

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:

* * *

(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) are added to subdivision (a) of section 405.4 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.

* * *

(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 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) 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 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) for adults, 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.

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 about 750,000 people in the U.S. each year. The mortality rate is alarming – between 20 percent and 50 percent – and the rate largely depends on how quickly patients are diagnosed and treated with powerful antibiotics to battle the bacteria racing through their systems.

In New York State the number of **severe** sepsis cases increased from 26,001 in 2005 to 43,608 in 2011 - an increase of 68%. Similarly, the number of sepsis cases in New York State increased from 71,049 in 2005 to 100,073 in 2011, an increase of 41%. Sepsis mortality is significant and ranges widely from one hospital to another. In New York, sepsis mortality ranges between 15% and 37%. A patient may have a greater chance of dying from sepsis if care is provided by an institution ill-prepared to deal with this illness or from providers not thoroughly trained in identifying and treating sepsis.

The likelihood of death following initial diagnosis of sepsis is more than 20%, and the window for administering effective treatment is short. Mortality rates from severe sepsis are on a similar scale to lung, breast, and colon cancer, and it is one of the leading causes of death in the intensive care unit. Sepsis kills more people than HIV/AIDS, prostate cancer, and breast cancer combined.

The 28-day mortality rate in sepsis patients is comparable to the 1960s hospital mortality rate for patients of acute myocardial infarction (“AMI”). Over recent years, there has been an improvement in the awareness and management of AMI, resulting in a decline in mortality, while sepsis remains an unacknowledged killer.

The number of severe sepsis cases is expected to grow at a rate of 1.5% annually, adding an additional one million cases per year in the United States alone by 2020. This will increase total mortality and increase the burden on health care resources. The increase is mainly due to the

growing use of invasive procedures, immune system modifying therapies and increasing numbers of elderly and high-risk individuals, such as those with diabetes, cancer and HIV. Older people are at an increased risk of sepsis as they are more vulnerable to infections due to aging, co-morbidities, use of invasive procedures, and problems associated with institutionalization. Individuals with diabetes, cancer, and HIV are at increased risk due to immune system and other dysfunction caused by their disease or its treatment.

Sepsis places a significant burden on health care resources, accounting for 40% of total ICU expenditures. Sepsis costs our health care system an estimated \$17 billion annually, and the average cost of treating the condition is \$50,000. (See http://www.nigms.nih.gov/Education/factsheet_sepsis.htm.)

The rapid diagnosis and management of sepsis is critical to successful treatment. The sepsis patient is usually already critically ill and requires immediate attention to avoid rapid deterioration; therefore, it is necessary to treat the patient at the same time as confirming the diagnosis. Due to the challenges of diagnosing and treating this complex condition, approximately 10% of sepsis patients do not receive prompt appropriate antibiotic therapy, which increases mortality by 10 to 15%.

In the absence of adoption of protocols as required by these regulations, it is estimated that New York will see dramatic increases in cases of sepsis and sepsis mortality as the numbers of persons who are at risk continue to increase.

Hospitals can significantly impact sepsis morbidity and mortality by adopting standard protocols. For example, since the implementation of Kaiser Permanente's Northern California sepsis

program mortality has been reduced for patients admitted to hospitals with sepsis, by more than 40 percent — and saved more than 1,400 lives. Similarly, Regions Hospital in Minnesota reports that initiatives launched in 2005 led to more than a 60 percent drop in sepsis mortality by 2011, and Intermountain Health Care reports a reduction in its sepsis mortality rate from 25% to 9%, saving 85 lives and \$38 million annually. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In particular, these regulations will promote the early identification and treatment of sepsis at general hospitals by focusing on the following areas:

- **Recognition** of risk factors, signs and symptoms of sepsis;
- **Resuscitation** with rapid intravenous fluids and administration of antibiotics upon diagnosis of sepsis;
- **Referral** to appropriate clinicians and teams as appropriate;
- **Measurement** and evaluation of current practices for purposes of informing future policy; and
- **Quality Improvement** measures that will permit development and dissemination of best practices through clinical and administrative information sharing.

The Department of Health (“the Department”) will publish guidance to assist facilities in developing protocols that include an appropriate process for screening all patients to ensure early recognition of patients with possible sepsis and, once possible sepsis has been documented, establishing clear timeframes for administration of antibiotics and full protocol implementation. At a conference of stakeholders, including hospital systems, convened by the Department in 2012, it emerged that the current best practice is to pursue administration of antibiotics and fluid

resuscitation within one hour of a diagnosis of sepsis, with full implementation of sepsis protocols within 3 hours for severe sepsis and six hours for septic shock. Given continual advancements in medical research and practice, these timeframes could change and accordingly will be set forth in guidance which will be updated as appropriate.

These regulations, requiring hospitals to adopt protocols to identify and treat sepsis, and another set of regulations requiring hospitals to provide patients and their parents or other medical decision-makers with critical information about the patient's care and to post a Parent's Bill of Rights, were inspired by the case of Rory Staunton, a 12-year-old boy who died of sepsis in April of 2012. Both sets of regulations, together known as "Rory's Regulations," will help New York State set a "gold standard" for patient care.

COSTS:

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

Costs to the regulated entities are expected to be minimal and to be primarily associated with the following: (a) adoption of and compliance with evidence-based protocols; (b) reporting information to inform risk-adjusted sepsis mortality measures; and (c) training staff to implement the sepsis protocols. It is likely that hospitals will realize overall cost savings as a result of early identification and treatment (see below).

In fact, many hospitals throughout the State are currently implementing sepsis initiatives. The Greater New York Hospital Association ("GNYHA") and the United Hospital Fund ("UHF")

have launched a joint program called the “Strengthening Treatment and Outcomes for Patients Sepsis Collaborative;” the North Shore-LIJ Health System recently launched an education program to train emergency and critical care nurses on how to identify sepsis at its earliest stages and provide treatment to improve patient outcomes; and the Healthcare Association of New York State (“HANYS”) has organized a collaborative to improve the identification and management of sepsis and test the value of collaborative improvement projects versus traditional medical and clinical staff education. This regulation will build on and support these initiatives going forward.

Research conducted nationally suggests the possibility of a significant return on investment. As noted, Intermountain Health Care in Utah has reported savings of \$38 million per year due to its sepsis program, and reports more favorable reimbursement from insurers for identifying potential septic patients faster and treating them in the intensive care unit earlier. (See *Needles in a Haystack: Seeking Knowledge with Clinical Informatics*, PwC Health Research Institute, 2012.)

In New York State, Stony Brook University Medical Center (“SBUMC”) reports that a recent campaign to reduce sepsis mortality was extremely successful, resulting in a 49 percent reduction in mortality and a decrease in length of stay for patients with severe sepsis. This resulted in a cost savings of more than \$740,000 for the 153 severe sepsis patients at SBUMC in 2010. (See <http://www.naph.org/Homepage-Sections/Explore/Innovations/Preventing-Hospital-Acquired-Conditions/Stony-Brook-Reduces-Sepsis-Mortality.aspx>.) Similarly, a recent sepsis initiative at South Nassau Communities Hospital resulted in a 44% reduction in sepsis mortality (See HANYS Quality Institute, *Healthcare Association of New York State, Leading the Quest for Quality 2011 Profiles in Quality and Patient Safety*.) Similar savings to those reported

by SBUMC are likely.

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, offset by savings, as discussed above.

Costs to the Department of Health:

There will be minimal additional costs to the Department of Health associated with the following: review of protocols submitted by hospitals to the Department; general programmatic oversight; development of measures to evaluate the impact of these regulations as they relate to the adoption of evidence-based sepsis protocols; and creation of a data system for purposes of analysis and reporting.

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:

Consistent with these regulations all hospitals will be required to submit evidence of the following:

- (a) adoption of an evidence-based sepsis protocol initially and then once every two years after that.
- (b) information sufficient to evaluate each hospital's adherence to its own sepsis protocol, including adherence to timeframes and implementation of all protocol components for adults and children;
- (c) data, as specified by the Department, to permit the evaluation of risk-adjusted severe sepsis mortality rates.

Duplication:

These regulations do not conflict with any State or Federal rules. Implementation of these regulations represents the first time New York State has required that facilities submit indication of adherence to evidence-based protocols for the early detection and treatment of sepsis and to report outcomes (risk-adjusted mortality). Thus, there is no duplication.

Alternative Approaches:

There are no viable alternatives. Implementation of these regulations is predicated on strong evidence indicating the effectiveness of implementing evidence-based protocols. In addition to requiring that all hospitals throughout the State develop and implement evidence-based sepsis

protocols, the regulations will require submission of data to the Department. This will allow the Department to monitor adherence to protocols, measure the impact of the protocols through risk-adjusted mortality statistics, and use the data and information obtained to inform the development of quality improvement initiatives.

Federal Requirements:

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

In December 2012, the National Quality Forum included a proposed measure of adherence to treatment bundles for patients treated for sepsis. This measure, which is currently under consideration, would focus on patients 18 years of age and older who present with symptoms of severe sepsis or septic shock who are eligible for the 3 hour (severe sepsis) and/or 6 hour (septic shock) early management bundle. The regulations proposed by the Department to measure adherence with established sepsis protocols will seek to be in alignment with the NQF measure when adopted.

Compliance Schedule:

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

Contact Person:

Katherine Ceroalo
New York State Department of Health
Bureau of House Counsel
Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
518-473-7488
518-473-2019-FAX
REGSQNA@health.state.ny.us

REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

The provisions of these regulations will apply to the 228 general hospitals in New York State, including 18 general hospitals operated by local governments. Three general hospitals in the State are considered small businesses. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those three hospitals considered small businesses as well as the 18 hospitals operated by local governments. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

Professional Services:

Professional services are not anticipated to be impacted as a result of the following: (a) reporting the adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measure.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform risk-adjusted Sepsis mortality measures; and (c) training staff to implement the sepsis protocols. This will apply to those hospitals (three) defined as small businesses.

Economic and Technological Feasibility:

It is economically and technologically feasible for small businesses to comply with these regulations.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have until December 31, 2013, to have sepsis protocols in place and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Small Business and Local Government Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are small businesses and operated by local governments, who are supportive of this initiative.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

Effect of Rule:

The provisions of these regulations will apply to general hospitals in New York State, including 47 general hospitals located in rural areas of the State. These hospitals will not be affected in any way different from any other hospital.

Compliance Requirements:

Compliance requirements are applicable to those hospitals located in rural areas. Compliance will require: (a) adoption of and compliance with the required sepsis protocols; (b) training staff to implement the sepsis protocols; and (c) reporting information to inform risk-adjusted sepsis mortality measures.

Professional Services:

Professional services will not be impacted as a result of these regulations.

Compliance Costs:

Compliance costs associated with these regulations will be minimal and will arise as a result of: (a) adopting and complying with evidence-based protocols; (b) reporting information to inform

risk-adjusted Sepsis mortality measures; and (c) training staff to implement the sepsis protocols. This will apply to those hospitals located in rural areas of New York State.

Minimizing Adverse Impact:

Adverse impact will be minimized through the provision of time sufficient to comply with the regulations. More specifically impacted entities will have until December 31, 2013, to have sepsis protocols in place and at least six months before information to inform risk adjusted mortality measures will have to be reported to the Department.

Rural Area Participation:

These regulations have been discussed with hospital associations that represent hospitals throughout the state, including those that are located in rural areas, who are supportive of this initiative.

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.