

# Public Health and Health Planning Council

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

*Thursday, October 10, 2019  
9:00 AM*

*Location: 90 Church Street 4<sup>th</sup> Floor, Room 4A & 4B, New York City*

### **A. Agenda**

#### **For Emergency Adoption**

Addition of Subpart 9-2 to Title 10 NYCRR –  
Required Signage Warning Against the Dangers  
of Illegal Products

#### **Program Area**

Office of Public  
Health

#### **Unit Representative**

Brad Hutton

#### **For Adoption**

Amendment of Sections 405.5 and 405.19 of  
Title 10 NYCRR – Registered Nurses in the  
Emergency Department

#### **Program Area**

Office of Primary  
Care and Health  
Systems Management

#### **Unit Representative**

Deirdre Astin

Amendment of Sections 405.7 and 751.9 of Title  
10 NYCRR – Patients’ Bill of Rights

Office of Primary  
Care and Health  
Systems Management

Deirdre Astin

Amendment of Parts 69, 400 & 405 and  
Addition of Part 795 to Title 10 NYCRR –  
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, October 9, 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 the Commissioner of Health by section 225 of the Public Health Law, Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to add a new Subpart 9-2, to be effective upon filing with the Department of State.

The title of Part 9 is amended to read as follows:

Part 9 [Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited] Prohibited Substances

A new Subpart 9-1, titled “Synthetic Phenethylamines and Synthetic Cannabinoids Prohibited” is added and section 9.1 through 9.6 are renumbered 9-1.1 through 9-1.6.

A new Subpart 9-2, titled “Required Signage”, is added to read as follows:

Section 9-2.1 Definitions.

As used in this Subpart, the following terms shall have the following meanings:

- (a) The terms “electronic cigarette” and “e-cigarette” mean an electronic device that delivers vapor which is inhaled by an individual user, and shall include any refill, cartridge and any other component of such a device; provided, however, that “electronic cigarette” and “e-cigarette” shall not mean any product approved by the United States food and drug administration as a drug or medical device, or manufactured and dispensed pursuant to title five-A of article thirty-three of the public health law.

(b) The terms “electronic liquid” and “e-liquid” means the solution, substance or material used in an e-cigarette and heated to produce an aerosol or emission to be inhaled by the user, whether the liquid contains nicotine or not.

#### 9-2.2 Required Signage Warning Against the Dangers of Illegal Products.

Any person operating a place of business wherein e-cigarettes or e-liquids are sold or offered for sale shall post in a conspicuous place a sign, to be published by the Department, that warns against the dangers of using illegal e-cigarette and e-liquid products.

#### Section 9-2.3 Penalties.

A violation of any provision of this Subpart is subject to all civil and criminal penalties as provided for by law. For purposes of civil penalties, each day that a place of business fails to post signage required by this Subpart shall constitute a separate violation under this Subpart.

#### Section 9-2.4 Severability.

If any provisions of this Subpart or the application thereof to any person or entity or circumstance is adjudged invalid by a court of competent jurisdiction, such judgment shall not affect or impair the validity of the other provisions of this Subpart or the application thereof to other persons, entities, and circumstances.

## **Regulatory Impact Statement**

### **Statutory Authority:**

The Public Health and Health Planning Council (PHHPC) is authorized by Section 225 of the Public Health Law (PHL) to establish, amend and repeal sanitary regulations to be known as the State Sanitary Code (SSC) subject to the approval of the Commissioner of Health. PHL Section 225(5)(a) provides that the SSC may deal with any matter affecting the security of life and health of the people of the State of New York.

### **Legislative Objectives:**

PHL Section 225(4) authorizes PHHPC, in conjunction with the Commissioner of Health, to protect public health and safety by amending the SSC to address issues that jeopardize health and safety. This regulation furthers the legislative objective by requiring sellers of e-liquids and e-cigarettes to post signage that warns against consumption of illegal products.

### **Needs and Benefits:**

Regulations are necessary to address the alarming number of people that have suffered injury or died from consuming illegal e-liquids and e-cigarette products, which can be adulterated with chemicals that are dangerous or deadly when inhaled. Currently, there is an outbreak of severe lung disease among persons who use illegal e-liquids and e-cigarettes, and the Department is engaged in an educational campaign to warn people against the use of these products. By requiring sellers of legitimate products to warn consumers against the dangers of illegitimate ones, the Department expects that consumers will become more educated and that consumption of illegal products will decrease.

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

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

**Costs to State Government and Local Government:**

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

**Local Government Mandates:**

The SSC establishes a minimum standard for regulation of health and sanitation. Local governments can, and often do, establish more restrictive requirements that are consistent with the SSC through a local sanitary code. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including 10 NYCRR Part 9, utilizing both civil and criminal options available.

**Paperwork:**

This regulation does not require any additional paperwork.

**Duplication:**

These regulations would not duplicate any State or federal regulations regarding e-cigarettes or e-liquids.

**Alternatives:**

The alternative to the regulation is to not exercise the Department's authority to require these notices to the public. That alternative was rejected.

**Federal Standards:**

There are no federal standards regarding signage for dangerous and illegal e-liquid and e-cigarette products.

**Compliance Schedule:**

The regulation will be effective upon filing with the Department of State.

**Contact Person:**

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

## **Regulatory Flexibility Analysis for Small Business and Local Governments**

### **Effect of Rule:**

The amendment will affect the small businesses that are engaged in selling e-liquids or e-cigarettes. The NYS Vapor Association (<http://nysva.org/>) claims there are at least 700 “vape shops” employing 2700 persons across the state.

Local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding.

### **Compliance Requirements:**

Small businesses must comply with the proposed regulation by posting signage published by the Department. Local governments must comply by enforcing the proposed regulations as they are part of the State Sanitary Code.

### **Professional Services:**

Small businesses will need no additional professional services to comply.

### **Compliance Costs:**

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

Requiring retailers to post a sign, published by the Department, will impose only minimal costs.

**Costs to State Government and Local Government:**

State and local governments will incur costs for enforcement. Exact costs cannot be predicted at this time because the extent of the need for enforcement cannot be fully determined. Some of the cost may be offset by fines and penalties imposed pursuant to the Public Health Law as well as through utilizing State Aid funding. In addition, the Department will be transmitting the sign electronically and posting a PDF of the poster on its website, and the Department may incur minimal costs of printing and making the sign available for order. Any such costs will be managed within existing resources.

**Economic and Technological Feasibility:**

The rule does not impose any economic or technological compliance burdens.

**Minimizing Adverse Impact:**

The New York State Department of Health will assist local governments by providing consultation, coordination and information and updates on its website. The Department will assist small businesses by providing the required sign electronically.

**Small Business and Local Government Participation:**

Small business and local governments were not consulted during the creation of this proposed rule; however, small businesses and local governments will be able to submit public comments during the public comment period.

**Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. Given the public health emergency caused by the consumption of illegal e-liquids and e-cigarettes, no cure period was included.

## **Rural Area Flexibility Analysis**

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb(4)(a) of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed regulation that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

## **Job Impact Statement**

No job impact statement is required pursuant to Section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

## **Emergency Justification**

As of September 9, 2019, New York State has 41 reported cases of vaping related pulmonary disease. As of September 6, 2019, over 450 possible cases of lung illness associated with the use of e-cigarette products have been reported to the federal Centers for Disease Control (CDC) from the following 33 states and territories: Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Iowa, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, North Carolina, Nebraska, New Jersey, New Mexico, New York, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Vermont, Wisconsin, West Virginia, and the U.S. Virgin Islands. Five deaths have been confirmed in California, Illinois, Indiana, Minnesota, and Oregon.

These emergency regulations are necessary to address the alarming number of people who have suffered injury or died from consuming illegal e-liquids and e-cigarette products, which can be adulterated with chemicals that are dangerous or deadly when inhaled. Currently, there is an outbreak of severe lung disease among persons who use illegal e-liquids and e-cigarettes, and the Department is engaged in an educational campaign to warn people against the use of these products. By requiring sellers of legitimate products to warn consumers against the dangers of illegitimate ones, the Department expects that consumers will become more educated and that consumption of illegal products will decrease.

Pursuant to the authority vested in the Public Health and Health Planning Council and Commissioner of Health by section 2803 of the Public Health Law, sections 405.5 and 405.19 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

A new paragraph (7) is added to subdivision (a) of section 405.5, to read as follows:

(7) Nursing services personnel employed in specialty areas, including, but not limited to, emergency services, must complete training and education specific to the specialty area. Nursing services personnel must be periodically reevaluated for competency and ongoing education and training provided to maintain competency in the specialty area.

Subparagraphs (ii) and (iii) of paragraph (2) of subdivision (d) of section 405.19 are amended to read as follows:

(ii) Emergency services supervising nurses shall be licensed and currently registered and possess current, comprehensive knowledge and skills in emergency health care. They shall [have at least one year of clinical experience,] be able to demonstrate skills and knowledge necessary to perform basic life support measures, and be current in ACLS and PALS or have current training and experience equivalent to ACLS and PALS, and meet the competency requirements of Section 405.5(a)(7);

(iii) Registered professional nurses in the emergency service shall be licensed and currently registered professional nurses who possess current, comprehensive knowledge and skills in emergency health care. They shall have [at least one year of clinical experience, have] successfully completed an emergency nursing orientation program, [and] be able to demonstrate skills and knowledge necessary to perform basic life support measures and meet the competency requirements of Section 405.5(a)(7). Within one year of assignment to the emergency service, each emergency service nurse shall be current in ACLS and PALS or have current training and experience equivalent to ACLS and PALS [and shall maintain current competence in ACLS as determined by the hospital].

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (PHL) § 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (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 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.

The Department of Health, pursuant to former PHL §2807-h(1), has granted hospitals limited waivers of 405.19(d)(2)(iii), allowing them to develop new graduate training programs based on training, education, and competency assessment. This authority expired on July 1, 2017. See L. 2014, Ch. 60, Pt. C, §67-b. Nevertheless, the results of these programs have been very successful. Therefore, removing the need to secure a waiver and allowing a training, education and competency-based program through regulation is sound public policy.

### **Needs and Benefits:**

The nursing shortages that currently exist both nationally and in New York State are expected to increase as both the age of the general population and working nurses increases. Similarly, shortages of nurses that work in high-stress specialty areas, such as critical care and the emergency department, will continue to occur during this nurse shortage and as hospitals

struggle with improving the recruitment and retention rates of new and seasoned nurses.

Recruiting nurses for emergency departments, specifically, is made even more challenging by current requirements, in 10 NYCRR Section 405.19, that all nurses working in emergency departments have one year of clinical experience and possess current, comprehensive knowledge and skills in emergency care. This results in hospitals being unable to recruit new graduates. Often, once these new graduates attain the required year of clinical experience, they are unwilling to transfer to the emergency department, preferring to use their newly gained competencies in the clinical area in which they were trained.

The Department of Health, pursuant to former PHL §2807-h(1), has granted hospitals limited waivers of 405.19(d)(2)(iii), allowing them to develop new graduate training programs based on training, education, and competency assessment. This authority expired on July 1, 2017. See L. 2014, Ch. 60, Pt. C, §67-b. Nevertheless, the results of these programs have been very successful.

The proposed regulations will allow hospitals to keep pace with demand for highly trained, emergency department nurses by allowing hospitals to recruit new graduate nurses to work in the emergency department, following a training, education and competency monitoring program developed and administered by the hospital's nursing education program required by 10 NYCRR Section 405.5. By eliminating the one year requirement, hospitals will be able to recruit new graduates and train them for work specifically in the emergency department. Similar to learning experiences in other parts of the hospital, new graduates would develop their clinical competencies by working alongside experienced staff who would supervise and mentor the new staff. This approach could also be adapted for float nurses who may have one year of experience but in a clinical specialty that does not specifically translate to emergency department

competency.

Patient safety and quality of care will be maintained, despite eliminating this nursing experience requirement, as hospitals will be responsible for developing, implementing and monitoring a training and education program that will allow nurses to obtain required skills while gaining invaluable experience within the emergency department.

## **COSTS:**

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

This amendment will allow general hospitals to expand their current nurse training programs to include curriculum for emergency department new graduates. Health care facilities will incur minimal costs in order to implement these programs.

### **Costs to Local Government:**

This proposal will not impact local governments unless they operate a general hospital, in which case costs will be the same as costs for private entities.

### **Costs to the Department of Health:**

The proposed regulatory changes will not result in any additional operational costs to the Department of Health.

### **Costs to Other State Agencies:**

The proposed regulatory changes will not result in any additional costs to other state agencies.

**Local Government Mandate:**

The proposed regulations do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

**Paperwork:**

General hospitals will be required to develop, implement and monitor nurse training programs for the emergency department, as they are currently required to do for other parts of the hospital. The regulation may initially increase paperwork as programs are in development, but overall the impact should be minimal.

**Duplication:**

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulations.

**Alternatives:**

The alternative would be to take no action, which represents no change in current requirements for general hospitals. However, the barrier to recruiting newly graduated nurses in emergency departments would still exist, making it increasingly difficult for hospitals to address their staffing shortages.

**Federal Standards:**

The proposed regulations do not duplicate or conflict with any federal regulations.

**Compliance Schedule:**

The regulations will be effective 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, Room 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 GOVERNMENTS**

### **Effect of Rule:**

The proposed regulation will apply to all general hospitals with emergency departments in New York State. This proposal will not impact local governments or small business unless they operate a general hospital. In such cases, the flexibility afforded by the regulations is expected to minimize any costs of compliance as described below.

### **Compliance Requirements:**

These regulations will require general hospitals to develop, implement and monitor training programs for emergency department nurses. This requirement expands requirements for nursing training and education that currently exist in Section 405.5.

### **Professional Services:**

General hospitals are already required to have nursing training programs; however, this amendment will make the programs available to new graduate nurses who are interested in emergency nursing.

### **Compliance Costs:**

Compliance costs are minimal, as they build upon existing requirements for nursing training and education found in Section 405.5.

**Economic and Technological Feasibility:**

This proposal is economically and technically feasible.

**Minimizing Adverse Impact:**

The anticipated adverse impact of the proposal is minimal. General hospitals, through their training programs, will ensure patient safety while new graduates are gaining competency and skill.

**Small Business and Local Government Participation:**

Organizations that include general hospitals as members were consulted on the proposed regulations. Additionally, the proposed regulation will have a 60-day public comment period.

**Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a “cure period” or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. As this proposed regulation does not create a new penalty or sanction, no cure period is necessary.

## 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>).

Approximately 17% of small health care facilities are located in rural areas.

|                     |                     |                      |
|---------------------|---------------------|----------------------|
| .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 47 general hospitals, approximately 90 diagnostic and treatment centers (D&TCs), 159 nursing homes, and 92 certified home health agencies in rural areas.

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

The proposed regulation is applicable to those general hospitals located in rural areas and is expected to impose minimal costs. Because the proposed regulatory requirements can be incorporated into existing processes, they are expected to minimally increase the administrative burden on these entities.

**Costs:**

General hospitals are already required to have nurse training and education programs. The cost of developing these training programs should be minimal.

**Minimizing Adverse Impact:**

The impact is minimal.

**Rural Area Participation:**

Organizations that include as members general hospitals located in rural areas were consulted on the proposed regulations.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

No job impact statement is required pursuant to section 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 section 2803 of the Public Health Law, sections 405.7 and 751.9 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (10) of subdivision (c) of section 405.7 of Title 10 is amended to read as follows:

(10) Receive all the information you need to give informed consent for an order not to resuscitate. You also have the right to designate an individual to give this consent for you if you are too ill to do so. If you would like additional information, please ask for a copy of the pamphlet “[Do Not Resuscitate Orders] Deciding About Health Care - A Guide for Patients and Families.”

Subdivision (l) of section 751.9 is amended to read as follows:

(l) express complaints about the care and services provided and to have the center investigate such complaints. The center is responsible for providing the patient or his/her designee with a written response within 30 days if requested by the patient indicating the findings of the investigation. The center is also responsible for notifying the patient or his/her designee that if the patient is not satisfied by the center response, the patient may complain to the New York State Department of [Health’s Office of Health Systems Management] Health;

Subdivisions (p) and (q) of section 751.9 are amended, and new subdivisions (r) and (s) are added to read as follows:

(p) authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors; [and]

(q) when applicable, make known your wishes in regard to anatomical gifts. Persons sixteen years of age or older may document their consent to donate their organs, eyes and/or tissues, upon their death, by enrolling in the NYS Donate Life Registry or by documenting their authorization for organ and/or tissue donation in writing in a number of ways (such as health care proxy, will, donor card, or other signed paper). The health care proxy is available from the center[.];

(r) view a list of the health plans and the hospitals that the center participates with; and

(s) receive an estimate of the amount that you will be billed after services are rendered.

## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

Public Health Law (PHL) § 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to implement the purposes and provisions of PHL Article 28 and to establish minimum standards governing the operation of health care facilities.

PHL § 24 requires diagnostic and treatment centers (D&TCs) to disclose the health care plans in which they are participating providers and the hospitals with which they are affiliated; and it also requires D&TCs to make available estimates of the amounts patients will be billed.

### **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.

PHL § 24 is intended to protect D&TC patients against unknowingly receiving care from out-of-network providers, resulting in surprise medical bills.

### **Needs and Benefits:**

Under PHL §24, D&TC patients have the right to receive information regarding the health plans and the hospitals that the center participates with and an estimate of the amount that the patient will be billed after services are rendered. The purpose of this disclosure is to ensure that patients have the information that they need to make decisions about their healthcare and to protect themselves against receiving unexpected bills. This proposed regulation revises the

D&TC Patients' Bill of Rights to inform patients of their rights under PHL §24 by adding new subdivisions (r) and (s) to 10 NYCRR §751.9. The proposed regulation mirrors similar provisions in the Patients' Bill of Rights applicable to general hospitals under 10 NYCRR 405.7.

The proposed amendment to Section 405.7 reflects a change to the Department publication that patients can request to provide them with additional information regarding medical decision-making, resuscitation, health care proxies and other end-of-life decision-making. This information was updated to implement the Family Health Care Decisions Act, effective in 2010. This regulation amendment will bring the regulations into conformance with the current Department publications.

The amendment to Section 751.9(l) deletes a reference to a Department office that has been renamed.

#### **COSTS:**

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

This amendment is a clarification of rights that patients already have in New York State. D&TCs will incur minimal costs to change the Patients' Bill of Rights made available to patients. D&TCs may also need to update training materials for staff.

##### **Costs to Local Government:**

This proposal will not impact local governments unless they operate a general hospital or D&TC, in which case the impact would be the same as outlined above for private parties.

**Costs to the Department of Health:**

The proposed regulatory changes will not result in any additional operational costs to the Department of Health, other than to provide for translations of the newly updated Bills of Rights.

**Costs to Other State Agencies:**

The proposed regulatory changes will not result in any additional costs to other state agencies.

**Local Government Mandate:**

The proposed regulations do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

**Paperwork:**

D&TCs are already required to make the Patients' Bill of Rights available to patients. Therefore, the proposed regulations should not increase their paperwork.

**Duplication:**

There are no relevant State regulations which duplicate, overlap or conflict with the proposed regulations.

**Alternatives:**

The alternative would be to take no action, which would result in a lack of consistency

between PHL §24 and the Patients' Bill of Rights.

**Federal Standards:**

The proposed regulations do not duplicate or conflict with any federal regulations.

**Compliance Schedule:**

The regulations will be effective 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, Room 2438  
Empire State Plaza  
Albany, New York 12237  
(518) 473-7488  
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## **REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

### **Effect of Rule:**

The proposed regulation will apply to all diagnostic and treatment centers (D&TCs) in New York State. This proposal will not impact local governments or small business unless they operate a general hospital or D&TC. In such case, the flexibility afforded by the regulations is expected to minimize any costs of compliance as described below.

### **Compliance Requirements:**

These regulations will require D&TCs to change their Patients' Bill of Rights.

### **Professional Services:**

This proposal will not require any additional use of professional services.

### **Compliance Costs:**

Compliance costs are minimal, as they only require editing and reprinting the Patients' Bill of Rights.

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

This proposal is economically and technically feasible.

### **Minimizing Adverse Impact:**

The anticipated impact of the proposal is minimal. D&TCs are already required to make

the Patients' Bill of Rights available to patients.

**Small Business and Local Government Participation:**

Organizations that include D&TCs as members were consulted on the proposed regulations. Additionally, the proposed regulation will have a 60-day public comment period.

**Cure Period:**

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on a party subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one is not included. As this proposed regulation does not create a new penalty or sanction, no cure period is necessary.

## 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>).

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| .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 approximately 90 diagnostic and treatment centers (D&TCs) in rural areas.

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

The proposed regulation is applicable to those D&TCs located in rural areas and is expected to impose minimal costs, because regulated facilities are already required to make the Patients' Bill of Rights available to patients. Because the proposed regulatory requirements can be incorporated into existing processes, they are not expected to increase the administrative burden on these entities.

**Costs:**

D&TCs are already required to post the Patients' Bill of Rights in areas that are highly visible to patients. The cost of the small wording change to the Patients' Bill of Rights will be insubstantial.

**Minimizing Adverse Impact:**

The impact is minimal.

**Rural Area Participation:**

Organizations that include as members general hospitals and D&TCs located in rural areas were consulted on the proposed regulations.

## **STATEMENT IN LIEU OF JOB IMPACT STATEMENT**

No job impact statement is required pursuant to section 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.

## **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 remains available to 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 as needed;
- (k) the midwifery birth center refers patients requiring physical or occupational therapy to an appropriate therapist as needed; 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 lactation consultant or licensed speech and 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) access to 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:**

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](mailto: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:**

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:**

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.