Definition of Pediatric Severe Sepsis Update

Effective date: 3/26/14

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:

Subparagraph (ii) of paragraph (8) of subdivision (a) of Section 405.4 is amended 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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(8) Definitions. For the purposes of this section, the following terms shall have the following meanings:

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(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 one of the following: cardiovascular organ dysfunction
or acute respiratory distress syndrome (ARDS) or two or more organ dysfunctions [or acute respiratory distress syndrome]; and
REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (“PHL”) Section 2800 provides that “hospital 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.

In response to these alarming 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 a definition of pediatric severe sepsis that was not exactly consistent with the current international definition. This amendment will refine the definition to assure complete consistency. The original wording was as follows:

“For pediatrics, severe sepsis shall mean sepsis plus two organ dysfunctions or acute respiratory distress syndrome.”

Proposed revised wording is:

“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”
There is no known opposition to this change. Physicians who specialize in pediatrics and pediatric critical care requested that this change be made to assure absolute consistency with established definitions and avoid any possible confusion on the part of hospitals and clinicians.

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 not later than December 31, 2013 are unchanged. There are no costs associated with this change. There is no impact on consumers or providers. This change assures 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 fiscal impact to State or local government as a result of this regulation.

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. Physicians who specialize in pediatrics and pediatric critical care requested that this change be made to assure absolute consistency with established definitions and 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.
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
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.