

Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements

*Thursday, October 11, 2018
9:30 AM*

*Location: New York State Department of Health offices at 90 Church Street, Public Service
Commission Board Room, 4th Floor, New York City*

A. Agenda

For Adoption	Program Area	Unit Representative
Amendment to 10 NYCRR Section 405.4 – Sepsis Protocols	Office of Quality and Patient Safety	Dr. Marcus Friedrich
For Information	Program Area	Unit Representative
Addition of 10 NYCRR Section 405.34 – Stroke Services	Office of Quality and Patient Safety	Dr. Marcus Friedrich
Amendment to 10 NYCRR Section 400.18 – Statewide Planning and Research Cooperative System (SPARCS)	Office of Quality and Patient Safety	Scott Franko

B. Information Announcements

1. Anyone wishing to make oral comments at this meeting should contact the Bureau of Policy and Standards Development by 11:00 A.M. on Wednesday, October 10, at (518) 408-1833 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.
2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

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.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval of the Commissioner of Health by Section 2803 of the Public Health Law, a new Section 405.34 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 405.34 Stroke services.

- (a) Definitions. The following terms when used in this section shall have the following meanings:
- (1) “Stroke patient” means a patient exhibiting the signs and symptoms of a suspected stroke.
 - (2) “Certifying organization” means an accrediting organization approved by The Centers for Medicare and Medicaid Services (CMS), that has applied to the Department and has been approved by the Department to certify that a hospital meets the criteria to provide advanced stroke care.
 - (3) “Certified stroke center” means a general hospital that has successfully completed a stroke center certification with a certifying organization.
 - (4) “Designated stroke center” means a certified stroke center approved by the Department to operate as a designated stroke center under this section.
- (b) General Provisions.
- (1) General hospitals may choose to participate in the designated stroke center program under this section.

- (2) Only a certified stroke center may apply for stroke center designation from the Department.
 - (3) No hospital shall hold itself out to the public as having a stroke center designation unless it has a stroke center designation under this section.
- (c) **Certifying Organization Application.** Accrediting organizations may apply, in a format determined by the Department, to be approved as certifying organizations. Upon review of the application, the Department may approve certifying organizations to perform stroke center certification.
- (d) **Stroke Center Designation.** Hospitals seeking stroke center designation shall:
- (1) Obtain and maintain continuous stroke center certification from a certifying organization. The Department may participate in any onsite visits conducted by the certifying organization during certification and recertification.
 - (2) Submit an application to the Department with a copy of the certifying organization's certification and supporting documents. When determining whether to approve a certified stroke center as a designated stroke center, the Department may take other criteria into consideration, including but not limited to investigations by federal or state oversight agencies.
- (e) **Issuing Authority.** The Department shall make the final determination on all applications for stroke center designation. The Department shall provide written notification to a hospital when an application for a stroke center designation is approved. If an application for stroke center designation is denied, the Department shall provide written notification

and a rationale for the denial, and shall allow additional opportunities for the hospital to apply for a stroke center designation.

(f) Withdrawal of Stroke Center Designation.

(1) The Department may withdraw a hospital's stroke center designation upon notice to a designated stroke center if:

(i) The designated stroke center does not comply with state or federal regulations relating to stroke centers.

(ii) The designated stroke center fails to comply with its certifying organization's certification requirements and certification lapses.

(iii) The designated stroke center requests withdrawal of stroke center designation.

(2) Before withdrawing a stroke center designation pursuant to subdivision (f)(1)(i) or (ii) of this section, the Department shall provide the designated stroke center with a written notice containing a statement of deficiencies. If the designated stroke center fails to adopt a plan of correction acceptable to the Department within thirty (30) days, the Department may withdraw the hospital's stroke center designation.

(3) If a hospital no longer maintains stroke center designation, the hospital shall immediately notify affected parties and provide the Department with a written plan describing specific measures it has taken to alter its arrangements and

protocols under subdivision (i) of this section within thirty (30) days of a withdrawal of stroke center designation.

(g) Transition Period.

(1) Hospitals designated as stroke centers by the Department prior to the effective date of this section shall have two years from the effective date of this section to initiate the stroke center certification process with a certifying organization approved by the Department. The process is initiated when a hospital enters into a contractual agreement with a certifying organization. Once the hospital has entered into a contractual agreement with a certifying organization, the hospital shall have one year to complete the certification process.

(2) Any hospital that does not initiate the stroke center certification process with a certifying organization within two years of the effective date of this section shall no longer maintain a stroke center designation and may no longer hold themselves out as a designated stroke center.

(h) Coordination Agreement. Designated stroke centers shall communicate and coordinate with one another to ensure appropriate access to care for stroke patients, in accordance with a written coordination agreement. The Department may issue guidance to specify the provisions of coordination agreements. Designated stroke centers shall have policies and procedures in place for timely transfer and receipt of stroke patients to and from other hospitals consistent with section 405.19 of this Part. Transport of stroke patients to the appropriate receiving hospital shall be in accordance with State Emergency Medical

Advisory Committee (SEMAC) approved EMS protocols developed and adopted pursuant to subdivision two of section 3002-a of the Public Health Law.

- (i) Emergency Medical Services Providers; Assessment and Transportation of Stroke Patients to Designated Stroke Centers. Designated stroke centers shall work with Emergency Medical Services agencies to ensure that stroke center destination protocols are consistent with protocols adopted by the State Emergency Medical Advisory Committee, the State Emergency Medical Services Council (SEMSCO), the Regional Emergency Medical Advisory Committee (REMAC), and the Regional Emergency Medical Services Council (REMSCO).
- (j) The Department shall maintain and post on its public web page a list of designated stroke centers. The Department shall notify the State EMS advisory bodies and EMS regions via established communication networks whenever there is a change to a hospital stroke center designation, including but not limited to a new designation or a withdrawal of designation.
- (k) Reporting of Data and Quality of Care Initiatives.
 - (1) Each designated stroke center shall submit data, as requested by the Department, that shall be sufficient to determine the performance of the hospital and the system of care on at least an annual basis and in a format determined by the Department.
 - (2) The Department shall define the data elements to be reported.
 - (3) Each designated stroke center shall conduct stroke quality improvement activities including, but not limited to:

- (i) evaluation of the quality and appropriateness of care provided;
- (ii) participation in regional and statewide quality improvement activities, including but not limited to activities conducted by the Regional Emergency Medical Advisory Committee, consistent with section 3006 of the Public Health Law;
- (iii) analysis of data to identify opportunities for improvement; and
- (iv) integration of these activities with the hospital's quality assurance program, as required by section 405.6 of this Part.

REGULATORY IMPACT STATEMENT

Statutory Authority:

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:

This proposed regulation will create a tiered voluntary stroke designation program and stroke system of care for hospitals in New York State.

Stroke, also known as brain attack, is a medical emergency. It occurs when a vessel in the brain is either ruptured (hemorrhagic stroke) or blocked by a clot (ischemic stroke), arresting the blood supply to the brain. Stroke is a deadly condition, and it is the fifth leading cause of death and a major cause of disability in the United States. Each year, about 795,000 people in the United States develop a stroke, producing an enormous economic and healthcare burden. It is estimated that there are almost three million survivors of stroke living with a long-term disability in the United States, with a societal cost of approximately \$34 billion.

Since stroke treatment is complex and time sensitive, advanced hospital care is crucial. Evidence has shown that a standardized approach to hospital care for patients with acute stroke improves outcomes by increasing survival and minimizing disability.

The current New York State Department of Health (NYSDOH) stroke designation program began as a demonstration pilot program in select areas of the state in 2002 and was later expanded in 2004 to the entire state. The designation program is voluntary. Since 2004, NYSDOH has only recognized one level of stroke center designation: The Primary Stroke Center. As of June 2018, there are 120 designated Primary Stroke Centers among 213 hospitals in New York State. According to the Centers for Disease Control, New York State has the second lowest stroke mortality rate in the United States, demonstrating the success of the current program. NYSDOH data shows that the mortality rate (risk-adjusted, 30-day, all cause) for stroke patients is lower in Primary Stroke Centers versus non-designated hospitals (13.76 vs. 16.08 deaths per 100 admissions).

Stroke care guidelines and clinical evidence have evolved, and these stroke regulations align with the latest guidelines to ensure patients continue receiving high quality advanced stroke care. A consensus statement from the Brain Attack Coalition in 2005 cited evidence that integration of a new level of stroke center, called a Comprehensive Stroke Center, into stroke systems of care would likely improve outcomes of patients who require these services. Nationally recognized accrediting organizations began certifying Comprehensive Stroke Centers in 2012. In 2015, the American Heart Association issued a Class 1A recommendation for endovascular therapy for eligible ischemic stroke patients with large vessel occlusion, and recommended that access to endovascular therapy should be incorporated into stroke systems of

care. Because the current NYSDOH stroke designation program has remained static, some NYS hospitals have sought Comprehensive Stroke Center certification from outside organizations.

The current NYSDOH stroke center designation program requires interested hospitals to submit an application demonstrating that they meet or exceed a set of 14 criteria that are based on “The Brain Attack Coalition Guidelines for Primary Stroke Centers,” originally published in the Journal of the American Medical Association in 2000 and updated in 2011. The application is then reviewed by the Office of Quality and Patient Safety (OQPS) in NYSDOH, and an on-site evaluation is done by a nurse and a medical director from NYSDOH at no charge to the applying hospital. Once the hospital passes all requirements, the NYSDOH designates the hospital as a New York State Primary Stroke Center.

Representatives from the NYSDOH began engaging stakeholders and soliciting comments and feedback internally and externally in the fall of 2017 from the following affected parties: Healthcare Association of New York State, Regional stroke coordinators from hospitals across the state, Stroke Advisory Committee, Greater New York Hospital Association, Iroquois Healthcare, American College of Physicians, The Medical Society of the State of New York, The Joint Commission/American Heart Association, DNV GL Healthcare, the Healthcare Facilities Accreditation Program, the Center for Improvement in Healthcare Quality, South Carolina stroke designation program, Fire Department of NY, Fort Drum Regional Health Planning Organization, and the State Emergency Medical Services Council (SEMSCO). The input received was the impetus for the proposed regulation.

This proposed regulation will create a tiered voluntary stroke designation program and stroke system of care for hospitals in New York State. During the transition period, EMS should continue to operate within their existing framework and per their protocols.

NYSDOH will designate nationally recognized accrediting organizations to certify the ability of hospitals to provide care to stroke patients. Currently, Primary, Thrombectomy Capable or Comprehensive levels are among levels of programs certified by nationally recognized certifying organizations. Certifying organizations will be required to adhere to evidence-based standards provided by the Department.

The regulation also gives the NYSDOH the authority to withdraw designation from a hospital for non-compliance and the failure to maintain or adhere to criteria for stroke designation. Pursuant to the proposed regulations, NYSDOH will continue to collect data and require stroke centers to maintain quality improvement efforts.

With this regulation, the NYSDOH will leverage the experience and resources of the certifying organizations and improve the quality of stroke care, using a multi-tiered system of stroke care that aligns with the latest evidence.

COSTS:

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

The proposed regulation will create costs for hospitals seeking stroke center designation. The certifying organizations each charge a fee for stroke certification, which includes the following services: a consultation visit, onsite survey, ongoing monitoring, data collection and reporting to NYSDOH. The cost of certification for hospitals varies by organization, and by level of stroke center certification, but ranges from \$2,500 - 55,000 every two years. However, the proposed regulation does not require hospitals to be fully accredited by the accreditation organization to receive stroke center designation. Instead, the proposed regulation only requires

hospitals to be certified by the accreditation organization for their disease-specific stroke program. This provision makes the stroke certification costs significantly less expensive than acquiring a full hospital accreditation.

A hospital may also incur infrastructure and staffing costs associated with meeting certification requirements. Stroke center designation could increase the volume of patients that a hospital receives, and consequently revenue, since patients are transported to designated stroke centers by EMS agencies, and community awareness of stroke center designation may increase patient self-referral.

Costs to Local and State Government:

The proposed regulations are not expected to impose any costs upon local or state governments. If a hospital operated by a State or local government chooses to apply to become a designated stroke center, it would have the same costs as hospitals that are not operated by a State or local government.

Costs to the Department of Health:

There will be little to no additional costs to the Department associated with the proposed regulations. The Department will monitor the certifying organizations and will supervise the stroke designation process with existing staff.

Local Government Mandates:

There are no local government mandates.

Paperwork:

Hospitals that participate in the stroke designation program must enter into a contractual agreement with an accreditation organization to initiate the stroke center certification process. Certified stroke centers applying for stroke center designation must submit an application to the Department.

Each hospital with stroke center designation will be required to submit data electronically for performance measurement.

Duplication:

These regulations do not duplicate any State or Federal rules, since there are no existing stroke regulations.

Alternative Approaches:

The Department could continue the existing stroke designation program. However, proposed regulations will ensure access to the highest standard of evidence-based care for stroke patients in New York.

Federal Requirements:

Currently there are no federal requirements regarding the stroke regulation.

Compliance Schedule:

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

Contact Person:

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**REGULATORY FLEXIBILITY ANALYSIS FOR
SMALL BUSINESSES AND LOCAL GOVERNMENT**

Effect of Rule:

Only general hospitals may apply to become a designated stroke center. There are no general hospitals in NYS that are classified as a small business. There are several hospitals run by local governments. There is a total of six hospitals operated by NYS counties.

Compliance Requirements:

The stroke designation program is a voluntary program, so there is no mandate for a hospital to participate. Those choosing to apply for stroke center designation will be expected to comply with NYSDOH stroke center requirements and certifying agency standards. These standards include maintenance of a stroke log and registry as well as reporting requirements for performance measures.

Professional Services:

A hospital choosing to participate in the stroke designation program will be required to receive certification from a nationally recognized accrediting organization with stroke center certifying authority.

Compliance Costs:

The proposed regulation will create costs for hospitals seeking stroke center designation. The certifying organizations each charge a fee for stroke certification, which includes the following services: a consultation visit, onsite survey, ongoing monitoring, data collection and reporting to NYSDOH. The cost of certification for hospitals varies by organization, and by level of stroke center certification, but ranges from \$2,500 - 55,000 every two years.

Economic and Technological Feasibility:

This regulation establishes a voluntary stroke designation program, and as such there is no mandate for compliance. Hospitals seeking stroke center designation shall have the resources, both economic and technological to meet requirements and standards of the program.

Minimizing Adverse Impact:

This regulation will not have any adverse economic impact on small businesses or local governments. Hospitals with stroke center designation will preferentially receive suspected stroke patients from EMS providers, increasing volume and having a positive economic impact.

Small Business and Local Government Participation:

NYSDOH has included various stakeholders in the development of this regulation, including general hospitals run by local governments through in person presentations and hospital association engagement.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to § 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to approval by the Commissioner of Health by Section 2816 of the Public Health Law, Section 400.18 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 400.18 is amended to read as follows:

10 NYCRR § 400.18 Statewide Planning and Research Cooperative System (SPARCS).

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

(1) Health care facilities shall mean facilities licensed under Article 28 of the Public Health Law.

(2) Identifying data elements shall mean those SPARCS [and Patient Review Instrument (PRI)] data elements that, if disclosed without any restrictions on use or re-disclosure would constitute an unwarranted invasion of personal privacy. A list of identifying data elements shall be specified by the Commissioner and will be made available publicly.

(3) Inpatient hospitalization data shall mean SPARCS data submitted by hospitals for patients receiving inpatient services at a general hospital that is licensed under Article 28 of the Public Health Law and that provides inpatient medical services.

(4) Outpatient data shall mean emergency department data, ambulatory surgery data, and outpatient services data.

(i) Emergency department data shall mean SPARCS data submitted by a facility licensed to provide emergency department services under Article 28 of the Public Health Law.

(ii) Ambulatory surgery data shall mean SPARCS data submitted by a facility licensed to

provide ambulatory surgery services under Article 28 of the Public Health Law.

(iii) Outpatient services data shall mean all data submitted by licensed Article 28 facilities excluding inpatient hospitalization data, emergency department data, and ambulatory surgery data.

(5) [Patient Review Instrument (PRI) data shall mean the data submitted on PRI forms by residential health care facilities, pursuant to section 86-2.30 of this Title.

(6) SPARCS Administrator shall mean a person in the SPARCS program designated by the Commissioner to act as administrator for all SPARCS activities.

[(7)] (6) SPARCS data shall mean the data collected by the Commissioner under section 2816 of the Public Health Law and this section, including inpatient hospitalization data and outpatient data.

[(8)] (7) SPARCS program shall mean the program in the New York State Department of Health (NYSDOH) that collects and maintains SPARCS data and discloses SPARCS [and Patient Review Instrument (PRI)] data.

(b) Reporting SPARCS data.

(1) Health care facilities shall report data as follows:

(i) Health care facilities shall submit, or cause to have submitted, SPARCS data in an electronic, computer-readable format through [NYSDOH's] a secure electronic network [according to the requirements of section 400.10 of this Part and the] designated by the Department according to specifications provided by the Commissioner.

(ii) All SPARCS data must be supported by documentation in the patient's medical and billing records.

(iii) Health care facilities must submit on a monthly basis to the SPARCS program, or cause to have submitted on a monthly basis to the SPARCS program, data for all

inpatient discharges and outpatient visits. Health care facilities must submit, or cause to have submitted, at least 95 percent of data for all inpatient discharges and outpatient visits within sixty (60) days from the end of the month of a patient's discharge or visit. Health care facilities must submit, or cause to have submitted, 100 percent of data for all inpatient discharges and outpatient visits within one hundred eighty (180) days from the end of the month of a patient's discharge or visit.

(iv) The SPARCS program may conduct an audit evaluating the quality of submitted SPARCS data and issue an audit report to a health care facility listing any inadequacies or inconsistencies in the data. Any health care facility so audited must submit corrected data to the SPARCS program within 90 days of the receipt of the audit report.

(2) Content of the SPARCS data.

(i) Health care facilities shall submit, or cause to have submitted, uniform bill data elements as required by the Commissioner. The data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website to the extent allowed by copyright law.

(ii) Health care facilities shall submit, or cause to have submitted, additional data elements as required by the Commissioner. Such additional data elements shall be from medical records or demographic information maintained by the health care facilities.

(iii) The list of specific SPARCS data elements and their definitions shall be maintained by the Commissioner, will be made available publicly, and may be modified by the Commissioner.

(c) Maintenance of SPARCS data.

The Commissioner shall be responsible for protecting the privacy and security of the health care information reported to the SPARCS program.

(d) Requests for SPARCS [and PRI] data.

(1) SPARCS [and PRI] data may be used for medical or scientific research or statistical or epidemiological purposes approved by the Commissioner.

(2) The Commissioner may determine that additional purposes are proper uses of SPARCS [and PRI] data.

(3) In determining the purpose of a request for SPARCS [and PRI] data, the SPARCS program shall not be limited to information contained in the data request form and may request supplemental information from the applicant.

(4) The Commissioner shall charge a reasonable fee to all persons and organizations receiving SPARCS [and PRI] data based upon costs incurred and recurring for data processing, platform/data center and software. The Commissioner may discount the base fee or waive the fee upon request to the SPARCS program. The fee may be waived in the following circumstances:

(i) Use by a health care facility of the data it submitted to the SPARCS program.

(ii) Use by a health care facility that is licensed under Article 28 of the Public Health Law for the purpose of rate determinations or rate appeals and for health care-related research.

(iii) Use by a Federal, New York State, county or local government agency for health care-related purposes.

(5) The SPARCS program shall follow applicable federal and state laws when determining whether SPARCS [and PRI] data contain identifying data elements may be

shared and whether a disclosure of SPARCS [and PRI] data constitutes an unwarranted invasion of personal privacy.

(6) All entities seeking SPARCS [and PRI] data must submit a request to the SPARCS program using standard data request forms specified by the SPARCS program. Data users shall take all necessary precautions to prevent unwarranted invasions of personal privacy resulting from any data analysis or release. Data users may not release any information that could be used, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information. Data users bear full responsibility for breaches or unauthorized disclosures of personal information resulting from use of SPARCS [or PRI] data. Applications for SPARCS [or PRI] data must provide an explicit plan for preventing breaches or unauthorized disclosures of personal information of any individual who is a subject of the information.

(7) Each data request form must include an executed data use agreement in a form prescribed by the SPARCS program. Data use agreements are required of: a representative of the requesting organization; a representative of each other organization associated with the project; and all individuals who will have access to any data including identifying data elements.

(8) The SPARCS program shall publish and make publicly available the name of the project director, the organization, and the title of approved projects.

(9) The SPARCS Administrator shall review and make recommendations on requests for SPARCS [and PRI] data containing identifying data elements to a data release committee established by the Commissioner. The data release committee shall have at least three members, including at least one member not otherwise affiliated with NYSDOH. The members of the data release committee shall be posted on the NYSDOH website.

Requests will be granted only upon formal, written approval for access by a majority of

the members of the data release committee. The Commissioner has the final authority over the approval, or disapproval, of all requests. Requests for identifying data elements shall be approved only if:

- (i) The purpose of the request is consistent with the purposes for which SPARCS [and PRI] data may be used;
- (ii) The applicant is qualified to undertake the project; and
- (iii) The applicant requires such identifying data elements for the intended project and is able to ensure that patient privacy will be protected.

(10) The SPARCS Administrator may recommend approval of a request in which future SPARCS data is to be supplied on a periodic basis under the following conditions:

- (i) SPARCS data may be requested for a predetermined time not to exceed three years beyond the current year provided that the organization and uses of the data remain as indicated in the data request form submitted to the SPARCS program.
- (ii) During the period of retention of SPARCS [or PRI] data, no additional individuals may access SPARCS [or PRI] data without an executed data use agreement on file with the SPARCS program.

(11) The Commissioner may rescind for cause, at any time, approval of a data request.

(e) Penalties.

(1) Any person or entity that violates the provisions of this section or any data use agreement may be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law.

(2) Any person or entity that violates the provisions of this section or any data use agreement may be denied access to SPARCS [or PRI] data.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Statewide Planning and Research Cooperative System (SPARCS) is a comprehensive health care data reporting system established in 1979 through cooperation between the health care industry and government. The enabling legislation for SPARCS is Section 2816 of the Public Health Law (PHL). The regulations pertaining to SPARCS are under Section 400.18 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR).

Legislative Objectives:

In 2001, the Legislature codified the Department's authority to collect SPARCS data by adding PHL § 2816. In 2011, the Legislature expanded this authority by authorizing the Department to develop and implement an All Payer Database for New York State. In doing so, the Legislature referenced the Department's need for greater flexibility in the forms of data submission.

The enactment of Public Health Law § 2816(6) authorized the Department to describe data elements by reference to information reasonably available to regulated parties, as such material may be amended in the future. This provision recognizes the Department's need for flexibility when determining data elements by authorizing the Department to adjust such data elements administratively.

Needs and Benefits:

The current regulation directs data to be submitted to SPARCS through the Health Commerce System (HCS). This rule making revises Section 400.18 to grant the SPARCS program the flexibility to explore other data intake options, consistent with Public Health

Law § 2816. This rule making also removes all references to Patient Review Instrument (PRI) data, which is an obsolete data source.

This rule making clarifies that input data dictionary elements are protected by copyright law. The Department will continue to precisely identify and publish a description of what data elements must be submitted to the extent it may do so under copyright law.

The proposed regulation changes will enhance the SPARCS program by modernizing the program's technology and functionality. Currently, HCS users regularly experience bandwidth issues, poor network performance, and slow data transfer speeds. These issues hinder the ability of data submitters to submit SPARCS data in a timely fashion. By leveraging new technology for SPARCS data intake, the SPARCS program will operate more efficiently.

Lastly, the proposed regulation specifies that data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website to the extent allowed by copyright law. The SPARCS program is in the process of changing its data format to require data to be submitted in the X12 837R ("X12") format, which is to some extent proprietary intellectual property owned by X12 Incorporated. See <http://www.x12.org/>, <http://members.x12.org/policies-procedures/cap01v3-bylaws.pdf>, <http://store.x12.org/store/ip-use>. Consistent with past practice, the Department will publish the data elements with specificity so that regulated parties will know exactly what data elements must be submitted, with the caveat that the Department will not publish intellectual property that it does not have a right to publish.

Costs:

Costs to Regulated Parties:

The rule change levies minor additional costs to health care facilities licensed under Article 28 of the PHL that may need to, in some cases, change their existing contracts with vendors to submit data, if they utilize a vendor. These minor additional costs would be solely related to changes needed to submit data to the Department's contractor rather than submitting data directly to the Department using the HCS. Data will continue to be submitted in the standard claims data format that all Article 28 facilities have already adopted under federal regulations in 42 CFR Part 162 as authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Costs to the NYSDOH:

The costs associated with this change will be offset by savings from no longer having to finance a mainframe system and changes needed to the HCS maintained by the NYS Office of Information Technology Services. This change will also allow for the reallocation of NYSDOH staff to areas needing additional resources.

Costs to State and Local Governments:

There are no anticipated costs to local governments as a result of this rule change, except that any PHL Article 28 facilities that are operated by local governments will incur the same costs as any other Article 28 facilities subject to this regulation.

Local Government Mandates:

This rule change imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The rule change imposes no significant reporting requirements, forms, or other paperwork upon regulated parties.

Duplication:

There will be no duplication of reporting efforts to New York State for health care facilities licensed under Article 28 of the PHL.

Alternatives:

There are no reasonable alternatives that could serve as a substitute, because the Department will no longer be able to collect data using the HCS. The Department's mainframe system for SPARCS was scheduled to sunset when key staff retired. The Office of Information Technology Services would no longer support COBOL/mainframe SPARCS translation. Likewise, the Office of Information Technology Services was sunsetting support for a key technology used to support the SPARCS application on the HCS.

Federal Standards:

The rule change does not exceed any minimum standards of the federal government for the same or similar subject area, as the federal government does not operate a national program like SPARCS.

Compliance Schedule:

The rule change will not alter SPARCS compliance schedules. Health care facilities licensed under Article 28 of the PHL will continue to submit data to SPARCS at the same frequency and levels they currently do.

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**STATEMENT IN LIEU OF
REGULATORY FLEXIBILITY ANALYSIS**

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

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

The rule change will have no impact on jobs and employment opportunities on the part of regulated parties (health care facilities licensed under Article 28 of the Public Health Law). The regulated health care facilities already have an existing data reporting infrastructure and are required to report SPARCS data. The way facilities submit data to SPARCS would not change. It would not be more burdensome or costly for data submitters as their data submission process would be very similar to what currently is in place. There will be no job impacts in any other segments or sectors of the job market. With regards to adverse employment effects, there is no expectation of job losses as a result of the rule.