Sepsis Regulations: Guidance Document
405.4 (a) (4)

(i) Protocols shall apply to all patients in the hospital except those excluded as described in (ii) below, and include use of explicit algorithms and/or alert systems to assist in the early identification of patients with severe sepsis and septic shock including an approach to stratifying patients into sepsis, severe sepsis, and septic shock based on a constellation of appropriate clinical and laboratory findings. Protocols directed at treatment should address both ER and inpatient presentations of severe sepsis and septic shock for adults and for children.

(ii) Protocols must make exclusion criteria explicit. Appropriate criteria for exclusion from application of a severe sepsis/septic shock protocol include the following: patients for whom the interventions in the protocol are clinically contraindicated; persons with advance directives in place at the time of care which preclude any of the protocol interventions; persons for whom the patient or surrogate decision maker declined or is unwilling to consent to such interventions; and those enrolled in IRB approved clinical trials for which trial interventions are inconsistent with established protocols. Protocols for children may exclude newborns and infants in the NICU. Hospitals will be required to track and provide a limited amount of information regarding excluded patients (including reasons for exclusions) for purposes of data reporting to the Department.

(iii) For adults, treatment targets to maintain adequate perfusion and oxygenation and normalize lactate must be specified, including explicit methods for measurement of adequate perfusion and oxygenation;

Protocols for adults should include at a minimum: measurement of lactate level and for those with severe sepsis unresponsive to initial fluid resuscitation (hypotension or elevated lactate), the delivery of appropriate crystalloid infusion with or without vasopressors and a quantitative method to monitor results and re-measure lactate (if elevated) within 6 hours of severe sepsis identification. Protocols must include a minimum amount for an initial fluid bolus. Timeframe goals to complete administration of interventions for severe sepsis and septic shock should be consistent with current evidence based recommendations. Protocols must also include criteria for on-going treatment and transfer of those adults who may require a more intensive level of care than is able to be provided at the initial facility.

(iv) For infants and children, protocols should include age-specific values for clinical and laboratory measurements pertinent to recognition of severe sepsis and septic shock. Protocols should address early intravenous (IV) or intraosseous (IO) access and be consistent with American College of Critical Care Medicine (ACCM) guidelines in terms of fluid resuscitation amounts, antibiotic administration, physiologic goals to be reached within 60 minutes of initial resuscitation of administration and use of cardiovascular drug therapy support in fluid refractory septic shock. Protocols must also include criteria for on-going treatment and transfer for those infants and children who may require a more intensive level of care than is able to be provided at the initial facility.

(v) Protocols for adults and children should include obtaining blood cultures prior to antibiotic administration, and other infectious source identification and control efforts as appropriate, with the goal of initiation of appropriate broad spectrum antibiotics within one hour of identification of severe sepsis or septic shock.

(vi) All protocols must clearly describe an explicit and quantitative approach used to guide resuscitation, including the following:

1. What physiologic measurements will be used to guide resuscitation interventions
2. What physiologic thresholds and/or clinical conditions will require insertion of central venous catheter with or without central venous pressure and central venous oxygen saturation monitoring to be considered

3. What physiologic thresholds and/or clinical conditions will require use of vasopressors

((5) Hospitals shall describe, in a document separate from treatment protocols, the manner and frequency with which they will provide initial and ongoing training to all staff responsible for implementation of sepsis protocols in the emergency room and on inpatient floors. Such training shall include, but not be limited to, appropriate medical (including physicians in training when present), nursing, pharmacy, and laboratory staff. Hospitals shall also describe how they make information technology resources available to assist in the implementation of protocols and the collection of required data for reporting to the Department of Health.

(6) Hospitals must submit information to the Department using a standardized format and electronic methodology developed by the Department no later than September 3, 2013. The information to be submitted will include the following:

a. CEO signed attestation of compliance with this regulation and commitment of institutional support to implement severe sepsis and septic shock protocols and reporting requirements, as required by regulation and contained within the hospital’s protocols;

b. Chief Medical Officer signed attestation that the required components of the protocols, as outlined in regulations and in this guidance document, are contained within the hospital’s protocols;

c. An indication as to whether the hospital is using an ‘invasive’ or ‘non-invasive’ protocol; ‘invasive’ protocol is defined by early insertion of a central venous catheter for all adult severe sepsis and septic shock patients with associated monitoring of central venous pressure and central venous oxygen saturation; if a hospital is using both approaches, a description of the circumstances or settings in which one or the other is being used;

d. Excerpts of the hospital’s relevant protocol document which documents the required elements as outlined in regulations and this guidance document;

e. The hospital’s explicit criteria for defining when a pediatric protocol will be applied versus an adult protocol; and

f. Criteria that will be used to decide when or how frequently protocols must be updated.

7 (i) Adherence measures for adults shall include patient specific, identifying information on the entirety of individuals who are eligible for severe sepsis or septic shock protocols and shall be consistent with the National Quality Forum approved severe sepsis measure with the following exceptions: (1) components which assume use of central venous pressure and central venous oxygen saturation shall not be reported if not relevant due to use of ‘non-invasive’ (no central venous access) protocol; (2) multiple definitions of ‘time zero’ shall be used for purposes of quality improvement and to recognize differences between characteristics of care delivered in the emergency department compared to inpatient units of hospitals. These definitions will include: (a) earliest time recorded (time of arrival); (b) time of triage; (c) time at which signs, symptoms, and laboratory findings are first consistent with definitions of severe sepsis or septic shock (time of meeting definitional criteria) and (d) time at which the severe sepsis or septic shock protocol was initiated.

Adherence measures for children shall include the entirety of individuals who are eligible for severe sepsis and septic shock protocols and shall be consistent with evidence-based guidelines.
Adherence measurement data shall be submitted to the Department using a web-enabled process in a format developed by the Department consistent with requirements for encryption, privacy and confidentiality.

(ii) Additional clinical variables necessary to calculate risk adjusted mortality rates shall be added to the data reporting tool used for calculation of protocol adherence rates. Clinical variables may include, but not be limited to, information regarding organ failure, lactate levels, infection site and etiology, ICU admission, vital signs, mental status, demographics including age, treatment site (emergency department vs inpatient unit), nursing home residence, use of vasopressors, use of mechanical ventilation, transfer status, complete blood count results.

8 (ii) Definitions: Severe Sepsis for pediatrics is defined as sepsis plus one of the following: cardiovascular organ dysfunction or acute respiratory distress syndrome (ARDS) or two or more organ dysfunctions-consistent with International Pediatric Sepsis Consensus Conference definition.