rate (tachypnea) (Goldstein, et al., 2005).
2. Severe sepsis includes sepsis plus one of the following clinical states: cardiovascular organ dysfunction (acute circulatory failure) or acute respiratory distress syndrome (ARDS); or two or more other organ systems with dysfunctions (respiratory, renal, neurologic, hematologic, or hepatic) (Goldstein, et al., 2005).
3. Septic shock is defined as sepsis and cardiovascular dysfunction (Goldstein, et al., 2005; Rivers, Ahrens, 2008). Unlike adults, the diagnosis of septic shock in children does not require the presence of low blood pressure (hypotension), as children often maintain normal

blood pressure until the advanced stages of shock (Goldstein, et al., 2005; Larsen et al., 2011; Melendez, Bachur, 2006; Skippen, et al., 2008). Shock occurs when the cardiovascular system is unable to provide energy resources (oxygen and glucose) to meet the needs of the tissues (Skippen, et al., 2008).

Outcomes of Having a Protocol for Identifying and Treating Children with Sepsis Syndrome in the ED

Early recognition of sepsis syndrome and prompt treatment in the ED are essential to achieving successful outcomes (Dellinger, et al., 2013; Melendez, Bachur, 2006; Saladino, 2004). It is relatively simple to recognize the advanced conditions of severe sepsis and septic shock; the key for health care providers is to identify the abnormal physiologic symptoms indicative of incipient sepsis syndrome and then to promptly initiate appropriate treatment to hinder or reverse progression to the later stages of severe sepsis and septic shock (Skippen, et al., 2008). Given the correlation between presenting physiologic characteristics and outcome, it is crucial that physicians promptly diagnose sepsis by collecting adequate and appropriate vital sign information prior to escalation to severe sepsis or septic shock (Rivers, Ahrens, 2008).

The current management strategy for treatment is goal-directed with institution of timely antimicrobial and hemodynamic (i.e., relating to the forces driving blood flow throughout the body) treatments. The point of all treatment is to kill the pathogen(s) triggering the sepsis and restore circulation and perfusion to vital organs (Khilnani, Deopujari, Carcillo, 2008). The components of early goal-directed therapy include prompt resuscitation of poor perfusion through the administration of intravenous fluids; appropriately targeted inotropic and/or vasopressor therapy; early empiric antimicrobial therapy; source control; appropriate and continuous monitoring of hemodynamic status; and additional supportive care as required (Melendez, Bachur, 2006).

Protocols provide a set of rules and an organized plan that encourage adherence to evidence-based recommendations in clinical settings. Improvements in outcomes following implementation of protocols that are grounded in evidence-based guidelines have been demonstrated (Cruz, et al., 2011; Larsen, et al., 2011; Rivers, Ahrens, 2008). Use of a sepsis protocol may also decrease the time necessary to reach treatment goals (Cruz, et al., 2011; Rivers, Ahrens, 2008).

The ED septic shock protocol developed and tested by Larsen and colleagues (2011) improved compliance in the delivery of rapid, aggressive fluid resuscitation, early antibiotics, and oxygen administration and was associated with decreased length of hospital stay.

The sepsis protocol initiated by Cruz, et al. (2011) was designed to alert clinicians early to abnormal vital signs and to facilitate adherence to national treatment guidelines regarding timely delivery of interventions. Implementation resulted in earlier recognition of suspected sepsis and substantial reductions in both time to receipt of time-sensitive therapies (first fluid bolus and antibiotics) and a decrease in treatment variation (Cruz, et al., 2011). The protocol also identified barriers to effective management and instituted mechanisms to harness additional resources to improve care. It emphasized standardization of fluids, antibiotics, laboratory studies, and patient disposition. Children whose care was guided by the use of the protocol received interventions

more rapidly and with less variation than patients treated prior to the development of the protocol (Cruz, et al., 2011).

As demonstrated in these two clinical initiatives, protocols facilitate rapid identification and treatment, which is an important aspect of taking care of children with sepsis syndrome. A limited window of opportunity exists for treating underlying injury once shock is present. Odds of mortality have been shown to double with each passing hour of persistent shock, and each hour of delay in resuscitation has been associated with a 50 percent increase in odds of mortality (Han, et al., 2003). The protocol used by Cruz and colleagues (2011) supported early recognition and diagnosis through its emphasis on the collection and documentation of vital signs. Vital sign trends are essential for monitoring a patient's response to therapy but may be obtained infrequently in the absence of a protocol because of lack of resources and standardization (Cruz, et al., 2011). The protocol allowed physicians to intervene earlier and secure resources for seriously ill children, helping to standardize and facilitate care without decreasing physician autonomy. The purpose of the protocol was not to change decision-making; instead, it promoted timely interventions based on rapid assessment, enabled by data presented in consistent, constructive formats (Cruz, et al., 2011).

Standardization is another valuable aspect of protocol implementation, as it facilitates an assessment of the effectiveness of various interventions. When procedures are presented via an orderly process, they can be applied consistently and reproducibly. Thus, protocols are a tool to promote the health care improvement process. Health care outcomes improve when protocols are used to remind clinicians to complete all the tasks necessary for optimal care (Rivers and Ahrens, 2008).

Performance Gap

Despite the availability of evidence-based guidelines for the care of children with sepsis, only a minority of children receive the standard of care. Process barriers are a common problem leading to delays in the recognition and treatment of pediatric shock. They include varying levels of experience among ED staff performing initial evaluations, lack of adequate nursing staff for resource-intensive patients, difficulty in obtaining frequent vital signs, lack of standardization of empiric antibiotics and diagnostic tests, lack of prioritization of medications, and barriers to patient flow through the hospital (Cruz, et al., 2011). Similarly, Oliveria and colleagues (2008) suggested reasons for delay may include inaccuracy in assessing the severity of a child's state of shock, shortage of health care providers, fatigue among medical teams, and difficulty in establishing adequate intravascular access. Rivers and Ahrens (2008) describe several potential impediments to implementing a sepsis protocol, including professional barriers, such as lack (or variation) of expertise and resistance to change; institutional barriers, such as departmental competition and limited staff; and physical barriers, such as lack of equipment or space. They opined that identification of one or more knowledgeable leaders with the resources and authority needed to address such barriers is essential to successfully advocate for a sepsis protocol initiative and to promote an atmosphere of teamwork and quality care (Rivers, Ahrens, 2008).

As severe sepsis and septic shock are time-sensitive conditions that demand immediate care, the timing and location of treatment are important considerations. Initiation of treatment cannot wait for arrival at the intensive care unit; treatment must begin when patients present to the ED

(Larsen, et al., 2011). Early recognition and treatment of severe sepsis and septic shock right from presentation in the ED will benefit all patients because it leads to more meticulous patient assessment (Larsen, et al., 2011). Implementation of sepsis protocols before transfer to the ICU should greatly improve outcomes for patients with severe sepsis (Rivers, Ahrens, 2008).

Given the nature of ED care, patients may wait several hours before they are evaluated by a physician. A sepsis protocol in the ED offers a process by which to identify patients at risk for septic shock who present at triage or whose course worsens while at they are in the ED. The goal of the protocol is earlier physician evaluation; it also helps provide nursing staff with guidelines to initiate timely care (Larsen, et al., 2011).

Another possible performance barrier relates to hospital type and location. Many children live far from medical facilities that offer specialized pediatric care. For those presenting with septic shock to remote community hospitals, treatment efforts made by the physicians are crucial to the children's survival and should be prioritized. Delay in care while waiting to transfer patients to a more advanced pediatric medical facility is unwise (Han, et al., 2003). Han and colleagues (2003), in a 9-year retrospective study, reported that 29 percent of infants and children who presented with septic shock at community hospitals and required transport to a larger medical center did not survive. In a separate report, Odetola et al. (2007) reported that pediatric patients with sepsis who were transferred incurred higher charges than those whose care did not entail transfer. The presence of an ED protocol at community hospitals that supports immediate treatment could be life-saving.

As clinical guidelines for the treatment of sepsis were developed at pediatric academic centers without accounting for use at community hospitals, barriers to their use may exist (Han, et al., 2003). For example, some community physicians may lack specialized technical skills involved in managing severe sepsis or septic shock. Educational barriers regarding the guidelines themselves may curtail implementation, if physicians are unaware of or lack support to execute stepwise, goal-directed interventions in a timely manner. However, most of the procedures detailed in current guidelines are easily within the scope of a community-based practice (Han, et al., 2003). Continued efforts to increase knowledge and comfort with sepsis guidelines among community physicians will likely improve outcomes. Odetola and colleagues (2007) also noted an urgent need for concerted clinical and educational efforts within the clinical care setting designed to limit the progression of sepsis severity, as multiple organ dysfunction portends poor outcomes including death.

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).**

Sepsis and Medicaid/CHIP

This measure is relevant for Medicaid/CHIP because children with sepsis may be enrolled in Medicaid/CHIP, and hospitals that treat children for sepsis are likely to encounter patients with Medicaid/CHIP coverage. Sepsis is one of the top 10 most expensive conditions managed by hospitals, accounting for 2.8 percent (\$24.8 billion) of the national hospital bill in 2005. Of these charges, approximately \$19.5 billion was charged to Medicare and Medicaid. Data from AHRQ's Healthcare Cost and Utilization Project (HCUP) show that the national cost of treating sepsis increased more (183 percent) than costs for treating other conditions between 1997 and 2005 (Rivers, Ahrens, 2008).

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).

Early identification of sepsis syndrome via the use of protocols is the crucial gap to be filled. New York State has enacted regulations to ensure that hospitals "have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care" (New York Codes, Rules, and Regulations Title 10 [Health], sections 405.2 and 405.4). The regulations, which went into effect in New York in 2013 and 2014, exemplify an interest and desire of health agencies for quality measures related to the care and treatment of pediatric sepsis syndrome.

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: No.**
- b. Care Setting – inpatient: No.**
- c. Care Setting – other – please specify: Yes; emergency department.**
- 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: No.**

- 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):** Yes; birth to 28 days.
- p. **Population – infants (29 days to 1 year) (specify age range):** Yes; 29 days to 1 year.
- q. **Population – pre-school age children (1 year through 5 years) (specify age range):**
Ages 1-5 years.
- r. **Population – school-aged children (6 years through 10 years) (specify age range):**
Ages 6-10 years.
- s. **Population – adolescents (11 years through 20 years) (specify age range):** Yes; ages 11-18 years (i.e., younger than age 19).
- t. **Population – other (specify age range):** Not applicable.
- u. **Other category (please specify):** Not applicable.

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

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

5.A. Research Evidence

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

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

This measure assesses the proportion of hospitals with a specific written protocol to identify and treat children with sepsis syndrome in the ED that, if followed, results in one or more desirable outcomes (for example, shortened time to treatment or reduced length of stay). Expert consensus and research have identified recognition of sepsis syndrome and aggressive treatment of its

symptoms as the bedrock of care for pediatric patients presenting with this potentially devastating condition. Clinical guidelines have identified a series of goal-directed, stepwise interventions focused on hindering progression to shock or reversing it. A sepsis management protocol, which provides a structured process to implement these best practices, is a fundamental step in successfully addressing sepsis syndrome in children presenting to the ED. This set of procedures helps clinicians quickly identify children with sepsis syndrome and triage them to receive immediate interventions—such as fluid resuscitation and parenteral antibiotics—that are essential to prevent the circulatory collapse that leads to organ failure and mortality. Table 3 (see Supporting Documents) summarizes several key sources of evidence for this measure, using the U.S. Preventive Services Task Force (USPSTF) rankings (criteria denoted as a note to Table 3).

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.

Children with infections often display the inflammatory triad of fever, tachycardia, and vasodilation (widening of the blood vessels) (Brierley, Carcillo, Choong, et al., 2009). Septic shock is suspected when children with these three symptoms display a change in mental status such as irritability, inappropriate cry, drowsiness, confusion, poor interaction with parents, lethargy, or if they cannot be aroused. Other clinical signs of septic shock in children with a suspected infection include (1) hypothermia or hyperthermia; (2) signs of inadequate tissue perfusion, including any of the following: prolonged capillary refill greater than 2 seconds, diminished pulses, mottled cool extremities, flash capillary refill, bounding peripheral pulses, or wide pulse pressure; and (3) decreased urine output less than 1 mL/kg/h. Because children often maintain their blood pressure until they are severely ill, systemic hypotension is not a requirement for diagnosis of septic shock in children; in fact, shock may occur long before blood pressure collapses (Goldstein, et al., 2005). While hypotension is not necessary for the clinical diagnosis of septic shock, its presence in a child with clinical suspicion of infection is confirmatory (Brierley, et al., 2009).

The current management strategy for septic shock focuses on antimicrobial and hemodynamic goal-directed therapies. All interventions are directed at killing the offending microorganism and restoring normal perfusion to vital organs and restoring the circulation (Saladino, 2004). Goals for the first hour of resuscitation are to maintain or restore the airway, oxygenation, and ventilation; maintain or restore circulation, defined as normal perfusion and blood pressure; and maintain or restore threshold heart rate (Brierley, et al., 2009). Therapeutic endpoints of resuscitation include capillary refill of 2 seconds or less, normal pulses with no differential between the quality of peripheral and central pulses, warm extremities, urine output greater than 1 mL/kg/h, normal mental status, normal blood pressure for age, normal glucose concentration, normal ionized calcium concentration (Brierley, et al., 2009; Dellinger, et al., 2013), decreased lactate, decreased base deficit, and mixed venous oxygen saturation of greater than 70 percent (Dellinger, et al., 2013).

Age is an important determinant of risk of bacterial infection, whether related to maturation of the immune system or exposure to microbes common to an environment or peer group (Saladino, 2004). The pathogens that cause severe sepsis vary with age and immunization status (Rooney,

Nadel, 2009). Group B streptococci, *Escherichia coli*, *Listeria*, and herpes simplex virus commonly cause neonatal infections; *Streptococcus pneumoniae* and *Neisseria meningitidis*, which tend to be community-acquired organisms, are seen more often in older children (Goldstein, et al., 2005; Rooney, Nadel, 2009). The introduction of conjugate vaccines given in infancy against *Haemophilus influenzae* type B, *S. pneumoniae*, and *N. meningitidis* has changed the epidemiology of severe sepsis in children (Rooney, Nadel, 2009). Those who are chronically ill or immunocompromised make up a larger portion of the population with severe sepsis in children than in adults (Goldstein, et al., 2005).

Viruses and fungi also cause sepsis, particularly in immunocompromised and very young or premature infants (Rooney, Nadel, 2009). Fungi account for approximately 5 percent of all cases of sepsis syndrome (Bochud, Bonten, Marchetti, et al., 2004). Most cases of fungal sepsis are caused by *Candida* species, which is associated with the highest mortality (40 percent) of all bloodstream pathogens. Between 1979 and 2000, the incidence of fungal sepsis increased threefold (Bochud, et al., 2004).

In decreasing order of frequency, the main sites of infection in patients with severe sepsis and septic shock are the lungs, bloodstream, abdomen, urinary tract, and skin and soft tissue (Bochud, et al., 2004). The pathophysiology of the disease is the same, however, irrespective of the precipitating pathogen (Rooney, Nadel, 2009).

Sepsis is a complex series of interactions between the invading pathogen and the different host systems in the body (Rooney, Nadel, 2009). It is a dynamic condition in which the roles of individual mediators may be transient and redundant, with many regulatory pathways activated. The process, however, ultimately leads to tissue damage and organ failure. In the early stages, immune cells react to the pathogen in a manner that creates potentially harmful molecules, which in turn, damage the endothelial cells. A cascade of inflammatory and coagulation responses leads to progressive organ impairment. Refractory vasodilation, fluid redistribution, and decreased myocardial function lead to shock. Severe sepsis becomes a self-perpetuating condition, as hypoxia and tissue ischemia exacerbate inflammatory and coagulation responses, resulting in further inflammation. A compensatory anti-inflammatory response syndrome develops, leading to relative immunosuppression, in which the host inflammatory cells are unable to respond to stimuli. The resulting immunoparalysis limits the response to the pathogen, contributing to morbidity and mortality (Rooney, Nadel, 2009).

The treatment of septic shock in children is intended to optimize perfusion of critical vascular beds and prevent or correct metabolic abnormalities that result from cellular hypoperfusion (Khilnani, et al., 2008). The ultimate goals are to prevent or reverse defects in cellular substrate delivery and metabolism and to support the entire patient until homeostasis is restored. For all forms of shock, treating the underlying cause is mandatory, and avoiding delay in treatment is essential. Delays in making the diagnosis and initiating treatment (fluid resuscitation and appropriate antibiotics), as well as suboptimal resuscitation, contribute to peripheral vascular failure and irreversible defects in oxygen supply, which can culminate in vital organ dysfunction (Khilnani, et al., 2008).

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 facility survey results.

Data and Methods

Our testing data consisted of results from a telephone survey of nurse managers and physician directors at 50 randomly selected hospitals with EDs in the states of Michigan and Ohio. Respondents were asked if their ED had a protocol for identifying and treating children with sepsis syndrome.

6.B. Validity

Validity of the measure is the extent to which the measure meaningfully represents the concept being evaluated. The method for establishing the validity of a measure will depend on the type of measure, data source, and other factors.

Explain your rationale for selecting the methods you have chosen, show how you used the methods chosen, and provide information on the results (e.g., R2 for concurrent validity).

The validity of this measure was determined from two perspectives: face validity and validity of the facility survey data.

Face Validity

The validity of this measure was determined from face validity, 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 a parent representative for families of children with sepsis syndrome convened by Q-METRIC. The Q-METRIC panel included nationally recognized experts in the identification and treatment of pediatric sepsis syndrome, representing neonatology, hematology/oncology, infectious diseases, emergency medicine, nursing, pediatric surgery, and pediatric intensive care. 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 sepsis panel included 15 experts, providing a

comprehensive perspective on sepsis syndrome 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 sepsis syndrome identification and treatment. Concepts and draft measures were rated by this group for their relative importance. This measure was highly rated, receiving an average score of 6.9 (with 9 as the highest possible score).

Validity of Abstracted Data

This measure was tested using facility survey data. Fifty hospitals were randomly selected in the states of Michigan and Ohio (Table 4, see Supporting Documents). After several calls (range of one to six, based on response), 27 hospital ED nurse managers or physician directors responded. Eleven of the 27 (41 percent) reported having a written protocol for the identification and treatment of children who present to the ED with sepsis syndrome (Table 5, see Supporting Documents); 16 facilities (59 percent) indicated that they did not have a protocol.

Validity of the data obtained through the telephone survey was to be assessed through verification of the existence of a protocol. Sites indicating that they had a sepsis protocol were asked to submit this protocol to the study team. The team was interested in verifying the existence of a protocol, not assessing the content of the protocols. Of those respondents who indicated they had a protocol (n=11), only two protocols were received (18 percent) despite multiple messages to the respondents. Some protocols could not be sent because they were incorporated into the hospitals' electronic health records (EHRs).

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

The facility survey did not contain questions related to the race/ethnicity of individuals using the ED.

7.B. Special Health Care Needs

The facility survey did not contain questions related to the special health care needs of individuals using the ED.

7.C. Socioeconomic Status

The facility survey did not contain questions related to the socioeconomic status of individuals using the ED.

7.D. Rurality/Urbanicity

The facility survey did not contain questions related to the geographic location of individuals using the ED.

7.E. Limited English Proficiency (LEP) Populations

The facility survey did not contain questions related to the primary language of individuals using the ED.

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 data obtained through a telephone survey of 50 randomly selected hospitals with EDs in the States of Michigan and Ohio. The ED director or nurse manager at each hospital was asked if the ED had a written protocol for the identification and treatment of children younger than 19 years of age with sepsis, severe sepsis, or septic shock. Those responding ‘yes’ were asked if the protocol existed in an electronic or paper format. Seven respondents chose to answer this question, with five indicating that the protocol existed electronically and two indicating that their facility maintained a paper protocol document (Table 6, see Supporting Documents).

Respondents were also asked if they would be willing to provide a copy of the protocol to the research team. Of those respondents who indicated they had a protocol, only two protocols (18 percent) were received despite multiple messages to the respondents. It is important to note that some protocols could not be sent by respondents because they were incorporated directly into the hospitals’ EHRs,

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?

The proposed measure was determined to be feasible by Q-METRIC using survey data from 27 hospitals with EDs in the States of Michigan and Ohio.

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.

New York State has enacted regulations to ensure that hospitals “have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis/septic shock that are based on generally accepted standards of care” (New York Codes, Rules, and Regulations Title 10 (Health), sections 405.2 and 405.4). Regulation 405.4 states that “staff shall be responsible for the collection, use, and reporting of quality measures related to the recognition and treatment of severe sepsis for purposes of internal quality improvement and hospital reporting to the Department. Such measures shall include, but not be limited to, data sufficient to evaluate each hospital's adherence rate to its own sepsis protocols, including adherence to timeframes and implementation of all protocol components for adults and children.” The hospital data will allow the Department to “develop risk-adjusted severe sepsis and septic shock mortality rates in consultation with appropriate national, hospital, and expert stakeholders.” Additionally, New York’s Public Health Law § 2805-m (2014) gives hospitals the time to ensure data are accurately reported prior to having the data made public.

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?

New York State requires hospitals to submit protocols for the early recognition and treatment of patients with severe sepsis and septic shock to the Department of Health for approval prior to implementation and to update these protocols periodically. Hospitals are also required to submit to the Department of Health sufficient data to assess adherence to its own sepsis protocols (New York Codes, Rules, and Regulations Title 10 (Health), section 405.4).

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

The New York State Report on Sepsis Care Improvement Initiative: Hospital Quality Performance (New York State Department of Health, 2015; revised 2017) provides results of the implementation of sepsis protocols and adherence to interventions identified within the protocols. Results of reported hospital data for second quarter 2014 through third quarter 2016 show improvements in protocol initiation, rapid and early treatment, and mortality over time (New York State Department of Health, 2015; revised 2017). Implementation of the mandate to identify and treat sepsis using protocols in New York State has been associated with lower mortality, as reported by Seymour, Gesten, Prescott, et al (2017).

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?
Survey data at the State health department level.

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 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?
None apparent.

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)

Yes.

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

Survey data at the health plan level.

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 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?

None apparent.

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)

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?

Not 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?

Hospital might be identifiable.

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 families with a straightforward means to assess how well basic levels of comprehensive care are being provided for children with severe sepsis or septic shock. Low rates for the provision of care 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 provided to children with sepsis syndrome.

This measure has not been assessed for comprehension, although respondents did not indicate that the survey questions were unclear. The primary information needed for this measure comes from facility survey data and includes facility contact information, which is widely available.

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.

Health information technology (IT) provides a platform on which a sepsis management protocol can be constructed. Sites lacking such protocols are able to use health IT to draft and disseminate either a text based version of the protocol or an order set consisting of key aspects of the protocol. In a study by Cruz et al. (2011), a triage tool was developed using IT as EHRs were introduced at the authors' hospital. The success of the protocol led to it being prioritized for integration into electronic algorithms, as well as into the hospital's evidence-based guidelines for shock. The authors point out that although the triage alert at the beginning of the protocol required an EHR, use of the protocol's flow sheet was not contingent on an EHR, though it could be incorporated into it (Cruz, et al., 2011).

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.

The most common way information will be captured to help calculate this measure will be from electronic or written orders that mention the protocol or order sets (e.g., “Initiate Sepsis protocol”). Alternatively, clinical notes may mention that the sepsis protocol was followed. Though less likely, it is possible that the actual scanned paper or electronic protocol will become a clinical document attached to the encounter, in which case either the clinical note header or text in the clinical note will signify the protocol has been used.

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 laboratory results and other diagnostic tests into EHRs, which are directly relevant to determining sepsis syndrome cases in the ED. These standards also indicate the requirement for EHRs to track specific patient conditions, such as pediatric sepsis syndrome. The ONC standards include the following specific requirements in the Certification criteria (U.S. Department of Health and Human Services, 2010) pertaining to Stage 2 Meaningful Use requirements:

Stage 2 (beginning in 2013): CMS has proposed that its goals for the Stage 2 meaningful use criteria expand upon the Stage 1 criteria to encourage the use of health IT for continuous quality improvement at the point of care. In addition, the exchange of information in the most structured format possible is encouraged. This can be accomplished through mechanisms such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results. Electronic transmission of diagnostic test results includes a broad array of data important to quality measurement, such as blood tests, microbiology, urinalysis, pathology tests, and radiology studies.

Incorporate clinical laboratory test results into the EHR as structured data:

1. Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.
2. Electronically display in human readable format any clinical laboratory tests that have been received with LOINC[®] codes.

3. Electronically display all the information for a test report specified at 42 CFR 493.1291© (1) through (7).

Generate lists of patients by specific conditions to use for quality improvement and reduction of disparities outreach:

4. Enable a user to electronically update a patient's record based upon received laboratory test results. 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.

Consequently, the inclusion of information to identify sepsis syndrome patients in EHRs provides the foundation for protocols to be triggered that are targeted to these cases. The time-sensitive nature of sepsis syndrome protocols can be tracked by EHRs as clinicians progress through the prescribed set of stepwise procedures for sepsis syndrome cases.

11.E. Health IT Calculation

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

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

1. Mention of the protocol or order sets within electronic or written orders, without actual implementation.
2. Clinical notes that mention the sepsis protocol was followed without actual implementation.
3. Possibly a scanned or electronic clinical document in the medical record.

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?

Health IT may enhance the use of this measure by providing real-time alerts for patients with one or more complaints that would be likely to trigger use of the protocol. For example, a physician or nurse seeing a patient with a chief complaint of fever and irritability can be alerted that the patient is eligible for the sepsis protocol. There are studies in the informatics literature demonstrating that this sort of trigger has improved overall compliance with guidelines and decreased time to initiate protocols in the ED (see also, Cruz et al., 2011).

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 proportion of hospitals with a specific written protocol to identify and treat children with the sepsis syndrome in the ED.

This measure was tested using survey data from hospitals with an ED. The primary information needed for this measure as tested includes facility contact information. As noted in section 11.C, future implementation of the measure may include the review of medical records for electronic or written orders that mention the protocol or order sets (e.g., “Initiate sepsis protocol”); clinical notes that may mention that the sepsis protocol was followed; or perhaps, though less likely, the actual scanned paper or electronic protocol within the medical record.

Q-METRIC testing determined that this measure is feasible, although validity testing was limited by the lack of protocol submissions by respondent facilities. However, continuing advances in the development and implementation of EHRs will improve the feasibility of regularly implementing this measure with the data they supply.

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, Protocol for Identifying Children with Sepsis Syndrome in the Emergency Department, assesses the proportion of hospitals with a specific written protocol to identify and treat children with the sepsis syndrome in the ED.

Sepsis is a potentially catastrophic condition that can escalate from infection to death within hours. Clinical practice parameters and clinical guidelines for the treatment of children with sepsis syndrome emphasize the critical importance of early recognition and aggressive treatment for all suspected cases of pediatric sepsis syndrome, including sepsis, severe sepsis, and septic shock. Clinicians must be ready to rapidly deploy a set of time-sensitive, goal-directed, stepwise procedures to hinder or reverse the cascade of events in sepsis that lead to organ failure in sepsis. One fundamental element of timely and appropriate treatment is a sepsis management protocol. Based on clinical guidelines, the protocol provides a set of consistent steps to help clinicians in the ED recognize sepsis syndrome in pediatric patients and promptly initiate evidence-based interventions likely to hinder or reverse the progression to septic shock. Protocols support immediate, consistent, and suitable treatment, regardless of care setting. They also help institutions centralize resources for very sick patients; foster acceptable levels of competence for the skills necessary to provide successful treatment; and produce uniform data amenable to useful comparison and analysis. Despite the clear value of such protocols, however, many hospitals lack these protocols, undermining the ability of staff in the ED to quickly identify and effectively treat children with sepsis syndrome.

Q-METRIC tested this measure among a total of 27 hospitals with EDs. Results showed that 41 percent of surveyed facilities had a protocol for identifying and treating children with sepsis syndrome in the ED.

This measure provides families, providers, and purchasers with a straightforward means of assessing how well basic levels of comprehensive care are being provided for children with sepsis, severe sepsis, or septic shock. The primary information needed for this measure comes from facility survey data and includes facility contact information, which is 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 EHRs.

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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.

AHRQ Publication No. 18-P002-1-EF
February 2018