

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 2800 and 2803 of the Public Health Law, Sections 405.2 and 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraphs (6) and (7) of subdivision (f) of section 405.2 are amended and a new paragraph (8) is added to read as follows:

(f) Care of patients. The governing body shall require that the following patient care practices are implemented, shall monitor the hospital's compliance with these patient care practices, and shall take corrective action as necessary to attain compliance:

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(6) hospitals which conduct, or propose to conduct, or otherwise authorize human research on patients or other human subjects shall adopt and implement policies and procedures pursuant to the provisions of Public Health Law, article 24-A for the protection of human subjects; [and]

(7) hospitals shall have available at all times personnel sufficient to meet patient care needs[.];

and

(8) hospitals shall have in place evidence-based protocols for the early recognition and treatment of patients with severe sepsis and septic shock that are based on generally accepted standards of care as required by subdivision (a) of section 405.4 of this Part.

New paragraphs (4), (5), (6), (7) and (8) of subdivision (a) of Section 405.4 are added to read as follows:

405.4 Medical staff.

- (a) Medical staff accountability. The medical staff shall be organized and accountable to the governing body for the quality of medical care provided to all patients.

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(4) The medical staff must adopt, implement, periodically update and submit to the Department evidence-based protocols for the early recognition and treatment of patients with severe sepsis and septic shock (“sepsis protocols”) that are based on generally accepted standards of care. Sepsis protocols must include components specific to the identification, care and treatment of adults, and of children, and must clearly identify where and when components will differ for adults and for children. These protocols must include the following components:

- (i) a process for the screening and early recognition of patients with sepsis, severe sepsis and septic shock;
- (ii) a process to identify and document individuals appropriate for treatment through severe sepsis and septic shock protocols, including explicit criteria defining those patients who should be excluded from the protocols, such as patients with certain clinical conditions or who have elected palliative care;
- (iii) guidelines for hemodynamic support with explicit physiologic and biomarker treatment goals, methodology for invasive or non-invasive hemodynamic monitoring, and timeframe goals;
- (iv) for infants and children, guidelines for fluid resuscitation with explicit timeframes for vascular access and fluid delivery consistent with current,

evidence-based guidelines for severe sepsis and septic shock with defined therapeutic goals for children;

(v) a procedure for identification of infectious source and delivery of early antibiotics with timeframe goals; and

(vi) criteria for use, where appropriate, of an invasive protocol and for use of vasoactive agents.

(5) Medical staff must ensure that professional staff with direct patient care responsibilities and, as appropriate, staff with indirect patient care responsibilities, including, but not limited to laboratory and pharmacy staff, is periodically trained to implement sepsis protocols required pursuant to paragraph (4) of this subdivision. Medical staff must ensure updated training when the hospital initiates substantive changes to the protocols.

(6) Hospitals shall submit sepsis protocols required pursuant to paragraph (4) of this subdivision to the Department for review not later than September 3, 2013. Hospitals must implement protocols after receipt of a letter from the Department indicating that the proposed protocols have been reviewed and determined to be consistent with the criteria established in this Part . Protocols are to be implemented no later than December 31, 2013. Hospitals must update protocols based on newly emerging evidence-based standards. Protocols are to be resubmitted at the request of the Department, not more frequently than once every two years unless the Department identifies hospital-specific performance concerns.

(7) Collection and Reporting of Sepsis Measures.

(i) The medical 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.

(ii) Hospitals shall submit data specified by the Department to permit the Department to develop risk-adjusted severe sepsis and septic shock mortality rates in consultation with appropriate national, hospital and expert stakeholders.

(iii) Such data shall be reported annually, or more frequently at the request of the Department, and shall be subject to audit at the discretion of the Department.

(8) Definitions. For the purposes of this section, the following terms shall have the following meanings:

(i) sepsis shall mean a proven or suspected infection accompanied by a systemic inflammatory response;

(ii) For adults, severe sepsis shall mean sepsis plus at least one sign of hypoperfusion or organ dysfunction; For pediatrics, severe sepsis shall mean sepsis plus two organ dysfunctions or acute respiratory distress syndrome; and

(iii) septic shock shall mean severe sepsis with persistent hypotension or cardiovascular organ dysfunction despite adequate IV fluid resuscitation;  
For pediatrics septic shock shall mean severe sepsis and cardiovascular dysfunction despite adequate IV fluid resuscitation.