

# Public Health and Health Planning Council

## *Codes, Regulations and Legislation Committee Meeting Agenda and Informational Announcements*

*Thursday, February 14, 2019  
9:30 AM*

- *Main Meeting Site - 90 Church Street 4<sup>th</sup> Floor, Room 4A & 4B, New York City*
- *Via Video Conference - New York State Department of Health Offices at 584 Delaware Avenue, 2nd Floor Video Conference Room, Buffalo, NY 14202*
- *Via Video Conference - New York State Department of Health Offices at the Triangle Building, 335 East Main Street, 1<sup>st</sup> Floor Conference Room, Rochester, New York 14604*

### **A. Agenda**

#### **For Adoption**

Addition of 10 NYCRR Section 405.34 –  
Stroke Services

#### **Program Area**

Office of Quality and  
Patient Safety

#### **Unit Representative**

Dr. Marcus Friedrich

Amendment to 10 NYCRR Part 14 –  
Food Service Establishments

Center for  
Environmental Health

Darby Greco

#### **For Information**

Amendments to 10 NYCRR Part 709 and 405 –  
Cardiac Services

#### **Program Area**

Office of Primary Care  
and Health Systems  
Management

#### **Unit Representative**

Daniel Sheppard

Addition of 10 NYCRR Part 795 –  
Midwifery Birth Centers

Office of Primary Care  
and Health Systems  
Management

Mark Hennessey

### **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, February 13, at (212) 417-6218 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 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:**

Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Rm. 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

**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 Commissioner of Health by Sections 225(4) and 201(1) of the Public Health Law, Subparts 14-1, 14-2, 14-4 and 14-5 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended to be effective upon filing a Notice of Adoption in the New York State Register, to read as follows:

New sections 14-1.89 is added to read as follows:

14-1.89 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.
- (d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

Section 14-2.3 is amended to include a new subdivision (g) to read as follows:

(g) For the purposes of this subdivision, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (1) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (2) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (3) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.
- (4) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

New section 14-4.96 is added to read as follows:

14-4.96 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

- (a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.
- (b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.
- (c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.

(d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

New sections 14-5.46 is added to read as follows:

#### 14-5.46 Use of Liquid Nitrogen and Dry Ice.

For the purposes of this section, liquid Nitrogen shall mean Nitrogen in its cryogenic liquid form, which comes in direct contact with food or is used as a food additive. Dry Ice shall mean Carbon Dioxide in its solid form, which comes in direct contact with food or is used as a food additive.

(a) Only food-grade liquid Nitrogen or Dry Ice may be added to food.

(b) Liquid Nitrogen, used in the preparation of food, is to be drained or allowed to evaporate completely prior to vending.

(c) Dry Ice, used in the preparation of food, shall be sublimated completely or removed prior to vending.

(d) Liquid Nitrogen or Dry Ice shall not be added to any food before service, such that a “fog” or “smoke” effect remains at time of service or is created during eating.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The New York State Public Health and Health Planning Council is authorized by New York State Public Health Law (PHL) Section 225(4) to establish, amend and repeal sanitary regulations known as the Sanitary Code of the State of New York (Sanitary Code), subject to approval by the Commissioner. PHL Section 201(1)(m) authorizes the New York State Department of Health (Department) to supervise and regulate the sanitary aspects of public eating and drinking establishments.

### **Legislative Objectives:**

This rulemaking is in accordance with the legislative objective of PHL Sections 225(4) and 201(1)(m) authorizing the PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety through the regulation of the sanitary aspects of Food Service Establishments. In accordance with this objective, the proposed amendments prohibit Food Service Establishment operators from using liquid Nitrogen or Dry Ice at the point of sale to protect the health and safety of New Yorkers patronizing Food Service Establishments.

### **Needs and Benefits:**

The Department is aware of new trends in food service that utilize liquid Nitrogen and Dry Ice at the point of sale. Using liquid Nitrogen and Dry Ice at the point of sale of

food products may cause serious injury if the consumer touches or consumes the residual liquid Nitrogen or Dry Ice.

One of these food trends is commonly referred to as “Dragon’s Breath.” Dragon’s Breath is made by pouring liquid Nitrogen over cereal puffs, popcorn or other similar foods, immediately before serving. The liquid Nitrogen (boiling point: -320°F) super cools the food which is then served in a cup with a skewer to be used to remove the puffs from the cup. When chewed the cold food condenses the moisture in the consumer’s breath creating the appearance of breathing smoke. The Department identified reports of injuries associated with Dragon’s Breath, including a 14-year old girl in Florida who suffered frost bite after touching liquid nitrogen in the cup, and a boy in Korea who suffered severe gastrointestinal injuries after drinking residual liquid Nitrogen. More recently, an incident was reported where a boy in Florida suffered an asthma attack which may have been triggered by consuming Dragon’s Breath. In September 2018, the Department received its first complaint of injury from liquid Nitrogen from a food product served in a New York State food service establishment. An 11-year old boy in Victor, NY reportedly experienced oral bleeding and burning sensation shortly after consuming Dragon’s Breath from a mall food service.

Currently, at least three local health departments in New York State have enacted local laws prohibiting the use of liquid Nitrogen at food service establishments and others are exploring similar actions. The US Food and Drug Administration (FDA), on August 30, 2018, issued a Consumer Advisory, advising consumers to avoid eating, drinking or handling foods prepared with liquid Nitrogen at the point of sale, citing the potential for injuries such as those described above. Consequently, the Department is proposing to

amend Part 14 to prevent consumers of Food Service Establishments from coming into contact with liquid Nitrogen or Dry Ice added at the point of sale of the food product.

Liquid Nitrogen is an FDA approved food additive and has various uses in the food service industry. Not all these uses of liquid Nitrogen have the potential for accidental service of liquid Nitrogen to the customer. Therefore, the proposed regulation amendment only pertains to the use of liquid Nitrogen just prior to service of the food product to the customer, to prevent accidental service of residual liquid Nitrogen.

The proposed amendment also restricts the use of Dry Ice (solid carbon dioxide) in foods at the point of service. Like liquid Nitrogen, Dry Ice is an approved food additive that is widely available and can be used to create a fog effect in foods. Dry Ice has a sublimation temperature of -109°F and, if touched or consumed in solid form, presents a risk of thermal injury like that of liquid Nitrogen. If the use of liquid Nitrogen is restricted without similar restrictions for Dry Ice, operators may use Dry Ice as a substitute ingredient.

**Costs:**

**Cost to Regulated Parties:**

The proposed amendments will impose minimal if any additional costs to regulated parties. Menu boards and signs may need to be updated to remove products that require the use of liquid Nitrogen or Dry Ice at point of sale. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

**Cost to State and Local Governments:**

There are no direct costs to State or Local Governments associated with the proposed amendments as the State and Local Governments are currently inspecting Food Service Establishments.

**Local Government Mandates:**

The proposed amendments do not impose any new mandates, duties or responsibilities on any county, city, town, village, school district, fire district or special district. City and County health departments already enforce Part 14 therefore health department staff will incorporate the proposed amendment as part of their existing program responsibilities.

**Paperwork:**

Adoption of this regulation does not impose any new paperwork requirements for regulated parties or State or local health departments.

**Duplication:**

The proposed amendments do not duplicate existing State or Federal requirements.

**Alternatives:**

The Department considered two alternatives to the proposed amendments. The first was to propose no regulatory change but recognize that local health departments may

adopt more stringent requirements through local laws or regulations. The second alternative included amending Part 14 of the State Sanitary Code to incorporate the requirements of the Department's previously issued guidance that require operators to maintain a written safety plan for the use of liquid Nitrogen, approved by the permit-issuing-official, with an additional requirement of providing a written consumer advisory be conspicuously posted at the point(s) of sale and service.

Both alternatives are inconsistent with FDA guidance to avoid consuming products with liquid Nitrogen added at the point of service. They also create a paperwork burden for operators and local health departments staff.

**Federal Standards:**

Nitrogen is an approved food additive and there are no Federal regulations restricting the use of liquid Nitrogen in food service establishments. The FDA does not have any direct regulatory authority over retail food operations. However, the FDA's consumer advisory warning to not eat foods with liquid Nitrogen added at the point of service establishes a clear federal position that the practice is considered unsafe.

**Compliance Schedule:**

The proposed amendments will become effective upon publication of a Notice of Adoption in the State Register.

**Contact Person:**

Ms. Katherine E. Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Empire State Plaza  
Corning Tower Building, Room 2438  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 FAX  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENT**

### **Effect on Small Business and Local Government:**

While many of New York State's food service establishments are considered small businesses, none of the amendments are directed solely at small businesses. The rule will apply to all 100,000 regulated food service establishments operating in New York State, although the vast majority of establishments do not use liquid Nitrogen or Dry Ice in the preparation of food. These establishments are already required to comply with the food safety provisions of Part 14. The proposed amendments will not result in significant costs to comply for regulated parties and none of the proposed amendments will apply solely to small businesses. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

Local Health Departments are already responsible for overseeing the food service operations of New York State, so there will not be a significant effect on local governments.

### **Compliance Requirements:**

Small businesses must comply with the proposed regulation by not utilizing liquid Nitrogen or Dry Ice in food products at the point of sale. The proposed amendments do not create any new reporting or record keeping requirements.

**Professional Services:**

The proposed amendments do not create a need for regulated parties to seek any professional services.

**Compliance Costs:**

The proposed amendments will impose minimal, if any additional, costs to regulated parties. Menu boards and signs may need to be updated to remove products that require the use of liquid Nitrogen or Dry Ice at point of sale. A small number of businesses which specialize in Dragon's Breath may be required to cease operating or modify their business to include other food items.

**Cost to State and Local Governments:**

There are no direct costs to Local Governments associated with the proposed amendments as Local Governments are currently inspecting Food Service Establishments.

**Economic and Technological Feasibility:**

The proposed amendments do not require any new technology and have a negligible economic impact.

**Minimizing Adverse Economic Impact:**

The regulations currently allow for a waiver to be granted at the discretion of the permit-issuing official, provided that alternative arrangements are made to protect the health and safety of the public.

**Small Business and Local Government Participation:**

The proposed amendments implement a recommendation received from the New York State Association of County Health Officials. When considering regulatory alternatives, the Department also sought input from the New York State Restaurant Association.

**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**

### **Nature of the Impact:**

The addition of Liquid Nitrogen and Dry Ice to food products at the point of service is a new novelty trend at food service operations. The proposed regulation's prohibition on the use of liquid Nitrogen and Dry Ice at the point of sale is expected to have no job impact on the majority of Food Service Establishments where such food products are not the focus of the business, as these food products make up only a small percentage of their sales. Businesses that specialize in or solely sell this type of product may be required to cease operating or modify their business to include other food items. We do not have an accurate estimate of the number of Food Service Establishments affected since there is no registration requirement for the use of liquid Nitrogen or Dry Ice, however the number is expected to be small.

### **Categories and Numbers Affected:**

The main category affected by this regulation is the Food Service Establishment that focuses its primary business on the sale of novelty foods that have liquid Nitrogen or Dry Ice added to them at the point of sale. Because of the lack of data about the number of food establishments that sell these types of food products, it is not possible to accurately estimate the number of jobs affected, however the number is expected to be small.

**Regions of Adverse Impact:**

The Department anticipates any jobs or employment impacts will occur equally throughout the regions of the state.

**Minimizing Adverse Impact:**

The Department will consider different types/levels of enforcement while retailers adapt to the new regulation.

## SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, sections 709.14 and 405.29 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Section 709.14 (a) is amended to change the focus of need reviews for PCI services from being site specific to health system related and to reflect the transition from State Hospital Review and Planning Council to Public Health and Health Planning Council.

Section 709.14 (b) (2) is amended to reflect the increased prevalence of cardiac surgical services since the regulation was last amended.

Section 709.14 (b) (3) is amended to remove the requirement of a documented projected volume of 300 PCI cases within two years of approval to initiate an adult cardiac surgery center and replace it with a requirement for a documented projected volume of 36 emergency PCI cases within two years of approval.

Section 709.14 (d) is amended to differentiate between PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site between (A)

those hospitals that are co-operated with a hospital that is a cardiac surgery center and (B) those hospitals that have a clinical sponsorship with a cardiac surgery center. The regulation sets forth factors in determining public need for both. The amendment removes site specific total volume requirements and focuses remaining volume requirements on only emergency cases at the applicant facility. The amendment of this subdivision goes on to set forth requirements specific to co-operated and clinically affiliated applicants.

Section 405.29 (a)(4)(i) is amended to make a non-material edit for readability.

Section 405.29 (c)(8)(i) is amended to include language delineating clinical sponsorship agreements and the required provisions thereof.

Section 405.29 (d)(2)(i)(b) is amended to make a non-material edit for readability.

Section 405.29 (e)(1)(iv)(j) is amended to revise cardiac catheterization laboratory center structure and service requirements to allow for clinical sponsorship agreements.

Section 405.29 (e)(2)(ii)(c) is amended to allow a co-operated parent cardiac surgery center to report to the cardiac reporting system on behalf of a PCI capable cardiac catheterization laboratory center.

Section 405.29 (e)(2)(iii) differentiates requirements for co-operated and sponsored PCI capable cardiac catheterization laboratory centers.

Section 405.29(e)(2)(iv) eliminates previous total volume threshold requirements and establishes minimum volume requirements focusing exclusively on emergency cases. PCI centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years will no longer be required to immediately surrender their approval or have it revoked. Instead, centers falling below those volume thresholds will be required to retain an independent physician consultant to conduct an annual appropriateness and quality review from which the Department will determine the disposition of the program.

Section 405.29 (e)(3) is clarified to reflect that no additional diagnostic cardiac catheterization services have been eligible for approval since the regulations were last amended on November 4, 2009.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2)(a) of the Public Health Law, sections 709.14 and 405.29 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended, to be effective after publication of Notice of Adoption in the New York State Register, to read as follows:

Subdivision (a) of section 709.14 is amended to read as follows:

(a) These standards will be used to evaluate certificate of need applications for cardiac catheterization laboratory center services and cardiac surgery center services. [All need determinations are hospital site specific.] It is the intent of the Public Health [State Hospital Review] and Health Planning Council that these standards, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of planning principles and decision-making tools for directing the distribution of cardiac catheterization laboratory center services and cardiac surgery center services. These planning principles and decision-making tools build on the existing regional resources that have been developed through the regulatory planning process. The goals and objectives of the standards expressed herein are expected to promote access to cardiac catheterization laboratory center services and cardiac surgery center services, and maintain provider and operator volumes associated with high quality care, and avoid the unnecessary duplication of resources while addressing the geographic distribution of services necessary to meet the needs of patients in need of emergency percutaneous

coronary interventional (PCI) procedures. Additionally, it is intended that the methodology provide sufficient flexibility to consider additional circumstances that reflect on the need for cardiac services[.], including providing flexibility for regional health systems to provide cardiac services at sites that are convenient to patients in the communities they serve.

Paragraph (2) of subdivision (b) of section 709.14 is amended to read as follows:

(2) Planning for cardiac surgery center services shall ensure that, to the extent possible, eighty percent of the total population of each HSA region resides within 100 miles of [a] one or more facilit[y]ies providing cardiac surgical services.

Paragraph (3) of subdivision (b) of section 709.14 is amended to read as follows:

(3) A facility proposing to initiate an adult cardiac surgery center must document a cardiac patient base and current cardiac interventional referrals sufficient to support a projected annual volume of at least 500 cardiac surgery cases and a projected annual volume of at least [300] 36 emergency PCI cases within two years of approval. The criteria for evaluating the need for additional adult cardiac surgery centers within the planning area shall include consideration of appropriate access and utilization, and the ability of existing services within the planning area to provide such services. Approval of additional adult cardiac surgery center services may be considered when each existing adult cardiac surgery center in the planning area is operating and expected to continue to

operate at a level of at least 500 cardiac surgical procedures per year. Waiver of this planning area volume requirement may be considered if:

(i) the HSA region's age adjusted, population based use rate is less than the statewide average use rate; and

(ii) existing adult cardiac surgery centers in the applicant facility's planning area do not have the capacity or cannot adequately address the need for additional cardiac surgical procedures, such determinations to be based on factors including but not necessarily limited to analyses of recent volume trends, analyses of Cardiac Reporting System data, and review by the area Health Systems Agency(s); and

(iii) existing cardiac surgical referral patterns within the planning area indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing cardiac surgical programs.

Subdivision (d) of section 709.14 is amended to read as follows:

(d) Public need for cardiac catheterization laboratory centers:

(1) PCI capable cardiac catheterization laboratory centers. The factors and methodology for determining the public need for PCI capable cardiac laboratory centers shall include, but not be limited to the following:

(i) PCI capable cardiac catheterization laboratory centers at hospitals with a cardiac surgery center on site. Applicants approved as cardiac surgery centers are approved PCI capable cardiac catheterization laboratory centers as provided under paragraph (b)(9) of this section and must meet standards at section 405.29(c), (e)(1) and (2) of this Title.

(ii) PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on site. [Factors for determining] Determinations of public need for PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site will be differentiated between: (A) hospitals that are established by the Public Health and Health Planning Council as co-operators with a hospital that is a cardiac surgery center as defined in section 405.29(3) of this Title; and (B) hospitals that have a clinical sponsorship with a cardiac surgery center as defined in section 405.3(f)(3) of this Title and that are applying to be a PCI capable cardiac catheterization laboratory center. For the purposes of this section, clinical sponsorship shall mean that the hospital applying to be a PCI capable cardiac catheterization laboratory center has entered into a clinical sponsorship agreement with a cardiac surgery center acceptable to the department and in accordance with the standards established in section 405.29(c)(8)(i) of this Title.

(iii) For both co-operated hospitals and hospitals that are proposing to enter into a clinical sponsorship agreement, factors for determining public need shall include, but are not limited to:

(a) the planning area for determining the public need for PCI capable cardiac catheterization laboratory centers at hospitals with no cardiac surgery on-site shall be the area within a one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather conditions, of the applicant facility, unless otherwise determined by the commissioner in accordance with section 709.1(c) of this Title;

[(b) evidence that existing PCI capable cardiac catheterization laboratory centers within the planning area cannot adequately meet the needs of patients in need of emergency percutaneous coronary interventions due to conditions such as capacity, geography, and or EMS limitations;]

[(c)] documentation by the applicant must demonstrate the hospital's ability to provide high quality appropriate care that would yield a minimum of 36 emergency PCI procedures per year within the first year of operation [and would yield a minimum of 200 total PCI cases per year within two years of start-up].

(1) Documentation of the number of cardiologists on staff at the proposed site, credentialed by the co-operated hospital, and/or employed by the clinical sponsorship hospital who currently perform percutaneous coronary interventions at other hospital sites and a summary of experience (including the most recent 3 years of volume and outcomes) for each.

(2) Documentation in support of volume projections for emergency PCI procedures must include, at a minimum: discharge data indicating the number of patients with a diagnosis of acute myocardial infarction (AMI) and/or other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patients in the applicant hospital's emergency department (as documented through hospital pharmacy records), and documentation of transfers to existing PCI capable cardiac catheterization laboratory centers for PCI.

(3) Additional documentation that may be submitted in support of [projected volume and] the need for a proposed PCI capable cardiac catheterization laboratory center include:

(i) the number of acute care beds at the applicant hospital and the range of acute care services provided;

(ii) documentation by the applicant of barriers that impact care experienced by specific population groups within the planning area and demonstration of cultural competency at the applicant site specific to the proposed populations to be served by the applicant;

(iii) documentation by the applicant demonstrating outreach to underserved populations that identifies potential new PCI cases within the service area;

(iv) emergency department discharge data;

(v) documentation by the applicant of regional demographics and transport patterns within the applicant's emergency medical service (EMS) region that impact the provision of cardiac care;

(vi) the geographic distribution of PCI capable cardiac catheterization laboratory center services and the ability of such existing centers to serve the patients in the applicant's service area;

(vii) letters from local physicians quantifying the number of PCI referrals from their practice and the portion of those that would have been treated at the applicant facility if PCI had been available;

[(viii) additional information that may be considered in projecting volume for an applicant from an established Article 28 network, or multi-site facility as defined at section 401.1 of this Title, with an approved cardiac surgery center within its system that is seeking to add a PCI capable cardiac catheterization laboratory center at a non-cardiac surgery hospital site within the system and for a co- applicant proposing to operate a PCI capable cardiac catheterization laboratory center without surgery onsite, under a co-operator agreement, approved by the department, with an existing cardiac surgery center. Such additional volume projection criteria include documentation by the applicant of the number of patients residing in the service area of the proposed site who have received percutaneous coronary interventions at the cardiac surgery center site and who would have been candidates to receive their procedures at the proposed non-surgery site.

(d) existing referral patterns indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing PCI capable cardiac catheterization laboratory centers and one of the following conditions exists:

(1) the proposed PCI capable cardiac catheterization laboratory center is located more than one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather and traffic conditions, from the nearest existing PCI capable cardiac catheterization laboratory center; or

(2) all existing PCI capable cardiac catheterization laboratory centers within one hour average surface travel time of the applicant facility, as determined by the department of transportation and adjusted for typical weather and traffic conditions, perform and are expected to continue to perform at a level of at least 300 PCI procedures per year after the addition of the proposed new program. Evidence for evaluating this expectation shall include, but not be limited to:

(i) data indicating the number of patients residing in the applicant's primary service area who are currently receiving percutaneous coronary intervention procedures at existing centers and the location of the centers where patients are receiving that care;

(ii) volume at existing PCI capable cardiac catheterization laboratory centers within one hour of the applicant hospital;

(iii) analysis provided by the applicant evaluating the portion of its proposed patient case load that would result in a redistribution of cases from existing centers and the portion that would represent new cases from currently under served populations. Such analysis shall include documentation of any outreach programs by the applicant facility that would support projections of new cases.]

([e]c) a written plan submitted by the applicant that demonstrates the hospital's ability to comply with standards for PCI capable cardiac catheterization laboratory centers at sections 405.29(c), (e)(1) and (2) of this Title;

([f]d) a written plan submitted by the applicant that outlines staff training and demonstrates the hospital's readiness to accommodate the needs of the PCI patients;

([g]e) a written plan has been submitted by the applicant which would promote access to cardiac catheterization laboratory center services for all segments of the hospital service area's population. The document shall include:

(1) a description of current and proposed initiatives for improving outcomes for patients with heart disease,

(2) a plan documenting the hospital's ability to maintain a comprehensive program in which high quality interventional procedures are provided as a component of a broad range of cardiovascular care within the hospital and within the community, to include an emphasis on processes of care and a description of how a patient will traverse through the system of care to be offered,

(3) a plan for ensuring continuity of care for patients transferred between facilities,

(4) documentation of outreach to regional EMS councils served by the applicant,

(5) documentation that EMS system capabilities have been taken into consideration in the delivery of cardiac services;

(6) a description of activities that promote planning for cardiac services within the region;  
and

(7) a description of current and proposed initiatives and strategies for reaching patients not currently served within the area.

([h]f) comments and recommendations received from community organizations;

([i]g) the hospital shall propose and implement a hospital heart disease prevention program as set forth at subparagraph (b)(5)(ii) of this section;

([j]h) [where public need is established herein, priority consideration shall be given to applicants that agree] a description of existing and planned activities to serve the medically indigent and [patients regardless of payment and can document a history of the provision of services to] populations that experience health disparities [;].

*(k)* Where public need is established herein, priority consideration shall be given to applicants that can demonstrate projected volume in excess of 300 PCI cases a year.

*(l)* Where public need is established herein, priority consideration will be given to the expansion of an existing service as opposed to the initiation of a new service.

*(m)* A written and signed affiliation agreement with a New York State Cardiac Surgery Center, acceptable to the department, has been submitted in accordance with standards at section 405.29(c)(8)(i) of this Title.

*(n)* In addition, hospital applicants proposing to jointly operate a PCI capable cardiac catheterization laboratory center at a hospital without cardiac surgery on-site under a co-operator agreement with a cardiac surgery center must:

*(1)* Submit a written and signed operational agreement between the applicant cardiac surgery center and the applicant hospital without cardiac surgery on site that demonstrates there will be an integration of expertise and resources from the cardiac surgery center that would support a high quality program at the proposed site and that is acceptable to the department. The agreement must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or

expiration of the agreement, and any changes must be found acceptable to the department prior to implementation. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated cardiac catheterization laboratory center.

(2) Submit documentation that demonstrates high quality cardiac care is provided at the applicant cardiac surgery center site and that expanding the service to the proposed site would serve as a benefit to patients and the community.

(3) Submit written documentation of governing body approval of the co-operator contract.]

Subparagraph (vi) of paragraph (2) of subdivision (d) of section 709.14 is amended to read as follows:

~~(vi)~~ Hospitals approved as cardiac surgery centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

Subdivision (d) of section 709.14 is amended by adding new paragraphs (4) and (5) as follows:

(4) For co-operated hospitals under subdivision (d)(1)(ii) of this section:

(i) The application for PCI services must be submitted jointly by the applicant facility and the co-operated parent.

(ii) Documentation acceptable to the department must be submitted demonstrating that all cardiac catheterization laboratory centers within the co-operated parent's system have staff sharing agreements that include, at a minimum, provisions for rotation and training of staff with the parent hospital and integration into the parent hospital's quality and patient safety programs, quality assurance and peer review.

(iii) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for maintaining the competency of the cardiac interventionalist physicians, nursing, and technical staff performing services at the applicant facility.

(iv) Documentation acceptable to the department must be submitted demonstrating that the co-operated parent hospital will be responsible for ensuring that the applicant facility can provide PCI services on a 24 hour a day, 365 days a year basis and is capable of

assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

(v) If the co-operated parent is not in the planning area of the applicant facility, then the applicant facility must document that it has an emergency transfer agreement with a New York State Cardiac Surgery Center in the planning area that has an on-site cardiac surgery program.

(5) For applicant hospitals in a clinical sponsorship relationship with a New York State Cardiac Surgery Center:

(i) the application for PCI services must be submitted by the applicant hospital.

(ii) the sponsoring New York State Cardiac Surgery Center must be located in the same planning area as the applicant hospital.

(iii) the sponsoring New York State Cardiac Surgery Center must perform at a level of at least 600 PCI procedures per year.

(iv) a written and signed PCI clinical sponsorship agreement with the sponsoring New York State Cardiac Surgery Center, acceptable to the department and in accordance with standards at section 405.29(c)(8)(i) of this Title, must be submitted. The PCI clinical sponsorship agreement must specify that the department shall be provided 60 days prior written notification of any proposed change, termination or expiration of the agreement, and any changes must be found acceptable to the department prior to implementation.

The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the applicant hospital's cardiac catheterization laboratory center.

(v) both the applicant hospital and the sponsoring hospital must submit written documentation demonstrating that the respective governing bodies have approved the clinical sponsorship agreement.

Subparagraph (i) of paragraph (4) of subdivision (a) of section 405.29 is amended to read as follows:

(i) a PCI capable cardiac catheterization laboratory center [cardiac catheterization laboratory center] performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients. Such PCI capable cardiac catheterization laboratory centers may be approved with or without cardiac surgery at the same hospital site, however, those with no cardiac surgery on site must meet additional criteria at subparagraph (c)(8)(i) of this section;

Subparagraph (i) of paragraph (8) of subdivision (c) of section 405.29 is amended to read as follows:

(i) In addition, cardiac catheterization laboratory centers located in hospitals with no cardiac surgery on-site must enter into and comply with a fully executed written clinical sponsorship agreement with a New York State cardiac surgery center. The agreement will include provisions that address, at a minimum:

(a) cardiac surgery center representatives shall participate in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and other reviews of the quality of cardiac care provided by the affiliated cardiac catheterization laboratory center and in the provision of recommendations for quality improvement of cardiac services. Each cardiac surgery center and each affiliated cardiac catheterization laboratory center hospital shall take actions necessary, including but not limited to entering into a written agreement to authorize such participation by the cardiac surgery center representatives in the affiliated cardiac catheterization laboratory center hospital's quality assurance committee and for purposes of such participation, the cardiac surgery center representative or representatives shall be deemed members of the affiliated cardiac catheterization laboratory center hospital's quality assurance committee. Cardiac surgery center representatives may only access confidential patient information for quality assurance committees as set forth in the affiliation agreements and these regulations. Members of hospitals' quality assurance committees must maintain the confidentiality of patient information and are subject to the confidentiality restrictions of Public Health Law section 2805-m and other applicable confidentiality restrictions as provided by law. The cardiac surgery center representative(s) shall participate in the review of information and data for quality improvement purposes as described in the agreement which may include:

(1) statistical data and reports used in quality improvement activities;

(2) the affiliated cardiac catheterization laboratory center hospital's quality improvement program, policies, and procedures;

(3) care provided by medical, nursing, and other health care practitioners associated with the cardiac services;

(4) appropriateness and timeliness of patient referrals and of patients retained at the affiliated cardiac catheterization laboratory center hospital who met criteria for transfer to the cardiac surgery center hospital; and

(5) adverse events or occurrences including death and major complications for patients receiving cardiac care at the affiliated cardiac catheterization laboratory center hospital.

(b) Joint cardiology/cardiac surgery conferences to be held at least quarterly, with a focus on continuous quality improvement to include review of: all cardiac laboratory related morbidity and mortality, review of a random selection of uncomplicated routine cases, patient selection, rates of normal outcomes for diagnostic studies performed, rates of studies needed to be repeated prior to intervention, quality of the studies conducted, rates of patients referred for and receiving interventional procedures subsequent to the

diagnostic cardiac catheterization procedure, and the number and duration of cardiac catheterization laboratory system failures;

(c) A mechanism for a telemedicine link between the cardiac catheterization laboratory center and the cardiac surgery center that provides the capability for off-site review of digital studies, and a commitment on the part of each hospital to provide timely treatment consultation by appropriate physicians on an as needed basis;

(d) the cardiac surgery center's involvement in developing privileging criteria for physicians performing cardiac catheterization procedures at the hospital with no cardiac surgery on-site;

(e) development and ongoing review of patient selection criteria and review of implementation of those criteria. The process shall include a comprehensive review of the appropriateness of treatment for a random selection of cases;

(f) consultation on equipment, staffing, ancillary services, and policies and procedures for the provision of cardiac catheterization laboratory procedures;

(g) a pre-procedure risk stratification tool which ensures that high risk and or complex cases are treated at a cardiac surgery center;

(h) procedures to provide for appropriate patient transfers between facilities;

(i) an agreement to notify the department of any proposed changes to the initial agreement and to obtain department approval prior to the change; [and]

(j) an agreement to jointly sponsor and conduct annual studies of the impact that the cardiac catheterization laboratory center service has on costs and access to cardiac services in the hospital's service area[.];

(k) a plan for how the proficiency of physicians, nurses and other staff at the affiliated cardiac catheterization laboratory center will be maintained through rotational or other training opportunities; and

(l) a plan for how the cardiac catheterization laboratory center will maintain the capacity to provide PCI services on a 24 hour a day, 365 days a year basis and be capable of assembling a dedicated team within 30 minutes of the activation call to provide coronary interventions 24 hours a day and 365 days each year.

Clause (b) of subparagraph (i) of paragraph (2) of subdivision (d) of section 405.29 is amended to read as follows:

(b) coronary care organized, staffed and available [-] on a 24-hour basis by clinical personnel trained in the care of critical care patients and equipped to provide the specialized care required of complex cardiac conditions; and

Clause (j) of subparagraph (iv) of paragraph (1) of subdivision (e) of section 405.29 is amended to read as follows:

(j) in addition to standards at subparagraph (c)(8)(i) of this section, for cardiac catheterization laboratory centers approved under a [co-operator] clinical sponsorship agreement as set forth in section 709.14(d)[(1)(ii)(n)](5) of this Title, the written and signed [co-operator] clinical sponsorship agreement between a cardiac surgery center and the cardiac catheterization laboratory center without cardiac surgery on site must be maintained and must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, any changes must be found acceptable to the department prior to implementation and any proposed termination or expiration shall require prior submission of a plan of closure to the department. The agreement shall provide for an integration of expertise and resources from the cardiac surgery center that would support a high quality program at the hospital without cardiac surgery on site, and shall delineate responsibilities of each institution. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated cardiac catheterization laboratory center.

Clause (c) of subparagraph (ii) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(c) the PCI capable cardiac catheterization laboratory center shall have a data manager who has special training in the clinical criteria used in the PCI module of the cardiac reporting system as provided by the department or its designee, is designated and authorized by the hospital and shall work in collaboration with the physician director to ensure accurate and timely reporting of cardiac reporting system data to the department. In addition to the data manager, relevant medical and administrative staff must be trained in the use of the cardiac reporting system and the specific data element definitions involved. For PCI capable cardiac catheterization laboratory centers that have a co-operated parent cardiac surgery center, responsibilities related to the cardiac reporting system may be performed by the cardiac surgery center on behalf of the data manager of the PCI capable cardiac catheterization laboratory center as long as all data is delineated at the facility level.

Subparagraph (iii) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(iii) patient selection criteria. PCI capable cardiac catheterization laboratory centers shall adopt criteria for appropriate coronary artery diagnostic and interventional procedures in accordance with generally accepted standards for cardiac patients. For centers with no

cardiac surgery on site and not co-operated with a New York State cardiac surgery center, patient selection criteria shall be reviewed and approved annually by the affiliated sponsored cardiac surgery center in accordance with subparagraph (c)(8)(i) of this section.

Subparagraph (iv) of paragraph (2) of subdivision (e) of section 405.29 is amended to read as follows:

(iv) minimum workload standards. [There shall be sufficient utilization of a center to ensure both quality and economy of services, as determined by the Commissioner.] Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of at least 36 emergency percutaneous coronary intervention cases per year. For hospitals that are part of [an] a co-operated article 28 network and multi-site facilities with more than one approved PCI capable cardiac catheterization laboratory center, and for PCI capable cardiac catheterization laboratory centers operating under a [co-operator]clinical sponsorship agreement pursuant to section 709.14(d)[(1)(ii)(c)(3)(viii)](5) of this Title, minimum volume standards for emergency PCI procedures are site specific and may not be combined for purposes of achieving minimum workload standards. [Any hospital seeking to maintain approval shall present evidence that the annual minimum workload standards have been achieved by the second full year following initiation of the service and maintained thereafter. Each PCI capable cardiac catheterization laboratory center must maintain a minimum volume of 150 percutaneous coronary intervention cases per

year including at least 36 emergency percutaneous coronary intervention cases per year. Hospitals with volumes below 400 percutaneous coronary intervention cases per year must comply with the following:

(a) PCI capable cardiac catheterization laboratory centers with an annual volume between 300 and 400 percutaneous coronary intervention cases shall undergo a review of cases and outcomes trends conducted by the department to evaluate the appropriateness and quality of care provided by the center;

(b) PCI capable cardiac catheterization laboratory centers with a volume between 150 and 300 percutaneous coronary intervention cases a year must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the region; and]

([c]a) PCI capable cardiac catheterization laboratory centers with an annual volume below 150 percutaneous coronary intervention cases a year for two consecutive calendar years, or a volume below 36 emergency percutaneous coronary intervention cases a year for two consecutive calendar years, [shall surrender approval to perform percutaneous

coronary interventions or have approval to perform the procedure revoked] must procure the services of an independent physician consultant, acceptable to the department, who shall conduct an annual review of the appropriateness and quality of the percutaneous coronary intervention cases performed at the facility and shall provide a copy of the findings directly to the department. Findings will be used by the department to determine whether continued approval or withdrawal of approval best meets the needs of the patients in the planning area.

Paragraph (3) of subdivision (e) of section 405.29 is amended to read as follows:

(3) Diagnostic cardiac catheterization services. [As of the effective date of these regulations, no] No additional diagnostic cardiac catheterization services shall be approved. Diagnostic cardiac catheterization services hospitals are not approved to perform percutaneous coronary intervention or cardiac surgery, are subject to annual reviews of volume, appropriateness of cases and other quality indicators for diagnostic cardiac catheterization, and must meet the following standards:

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The authority for the promulgation of these regulations is contained in Sections 2800 and 2803(2) of the Public Health Law (PHL). In particular, PHL Section 2803 (2) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner, 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 objective of PHL Article 28 includes the protection and promotion of the health of the residents of the state by requiring the efficient provision and proper utilization of health services, of the highest quality and at a reasonable cost.

### **Needs and Benefits:**

Title 10 Health Codes Rules and Regulations (10 NYCRR) Section 709.14 provides standards to be used in evaluating certificate of need (CON) applications for cardiac catheterization laboratory and cardiac surgery services in hospitals located in New York State. Alongside 10 NYCRR Section 709.1, these regulations are intended as a set of planning principles and decision-making tools for directing the distribution of these services, with a goal of ensuring appropriate access to high quality services while

avoiding the unnecessary duplication of resources. 10 NYCRR Section 405.29 provides standards for the provision of cardiac services.

Section 709.14 was last amended in November 2009 to allow the provision of Percutaneous Coronary Intervention (PCI) services (commonly referred to as angioplasty or stenting) outside of a Cardiac Surgery Center by defining and establishing a need methodology Cardiac Catheterization Laboratory Centers. The need methodology focused on the premise that a minimum volume of procedures at a facility ensures quality. Additional programs were deemed imprudent if they could not reasonably project certain volumes and unnecessary if their approval would cause an existing program at a facility in the same service area to fall below the minimum volume thresholds.

Since those last amendments, significant advances in technology and medical practice have made PCI and cardiac surgery procedures safer. In addition, standalone community hospitals are increasingly becoming part of integrated regional health care networks that are anchored by large academic medical centers. This transformation is increasing the potential for expanded access to quality cardiac care in these communities. Also, recent research by the University at Albany School of Public Health has shown that the correlation between volume and outcomes for PCI services has decreased in importance but that some minimal threshold is still needed.

The existing regulations have the effect of limiting new program entrants into geographic

markets, and they are not aligned with the increasing prevalence of integrated regional health care systems that are operated and governed by large academic medical centers. Such systems improve the coordination and delivery of health care services and help improve quality and ensure the financial sustainability of community hospitals within the network. In such systems, the co-established parent hospital governs the member hospitals through its reserve powers. Several of these systems have achieved broad clinical integration, including joint clinical department heads, quality assurance and training programs, information systems with data exchange and the sharing of clinical and support staff such as specialty teams.

A Regulatory Modernization Initiative convened by the Department of Health in the Fall of 2017 solicited industry and stakeholder input, considered all the above factors, and made recommendations that form the basis for these amendments herein. The regulations, once promulgated, will form a new basis for cardiac catheterization program approval and operation. The result will be greater, more convenient access to safe, quality PCI services and perhaps lifesaving and more timely access to emergency PCI.

Hospitals approved as PCI Capable Cardiac Catheterization Laboratory Centers will be required to provide emergency PCI on a 24-hour, 7 day a week, 365 days a year basis. Such hospitals will also be required to provide data to the Cardiac Reporting System as those who already provide this care do now.

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

It is a voluntary choice for hospitals to provide these PCI services and not a mandate.

There are approximately 66 hospitals that are currently PCI Capable Cardiac Catheterization Laboratory Centers out of 223 hospitals. The cost of implementation and compliance of these regulations is expected to be minimal for the affected entities already caring for these patients. Hospitals that voluntarily choose to provide such services, and that do not currently do so, will need to adhere to these standards and may incur costs to upgrade their services.

**Cost to State and Local Government:**

Any hospital in New York State that is part of State or local government that chooses to provide cardiac services will need to comply with these provisions. As discussed above, the cost of implementation and compliance of these regulations is expected to be minimal for entities already caring for these patients.

**Cost to the Department of Health:**

The Department of Health will need to monitor and provide surveillance and oversight for the system of care provided to these patients. It is not expected to incur any additional costs, as existing staff will be utilized to conduct such surveillance and oversight.

**Local Government Mandates:**

There are no local mandates within this regulatory amendment.

**Paperwork:**

Hospitals seeking to provide Cardiac Catheterization Laboratory Center Services with no Cardiac surgery onsite under the sponsorship model will be required to maintain a clinical sponsorship agreement with an existing Cardiac Surgery Center. Hospitals seeking to provide Cardiac Catheterization Laboratory Center Services with no Cardiac surgery onsite under the co-operator model will be required to maintain a staff sharing agreement with the parent Cardiac Surgery Center. Cardiac Surgery and Cardiac Catheterization Laboratory Centers will continue to be required to report data to the Department.

**Duplication:**

This regulation does not duplicate any other state or federal law or regulation.

**Alternative Approaches:**

The Department considered maintaining some lower total volume thresholds of PCI procedures for approval of a new program as an incremental approach. However, given the weakening correlation between volume and outcomes for PCI services generally, any threshold, albeit lower, would still be somewhat arbitrary and problematic. Instead, to facilitate access to timely emergency PCI procedures, volume requirements for non-emergency procedures will be eliminated where the emergency PCI volume and standards associated with high quality care can be maintained.

**Federal Requirements:**

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

**Compliance Schedule:**

This proposal will go into effect upon a Notice of Adoption in the New York State Register.

**Contact Person:**

Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Rm 2438  
Empire State Plaza  
Albany, NY 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
[REGSQNA@health.ny.gov](mailto:REGSQNA@health.ny.gov)

## **REGULATORY FLEXIBILITY ANALYSIS**

### **Effect of Rule:**

Three hospitals are considered small businesses (defined as 100 employees or less) and will be affected by this rule. Similarly, any hospital that is operated by a local government will be affected by this rule.

### **Compliance Requirements:**

Those hospitals that are considered a small business will be required to have written transfer agreements in place with hospitals that will be receiving cardiac patients and with emergency medical services to transport these patients to the appropriate facility for definitive care in a timely and appropriate manner.

### **Professional Services:**

This regulatory amendment does not appreciably change the professional services required to provide Cardiac Catheterization Laboratory Center Services.

### **Compliance Costs:**

This regulatory amendment does not appreciably change the compliance costs associated with the provision of Cardiac Catheterization Laboratory Center Services.

### **Economic and Technological Feasibility:**

This proposal is economically and technically feasible.

**Minimizing Adverse Impact:**

There is no adverse impact.

**Small Business and Local Government Participation:**

Outreach to the affected parties was conducted through the recent Regulatory Modernization Initiate Process. Organizations who represent the affected parties and the public can obtain the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC) and a copy of the proposed regulation on the Department's website. The public, including any affected party, is invited to comment during the Codes and Regulations Committee meeting.

**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**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.

## **SUMMARY OF EXPRESS TERMS**

This regulation amends Title 10 of the New York Codes, Rules and Regulations to add a new Article 10 to the State Hospital Code and a new Part 795 – Midwifery Birth Centers.

The new Part 795 defines midwifery birth center and sets standards for such birth centers aligned with national evidence-based standards. Part 795 allows midwifery birth centers to demonstrate compliance with these regulations by obtaining accreditation from an accrediting organization approved by the Department, in lieu of routine surveillance by the Department.

Part 795 requires a midwifery birth center to have a center director, who may be a midwife. The center director may appoint a consulting physician and must have collaborative relationships as required by the Education Law and this regulation.

Part 795 sets standards for staffing at midwifery birth centers and requires at least two staff members with training and skills in resuscitation, one for the patient giving birth and one for the post-delivery neonate, to be present at every birth.

Part 795 requires midwifery birth centers to have quality assurance programs and plans for emergency care, including transfer when indicated.

Pursuant to the authority vested in the Public Health and Health Planning Council, and subject to the approval of the Commissioner of Health, by sections 2801 and 2803(11) of the Public Health Law, sections 69-8.1, 69-10.1, 400.9, and 405.21 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, and Subchapter C of Chapter V of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Article 10, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (d) of section 69-8.1 is amended to read as follows:

(d) institution caring for infants (facility) means all general hospitals having maternity and infant services or premature infant services as defined in section 405.21 of this Title, [and] primary care hospitals and critical access hospitals as defined in section 407.1 of this Title, [and] birthing centers as defined in section 754.1 of this Title, and midwifery birth centers as defined in section 795.1 of this Title.

Subdivision (r) of section 69-10.1 is amended to read as follows:

(r) “Hospital” means a general hospital or a maternity hospital, including a birthing center located is a general hospital or a maternity hospital, [or] a birthing center operating as a diagnostic and treatment center, or a midwifery birth center, as defined by section 2801 or the public health law.

Paragraph (2) of subdivision (b) of section 400.9 is amended to read as follows:

(2) include in such agreement reasonable assurance that there will be transfer of the patient or resident whenever deemed medically appropriate and mutually agreed upon by the physician responsible for the medical care in the referring facility, or by the midwife responsible for the medical care in the case of a referring midwifery birth center, and by the physician who will become responsible for the medical care in the receiving facility, or, in the case of a certified home health agency, by the physician who will become responsible for the medical care when such patient or resident is to receive services from the certified home health agency;

Subparagraph (i) of paragraph (9) of subdivision (c) section 405.21 is amended to read as follows:

(i) Such transfer shall be accomplished in accordance with the provisions of sections 754.2(e) [and], 754.4, 795.2(e) and 795.4 of this Title.

A new Article 10 is added to read as follows:

## Article 10 – Midwifery Birth Centers

### Part 795 Midwifery Birth Centers

#### § 795.1 Definitions. As used in this Part:

- (a) A *midwifery birth center* means a facility licensed pursuant to Article 28 of the Public Health Law that is engaged principally in providing prenatal and obstetric care, and where such services are provided principally by midwives. The facility shall be organized to provide prenatal, child birth and postpartum care and primary preventive reproductive health care to patients at low risk. Services are provided by a midwife, licensed pursuant to Article 140 of the Education Law, to

patients at low risk, during pregnancy, labor, delivery, and who require only a stay of less than 24 hours after birth. Such services shall include newborn evaluation, resuscitation and referral. Midwifery birth center services are based on a philosophy that promotes a home-like setting and family-centered approach to care and views pregnancy and delivery as a normal physiological process requiring limited technological and pharmacological support. The center services are designed to meet the specific needs of the population being served and promote optimum pregnancy outcomes. The licensed midwife provides care for the low-risk patient during pregnancy and stays with the patient during labor from the time of admission to the midwifery birth center through the immediate postpartum period, providing continuous physical and emotional support, evaluating progress, facilitating family interaction and assisting the patient in labor and delivery. Other health care providers can provide prenatal and postpartum care to midwifery birth center patients. They may also provide supportive care during labor and delivery, but the attending provider for birth must be a licensed midwife.

(b) *A patient at low risk* means a patient who has: a normal medical, surgical, and obstetrical history; a normal, uncomplicated pregnancy as determined by adequate prenatal care; and prospects for a normal, uncomplicated gestation and birth. Risk shall be determined using standardized criteria based on generally accepted standards of professional practice.

(c) The *Department* means the New York State Department of Health.

§ 795.2 Administrative requirements. The operator shall ensure that:

- (a) only patients at low risk are admitted and cared for at the midwifery birth center;
- (b) written policies, procedures and standard risk assessment criteria for determining low-risk pregnancies based upon generally accepted standards of practice are developed and implemented;
- (c) written policies, procedures and protocols for the management of care are implemented pursuant to generally accepted standards of practice and in accordance with midwifery birth center philosophy;
- (d) a record is made of all informed consent, including shared decision making, that indicates concurrence from both caregiver and patient parties;
- (e) there is a transfer agreement with one or more perinatal centers for medical care of patients when complications arise antepartum, intrapartum, or postpartum and that meets the following requirements:
  - (1) compliance with section 400.9 of this Title;
  - (2) the surface travel time to reach a receiving perinatal hospital is less than two hours under usual weather and road conditions; and
  - (3) the receiving hospital is accessible and convenient to the patient's place of residence whenever possible;
- (f) support services such as laboratory, radiology and imaging, and family planning services not provided by the midwifery birth center are available by referral;
- (g) the midwifery birth center services are available 24 hours a day for the admission of patients, professional consultation and prompt response to inquiries;
- (h) kitchen facilities are available to enable families to store and prepare food brought in for the laboring family;

- (i) the midwifery birth center acts in accordance with the requirements of section 405.21(c)(14) of this Title with respect to a voluntary acknowledgement of paternity for a child born out of wedlock;
- (j) the midwifery birth center refers patients for genetic screening, carrier testing, and genetic counseling;
- (k) the midwifery birth center refers patients requiring physical or occupational therapy to an appropriate therapist; and
- (l) the needs of infants demonstrating difficulty feeding and swallowing are addressed to ensure the infant is healthy and developing properly, including referral to a licensed speech-language pathologist as needed.

§ 795.3 Service restrictions. The operator shall ensure that:

- (a) only patients at low risk are admitted and cared for at the midwifery birth center;
- (b) surgical procedures are limited to those which may be performed during and after an uncomplicated childbirth, such as episiotomy and repair. Other surgical procedures, including forceps and vacuum extraction are not permitted;
- (c) general and regional anesthesia are not administered at the center; and
- (d) labor is not induced, inhibited, stimulated or augmented with pharmacological agents acting directly on the uterus during the first or second stages of labor.

§ 795.4 Midwifery birth center transfer procedures.

- (a) The midwifery birth center shall maintain the capability to evaluate, stabilize and transfer patients other than patients at low risk, including newborns. The midwifery birth center shall refer or transfer patients for any health care services that fall outside the scope of midwifery birth center resources and risk criteria at

- any point during the course of care. The midwifery birth center shall initiate transfer when risks are identified, including when there is prolonged labor, fetal distress, or a need for spinal or epidural anesthesia, or when there may be an operative or cesarean birth.
- (b) Midwifery birth centers shall have written plans and procedures for the transfer of patients to the obstetrical or pediatric services of the receiving hospital(s) when complications arise. Such plans and procedures shall include arrangements for an ambulance service and, when necessary, accompanying the patient in the ambulance with a clinical staff member of the midwifery birth center.
  - (c) The operator, in consultation with the receiving hospital(s), shall develop a list of indicators necessitating transfer and a written procedure for automatic acceptance of such transfers by the receiving hospital, which shall include transfer of patients when neonatal abstinence syndrome or fetal alcohol syndrome is evident or suspected.
  - (d) The operator shall implement a system to ensure that a copy of the medical record accompanies the patient upon transfer to the hospital.
  - (e) The operator shall establish a mechanism for jointly reviewing all transfer cases by the receiving hospital(s) and the midwifery birth center as part of the quality assurance program specified in section 795.9 of this Part.

§ 795.5 Midwifery birth center director and medical consultants. The operator shall appoint a midwifery birth center director who:

- (a) is a licensed midwife or physician;

- (b) maintains documentation of collaborative relationships required under Section 6951 of the Education Law;
- (c) approves all policies, procedures and protocols for the management of care;
- (d) approves standardized criteria for admission screening and monitoring risk status during pregnancy, labor, birth and postpartum;
- (e) is available for consultation and referral or has made arrangements with a qualified physician for these services;
- (f) may appoint a consultant physician who:
  - (1) is a qualified specialist, as defined in section 700.2 of this Title, in pediatrics or family practice and who has pediatric privileges that include admission and care of newborns at the receiving hospital(s). In the absence of pediatric privileges, there must be formal arrangements included in the transfer agreement for the provision of pediatric care at the receiving hospital(s); and
  - (2) is available for consultation and referral;
- (g) ensures that the midwifery birth center has:
  - (1) collaborative relationships with one or more licensed physicians who are board certified as obstetrician-gynecologists by a national certifying body, who practice obstetrics, and who have obstetric privileges at one or more general hospitals licensed under Article 28 of the Public Health Law;
  - (2) collaborative relationships with pediatricians and other medical specialists needed to meet patients' needs, including with at least one pediatrician who has pediatric privileges that include admission and care of newborns at the receiving hospital(s). In the absence of pediatric privileges, there

shall be arrangements for the provision of pediatric care at the receiving hospital(s); and

- (3) transfer agreements with perinatal centers licensed under Article 28 of the Public Health Law to provide:
  - (i) obstetrics through a licensed physician having obstetrical privileges at such perinatal center;
  - (ii) consultation, collaborative management and referral to address the health status and risks of the provider's patients; and
  - (iii) emergency medical coverage for patients; and
- (h) has standardized criteria for admission screening and monitoring risk.

§ 795.6 Clinical staff. The operator shall ensure that:

- (a) a licensed midwife attends each patient from the time of admission, during labor, during the birth and through the immediate postpartum period, and that such practitioner maintains current certification by the American Academy of Pediatrics as a Neonatal Resuscitation Program (NRP) provider;
- (b) a second trained staff person is also present at each birth who:
  - (1) is under the supervision of the licensed midwife;
  - (2) has specialized training in labor and delivery techniques and care of the midwifery birth center patient;
  - (3) receives planned and ongoing training as needed to perform assigned duties effectively; and
  - (4) maintains current status as a NRP provider;

- (c) trained and qualified staff are available to educate and assist patients to initiate breastfeeding; and
- (d) at least two people who attend patients during labor, delivery and postpartum are currently certified NRP, Basic Life Support (BLS), and Advanced Cardiac Life Support (ACLS) providers and are able to provide oxygen and all equipment necessary to maintain airways for the patient and infant.

§ 795.7 Services for the care of patients. All patients shall be assessed to determine availability of sufficient resources prior to and following delivery. The operator shall ensure that the midwifery birth center provides at least the following:

- (a) admission screenings to ensure that only patients at low risk are admitted to the midwifery birth center;
- (b) active participation by patients and families in their own plan of health care, which shall include but not be limited to:
  - (1) orientation to the midwifery birth center services and its philosophy and goals preceding registration; and
  - (2) attendance at prenatal education classes approved by the clinical staff which address, at a minimum, labor and delivery, infant care and feeding, parenting, nutrition, the effects of smoking, alcohol and other drugs on fetal development and on the newborn patient, signs of postpartum depression, what to expect if transferred, and the newborn screening program, including hearing screening, with the provision and distribution of newborn screening educational literature;
- (c) prenatal and intrapartum care including:

- (1) a plan of care developed according to accepted professional standards;
- (2) selection of pediatric services by the patient for follow-up care of the infant;
- (3) providing HIV counseling and recommending voluntary testing to pregnant patients during a prenatal visit. Counseling and/or testing, if accepted, shall be provided pursuant to Public Health Law Article 27-F. Information regarding the patient's HIV counseling and HIV status must be transferred as part of the patient's medical history to the labor and delivery site. Patients with positive test results shall be referred to the necessary health and social services within a clinically appropriate time;
- (4) continuous risk assessment of all patients;
- (5) labor support and professional attendance at birth for the patient and the patient's family;
- (6) consultation with perinatal qualified mental health professionals to determine the appropriate course of action for patients who screen positive during the prenatal screening for depression or perinatal mood disorder or who have other mental health conditions;
- (7) a system for screening patients prior to admission for alcohol/substance use during pregnancy and for prior physical, sexual and emotional abuse, as part of routine obstetric care, and for referral of patients as appropriate to a higher-level facility; and
- (8) a system for directing patients to appropriate health care providers for further diagnosis and treatment, including consultation by a radiologist or

qualified provider who can interpret imaging results when results are inconclusive or an abnormality is detected that requires immediate care;

(d) postpartum care including:

- (1) care in the midwifery birth center to be provided for a minimum of four hours and a maximum of 24 hours after the third stage of labor is complete;
- (2) a physical assessment of the newborn with the required eye prophylaxis in accordance with sections 12.2 and 12.3 of this Title and newborn screening tests in accordance with Part 69 of this Title;
- (3) birth registration in accordance with section 4130 of the Public Health Law;
- (4) a physical assessment of the patient in accordance with established protocols including the evaluation of Rh status, need for Rh prophylaxis and the patient's ability to feed the infant prior to discharge from the center; and
- (5) the transfer to the newborn's medical record of a patient's HIV test result, if one exists; and

(e) discharge and follow-up including:

- (1) a program for discharge and follow-up of the patient and infant in their home for the immediate postpartum period unless arrangements have been made for the infant to be seen by another health care provider. The home visits may be performed by licensed professional nursing staff from the midwifery birth center, if the facility is approved under article 36 of the Public Health Law, or through an agreement with a certified or licensed

home health agency, to include an assessment of the parent-child relationship, an evaluation of the nutritional status of the infant and the physical and psychological status of the patient, performance of a hematocrit, rubella vaccination and Rh prophylaxis, if indicated, and newborn screening blood collection in accordance with Part 69 of this Title;

- (2) assurance of immediate and ongoing pediatric care;
- (3) provision of family planning counseling or arrangements for such services, if desired by the patient; and
- (4) arrangements for follow-up visits at the midwifery birth center within a six-week period following the birth.

§ 795.8 Medical records. The operator shall ensure that, in addition to meeting the requirements in section 751.7 of this Title:

- (a) The medical record for each patient shall contain the following information:
  - (1) results of physical and risk assessments;
  - (2) patient history, to include medical, surgical, gynecological and psychosocial history;
  - (3) record of informed consent, including shared decision making, for midwifery birth center services;
  - (4) ongoing assessments of fetal growth and development;
  - (5) periodic evaluations of patient health;
  - (6) results of laboratory tests;
  - (7) labor and birth information;

- (8) newborn patient physical assessment, including APGAR scores, maternal-newborn interaction, ability to feed, eye prophylaxis, vital signs and accommodation to extrauterine life;
  - (9) postpartum assessment;
  - (10) discharge and follow-up plans;
  - (11) home visit reports;
  - (12) midwifery birth center follow-up visit report; and
  - (13) documentation of family planning counseling and the arrangements made for family planning services, if any.
- (b) The medical record for each newborn shall be cross-referenced with the patient's medical record and contain the following information:
- (1) copy of the newborn physical assessment;
  - (2) results from newborn screening tests;
  - (3) discharge summary with follow-up plans; and
  - (4) home visit report.

§ 795.9 Quality assurance. In addition to meeting the requirements set forth in section 795.8 of this Title, the operator shall ensure that there is a review of all pregnant and postpartum patients and/or newborn hospital transfers, with reasons for such transfers documented. Findings from these reviews shall be used by the operator and midwifery birth center director in the development and revision of policies and in the consideration of renewing or granting staff privileges.

§ 795.10 Emergency care. The midwifery birth center shall have the capability and equipment to provide care to patients at low risk and a readiness at all times to meet any unexpected needs of patients within the center, and to facilitate transport to an acute care setting when necessary. The midwifery birth center shall stabilize and transfer patients to an appropriate general hospital for continued care when medically indicated. Staff with required current course completion status in NRP, BLS, and ACLS shall be available and shall have immediate access to all necessary equipment in accordance with these certifications to initiate resuscitation of patients. The midwifery birth center must have availability of adequate numbers of qualified professionals with competence and ability to stabilize and transfer high-risk patients. The operator shall ensure that at a minimum:

- (a) emergency equipment and supplies approved by the midwifery birth center director are available for use for resuscitation of both adult and neonate patients and include at least the following:
  - (1) intravenous therapy equipment;
  - (2) infant warmer;
  - (3) infant transport equipment;
  - (4) oxygen and oxygen administration equipment for patient and infant;
  - (5) airways and manual breathing bags for patient and infant;
  - (6) suction machine and equipment for patient and infant;
  - (7) adult and infant laryngoscope and endotracheal tubes; and
  - (8) medications and intravenous fluids with supplies and equipment for administration;
- (b) center staff are certified in NRP, BLS, and ACLS resuscitation and other emergency procedures; and

- (c) a licensed midwife, and one other staff member, both trained in NRP, BLS, and ACLS emergency procedures, are on duty in the center when patients are in the midwifery birth center.

§ 795.11 Midwifery birth center accreditation.

- (a) Midwifery birth centers must comply with sections 400.2 through 400.7, 400.9, and 400.10, and sections 751.5 through 751.10 of this Title and must comply with evidence-based standards for midwifery birth centers published by a national standards body selected by the Department and published on the Department's website. The Department may accept, as evidence of compliance with minimum operational standards in this subdivision, accreditation by an accreditation agency that the Department has determined has accrediting standards sufficient to assure the Department that midwifery birth centers so accredited are in compliance with such minimum operational standards. The Department may enter into collaborative agreements with one or more accreditation agencies to provide that such an agency's accreditation survey can be used in lieu of a survey by the Department. As part of such collaborative agreements, an accreditation agency may, at the Department's discretion, investigate complaints received by the Department related to care and services provided by a midwifery birth center. Notwithstanding any such collaborative agreements, the Department reserves the right to survey any midwifery birth center for compliance with the evidence-based standards established pursuant to this section. A list of accreditation agencies with which the Department has a collaborative agreement will be posted on the Department's website.

- (b) Except as otherwise prohibited by law, all survey reports, complaint investigation results, plans of correction, interim self-evaluation reports, certificates of accreditation, notices of noncompliance, or any other document, provided to the Department by an accreditation agency, pursuant to a collaborative agreement with the Department, shall be subject to public disclosure.
- (c) The midwifery birth center shall notify the Department in writing within seven days of failure to be accredited, re-accredited or the loss of accreditation by the accreditation agency.

§ 795.12 Application for establishment.

- (a) An application to the Public Health and Health Planning Council (Council) for establishment of a midwifery birth center, as required by law, shall be in writing on forms provided by the Department and executed by the chief executive officer or other officer duly authorized by the proposed operator. An original and eight copies shall be filed with the Council through the project management unit in the Department's central office in Albany, which shall transmit one copy to the health systems agency having geographic jurisdiction.
- (b) Applications to the Council shall contain information and data with reference to:
  - (1) the public need for the existence of the proposed midwifery birth center at the time and place and under the circumstances proposed;
  - (2) the character, experience, competency and standing in the community of the proposed incorporators, directors, stockholders, sponsors, individual operators or partners;
  - (3) the financial resources and sources of future revenue of the midwifery birth center to be operated by the applicant;

- (4) the fitness and adequacy of the premises and equipment to be used by the applicant for the proposed midwifery birth center; and
- (5) such additional pertinent information and documents necessary for the Council's consideration, as determined by the Department.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Chapter 397 of the Laws of 2016 amended the definition of hospital in section 2801 of the Public Health Law to add midwifery birth centers under the supervision of a midwife, and added a new subdivision 11 to section 2801 to give the New York State Department of Health (the Department) specific authority to establish regulations relating to the establishment, construction, and operation of midwifery birth centers, in consultation with representatives of midwives, midwifery birth centers, and general hospitals providing obstetric services.

The 2016 law supplemented the authority of the Department and the Public Health and Health Planning Council (PHHPC) under section 2803 of the Public Health Law to regulate health care facilities, including birth centers.

### **Legislative Objectives:**

Chapter 397 of the Laws of 2016 was intended to remove barriers that restrict the establishment of freestanding birth centers led by licensed midwives and to permit the Department to determine, with consultation, which Article 28 certificate-of-need requirements are appropriate and reasonable for the scope of services provided by midwifery birth centers. Education Law requirements governing the practice of midwifery will continue to apply to all midwives, regardless of the practice setting.

## **Needs and Benefits:**

There are currently only three freestanding birth centers in New York. All of these are directed by physicians. This regulation -- which encourages the creation of midwife-led centers -- will foster the growth of birth centers throughout New York.

Evidence shows that midwifery birth centers can offer high-quality, cost-effective maternity and neonatal care. Research indicates that freestanding birth centers operated by midwives tend to have low cesarean-section rates, fewer labor inductions, and successful parent bonding and breastfeeding without prolonged separation. Midwife-led birth centers promote wellness-based birth over technology and interventions. They consistently earn high patient satisfaction from women seeking a welcoming environment without restrictions on the presence of supportive staff, friends, and family members. They can provide more cost-effective maternity and neonatal care with outcomes that are comparable to births in other settings. Midwifery birth centers can play a vital part in serving the needs of mothers and families in New York State.

This regulation implements Chapter 397 of the Laws of 2016 by creating a new Part 795 authorizing midwifery birth centers. Under these regulations, the midwifery birth center director may be a licensed midwife or a physician, provided that they maintain documentation of collaborative relationships required under Section 6951 of the Education Law.

These regulations allow midwifery birth centers to meet national standards set by a standards-setting agency selected by the Department in lieu of meeting some provisions of the State Hospital Code. This regulation also allows accreditation of midwifery birth centers in lieu of surveillance by the Department, although the Department retains the authority to inspect midwifery birth centers at its discretion. An accreditation agency can

ensure high quality of care consistent with Department regulations and nationally recognized standards in a manner that is flexible and imposes less of a resource and cost burden on the Department.

A physician-led birth center that is a diagnostic and treatment center and is regulated under 10 NYCRR Part 754 must have a transfer agreement with a perinatal hospital located within 20 minutes' transport time from the birth center to the receiving hospital. Under this regulation, for a midwifery birth center, the surface travel time to reach a receiving perinatal hospital must be less than two hours under usual weather and road conditions. This will allow birth centers to be established in rural areas that would otherwise not have access to this type of care.

This regulation requires that the medical record for each patient at a midwifery birth center must contain a record of informed consent, including shared decision making, for birth center services. Public Health Law §2805-d, which generally requires a patient's informed consent when receiving health care services, is applicable to midwifery birth centers.

## **COSTS:**

### **Costs to Private Regulated Parties:**

A provider seeking to establish a midwifery birth center would require the approval of the Department as part of the Certificate of Need process. An application for a Certificate of Need for a midwifery birth center will be subject to a fee, established by Public Health Law § 2801-a, of \$2,000. An additional fee of 0.55% of the midwifery birth center's total project cost would be assessed upon approval of the Certificate of Need.

A provider opting to obtain accreditation, in accordance with these proposed regulations, would also be subject to fees charged by the accreditation agency. According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar- per-month fee is assessed during the lifetime of the accreditation. All of these costs are subject to change. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit.

**Costs to State and Local Governments:**

The Department does not anticipate that any birth centers will be operated by State or local government.

Local ordinances would be enforced at midwifery birth centers in a comparable manner to any other local businesses.

**Costs to the Department of Health:**

There will be no additional costs to the Department, as systems already exist to approve and regulate birth centers and, as proposed, the services of the national standards setting body and accreditation would fulfill many obligations typically fulfilled by the Department.

**Local Government Mandates:**

The proposed regulations impose no new mandates on any county, city, town or village government.

**Paperwork:**

To become a new birth center, including a midwifery birth center, an applicant will need to follow certificate of need process as required by Public Health Law Article 28. This regulation does not create new reporting requirements.

**Duplication:**

There are no duplicative or conflicting rules.

**Alternatives:**

One alternative would be for the State to not allow accreditation of birth centers by a nationally recognized organization as evidence of compliance with minimum operational and construction standards. However, this alternative was rejected as inefficient and unnecessary.

Another alternative was to require midwifery birth centers to meet the exact same requirements as physician-led birth centers, other than allowing the center to be directed by a midwife. This alternative was rejected, because the Department believes that the Legislature intended and the public interest would best be served by the Department creating a regulatory framework that facilitates the establishment of distinct midwifery birth centers.

**Federal Standards:**

The proposed regulation does not exceed any minimum standards of the Federal government.

**Compliance Schedule:**

The proposed regulation will take effect upon a Notice of Adoption in the New York State Register.

**Contact Person:**

Katherine Ceroalo  
New York State Department of Health  
Bureau of Program Counsel, Regulatory Affairs Unit  
Corning Tower Building, Rm. 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
(518) 473-2019 (FAX)  
REGSQNA@health.ny.gov

## **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

### **Effect of Rule:**

The proposed regulations will apply to midwifery birth centers in New York State. This proposal will not impact local governments or small businesses unless they operate such facilities. Many of the midwifery birth centers will be small businesses under the definition in the State Administrative Procedure Act (SAPA). In such case, the flexibility afforded by the regulations is expected to minimize delays and any costs of compliance as described below.

### **Compliance Requirements:**

Pursuant to this rule, midwifery birth centers that are small businesses will be required to maintain appropriate documentation of professional credentialing and agreements between the birth center and other receiving medical facilities.

These regulations utilize the approach of allowing accreditation instead of traditional surveillance. This is intended to allow for oversight to be performed by accrediting organizations with specific experience measuring standards of compliance for midwifery birth centers. Small businesses may be required to enter into a contractual relationship with an accrediting organization.

### **Professional Services:**

This proposal is not expected to require any additional use of professional services.

**Compliance Costs:**

A provider seeking to establish a midwifery birth center would require the approval of the Department as part of the Certificate of Need process. An application for a Certificate of Need for a midwifery birth center will be subject to a fee, established by Public Health Law § 2801-a, of \$2,000. An additional fee of 0.55% of the midwifery birth center's total project cost would be assessed upon approval of the Certificate of Need.

A provider opting to obtain accreditation, in accordance with these proposed regulations, would also be subject to fees charged by the accreditation agency. According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar- per-month fee is assessed during the lifetime of the accreditation. All of these costs are subject to change and will vary by size of birth center. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit.

**Economic and Technological Feasibility:**

This proposal is economically and technically feasible, as these regulations would enable the establishment of midwifery birth centers and do not impose requirements on existing birth centers.

**Minimizing Adverse Impact:**

No adverse impact is anticipated, as these regulations would enable the establishment of midwifery birth centers and do not impose requirements on existing birth centers.

**Small Business and Local Government Participation:**

The Department convened a 49-member expert panel to make recommendations for the perinatal system in New York State, which includes freestanding birth centers, Level 1 hospitals, Level II hospitals, Level III hospitals, and Regional Perinatal Centers (RPCs), as described in 10 NYCRR Part 721. Regulated parties will also have an opportunity to submit comments during the notice and comment period.

## RURAL AREA FLEXIBILITY ANALYSIS

### Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (<http://quickfacts.census.gov>).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
	Schenectady County	

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

There are no birth centers currently operating in rural areas.

**Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:**

Pursuant to this rule, midwifery birth centers will be required to maintain appropriate documentation of professional credentialing and agreements between the birth center and other receiving medical facilities.

These regulations utilize the approach of allowing accreditation instead of traditional surveillance. This is intended to allow for oversight to be performed by accrediting organizations with specific experience measuring standards of compliance for midwifery birth centers. Birth centers may be required to enter into contractual relationships with these accrediting organizations.

Professional services such as midwives and other health care practitioners will be needed to operate a midwifery birth center. It is also anticipated that staff will be needed to maintain the center and provide for a setting that is safe from biological or environmental hazards.

**Costs:**

A provider seeking to establish a midwifery birth center would require the approval of the Department as part of the Certificate of Need process. An application for a Certificate of Need for a midwifery birth center will be subject to a fee, established by Public Health Law § 2801-a, of \$2,000. An additional fee of 0.55% of the midwifery birth center's total project cost would be assessed upon approval of the Certificate of Need.

A provider opting to obtain accreditation, in accordance with these proposed

regulations, would also be subject to fees charged by the accreditation agency. According to a national accreditation organization for midwifery birth centers, the Commission on the Accreditation of Birth Centers, typical fee structures for birth centers are as follows: a new birth center would be charged an initial registration fee of 4,000 dollars and a follow-up visit fee, one year later of 3,300 dollars. After that, a 250 dollar- per-month fee is assessed during the lifetime of the accreditation. All of these costs are subject to change and will vary by size of birth center. Foundation grants may be available to potentially cover half of the costs for the initial and follow-up visit. These costs would be the same in a rural or non-rural area.

**Minimizing Adverse Impact:**

It is intended that midwifery birth centers will meet some of the needs of rural communities to provide birth services in the absence of a nearby hospital. The Department has added a standard within this rule allowing for midwifery birth centers to operate in any area of the state as long as the center is located within a two-hour road travel radius of a potential receiving hospital. This provision was specifically designed to allow for the possibility that a birth center could open in a rural community.

Allowing accreditation will minimize any adverse impact associated with the Department's surveillance process and will help to allow these centers to operate in rural communities.

**Rural Area Participation:**

The Department held meetings to seek input from practitioners in rural settings. The Department conducted outreach with state and national professional associations of midwifery birth centers, as well as representatives of midwives, midwifery birth centers,

and general hospitals. This included practitioners practicing and intending to practice in rural settings. The proposed regulation will have a 60-day public comment period.

## **JOB IMPACT STATEMENT**

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.