

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, Section 405.4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (a) of Section 405.4 is amended to read as follows:

- (a) *Medical staff accountability.* The medical staff shall be organized and accountable to the governing body for the quality of the medical care provided to all patients.
- (1) The medical staff shall establish objective standards of care and conduct to be followed by all practitioners granted privileges at the hospital. Those standards shall:
    - (i) be consistent with prevailing standards of medical and other licensed health care practitioner standards of practice and conduct; and
    - (ii) afford patients their rights as patients in accordance with the provisions of this Part.
  - (2) The medical staff shall establish mechanisms to monitor the ongoing performance in delivering patient care of practitioners granted privileges at the hospital, including monitoring of practitioner compliance with bylaws of the medical staff and pertinent hospital policies and procedures.
  - (3) The medical staff shall review and, when appropriate, recommend to the governing body, the limitation or suspension of the privileges of practitioners who do not practice in compliance with the scope of their privileges, medical staff bylaws, standards of

performance and policies and procedures, and assure that corrective measures are developed and put into place, when necessary.

(4) The medical staff shall 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 rapidly 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], including monitoring, therapeutic endpoints 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; and

- (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) The medical staff shall 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, are periodically trained to implement sepsis protocols required pursuant to paragraph (4) of this subdivision. Medical staff shall 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 these 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 sepsis protocols required pursuant to paragraph (4) of this section based on newly emerging evidence-based standards. Protocols are to be [resubmitted] submitted to the Department 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. Hospitals shall submit data to the Department or the Department's designee in the form and format, and according to such specifications as may be required by the Department.
- (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. Sepsis is a life threatening medical emergency that requires early recognition and intervention. For the purposes of [this section] hospital data collection, the following terms shall have the following meanings:

- (i) *sepsis* shall mean a [proven] confirmed or suspected infection accompanied by two [a] systemic inflammatory response syndrome (SIRS) criteria;
- (ii) [for adults,] *severe sepsis* shall mean sepsis complicated by [plus at least one sign of hypoperfusion or organ dysfunction; for pediatrics, *severe sepsis* shall mean sepsis plus one of the following: cardiovascular organ dysfunction or acute respiratory distress syndrome (ARDS) or two or more] organ [dysfunctions] dysfunction; and
- (iii) for adults, *septic shock* shall mean [severe sepsis with persistent] sepsis-induced hypotension persisting [or cardiovascular organ dysfunction] despite adequate IV fluid resuscitation and/or evidence of tissue hypoperfusion; for pediatrics, septic

shock shall mean [severe] sepsis and cardiovascular organ dysfunction [despite adequate IV fluid resuscitation].

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (“PHL”) Section 2800 provides that “[h]ospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, . . . the department of health shall have the central, comprehensive responsibility for the development and administration of the state’s policy with respect to hospital related services . . .”

PHL Section 2803 authorizes the Public Health and Health Planning Council (“PHHPC”) to adopt rules and regulations to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

### **Legislative Objectives:**

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high quality health services at a reasonable cost.

**Needs and Benefits:**

Sepsis is a range of clinical conditions caused by the body's systemic response to an infection and affects more than 1.5 million people in the U.S. each year.

In New York State 47,081 cases of sepsis were reported in 2016 with 11,982 deaths – a mortality rate of approximately 25 percent. However, the number of sepsis cases and the sepsis mortality rate varies widely from one hospital to another. The morbidity rate largely depends on how quickly patients are diagnosed and treated with powerful antibiotics to battle the bacterial infection. A patient may have a greater chance of dying from sepsis if care is provided by an institution poorly prepared to deal with this illness or from providers not thoroughly trained in identifying and treating sepsis.

In response to alarming sepsis statistics, regulations were enacted effective May 1, 2013 to require all hospitals licensed to operate in New York State to have in place and implement evidence-based protocols for the early identification and treatment of severe sepsis and septic shock. The sepsis regulations as originally drafted included guidelines and a definition of sepsis that is no longer consistent with the current international guidelines. This amendment will refine the guideline requirements and the definition to assure complete consistency. The amendment also makes other, minor technical changes to clarify language without changing the meaning or intent.

## **COSTS:**

### **Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:**

Existing sepsis regulations that require all hospitals to submit evidence-based protocols for the early identification and treatment of sepsis to NYSDOH are unchanged. Costs to the regulated entities are expected to be minimal and to be primarily associated with efforts needed to update internal protocols and definitions to align with the proposed changes. There is no impact on consumers or providers. This change ensures consistency in definitions but in no way alters the intent or impact of the current regulations.

### **Costs to Local and State Government:**

There is no anticipated fiscal impact to State or local government as a result of this regulation, except that hospitals operated by the State or local governments will incur minimal costs as discussed above.

### **Costs to the Department of Health:**

There will be no additional costs to the Department of Health associated with this definition change.

### **Local Government Mandates:**

Hospitals operated by State or local government will be affected and be subject to the same requirements as any other hospital licensed under PHL Article 28.

**Paperwork:**

There is no additional paperwork associated with this change in wording.

**Duplication:**

These regulations do not duplicate any State or Federal rules and assure consistency with established and clinically accepted definitions in use throughout the Nation.

**Alternative Approaches:**

There are no viable alternatives. Stakeholders requested that this change be made to assure absolute consistency with established definitions and to avoid any possible confusion on the part of hospitals and clinicians.

**Federal Requirements:**

Currently there are no federal requirements regarding the adoption of sepsis protocols or for reporting adherence to protocols or risk adjusted mortality.

**Compliance Schedule:**

These regulations will take effect upon publication of a Notice of Adoption in the New York *State Register*.

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**STATEMENT IN LIEU OF  
REGULATORY FLEXIBILITY ANALYSIS  
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS**

No regulatory flexibility analysis is required pursuant to Section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

**STATEMENT IN LIEU OF  
RURAL AREA FLEXIBILITY ANALYSIS**

No rural area flexibility analysis is required pursuant to Section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

## **JOB IMPACT STATEMENT**

Pursuant to the State Administrative Procedure Act (SAPA) section 201-a(2)(a), a Job Impact Statement for this amendment is not required because it is apparent from the nature and purposes of the proposed rules that they will not have a substantial adverse impact on jobs and employment opportunities.

## ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received comments from a patient advocate and a health care association.

**COMMENT:** A commenter stated that there is a new test and technology that can detect sepsis in minutes and the commenter felt the new test could help hospitals and the Department in its efforts to improve sepsis detection and care. No additional information was provided by the commenter.

**RESPONSE:** The Department continuously reviews new evidence and seeks information on new technologies and processes that may enhance patient care and outcomes. The Department will take the comment under advisement. No changes to the regulation were made as a result of this comment.

**COMMENT:** A commenter stated that the Department should further modify the regulation at section 405.4(a)(6) to remove the requirement for hospitals to submit written sepsis protocols to the Department. The commenter stated that the requirement is no longer necessary as all hospitals have written protocols in place to meet State and Federal reporting requirements. The commenter stated that the reporting requirements have evolved and compliance with reporting ensures little variation among hospital protocols. The commenter stated that given the small amount of variation across hospitals and given that the differences in protocols among hospitals are limited to internal processes and systems but not clinical processes, that the Department should instead accept an affirmative attestation from hospitals related to their use of written triage and treatment protocols.

**RESPONSE:** The Department agrees that there is no benefit to requiring ongoing submission of protocols each time a protocol is revised by hospitals. As a result of this comment, the final regulation requires that protocols are only submitted to the Department at the request of the Department. In addition, the final regulation eliminates the requirement that hospitals must receive a letter from the Department indicating that the proposed protocols have been reviewed and determined to be consistent with the criteria in section 405.4(a)(4).

**COMMENT:** A commenter stated that the Department should reduce the burden and frequency of hospital data submission audits from quarterly to annually. The commenter stated that quarterly audits require significant hospital resources and that because of the work that has been done by hospitals to improve the integrity of the data, the Department requirement should be aligned with the annual Federal requirement.

**RESPONSE:** Section 405.4(a)(7)(iii) requires hospitals to submit sepsis clinical data annually or more frequently and permits the Department to audit the data at the discretion of the Department. The regulation does not specify a timeframe for audit of sepsis clinical data. The Department will take the comment under advisement. No changes to the regulation were made as a result of this comment.