

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.

## ASSESSMENT OF PUBLIC COMMENT

Public comments were submitted to the New York State Department of Health (Department) in response to the proposed regulation. The public comment period for this regulation ended on December 17, 2018. The Department received comments from physicians, health care associations and legislators. The comments and the Department's responses are summarized below.

**COMMENT:** A commenter recommended that section 405.34(g)(2) be amended to clarify that a hospital will not be prohibited from becoming a designated stroke center if it does not seek to become certified in the two-year period following the adoption of the regulations. The commenter expressed concern that hospitals may be discouraged from applying for certification if they do not apply within the two-year transition period.

**RESPONSE:** The intent of the proposed regulation at section 405.34(g) is to offer a transition period for hospitals that are currently recognized as stroke centers in NYS. Section 405.34(g)(1) states that hospitals currently recognized as designated stroke centers by the Department prior to the effective date of this section shall have two years from the effective date of the regulation to initiate the stroke center certification process with a Department approved certifying organization. In the event that a hospital currently recognized as a stroke center does not initiate the process within two years of the effective date of the regulation, the hospital will lose its designation but could be designated in the future as provided in this regulation. The Department will continue to work to make transition period details clear to all hospitals in NYS. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** A commenter noted that the Regulatory Impact Statement associated with the proposed regulations listed the Primary, Thrombectomy-Capable and Comprehensive Stroke programs as the levels hospitals may apply for in the proposed Stroke Services program in NYS, but the nationally-available Acute Stroke Ready (ASR) level was not included in the description.

**RESPONSE:** The Department spent considerable time engaging stakeholders prior to proposing regulations to understand whether there would be interest from hospitals in pursuing the ASR level. The Department will continue to engage hospitals to gauge the need for and interest in the ASR level and will make it available should need and interest be identified. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** A commenter recommended that the Department streamline the proposed application process, which requires a hospital to submit a request for designation to the Department after the hospital has been certified by a certifying organization. The commenter suggested that a hospital approved by the certifying organization should be recognized by the Department without a separate application process.

**RESPONSE:** Section 405.34(d)(2) requires hospitals seeking stroke center designation to apply to the Department with a copy of the certifying organization's certification and supporting documents. This section allows the Department to perform a final review to ensure that all standards have been satisfied by the hospital prior to designation and to review for, at a minimum, potential investigations by federal or State oversight agencies that may preclude the Department from designating the hospital. This step will also trigger internal Department processes which include notifying the NYS Bureau of Emergency Medical Services (EMS) of a new stroke designation and updates to internal and public systems acknowledging the new

hospital designation as a destination for EMS providers transporting patients. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** A commenter urged the Department to streamline, align and focus on the performance measures that are the most meaningful for improving stroke care. The commenter stated that performance measures should be consistent with the Accrediting Organizations (AOs) approved to certify NYS hospitals for stroke services and that two measures currently collected by the Department are not required by the AOs: dysphagia screening and smoking cessation. The commenter also noted that at least one of the AOs leverages sampling for stroke measures which reduces the burden of reporting without losing data validity.

**RESPONSE:** The Department will continue its ongoing efforts to capture meaningful data to advance the goals of making high-quality stroke care available in a timely manner to patients suffering from a suspected stroke. To that end, the Department, in collaboration with the Stroke Advisory Committee, has been developing reporting requirements that allow robust evaluation of hospital and stroke system of care performance while minimizing the burden of excessive reporting. The Department will take these comments under advisement when finalizing reporting requirements for the program. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** Multiple commenters shared concern over the potential burden for hospitals of reporting data to the Department and the AO. One commenter stated that most hospitals submit stroke quality measures to the American Heart Association (AHA) Get With The Guidelines (GWTG) program and that, to fulfill the Department's requirements, hospitals that submit to

GWTG but select an AO other than The Joint Commission/AHA may be forced to double-report the same measures to the AO they select, thereby causing an undue reporting burden on these hospitals. One commenter commended the Department for allowing hospitals to select from multiple AOs to become certified in the proposed program, but shared concern that the potential for double-reporting could undermine the Department's efforts to allow for multiple AOs. A separate commenter urged the Department to ensure that hospitals can report to both the AO and the Department through a single data submission to streamline data collection and submission to reduce burden and to enable hospitals to dedicate their limited resources to quality and patient safety.

**RESPONSE:** The Department engaged numerous stakeholders to assess potential issues surrounding data collection and the barriers associated with the available stroke registries. The Department has continuously emphasized the importance of data collection for the purposes of performance monitoring and quality improvement to foster a successful program that provides the highest quality care to suspected stroke patients. To that end, the Department has specifically not required any single data collection tool or stroke registry in the proposed regulations to avoid administrative burden or additional costs to hospitals. The Department will only require that hospitals submit performance measurement data to the Department; however, the Department is aware that AOs have varying data requirements, with some requiring no data submission and others requiring extensive data reporting. The Department will take these comments under advisement and will continue working with AOs that become certifying organizations and hospitals to minimize double-reporting of performance measurement data. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** A commenter noted that the proposed program will require regions to adopt new stroke patient triage protocols, processes and agreements across hospitals so that patients are appropriately transported to the closest stroke designated center based on an assessment of their stroke acuity. The commenter stated that regions will also need to ensure that their EMS services are adequately trained and EMTs are appropriately scoring and triaging patients. The commenter further stated that some regions, including New York City (NYC), have already approved ambulance triage and transport protocols and have begun implementation of these protocols. While the commenter offered support for the proposed three-year transition period, the commenter stated that questions have been raised about whether the transition period applies to NYC and other regions and whether hospitals need to move more quickly. The commenter urged the Department and the State Emergency Medical Advisory Committee (SEMAM) to monitor and ensure a level of uniformity, particularly with respect to allowing hospitals time to transition and train EMTs as the regulations are implemented. Another commenter stated that as NYS moves from a single-tiered stroke program to tiered certifications the Department should work closely with EMS to monitor potential disruptions to the healthcare system to ensure that patients continue to receive timely, expert stroke care in NYS.

**RESPONSE:** The Department has worked extensively over the last year to engage critical stakeholders, including the Regional Emergency Medical Advisory Committees (REMACs) and the SEMAM, on issues related to developing guidelines for regions that are developing and implementing stroke systems of care that include all levels of NYS stroke facility designation. The Department has also clarified in numerous live and virtual presentations that the proposed regulations will apply to all regions in NYS, including NYC, at the time of adoption. The Department is committed to continuing to work with the REMACs and the SEMAM to establish

a framework and guidelines for the development and implementation of regional stroke systems of care. The proposed regulation does not require regions to adopt new triage protocols. Additional information and written guidance will be made available by the Department to address the change from a single tiered stroke program to a tiered certification system. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** Multiple commenters wrote in support of modifications to the proposed regulations to address EMS triage and transport plans, as well as hospital transfer plans, to address and support patients with a specific type of severe ischemic stroke called an emergent large vessel occlusion (ELVO), as patients with ELVO have a significantly higher rate of mortality and disability. Commenters stated that a newly developed procedure called mechanical thrombectomy has provided a vastly more successful treatment for ELVO patients. Commenters stated that EMS protocol and transport plans should ensure that patients are receiving proper treatment in a timely fashion and the proposed regulations should address the ELVO patient group to ensure that those within the regional systems of care (including hospitals, EMS providers, REMACs, the SEMAC) throughout NYS address this need by continuously updating their system based on data that supports direct transport of ELVO patients to hospitals capable of performing mechanical thrombectomy whenever necessary. Commenters noted that ensuring patients are sent to the most appropriate medical centers depending on the severity of their stroke, the Department will be doing what has already been done for patients suffering heart attacks or trauma.

**RESPONSE:** These comments are noted. The Department is developing guidance in consultation with the Stroke Advisory Committee to address the rapid triage and transport of

suspected stroke patients to the most appropriate hospital setting based on hospital capability. The guidance will highlight requirements for transfer agreements between hospitals to address the need for transportation to appropriate settings depending on patient acuity and will be part of certification standards. In light of the comments, the Department will include guidance specific to the ELVO patient population to address the need for EMS protocol and stroke center transport plans for patients with ELVO. The Department is committed to continuing to work with the REMACs and the SEMAC to develop and implement guidelines and protocols to address the appropriate triage of patients. The changes proposed by the commenters are beyond the scope of the proposed regulations as the Department is not seeking to amend the regulations in section 405.19 as they relate to EMS providers. No changes to the proposed regulations were made as a result of these comments.

**COMMENT:** Several commenters wrote in support of the proposed regulations. One commenter noted that while stroke outcomes in New York State (NYS) are among the best in the country, the proposed regulations will enable NYS to improve and better coordinate stroke care across all providers regionally, based on a patient's needs and acuity. Another commenter thanked the Department for leading stroke experts around NYS with the common goal of improving patient care and outcomes. Several commenters noted the proposed updates to stroke services in NYS are encouraging and a move in the right direction.

**RESPONSE:** These comments in support are noted by the Department. No changes to the proposed regulations were made as a result of these comments.