

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, Section 405.34 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 (g) of section 405.34 is amended to read as follows:

(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.
- (3) The Department may extend the transition period specified in paragraphs (1) and (2) of this subdivision as deemed necessary. The Department will notify all impacted hospitals of any decision to extend the transition period.

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:

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, expedited hospital care is critical. Evidence has shown that a standardized approach to hospital care for patients with acute stroke improves outcomes by increasing survival and decreasing disability.

The stroke regulation in 10 NYCRR section 405.34 requires hospitals that received designation as a stroke center prior to the enactment of the regulation to enter into a contractual

agreement with a certifying organization recognized by the Commissioner of Health within two years of the effective date of the regulation. Within a year after the hospital enters into a contractual agreement with the certifying organization, they must complete their certification as a stroke center and request designation as a stroke center from the Department. Thus, any hospital that does not complete the certification and designation process by March 19, 2022 would relinquish their designation as a stroke center.

Due to the COVID-19 pandemic all regular surveys and reviews scheduled by certifying organizations were temporarily suspended. Approximately 100 hospitals still need to comply with the regulation. It has become clear that the length of time the certification process can take from the time a contract between a certifying organization and a hospital is initiated to the time a hospital is surveyed and designated could force many hospitals to relinquish their stroke designations as a result of backlogs caused by the COVID-19 pandemic. This amendment will give the Department the ability to extend the transition timeline to allow hospitals to complete the stroke designation process outlined by this regulation while they maintain their stroke designation status and continue to be a destination for patients in their communities that need access to stroke services.

COSTS:

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

Costs to the regulated entities related to this amendment are none. There is no impact on consumers or providers.

Costs to Local and State Government:

There is no anticipated fiscal impact to State or local government as a result of this amendment.

Costs to the Department of Health:

There will be no additional costs to the Department of Health associated with this amendment.

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.

Alternative Approaches:

There are no viable alternatives. Stakeholders requested that this change be made to assure adequate time for hospitals to comply with the regulation timeline.

Federal Requirements:

Currently there are no federal requirements.

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.

ASSESSMENT OF PUBLIC COMMENT

The Department of Health (Department) received one comment regarding the proposed amendment.

COMMENT: Greater New York Hospital Association supports the proposed amendment and the suggested modifications to the transition timeline to allow the Department to extend the allowable time for hospitals designated as stroke centers to become certified by an approved accrediting organization beyond March 2022.

RESPONSE: The Department acknowledges and appreciates the support of Greater New York Hospital Association for this regulation.