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*.

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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.