Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

December 10, 2015 at 10:00 AM

Location:
Location: Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

A. Agenda

Emergency Adoption	**Program Area**	**Unit Representative**
Part 4 of Title 10 NYCRR – Protection Against Legionella	Center for Environmental Health	Dr. Nathan Graber

Adoption	**Program Area**	**Unit Representative**
Part 9 of Title 10 NYCRR – Synthetic Phenethylamines and Synthetic Cannabinoids	Bureau of Narcotics Enforcement	Joshua Vinciguerra

For Information	**Program Area**	**Unit Representative**
Part 300 to Title 10 NYCRR – Statewide Health Information Network for New York (SHIN-NY)	Division of Quality and Patient Safety	James Kirkwood

For Discussion	**Program Area**	**Unit Representative**
Subpart 7-2 of Title 10 NYCRR – Children's Camps	Bureau of Community Environmental Health and Food Protection	Tim Shay

Department Update to Codes Committee	**Program Area**	**Unit Representative**
Department Timeline and Process for Consideration Regarding Laboratory Test Result Access	OPH	TBD

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, November 18, 2015, at 518-402-5914 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(5)(a) of the Public Health Law, Part 4 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added, to be effective upon filing with the Secretary, to read as follows:

4.1 Scope.

All owners of cooling towers, and all general hospitals and residential health care facilities as defined in Article 28 of the Public Health Law, shall comply with this Part.

4.2 Definitions.

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

(a) Building. The term "building" means any structure used or intended for supporting or sheltering any use or occupancy. The term shall be construed as if followed by the phrase "structure, premises, lot or part thereof" unless otherwise indicated by the text.

(b) Commissioner. The term "commissioner" means the New York State Commissioner of Health.

(c) Cooling Tower. The term "cooling tower" means a cooling tower, evaporative condenser or fluid cooler that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration or energy production system.

(d) Owner. The term "owner" means any person, agent, firm, partnership, corporation or other legal entity having a legal or equitable interest in, or control of the premises.

4.3 Registration.

All owners of cooling towers shall register such towers with the department within 30 days after the effective date of this Part. Thereafter, all owners of cooling towers shall register such towers with the department prior to initial operation, and whenever any owner of the cooling tower changes. Such registration shall be in a form and manner as required by the commissioner and shall include, at a minimum, the following information:

(a) street address of the building at which the cooling tower is located, with building identification number, if any;

(b) intended use of the cooling tower;

(c) name(s), address(es), telephone number(s), and email address(es) of all owner(s) of the building;

(d) name of the manufacturer of the cooling tower;

(e) model number of the cooling tower;

(f) specific unit serial number of the cooling tower;

(g) cooling capacity (tonnage) of the cooling tower;

(h) basin capacity of the cooling tower;

(i) whether systematic disinfection is maintained manually, through timed injection, or through continuous delivery;

(j) the contractor or employee engaged to inspect and certify the cooling tower; and

(k) commissioning date of the cooling tower.

4.4 Culture sample collection and testing; cleaning and disinfection.

(a) All owners of cooling towers shall collect samples and obtain culture testing:

(1) within 30 days of the effective date of this Part, unless such culture testing has been obtained within 30 days prior to the effective date of this Part, and shall take immediate actions in response to such testing, including interpreting Legionella culture results, if any, as specified in Appendix 4-A.

(2) in accordance with the maintenance program and plan, and shall take immediate actions in response to such testing as specified in the plan, including interpreting Legionella culture results, if any, as specified in Appendix 4-A; provided that if a maintenance program and plan has not yet been obtained in accordance with section 4.6 of this Part, bacteriological culture samples and analysis (dip slides or heterotrophic plate counts) to assess microbiological activity shall be obtained, at intervals not exceeding 90 days while the tower is in use, and any immediate action in response to such testing shall be taken, including interpreting Legionella culture results, if any, as specified in Appendix 4-A.

(b) Any person who performs cleaning and disinfection shall be a commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower and certified in accordance with the requirements of Article 33 of the Environmental Conservation Law and 6 NYCRR Part 325, or a pesticide apprentice under the supervision of a certified applicator.

(c) Only biocide products registered by the New York State Department of Environmental Conservation may be used in disinfection.

(d) All owners shall ensure that all cooling towers are cleaned and disinfected when shut down for more than five days.

4.5 Inspection and certification.

(a) Inspection. All owners of cooling towers shall inspect such towers within 30 days of the effective date of this Part, unless such tower has been inspected within 30 days prior to the effective date of this Part. Thereafter, owners shall ensure that all cooling towers are inspected at intervals not exceeding every 90 days while in use. All inspections shall be performed by a: New York State licensed professional engineer; certified industrial hygienist; certified water technologist; or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015, as incorporated by section 4.6 of this Part.

(1) Each inspection shall include an evaluation of:

(i) the cooling tower and associated equipment for the presence of organic material, biofilm, algae, and other visible contaminants;

(ii) the general condition of the cooling tower, basin, packing material, and drift eliminator;

(iii) water make-up connections and control;

(iv) proper functioning of the conductivity control; and

(v) proper functioning of all dosing equipment (pumps, strain gauges).

(2) Any deficiencies found during inspection will be reported to the owner for immediate corrective action. A person qualified to inspect pursuant to paragraph (a) of this section shall document all deficiencies, and all completed corrective actions.

(3) All inspection findings, deficiencies, and corrective actions shall be reported to the owner, recorded, and retained in accordance with this Part, and shall also be reported to the department in accordance with section 4.10 of this Part.

(b) Certification. Each year, the owner of a cooling tower shall obtain a certification from a person identified in paragraph (a) of this section, that such cooling tower was inspected, tested, cleaned, and disinfected in compliance with this Part, that the condition of the cooling tower is appropriate for its intended use, and that a maintenance program and plan has been developed and implemented as required by this Part. Such certification shall be obtained by November 1, 2016, and by November 1 of each year thereafter. Such certification shall be reported to the department.

4.6 Maintenance program and plan.

(a) By March 1, 2016, and thereafter prior to initial operation, owners shall obtain and implement a maintenance program and plan developed in accordance with section 7.2 of Legionellosis: Risk Management for Building Water Systems (ANSI/ASHRAE 188-2015), 2015 edition with final approval date of June 26, 2015, at pages 7-8, incorporated herein by reference. The latest edition of ASHRAE 188-2015 may be purchased from the ASHRAE website (www.ashrae.org) or from ASHRAE Customer Service, 1791 Tullie Circle, NE, Atlanta, GA 30329-2305. E-mail: orders@ashrae.org. Fax: 678-539-2129. Telephone: 404-636-8400, or toll free 1-800-527-4723. Copies are available for inspection and copying at: Center for Environmental Health, Corning Tower Room 1619, Empire State Plaza, Albany, NY 12237.

(b) In addition, the program and plan shall include the following elements:

(1) a schedule for routine bacteriological sampling and analysis (dip slides or heterotrophic plate counts) to assess microbiological activity and a schedule for Legionella sampling and culture analysis; provided that where the owner is a general hospital or residential health care facility, as defined in Article 28 of the Public Health

Law, routine testing shall be performed at a frequency in accordance with the direction of the department.

(2) emergency sample collection and submission of samples for Legionella culture testing to be conducted in the case of events including, but not limited to:

(i) power failure of sufficient duration to allow for the growth of bacteria;

(ii) loss of biocide treatment sufficient to allow for the growth of bacteria;

(iii) failure of conductivity control to maintain proper cycles of concentration;

(iv) a determination by the commissioner that one or more cases of legionellosis is or may be associated with the cooling tower, based upon epidemiologic data or laboratory testing; and

(v) any other conditions specified by the commissioner.

(3) immediate action in response to culture testing, including interpreting Legionella culture results, if any, as specified in Appendix 4-A; provided that where the owner is a general hospital or residential health care facility, as defined in Article 28 of the Public Health Law, the provisions shall additionally require immediately contacting the department for further guidance, but without any delay in taking any action specified in Appendix 4-A.

(c) An owner shall maintain a copy of the plan required by this subdivision on the premises where a cooling tower is located. Such plan shall be made available to the department or local health department immediately upon request.

4.7 Recordkeeping.

An owner shall keep and maintain records of all inspection findings, deficiencies, corrective actions, cleaning and disinfection, and tests performed pursuant to this Part, and certifications, for at least three years. An owner shall maintain a copy of the maintenance program and plan required by this Part on the premises where a cooling tower is located. Such records and plan shall be made available to the department or local health department immediately upon request.

4.8 Discontinued use.

The owner of a cooling tower shall notify the department within 30 days after removing or permanently discontinuing use of a cooling tower. Such notice shall include a statement that such cooling tower has been disinfected and drained in accordance with the same procedures as set forth in the shutdown plan, as specified in the maintenance program and plan required pursuant to this Part.

4.9 Enforcement.

(a) An officer, employee or agent of the department or local health department may enter onto any property to inspect the cooling tower for compliance with the requirements of this Part, in accordance with applicable law.

(b) Where an owner does not register, obtain certification, clean or disinfect, culture test or inspect a cooling tower within the time and manner set forth in this Part, the department or local health department may determine that such condition constitutes a nuisance and may take such action as authorized by law. The department or local health department may also take any other action authorized by law.

(c) A violation of any provision of this Part is subject to all civil and criminal penalties as provided for by law. Each day that an owner remains in violation of any provision of this Part shall constitute a separate and distinct violation of such provision.

4.10 Electronic registration and reporting.

(a) (1) Within 30 days of the effective date of this Part, and thereafter within 10 days after any action required by this Part, owners shall electronically input the following information in a statewide electronic system designated by the commissioner:

(i) registration information;

(ii) date of last routine culture sample collection, sample results, and date of any required remedial action;

(iii) date of any legionella sample collection, sample results, and date of any required remedial action;

(iv) date of last cleaning and disinfection;

(v) dates of start and end of any shutdown for more than five days;

(vi) date of last certification and date when it was due;

(vii) date of last inspection and date when it was due;

(viii) date of discontinued use; and

(ix) such other information as shall be determined by the department.

(2) The commissioner may suspend this requirement in the event that the electronic system is not available.

(b) The data in the system referenced in paragraph (a) shall be made publicly available, and shall be made fully accessible and searchable to any local health department. Nothing in this Part shall

preclude a local health department from requiring registration and reporting with a local system or collecting fees associated with the administration of such system.

4.11 Health care facilities

(a) All general hospitals and residential health care facilities, as defined in Article 28 of the Public Health Law, shall, as the department may determine appropriate:

(1) adopt a Legionella sampling plan for its facilities' potable water distribution system;

(2) report the results of such sampling; and

(3) take necessary responsive actions.

(b) With respect to such general hospitals and residential health care facilities, the department shall investigate to what extent, if any, requirements more stringent than those set forth in this Part are warranted.

4.12 Severability.

If any provisions of this Part 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 Part or the application thereof to other persons, entities, and circumstances.

Appendix 4-A

Interpretation of Legionella Culture Results from Cooling Towers	
Legionella Test Results in CFU[1] /ml	Approach

No detection (< 10 CFU /ml)	Maintain treatment program and *Legionella* monitoring.
For levels at ≥ 10 CFU /ml but < 1000 CFU /ml perform the following:	○ Review treatment program. ○ Institute immediate *online disinfection*[2] to help with control ○ Retest the water in 3 – 7 days. ▪ Continue to retest at the same time interval until two consecutive readings show acceptable improvement, as determined by a person identified in 10 NYCRR 4.5(a). Continue with regular maintenance strategy. ▪ If < 100 CFU /ml repeat *online disinfection*[2] and retest. ▪ If ≥100 CFU /ml but < 1000 CFU /ml further investigate the water treatment program and immediately perform *online disinfection*. [2] Retest and repeat attempts at control strategy. ○ If ≥ 1000 CFU /ml undertake control strategy as noted below.
For levels ≥ 1000 CFU /ml perform the following:	○ Review the treatment program ○ Institute immediate *online decontamination*[3] to help with control ○ Retest the water in 3 – 7 days. ▪ Continue to retest at the same time interval until two consecutive readings show acceptable improvement, as determined by a person identified in 10 NYCRR 4.5(a). Continue with regular maintenance strategy. ▪ If < 100 CFU /ml repeat *online disinfection*[2] and retest;

	▪ If ≥ 100 CFU /ml but < 1000 CFU /ml further investigate the water treatment program and immediately perform *online disinfection*.[2] Re-test and repeat attempts at control strategy. ▪ If ≥ 1000 CFU /ml carry out *system decontamination*[4]

[1] Colony forming units.

[2] Online disinfection means – Dose the cooling tower water system with either a different biocide or a similar biocide at an increased concentration than currently used.

[3] Online decontamination means – Dose the recirculation water with a chlorine-based compound equivalent to at least 5 mg/l (ppm) free residual chlorine for at least one hour; pH 7.0 to 7.6.

[4] System decontamination means – Maintain 5 to 10 mg/l (ppm) free residual chlorine for a minimum of one hour; drain and flush with disinfected water; clean wetted surface; refill and dose to 1 – 5 mg/l (ppm) of free residual chlorine at pH 7.0 – 7.6 and circulate for 30 minutes. Refill, re-establish treatment and retest for verification of treatment.

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 or health, or the preservation or improvement of public health, in the state of New York.

Legislative Objectives:

This rulemaking is in accordance with the legislative objective of PHL Section 225 authorizing the 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. Specifically, these regulations establish requirements for cooling towers relating to: registration, reporting and recordkeeping; testing; cleaning and disinfection; maintenance; inspection; and certification of compliance. Additionally, these regulations require general hospitals and nursing homes to implement a *Legionella* sampling plan and take necessary responsive actions, as the department may deem appropriate.

Needs and Benefits:

Improper maintenance of cooling towers can contribute to the growth and dissemination of *Legionella* bacteria, the causative agent of legionellosis. Optimal conditions for growth of *Legionella* include warm water that is high in nutrients and protected from light. People are exposed to *Legionella* through inhalation of aerosolized water containing the bacteria. Person-

to-person transmission has not been demonstrated. Symptoms of legionellosis may include cough, shortness of breath, high fever, muscle aches, and headaches, and can result in pneumonia. Hospitalization is often required and between 5-30% of cases are fatal. People at highest risk are those 50 years of age or older; current or former smokers; those with chronic lung diseases; those with weakened immune systems from diseases like cancer, diabetes, or kidney failure; and those who take drugs to suppress the immune system during chemotherapy or after an organ transplant. The number of cases of legionellosis reported in New York State between 2005-2014 increased 323% when compared to those reported in the previous ten year period.

Outbreaks of legionellosis have been associated with cooling towers. A cooling tower is an evaporative device that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration, or energy production system. Because water is part of the process of removing heat from a building, these devices require disinfectants—chemicals that kill or inhibit bacteria (including *Legionella*)—as means of controlling bacterial overgrowth. Overgrowth may result in the normal mists ejected from the tower having droplets containing *Legionella*.

For example, in 2005, a cooling tower located at ground level adjacent to a hospital in New Rochelle, Westchester County resulted in a cluster of 19 cases of legionellosis and multiple fatalities. Most of the individuals were dialysis patients or companions escorting the patients to their dialysis session. One fatality was in the local neighborhood. The cooling tower was found to have insufficient chemical treatment. The entire tower was ultimately replaced by the manufacturer in order to maintain cooling for the hospital and to protect public health. In June and July of 2008, 12 cases of legionellosis including one fatality were attributed to a small evaporative condenser on Onondaga Hill in Syracuse, Onondaga County. An investigation

found that the unit was not operating properly and this resulted in the growth of microorganisms in the unit. Emergency biocide treatment was initiated and proper treatment was maintained. No new cases were then detected thereafter.

Recent work has shown that sporadic cases of community legionellosis are often associated with extended periods of wet weather with overcast skies. A study conducted by the New York State Department of Health that included data from 13 states and one United States municipality noted a dramatic increase in sporadic, community acquired legionellosis cases in May through August 2013. Large municipal sites such as Buffalo, Erie County reported 2- to 3-fold increases in cases without identifying common exposures normally associated with legionellosis. All sites in the study except one had a significant correlation, with some time lag, between legionellosis case onset and one or more weather parameters. It was concluded that large municipalities produce significant mist (droplet) output from hundreds of cooling towers during the summer months. Periods of sustained precipitation, high humidity, cloud cover, and high dew point may lead to an "urban cooling tower" effect. The "urban cooling tower" effect is when a metropolitan area with hundreds of cooling towers acts as one large cooling tower producing a large output of drift, which is entrapped by humid air and overcast skies.

More recently, 133 cases of legionellosis, which included 16 fatalities, occurred in Bronx, NY (July-September, 2015). This event was preceded by an outbreak in Co-Op City in the Bronx, from December 2014 to January 2015, which involved 8 persons and no fatalities. Both of these outbreaks have been attributed to cooling towers, and emergency disinfection of compromised towers helped curtail these outbreaks. These events highlight the need for proper maintenance of cooling towers.

The heating, ventilation, and air-conditioning (HVAC) industry has issued guidelines on how to: seasonally start a cooling tower; treat it with biocides and other chemicals needed to protect the components from scale and corrosion; set cycles of operations that determine when fresh water is needed; and shut down the tower at the end of the cooling season. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has recently released a new Standard entitled *Legionellosis: Risk Management for Building Water Systems* (ANSI/ASHRAE Standard 188-2015). Section 7.2 of that document outlines components of the operations and management plan for cooling towers. The industry also relies on other guidance for specific treatment chemicals, emergency disinfection or decontamination procedures, and other requirements.

However, none of the guidance is obligatory. Consequently, maintenance deficiencies such as poor practice in operation and management can result in bacterial overgrowth, increases in *Legionella*, and mist emissions that contain pathogenic legionellae. This regulation requires that all owners of cooling towers ensure proper maintenance of the cooling towers, to protect the public and address this public health threat.

Further, these regulations requires that all owners of cooling towers ensure proper maintenance of the cooling tower *Legionella* sampling plan for their potable water system, report the results, and take necessary actions to protect the safety of their patients or residents, as the Department may deem appropriate. The details of each facility's sampling plan and remedial measures will depend on the risk factors for acquiring Legionnaires' disease in the population served by the hospital or nursing home.

Most people in nursing homes should be considered at risk, as residents are typically over 50 years of age. In general hospitals, persons at risk include those over 50 years of age, as well

as those receiving chemotherapy, those undergoing transplants, and other persons housed on healthcare units that require special precautions. Additional persons who might be at increased risk for acquiring Legionnaires' disease include persons on high-dose steroid therapy and persons with chronic lung disease. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

An environmental assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems, and any chemical treatment systems. The purpose of the assessment is to discover any vulnerabilities that would allow for amplification of *Legionella* and to determine appropriate response actions in advance of any environmental sampling for *Legionella*. Initial and ongoing assessment should be conducted by a multidisciplinary team that represents the expertise, knowledge, and functions related to the facility's operation and service. A team should include, at a minimum, representatives from the following groups: Infection Control, Physical Facilities Management, Engineering, Clinicians, Laboratory, and Hospital Management.

Costs:

Costs to Private Regulated Parties:

Building owners already incur costs for routine operation and maintenance of cooling towers. This regulation establishes the following new requirements:

- Routine Bacteriological Culture Testing – The regulations require routine bacteriological testing pursuant to their cooling tower maintenance program and plan. The cost per dip

slide test is $3.50. Assuming that some plans may require tests be performed twice a week, this could result in an annual cost of $364. If heterotrophic plate count analysis is used the cost per sample on average is $25.

- Emergency *Legionella* Culture Testing – Owners of cooling towers are required to conduct additional testing for Legionella in the event of disruption of normal operations or process control, or when indicated by epidemiological evidence. The average cost of each sample analysis is estimated to be approximately $125.00.
- Maintenance Program and Plan Development – The formulation of a cooling tower program and sampling plan would require 4 to 8 hours at $150 per hour ($600 to $1200). The range represents the cost for reviewing and modifying an existing plan versus the preparation of a new plan.
- Inspection – Owners of cooling towers shall obtain the services of a professional engineer (P.E.), certified industrial hygienist (C.I.H.), certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015, for inspection of the cooling towers at intervals not exceeding 90 days while in use. The cost of such services is estimated to be approximately $150.00 per hour and estimated to take approximately eight (8) hours.
- Annual Certification – The same persons qualified to perform inspections are qualified to perform annual certifications. The certification can follow one of the required inspections and requires some additional evaluation and considerations. The cost of such services is estimated to be approximately $150.00 per hour and is estimated to take approximately four (4) hours.

- Emergency Cleaning and Disinfection – If emergency cleaning and disinfection is required, owners of cooling towers are required to obtain the services of a certified commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower, or a pesticide apprentice under the supervision of a certified applicator. The cost of such services is estimated to be approximately $5,000.00 for labor, plus the cost of materials.
- Recordkeeping and Electronic Reporting – Owners of cooling towers are required to maintain certain specified records and to electronically report certain specified information. The costs of these administrative activities are predicted to be minimal.
- Health Care Facilities – The cost of adopting a sampling plan for Article 28 facilities is dependent upon any existing plan and the status of existing record keeping. It is estimated that with prior records and a maintenance plan the time required should a consultant be hired would be 6.5 hours at $150 per hour ($975). Without a prior plan and poor maintenance documentation the time required would be 13 hours at $150 per hour ($1950). It is anticipated that facilities may develop the plan using existing staff.

Costs to State Government and Local Government:

State and local governments will incur costs for administration, implementation, and enforcement. Exact costs cannot be predicted at this time. However, some local costs may be offset through the collection of fees, fines and penalties authorized pursuant to this Part. Costs to State and local governments may be offset further by a reduction in the need to respond to community legionellosis outbreaks.

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. PHL § 228. Local governments have the power to enforce the provisions of the State Sanitary Code, including this new Part, utilizing both civil and criminal options available. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Paperwork:

The regulation imposes new registration, reporting and recordkeeping requirements for owners of cooling towers.

Duplication:

This regulation does not duplicate any state requirements.

Alternatives:

The no action alternative was considered. Promulgating this regulation was determined to be necessary to address this public health threat.

Federal Standards:

There are no federal standards or regulations pertaining to registration, maintenance, operation, testing, and inspection for cooling towers.

Compliance Schedule:

On August 17, 2015, when this regulation first became effective, owners were given until September 16, 2015, to register their cooling towers and perform bacteriological sampling. Now that the deadline has past, all owners should have registered their cooling towers, and any owners that have not registered their cooling towers must come into compliance immediately. All owners must register such towers prior to initial operation.

By March 1, 2016, all owners of existing cooling towers must obtain and implement a maintenance program and plan. Until such plan is obtained, culture testing must be performed every 90 days, while the tower is in use.

All owners must inspect their cooling towers at least every 90 days while in use. All owners of cooling towers shall obtain a certification that regulatory requirements have been met by November 1, 2016, with subsequent annual certifications by November 1st of each year.

Owners must register cooling towers and report certain actions, using a statewide electronic system. Reportable events include date of sample collections; date of cleaning and disinfection; start and end dates of any shutdown lasting more than five days; dates of last inspection and when due; dates of last certification and when due; and date of discontinued use. These events must be reported to the statewide electronic system within 10 days of occurrence.

Contact Person:

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The rule will affect the owner of any building with a cooling tower, as those terms are defined in the regulation. This could include small businesses. At this time, it is not possible to determine the number of small businesses so affected. This regulation affects local governments by establishing requirements for implementing, administering, and enforcing elements of this Part. Local governments have the power to enforce the provisions of the State Sanitary Code, including this new Part. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Compliance Requirements:

Small businesses that are also owners of cooling towers must comply with all provisions of this Part. A violation of any provision of this Part is subject to all civil and criminal penalties as provided for by law. Each day that an owner remains in violation of any provision of this Part shall constitute a separate and distinct violation of such provision.

Professional Services:

To comply with inspection and certification requirements, small businesses will need to obtain services of a P.E., C.I.H., certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015. Small businesses will need to secure laboratory services for routine culture sample testing and, if certain events occur, emergency *Legionella* culture testing.

To comply with disinfection requirements, small businesses will need to obtain the services of a commercial pesticide applicator or pesticide technician, or pesticide apprentice under supervision of a commercial pesticide applicator. These qualifications are already required for the properly handling of biocides that destroy *Legionella*.

Compliance Costs:

Costs to Private Regulated Parties:

Building owners already incur costs for routine operation and maintenance of cooling towers. This regulation establishes the following new requirements:

- Routine Bacteriological Culture Testing – The regulations require routine bacteriological testing pursuant to industry standards. The cost per test is $3.50. Assuming tests are performed twice a week, this would result in an annual cost of $364.
- Emergency *Legionella* Culture Testing – Owners of cooling towers are required to conduct additional testing for Legionella in the event of disruption of normal operations. The average cost of each sample analysis is estimated to be approximately $125.00.
- Inspection – Owners of cooling towers shall obtain the services of a professional engineer (P.E.), certified industrial hygienist (C.I.H.), certified water technologist, or environmental consultant with training and experience performing inspections in accordance with current standard industry protocols including, but not limited to ASHRAE 188-2015; for inspection of the cooling towers at intervals not exceeding once every 90 days while the cooling towers are in use. The cost of such services is estimated to be approximately $150.00 per hour and estimated to take approximately eight (8)

hours.

- Annual Certification – The same persons qualified to perform inspections are qualified to perform annual certifications. The cost of such services is estimated to be approximately $150.00 per hour and is estimated to take approximately four (4) hours.
- Emergency Cleaning and Disinfection – If emergency cleaning and disinfection is required, owners of cooling towers are required to obtain the services of a certified commercial pesticide applicator or pesticide technician who is qualified to apply biocide in a cooling tower, or a pesticide apprentice under the supervision of a certified applicator. The cost of such services is estimated to be approximately $5,000.00 for labor, plus the cost of materials.
- Recordkeeping and Electronic Reporting – Owners of cooling towers are required to maintain certain specified records and to electronically report certain specified information. The costs of these administrative activities are predicted to be minimal.
- The formulation of a cooling tower program and sampling plan would require 4 to 8 hours at $150 per hour ($600 to $1200). The range represents the cost for reviewing and modifying an existing plan versus the preparation of a new plan.
- Formulation of a sampling plan for Article 28 facilities is dependent upon any existing plan and the status of existing record keeping. It is estimated that with prior records and a maintenance plan the time required should a consultant be hired would be 6.5 hours at $150 per hour ($975). Without a prior plan and poor maintenance documentation the time required would be 13 hours at $150 per hour ($1950). It is anticipated that facilities may develop the plan using existing staff.

Costs to State Government and Local Government:

State and local governments possess authority to enforce compliance with these regulations. Exact costs cannot be predicted at this time. However, some local costs may be offset through the collection of fees, fines and penalties authorized pursuant to this Part. Costs to State and local governments may be offset by a reduction in the need to respond to community legionellosis outbreaks.

Economic and Technological Feasibility:

Although there will be an impact of building owners, including small businesses, compliance with the requirements of this regulation is considered economically and technologically feasible as it enhances and enforces existing industry best practices. The benefits to public health are anticipated to outweigh any costs. This regulation is necessary to protect public health.

Minimizing Adverse Impact:

The New York State Department of Health will assist local governments by providing a cooling tower registry and access to the database, technical consultation, coordination, and information and updates.

Small Business and Local Government Participation:

Development of this regulation has been coordinated with New York City.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by the improper maintenance and testing of cooling towers, the risk that some small businesses will not comply with regulations justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas. The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any disproportionate reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

The Department of Health expects there to be a positive impact on jobs or employment opportunities. The requirements in the regulation generally coincide with industry standards and manufacturers specification for the operation and maintenance of cooling towers. However, it is expected that a subset of owners have not adequately followed industry standards and will now hire firms or individuals to assist them with compliance and to perform inspections and certifications.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the proposed regulations.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employments opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

Emergency Justification

Improper maintenance of cooling towers can contribute to the growth and dissemination of *Legionella* bacteria, the causative agent of legionellosis. Legionellosis causes cough, shortness of breath, high fever, muscle aches, headaches and can result in pneumonia. Hospitalization is often required, and between 5-30% of cases are fatal. People at highest risk are those 50 years of age or older, current or former smokers, those with chronic lung diseases, those with weakened immune systems from diseases like cancer, diabetes, or kidney failure, and those who take drugs to suppress the immune system during chemotherapy or after an organ transplant. The number of cases of legionellosis reported in New York State between 2005-2014 increased 323% when compared to those reported in the previous ten year period.

Outbreaks of legionellosis have been associated with cooling towers. A cooling tower is an evaporative device that is part of a recirculated water system incorporated into a building's cooling, industrial process, refrigeration, or energy production system. Because water is part of the process of removing heat from a building, these devices require biocides—chemicals that kill or inhibit bacteria (including *Legionella*)—as means of controlling bacterial overgrowth. Overgrowth may result in the normal mists ejected from the tower having droplets containing *Legionella*.

For example, in 2005, a cooling tower located at ground level adjacent to a hospital in New Rochelle, Westchester County resulted in a cluster of 19 cases of legionellosis and multiple fatalities. Most of the individuals were dialysis patients or companions escorting the patients to their dialysis session. One fatality was in the local neighborhood. The cooling tower was found to have insufficient chemical treatment. The entire tower was ultimately replaced by the

manufacturer in order to maintain cooling for the hospital and to protect public health. In June and July of 2008, 12 cases of legionellosis including one fatality were attributed to a small evaporative condenser on Onondaga Hill in Syracuse, Onondaga County. An investigation found that the unit was not operating properly and this resulted in the growth of microorganisms in the unit. Emergency biocide treatment was initiated and proper treatment was maintained. No new cases were then detected thereafter.

Recent work has shown that sporadic cases of community legionellosis are often associated with extended periods of wet weather with overcast skies. A study conducted by the New York State Department of Health that included data from 13 states and one United States municipality noted a dramatic increase in sporadic, community acquired legionellosis cases in May through August 2013. Large municipal sites such as Buffalo, Erie County reported 2- to 3-fold increases in cases without identifying common exposures normally associated with legionellosis. All sites in the study except one had a significant correlation, with some time lag, between legionellosis case onset and one or more weather parameters. It was concluded that large municipalities produce significant mist (droplet) output from hundreds of cooling towers during the summer months. Periods of sustained precipitation, high humidity, cloud cover, and high dew point may lead to an "urban cooling tower" effect. The "urban cooling tower" effect is when a metropolitan area with hundreds of cooling towers acts as one large cooling tower producing a large output of drift, which is entrapped by humid air and overcast skies.

More recently, 133 cases of legionellosis, which included 16 fatalities, occurred in Bronx, NY (July-September, 2015). This event was preceded by an outbreak in Co-Op City in the Bronx, from December 2014 to January 2015, which involved 8 persons and no fatalities. Both of these outbreaks have been attributed to cooling towers, and emergency disinfection of

compromised towers helped curtail these outbreaks. These events highlight the need for proper maintenance of cooling towers.

The heating, ventilation, and air-conditioning (HVAC) industry has issued guidelines on how to seasonally start a cooling tower; treat it with biocides and other chemicals needed to protect the components from scale and corrosion; and set cycles of operations that determine when fresh water is needed; and how to shut down the tower at the end of the cooling season. The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has recently released a new Standard entitled *Legionellosis: Risk Management for Building Water Systems* (ANSI/ASHRAE Standard 188-2015). Section 7.2 of that document outlines components of the operations and management plan for cooling towers. The industry also relies on other guidance for specific treatment chemicals, emergency disinfection or decontamination procedures and other requirement.

However, none of the guidance is obligatory. Consequently, poor practice in operation and management can result in bacterial overgrowth, increases in legionellae, and mist emissions that contain a significant dose of pathogenic legionellae. This regulation requires that all owners of cooling towers ensure proper maintenance of the cooling towers, to protect the public and address this public health threat.

Further, these regulations require all general hospitals and residential health care facilities (i.e., nursing homes) to develop a sampling plan, report the results, and take necessary actions to protect the safety of their patients or residents. The details of each facility's sampling plan and remedial measures will depend on the risk factors for acquiring Legionnaires' disease in the

population served by the hospital or nursing home.

Most people in nursing homes should be considered at risk, as residents are typically over 50 years of age. In general hospitals, persons at risk include those over 50 years of age, as well as those receiving chemotherapy, those undergoing transplants, and other persons housed on healthcare units that require special precautions. Additional persons who might be at increased risk for acquiring Legionnaires' disease include persons on high-dose steroid therapy and persons with chronic lung disease. Certain facilities with higher risk populations, such as those with hematopoietic stem-cell transplant (HSCT) and solid organ transplant units, require more protective measures.

An environmental assessment involves reviewing facility characteristics, hot and cold water supplies, cooling and air handling systems and any chemical treatment systems. The purpose of the assessment is to discover any vulnerabilities that would allow for amplification of Legionella spp. and to determine appropriate response actions in advance of any environmental sampling for Legionella. Initial and ongoing assessment should be conducted by a multidisciplinary team that represents the expertise, knowledge and functions related to the facility's operation and service. A team should include, at a minimum, representatives from the following groups: Infection Control; Physical Facilities Management; Engineering; Clinicians; Laboratory; and Hospital Management.

These regulations, which originally became effective on August 17, 2015, implemented important requirements that protect the public from the threat posed by *Legionella.* To ensure that protection is maintained, the Commissioner of Health and the Public Health and Health

Planning Council have determined it necessary to file these regulations on an emergency basis. Public Health Law § 225, in conjunction with State Administrative Procedure Act § 202(6) empowers the Council and the Commissioner to adopt emergency regulations when necessary for the preservation of the public health, safety or general welfare and that compliance with routine administrative procedures would be contrary to the public interest.

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, section 9.1 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon publication of a Notice of Adoption in the New York State Register.

Subdivision (b) of section 9.1 is amended as follows:

(b) Synthetic Cannabinoid means any manufactured chemical compound that is a cannabinoid receptor agonist and includes, but is not limited to any material, compound, mixture, or preparation that is not listed as a controlled substance in Schedules I through V of § 3306 of the Public Health Law, and not approved by the federal Food and Drug Administration (FDA), and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues (analogs), and salts of isomers and homologues (analogs), unless specifically exempted, whenever the existence of these salts, isomers, homologues (analogs), and salts of isomers and homologues (analogs) is possible within the specific chemical designation:

(1) Naphthoylindoles. Any compound containing a 3-(1-Naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH 007, JWH 015, JWH 018, JWH 019, JWH 073, JWH 081, JWH 98, JWH 122, JWH 164, JWH 200, JWH 210, JWH 398, AM 2201, MAM 2201, EAM 2201 and WIN 55 212.)

(2) Naphthylmethylindoles. Any compound containing a 1 H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited to: JWH-175, and JWH-184.)

(3) Naphthoylpyrroles. Any compound containing a 3-(1-naphthoyl) pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH 307.)

(4) Naphthylmethylindenes. Any compound containing a naphthylmethyl indenes structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent and whether or not substituted in the naphthyl ring to any extent. (Other names in this structural class include but are not limited: JWH-176.)

(5) Phenylacetylindoles. Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any

extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: RCS-8 (SR-18), JWH 201, JWH 250, JWH 203, JWH-251, and JWH-302.)

(6) Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. (Other names in this structural class include but are not limited to: CP 47,497 (and homologues (analogs)), cannabicyclohexanol, and CP 55,940.)

(7) Benzoylindoles. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methy1-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. (Other names in this structural class include but are not limited to: AM 694, Pravadoline (WIN 48,098), RCS 4, AM-2233 and AM-679.)

(8) [2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo [1,2,3-de]-1, 4-benzoxazin-6-yl]-1-napthalenylmethanone. (Other names in this structural class include but are not limited to: WIN 55,212-2.)

(9) (6aR,10aR)-9-(hydroxymethyl)-6, 6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10, 10a-tetrahydrobenzo[c]chromen-1-ol. (Other names in this structural class include but are not limited to: HU-210.)

(10) (6aS, 10aS)-9-(hydrxymethyl)-6,6-demethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo{c}chromen-l-ol (Dezanabinol or HU-211)

(11) Adamantoylindoles. Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the adamantyl ring system to any extent. (Other names in this structural class include but are not limited to: AM-1248.)

(12) Adamantoylindazoles including but not limited to Adamantyl Carboxamide Indazoles. Any compound containing a 3-(1-adamantoyl)indazole structure with substitution at the nitrogen atom of the indazole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the adamantyl ring system to any extent. (Other names in this structural class include but are not limited to: AKB-48, MAB-CHMINACA, 5F-AKB-48.)

(13) Tetramethylcyclopropylcarbonylindoles or any compound structurally derived from 3-(2,2,3,3-tetramethylcyclopropylcarbonyl) indole by substitution at the nitrogen atom of the indole ring with alkyl,haloalkyl, alkenyl, cyanoalkyl, hydroxyalkyl, cycloalkylmethyl, cycloalkylethyl, (N-methylpiperidin-2-yl)methyl or 2-(4-morpholinyl)ethyl, whether or not further substituted in the indole ring to any extent, including without limitation the following: UR-11, XLR-11, A-796,260.

(14) Any other synthetic chemical compound that is a cannabinoid receptor agonist that is not listed in Schedules I through V of § 3306 of the Public Health Law, or is not an FDA approved drug.

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. Accordingly, PHHPC has issued 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. This amendment would add additional chemicals to the list of explicitly prohibited synthetic cannabinoids.

Needs and Benefits:

"Synthetic cannabinoids" encompass a wide variety of chemicals that are designed specifically to stimulate the same receptor in the body as cannabinoid 9-tetrahydrocannabinol (THC). However, they cause additional side effects that mimic other controlled substances and have been linked to severe adverse reactions, including death and acute renal failure. Reported side effects include: tachycardia (increased heart rate); paranoid behavior, agitation and irritability; nausea and vomiting; confusion; drowsiness; headache; hypertension; electrolyte

abnormalities; seizures; and syncope (loss of consciousness). Additional signs and symptoms of synthetic cannabinoids include: anxiety; tremor; hallucinations; and violent behavior. These effects can be similar to those of phencyclidine (PCP). It has been reported that some recent patients have presented with both somnolence (drowsiness) and bradycardia (decreased heart rate), some requiring endotracheal intubation.

Synthetic cannabinoids are frequently applied to plant materials and then packaged as incense, herbal mixtures or potpourri. They often carry a "not for human consumption" label, and are not approved for medical use in the United States. Products containing synthetic cannabinoids are, in actuality, consumed by individuals, most often by smoking, either through a pipe, a water pipe, or rolled in cigarette papers.

Products containing synthetic cannabinoids have become prevalent drugs of abuse. In 2012, before 10 NYCRR Part 9 was promulgated, calls to New York State Poison Control Centers relating to the consumption of synthetic cannabinoids had increased dramatically. Over half of the calls to the Upstate Poison Control Center in 2011 involved children under the age of 19, which was consistent with the results of a 2011 "Monitoring the Future" national survey of youth drug-use trends that showed that 11.4% of 12th graders used a synthetic cannabinoid during the twelve months prior to the survey, making it the second most commonly used illicit drug among high school seniors at the time.

In 2012, the Department issued 10 NYCRR Part 9, which addressed this emergent threat to public health by prohibiting the possession, manufacture, distribution, sale or offer of synthetic cannabinoids and other substances. Thereafter, New York State experienced a substantial decrease in reported cases of adverse health effects related to synthetic cannabinoid use, an achievement that was sustained until the early part of this year.

Recently, however, New York State experienced a dramatic increase in synthetic cannabinoid-related adverse events and emergency department visits. During April 1 to June 30, New York State has seen more than 1,900 emergency department visits and 680 poison control center calls due to reports of adverse health effects associated with synthetic cannabinoid use. This represents more than a tenfold increase over the same time period in 2014, when there was more than 150 emergency department visits and 50 poison control center calls reported. Nationally, there have been 15 synthetic cannabinoid-related deaths reported to poison control centers during from January to May of 2015. In New York, no fatalities have been reported to date, although there has been a 44% increase in the proportion of patients being admitted to critical care units from April 6 to June 30, 2015 when compared to the proportion of patients admitted to the critical care unit from Jan 1, 2011 to April 5, 2015. Calls received by poison control centers generally reflect only a small percentage of actual instances of poisoning.

Testing has identified synthetic cannabinoids that were not known to the Department in 2012, when 10 NYCRR Part 9 was first issued, and that are associated with the recent increase in cannabinoid-related adverse events and emergency department visits. Identifying these new synthetic cannabinoids in the regulation will simplify and enhance the efforts of local governments to control these dangerous chemicals.

Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

There will be no additional cost to State Government. Local governments are already enforcing 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. The addition of these chemicals is expected to have negligible cost on local enforcement programs.

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. PHL § 228. 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. PHL §§ 228, 229, 309(1)(f) and 324(1)(e).

Paperwork:

The regulation imposes no new reporting or filing requirements.

Duplication:

The federal Synthetic Drug Abuse Prevention Act of 2012 banned the sale and distribution of products containing the synthetic cannabinoids identified in this regulation, by placing them on the federal schedule I list of substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]). This regulation does not conflict with or duplicate that federal law, because it provides local enforcement authority, which the federal law does not provide.

Alternatives:

The Department considered relying on the existing regulation to address these recently identified synthetic cannabinoids. However, the Department determined that amending the regulation to explicitly identify these substances would enhance state and local enforcement authority and more effectively address this public health threat.

Federal Standards:

As noted above, the Synthetic Drug Abuse Prevention Act of 2012 places synthetic cannabinoids on the federal schedule I list of substances under the federal Controlled Substances Act (21 U.S.C. § 812[c]). This regulation does not conflict with or duplicate that federal law, because it provides local enforcement authority, which the federal law does not provide.

Compliance Schedule:

Regulated parties should be able to comply with these regulations effective upon publication of a Notice of Adoption in the New York State Register.

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Regulatory Flexibility Analysis for Small Business and Local Governments

Effect of Rule:

The amendment will affect only the small businesses that are engaged in selling products containing synthetic cannabinoids. The Department does not have information concerning the number of small businesses that currently sell these products. However, in 2011 and 2012, Commissioner's Orders were issued banning certain synthetic phenethylamines and synthetic cannabinoids, resulting in approximately 8,000 establishments being served with one or both Orders by public health authorities. Banned product was found in 286 of these locations. Subsequent to these efforts, the number of related complaints dropped significantly.

This regulation affects local governments by establishing a minimum standard regarding the possession, manufacture, distribution, sale or offer of sale of additional synthetic cannabinoids. Local governments have the power and duty to enforce the provisions of the State Sanitary Code, including Part 9, utilizing any civil and criminal remedies that may available. PHL §§ 228, 229, 309(1)(f) and 324(e). Local governments are also empowered to establish a local sanitary code that is more restrictive than the State Sanitary Code.

Compliance Requirements:

Small businesses must comply by not engaging in any possession, manufacturing, distribution, sale, or offer of sale of the additional synthetic cannabinoids.

Local governments must comply by enforcing the State Sanitary Code. Local boards of health may impose civil penalties for a violation of this regulation of up to $2,000 per violation, pursuant to PHL § 309(1)(f). Pursuant to PHL § 229, local law enforcement may seek criminal penalties for a first offense of up to $250 and 15 days in prison, and for each subsequent offense

up to $500 and 15 days in prison.

Professional Services:

Small businesses will need no additional professional services to comply. Local governments, in certain instances where local governments enforce, will need to secure laboratory services for testing of substances.

Compliance Costs:

Costs to Private Regulated Parties:

The regulation imposes no new costs for private regulated parties.

Costs to State Government and Local Government:

There will be no additional cost to State Government. Local governments are already enforcing 10 NYCRR Part 9, which prohibits the possession, manufacture, distribution, sale or offer of synthetic phenethylamines and cannabinoids. The addition of these chemicals is expected to have negligible cost on local enforcement programs.

Economic and Technological Feasibility:

Although there will be an impact on small businesses that sell these products, the prohibition is justified by the extremely dangerous nature of these products.

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.

Small Business and Local Government Participation:

The Department will work with local governments to provide technical information concerning the newly-listed synthetic cannabinoids.

Cure Period:

Violation of this regulation can result in civil and criminal penalties. In light of the magnitude of the public health threat posed by these substances, the risk that some small businesses will not comply with regulations and continue to make or sell or distribute the substance justifies the absence of a cure period.

Rural Area Flexibility Analysis

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural areas, nor will it impose any additional reporting, record keeping or other compliance requirements on public or private entities in rural areas.

Job Impact Statement

Nature of the Impact:

The Department of Health does not expect there to be a positive or negative impact on jobs or employment opportunities.

Categories and Numbers Affected:

The Department anticipates no negative impact on jobs or employment opportunities as a result of the amended rule.

Regions of Adverse Impact:

The Department anticipates no negative impact on jobs or employment opportunities in any particular region of the state.

Minimizing Adverse Impact:

Not applicable.

SUMMARY OF EXPRESS TERMS

Public Health Law § 206(18-a)(d) gives the Department broad authority to promulgate regulations, consistent with federal law and policies, that govern the Statewide Health Information Network for New York (SHIN-NY).

This regulation makes clear that, consistent with 42 USC § 17938, Qualified entities (QEs) may, without patient authorization, make patient information available among SHIN-NY participants or other entities otherwise serving the patient so long as the QEs enter into and adhere to participation agreements that comply with federal requirements under HIPAA and 42 CFR Part 2 for business associates and qualified service organizations. This regulation specifies consent requirements to access patient information made available through the QEs. This regulation incorporates legal requirements related to disclosure of patient information without consent, as well as laws that specifically authorize disclosure of patient information for health care purposes, including public health and health oversight purposes, without the type of written, signed authorization that contains all of the elements that would be required for a health care provider to get permission to disclose patient information to a third party for purposes other than health care.

In order to participate in the SHIN-NY, regional health information organizations will need to be certified as QEs by the Department and satisfy certification requirements on an ongoing basis under the procedures established by this regulation.

Pursuant to the authority vested in the Commissioner of Health and the Public Health and Health Planning Council by sections 201, 206(1) and (18-a)(d), 2800, 2803, 2816, 3600, 3612, 4000, 4010, 4400, 4403, 4700 and 4712 of the Public Health Law, a new Part 300 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is added to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Part 300

Statewide Health Information Network for New York (SHIN-NY)

Sec.

300.1 Definitions

300.2 Establishing the SHIN-NY

300.3 Statewide collaboration process and SHIN-NY policy guidance

300.4 Qualified Entities

300.5 Sharing of patient information

300.6 Participation of health care facilities

§ 300.1 Definitions. For the purposes of this Part, these terms shall have the following meanings:

(a) "Statewide Health Information Network for New York" or "SHIN-NY" means the technical infrastructure and the supportive policies and agreements that make possible the electronic exchange of clinical information among qualified entities and qualified entity participants for authorized purposes to improve the quality, coordination and efficiency

of patient care, reduce medical errors and carry out public health and health oversight activities, while protecting patient privacy and ensuring data security.

(b) "Qualified entity" means a not-for-profit regional health information organization or other entity that has been certified under section 300.4 of this Part.

(c) "Qualified entity participant" means any health care provider, health plan, governmental agency or other type of entity or person that has executed a participation agreement with a qualified entity, pursuant to which it has agreed to participate in the SHIN-NY.

(d) "Health care provider" means a health care provider as defined in paragraph (b) of subdivision one of section 18 of the Public Health Law entitled "Access to patient information."

(e) "Statewide collaboration process" means an open, transparent process within which multiple SHIN-NY stakeholders contribute to recommendations for SHIN-NY policy guidance.

(f) "SHIN-NY policy guidance" means the set of policies and procedures, including technical standards and SHIN-NY services and products that are approved by the New York State Department of Health.

(g) "Patient information" means health information that is created or received by a qualified entity participant and relates to the past, present, or future physical or mental health or condition of an individual or the provision of health care to an individual, and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(h) “Minor consent patient information” means patient information relating to health care of a patient under 18 years of age for which the patient provided his or her own consent as permitted by law, without a parent’s or guardian’s permission.

(i) “Health oversight agency” means an agency or authority of the United States, or New York State, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

(j) “Public health authority” means an agency or authority of the United States, the New York State Department of Health, a New York county health department or the New York City Department of Health and Mental Hygiene, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(k) “Written authorization” means a signed consent that complies with the requirements for written authorizations in this Part. A written authorization may be an electronic record with an electronic signature, as provided by State Technology Law Article 3 (Electronic Signatures and Records Act).

(l) “Law” means a federal, state or local constitution, statute, regulation, rule, common law, or other governmental action having the force and effect of law, including the

charter, administrative code and rules of the city of New York. Required by law means a mandate contained in law that compels a person or entity to make a use or disclosure of patient information and that is enforceable in a court of law.

§ 300.2 Establishing the SHIN-NY. The New York State Department of Health may:

(a) Oversee the implementation and ongoing operation of the SHIN-NY.

(b) Implement the infrastructure and services to support the private and secure exchange of health information among qualified entities and qualified entity participants.

(c) Administer the statewide collaboration process and facilitate the development, regular review and update of SHIN-NY policy guidance.

(d) Perform regular audits, either directly or through contract, of qualified entity functions and activities as necessary to ensure the quality, security and confidentiality of data in the SHIN-NY.

(e) Provide technical services, either directly or through contract, to ensure the quality, security and confidentiality of data in the SHIN-NY.

(f) Assess qualified entity participation in the SHIN-NY and, if necessary, suspend a qualified entity's access to or use of the SHIN-NY, when it reasonably determines that the qualified entity has created, or is likely to create, an immediate threat of irreparable harm to the SHIN-NY, to any person accessing or using the SHIN-NY, or to any person whose information is accessed or transmitted through the SHIN-NY.

(g) Publish reports on health care provider participation and usage, system performance, data quality, the qualified entity certification process, and SHIN-NY security.

(h) Take such other actions as may be needed to promote development of the SHIN-NY.

§ 300.3 Statewide collaboration process and SHIN-NY policy guidance.

(a) SHIN-NY policy guidance. The New York State Department of Health may establish SHIN-NY policy guidance as set forth below:

(1) The New York State Department of Health shall establish or designate a policy committee to make recommendations on SHIN-NY policy guidance and standards.

(2) Policy committee agendas, meeting minutes, white papers and recommendations shall be made publicly available.

(3) The New York State Department of Health shall consider SHIN-NY policy guidance recommendations made through the statewide collaboration process and may accept or reject SHIN-NY policy guidance recommendations at its sole discretion.

(b) Minimum contents of SHIN-NY policy guidance. SHIN-NY policy guidance standards shall include, but not be limited to policies and procedures on:

(1) privacy and security;

(2) monitoring and enforcement;

(3) minimum service requirements;

(4) organizational characteristics of qualified entities; and

(5) qualified entity certification.

§ 300.4 Qualified entities.

(a) Each qualified entity shall:

(1) Maintain and operate a network of qualified entity participants seeking to securely exchange patient information.

(2) Connect to the statewide infrastructure to allow qualified entity participants to exchange information with qualified entity participants of other qualified entities.

(3) Submit to regular audits of qualified entity functions and activities by the New York State Department of Health as necessary to ensure the quality, security, and confidentiality of data in the SHIN-NY.

(4) Ensure that data from qualified entity participants is only made available through the SHIN-NY in accordance with applicable law.

(5) Enter into agreements with qualified entity participants that supply patient information to, or access patient information from, the qualified entity. A qualified entity must be the "business associate," as defined in 42 USC § 17921, of any qualified entity participant that supplies patient information and is a health care provider, and must be a qualified service organization of any qualified entity participant that supplies patient information and is an alcohol or drug abuse program required to comply with federal regulations regarding the confidentiality of alcohol and substance abuse patient records.

(6) Allow participation of all health care providers in the geographical area served by the qualified entity that are seeking to become qualified entity participants, list the names of such qualified entity participants on its website, and make such information available at the request of patients.

(7) Submit reports on health care provider participation and usage, system performance and data quality, in a format determined by the New York State Department of Health.

(8) Adopt policies and procedures to provide patients with access to their own patient information that is accessible directly from the qualified entity, except as prohibited by law.

(9) Implement policies and procedures to provide patients with information identifying qualified entity participants that have obtained access to their patient information using the qualified entity, except as otherwise prohibited by law.

(b) Each qualified entity shall have procedures and technology:

(1) to exchange patient information for patients of any age, consistent with all applicable law regarding minor consent patient information;

(2) to allow patients to deny access to specific qualified entity participants; and

(3) to honor a minor's consent or revocation of consent to access minor consent patient information.

(c) Each qualified entity shall provide the following minimum set of core services to qualified entity participants:

(1) Allow qualified entity participants to search existing patient records on the network.

(2) Make available to qualified entity participants and public health authorities a clinical viewer to securely access patient information.

(3) Permit secure messaging among health care providers.

(4) Provide tracking of patient consent.

(5) Provide notification services to establish subscriptions to pre-defined events and receive notifications when those events occur.

(6) Provide identity management services to authorize and authenticate users in a manner that ensures secure access.

(7) Support public health reporting to public health authorities.

(8) Deliver diagnostic results and reports to health care providers.

(d) The New York State Department of Health shall certify qualified entities that demonstrate that they meet the requirements of this section to the satisfaction of the New York State Department of Health. The New York State Department of Health may, in its sole discretion, select a certification body to review applications and make recommendations to the New York State Department of Health regarding certification. The New York State Department of Health shall solely determine whether to certify qualified entities. To be certified, a qualified entity must demonstrate that it meets the following requirements:

(1) The qualified entity is capable of supporting and advancing the use of health information technology in the public interest and has a board of directors and officers with such character, experience, competence and standing as to give reasonable assurance of its abilities in this respect.

(2) The qualified entity has the capability and infrastructure to operationalize the requirements in this section.

(3) The qualified entity has technical infrastructure, privacy and security policies and processes in place to: manage patient consent for access to health information; support the authorization and authentication of users who access the system; audit system use; and implement remedies for breaches of patient information.

(e) The New York State Department of Health shall periodically require qualified entities to demonstrate continued compliance with the certification standards required pursuant to subdivision (d) of this section through a process of audit and re-certification by the New York State Department of Health or a certification body designated by the New York State Department of Health.

(f) The New York State Department of Health may, as it deems appropriate, audit qualified entities to ensure ongoing compliance with criteria and standards.

§ 300.5 Sharing of Patient Information.

(a) General standard. Qualified entity participants may only exchange patient information as authorized by law and consistent with their participation agreements with qualified entity participants. Under subdivision six of section 18 of the Public Health Law, individuals who work for a qualified entity are deemed personnel under contract with a health care provider that is a qualified entity participant. As such, a qualified entity participant may disclose to such a qualified entity necessary patient information without a written authorization from the patient of the qualified entity participant. Qualified entity participants may, but shall not be required to, provide patients the option to withhold patient information, including minor consent patient information, from the SHIN-NY. Except as set forth in subdivision (b)(2) or (c) of this section, a qualified entity shall only allow access to patient information by qualified entity participants with a written authorization from:

(1) the patient; or

(2) when the patient lacks capacity to consent, from:

(i) another qualified person under section 18 of the Public Health Law;

(ii) a person with power of attorney whom the patient has authorized to access records relating to the provision of health care under General Obligations Law Article 5, Title 15; or

(iii) a person authorized pursuant to law to consent to health care for the individual.

(b) Written authorization.

(1) Written authorizations must specify to whom disclosure is authorized.

(i) Patient information may not be disclosed to persons who, or entities that, become qualified entity participants subsequent to the execution of a written authorization unless:

(*a*) the name or title of the individual or the name of the organization are specified in a new written authorization; or

(*b*) the patient's written authorization specifies that disclosure is authorized to persons or entities becoming qualified entity participants subsequent to the execution of the written authorization and the qualified entity has documented that it has notified the patient, or the patient has declined the opportunity to receive notice, of the persons or entities becoming qualified entity participants subsequent to the execution of the written authorization.

(ii) Any written authorization shall remain in effect until it is revoked in writing or explicitly superseded by a subsequent written authorization. A patient may revoke a written authorization in writing at any time by following procedures established by the qualified entity.

(2) A minor's parent or legal guardian may authorize the disclosure of the minor's patient information, other than minor consent patient information.

(3) Minor consent patient information.

(i) In general, a minor's minor consent patient information may be disclosed to a qualified entity participant if the minor's parent or legal guardian has provided authorization for that qualified entity participant to access the minor's patient information through the SHIN-NY. Such access shall be deemed necessary to provide appropriate care or treatment to the minor. However, if federal law or regulation requires the minor's

authorization for disclosure of minor consent patient information or if the minor is the parent of a child, has married or is otherwise emancipated, the disclosure may not be made without the minor's authorization.

(ii) In no event may a qualified entity participant disclose minor consent patient information to the minor's parent or guardian without the minor's authorization.

(4) Minor consent patient information includes, but is not limited to patient information concerning:

(i) treatment of such patient for sexually transmitted disease or the performance of an abortion as provided in section 17 of the Public Health Law;

(ii) the diagnosis, treatment or prescription for a sexually transmitted disease as provided in section 2305 of the Public Health Law;

(iii) medical, dental, health and hospital services relating to prenatal care as provided in section 2504(3) of the Public Health Law;

(iv) an HIV test as provided in section 2781 of the Public Health Law;

(v) mental health services as provided in section 33.21 of the Mental Hygiene Law;

(vi) alcohol and substance abuse treatment as provided in section 22.11 of the Mental Hygiene Law;

(vii) any patient who is the parent of a child or has married as provided in section 2504 of the Public Health Law or an otherwise legally emancipated minor;

(viii) treatment that a minor has a Constitutional right to receive without a parent's or guardian's permission as determined by courts of competent jurisdiction;

(ix) Treatment for a minor who is a victim of sexual assault as provided in section 2805-i of the Public Health Law;

(x) Emergency care as provided in section 2504(4) of the Public Health Law.

(c) Access without written authorization. A qualified entity shall, where permitted by law, allow access to patient information without written authorization when:

(1) Prior consent has already been obtained for the disclosure as required by subdivision 23 of section 6530 of the Education Law, and no provision of law requires any additional written authorization.

(2) Disclosure to the individual entity accessing the patient information is:

(i) required by law; or

(ii) authorized by law:

(*a*) to a public health authority for public health activities;

(*b*) to a health oversight agency for health oversight activities; or

(c) to a federally designated organ procurement organization for purposes of facilitating organ, eye or tissue donation and transplantation.

(3) The health care provider treating the patient, a person acting at the direction of such health care provider, or other professional emergency personnel has documented that an emergency condition exists and the patient is in immediate need of medical attention, and an attempt to secure consent would result in delay of treatment which would increase the risk to the patient's life or health.

§ 300.6 Participation of health care facilities.

(a) One year from the effective date of this regulation, general hospitals as defined in subdivision ten of section two thousand eight hundred one of the Public Health Law, and two years from the effective date of this regulation, all health care facilities as defined in paragraph (c) of subdivision one of section eighteen of the Public Health Law, including

those who hold themselves out as urgent care providers, utilizing certified electronic health record technology under the federal Health Information Technology for Economic and Clinical Health Act (HITECH), must become qualified entity participants in order to connect to the SHIN-NY through a qualified entity, and must allow private and secure bi-directional access to patient information by other qualified entity participants authorized by law to access such patient information. Bi-directional access means that a qualified entity participant has the technical capacity to upload its patient information to the qualified entity so that it is accessible to other qualified entity participants authorized to access the patient information and that the qualified entity participant has the technical capacity to access the patient information of other qualified entity participants from the qualified entity when authorized to do so.

(b) The New York State Department of Health may waive the requirements of subdivision (a) of this section for health care facilities that demonstrate, to the satisfaction of the New York State Department of Health:

(1) economic hardship;

(2) technological limitations or practical limitations to the full use of certified electronic health record technology that are not reasonably within control of the health care provider; or

(3) other exceptional circumstances demonstrated by the health care provider to the New York State Department of Health as the Commissioner may deem appropriate.

SUMMARY OF THE REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law Section 206(18-a)(d) authorizes the Commissioner of Health to make rules and regulations to promote the development of a self-sufficient Statewide Health Information Network for NY (SHIN-NY) to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records (EHRs), personal health records (PHRs) and public health information systems while protecting patient privacy and ensuring data security. The Department of Health is exercising this authority in conjunction with its authority under Public Health Law Articles 28, 36, 40, 44 and 47 to regulate health care facilities as defined in Public Health Law section 18.

Purpose of Regulation:

This regulation will establish requirements for qualified entities and qualified entity participants in the SHIN-NY to allow them to securely exchange information across the state.

- Qualified Entities (QEs) (including RHIOs), through participation agreements with providers and patient consent, would implement a minimum set of core services. The QEs must also comply with federal and State laws, including laws regarding the confidentiality of alcohol and drug abuse treatment records under 42 CFR Part 2, confidential HIV-related information under PHL Article 27-F and mental health records under Mental Hygiene Law Article 33.
- The regulations would allow for the exchange of health information about minors

of any age in a way that complies with current state and federal laws and regulations related to minor consented services.

- The department would create a certification process for QEs/RHIOs that ensures standard criteria are met for providing services to its members and that the number of QEs is sufficient to provide access to health information exchange services statewide.

Benefits of Regulation:

The regulation is intended to support the triple aim of improving the patient care experience (including quality and cost), improving the health of populations, and reducing the per capita cost of health care through the broad adoption of health information exchange by:

- increasing patient record availability to health care providers across the state;
- establishing the core set of health information exchange (HIE) services that provide clinical and administrative value to the healthcare system and are available to all providers and all patients in New York State; and
- reducing barriers for EHR integration with HIE services.

State and Local Cost:

To date, the development of the SHIN-NY and expansion of EHR adoption has been funded through a combination of federal and state funds distributed through grant programs, as well as private contributions from participating health plans, providers and other stakeholders. Currently, over 170 hospitals and over 8200 primary care providers

qualify for "meaningful use" incentives under Medicaid and Medicare. In addition, through HEAL NY funding, it is expected that over 7800 primary and specialty care providers were supported to have adopted EHRs and be connected to the SHIN-NY by the end of 2013. Over 80% of hospitals and over 75% of Federally Qualified Health Centers (FQHCs) in New York State participate in RHIOs.

Investment in the operation of the SHIN-NY will also generate a substantial return through the elimination of wasted expenditures and promoting better quality health care at a lower cost. Three studies conducted in Rochester by the Health Information Technology Evaluation Collaborative (HITEC), an academic research consortium under contract with the State Department of Health to perform evaluation activities for the HEAL NY Program, identified improved quality and reduction in duplicative testing and in readmission rates for a two year study period for events in 2009-2010. Use of the Rochester RHIO by five Emergency Departments (EDs) resulted in 6 averted admissions per 100 patients who came to the ED, resulting in $9 million projected savings annually across the adult community. Extrapolating the cost savings across the state would result in an annual savings of $52 million. During the same study period, image exchange use through the Rochester RHIO within 90 days following an initial imaging procedure reduced the probability of repeat imaging by 35%. Finally, use of the Rochester RHIO after hospital discharge resulted in a 55% reduction in readmission within 30 days. These highly significant findings with important financial implications further demonstrate the value of the SHIN-NY.

An 18-month study in the Buffalo region looked at the number of multiple CT scans ordered for the same body part, for the same patient, over a six-month period.

During the period, 2,763 CT scans were deemed to be potentially unnecessary, duplicative tests. 90% of the potentially duplicative tests were ordered by physicians who never or infrequently access the local health information exchange. By local calculations, that amounts to a potential additional cost of $1.3 million over a six-month period for one test in one region of the state.

Costs to Regulated Entities:

The proposed regulation will require that health care facilities connect to the SHIN-NY.

Average interface costs for hospitals are $75,000 while interface costs for physician practices vary but generally average $5000 – 10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Some RHIOs have established this functionality for their participants, and therefore, there are reduced associated interface costs for their participants, which include physician practices. In some regions of the State, health plans have absorbed the interface costs for their network providers because they see the value of having their physicians connected to the SHIN-NY. Only health care providers, regulated by the Department of Health, using certified EHR technology need to comply with these requirements. Currently, adoption of certified EHR technology for health care facilities outside of hospitals and FQHCs is low because they are not eligible to receive meaningful use incentive payments.

Local Government Mandates:

The State Enterprise Health Information Exchange as part of the SHIN-NY is designed to streamline how providers interact with the many public health information systems that currently exist, to decrease reporting burdens, promote bidirectional information exchange, and advance public health priorities. Health care facilities operated by local governments will be required to comply with these regulations in the same manner as other health care facilities. Should local health departments need to make expenditures to comply with the regulatory requirements, they have opportunities to request funding through Article 6 Local Assistance Grant Program, and possibly other sources. Additionally, local agencies could seek a waiver to connect to their RHIO if funding is not available.

Paperwork:

Entities that wish to become QEs will need to submit an application for review by DOH to determine if the criteria outlined in the regulation have been met as well as meeting other criteria as may be required under the QE certification process.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternatives:

The Department established a statewide collaboration process to establish a governance and policy framework to allow health information sharing among disparate

providers to improve quality, improve efficiency and reduce costs of health care on a statewide basis while ensuring the patient privacy and ensuring data security of patient information.

While other states have different models for health information exchange, and NY considered the approaches and models used in other states through its statewide collaborative process, based on the size, complexity and diversity of New York and the resources that were available, the State Department of Health determined that this model was the best approach to allow for statewide health information exchange.

Federal Standards:

This rule aligns with current federal laws and regulations governing the adoption of interoperable exchange of health information and meaningful use requirements under the HITECH provisions of ARRA, as well as federal standards regarding the exchange of certain alcohol and drug abuse patient records under 42 CFR Part 2.

Compliance Schedule:

Since RHIOs or QEs are largely operational in NYS and the majority of hospitals and federally qualified health centers are already participants, and the number of physicians practices participating continues to grow and the infrastructure for the SHIN-NY is already in development, the estimated time period needed for regulated persons or entities to achieve compliance with the rule is practicable.

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REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law § 206(18-a)(d) authorizes the Commissioner to make such rules and regulations as may be necessary to implement federal policies and disburse funds as required by the American Recovery and Reinvestment Act of 2009 and to promote the development of a self-sufficient Statewide Health Information Network for New York (SHIN-NY) to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data and public health information systems, while protecting patient privacy and ensuring data security. Such rules and regulations shall include, but not be limited to requirements for organizations covered by 42 USC 17938 or any other organizations that exchange health information through the SHIN-NY.

Meaning of "implement federal policies"

The federal government, through the Office of the National Coordinator for Health Information Technology (ONC) within the Department of Health and Human Services (HHS), has been promoting and subsidizing the adoption of health IT for many years. According to the ONC-Coordinated Federal Health IT Strategic Plan: 2008-2012 (June 3, 2008), upon publication of Executive Order 13335 on April 27, 2004, President George W. Bush set a target for the majority of Americans to have access to electronic health records (EHRs) by 2014. Under EO 13335 (3 CFR 13335), ONC is charged with directing "the nationwide implementation of interoperable health information technology

in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures."

Meaning of "disburse funds as required by the American Recovery and Reinvestment Act of 2009"

The American Recovery and Reinvestment Act (ARRA) of 2009 (P.L. 111-5) includes within it the Health Information Technology for Economic and Clinical Health (HITECH) Act (HITECH is ARRA Division A, Title XIII-Health Information Technology and ARRA Division B, Title IV-Medicare and Medicaid Health Information Technology).

Under HITECH, HHS has provided and is continuing to provide billions of dollars for:

- Medicare and Medicaid incentive payments to health care providers that adopt "meaningful use" of certified electronic health record (EHR) technology. 42 USC §§ 299b-31, 299b-33, 1395w-4, 1395w-23, 1395ww, 1396b; 42 CFR Part 495.
- Grants to states to promote health IT. New York State received a federal grant to prepare and submit to the federal government a statewide health IT plan to develop health information exchange across health care systems and to move New York State toward the meaningful use of certified EHR technology. 42 USC § 300jj-33. These regulations implement that plan.
- The creation and funding of health IT Regional Extension Centers (RECs) to assist health care providers in the selection, acquisition, implementation and meaningful use of certified EHR technology to improve health care quality and

outcomes. Two RECs in New York have received federal grants. 42 USC § 300jj-32.

Meaning of "the development of a self-sufficient statewide health information network for New York (SHIN-NY)"

On the State level, New York is creating a Statewide Health Information Network for New York (SHIN-NY). Under the Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) Capital Grant Program (PHL § 2818) Phases 1, 5, 10, 17 and 22, New York promoted broad adoption of EHRs and other health IT tools and is subsidizing the operations of Regional Health Information Organizations (RHIOs) that facilitate health information exchange between disparate providers and health systems. The creation of the SHIN-NY and the expenditure of federal and State funds for health IT is being coordinated by DOH's Office of Quality and Patient Safety (OQPS). The Legislature established the OQPS Bureau of Health Information Exchange (referred to in the law as "the office of Health e-Links New York") "to enhance the adoption of an interoperable regional health information exchange and technology infrastructure that will improve quality, reduce the cost of health care, ensure patient privacy and security, enhance public health reporting including bioterrorism surveillance and facilitate health care research in the state of New York" (L. 2006, ch. 57, Part G, § 1), and the Legislature has since then appropriated money in the Chapter 54 budget appropriation laws to fund the office of Health e-Links (or "health e-link"). In the 2014-2015 budget, the Legislature appropriated $55 million for the SHIN-NY (L. 2014, ch. 54), and in the 2015-2016 budget, the Legislature appropriated $45 million for the SHIN-NY.

Meaning of "organizations covered by 42 USC 17938"

Federal regulations implementing the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 are in 45 CFR Parts 160 and 164, and HITECH made a number of amendments to those federal regulations. One such amendment is a section of HITECH codified in 42 USC § 17938 ("Business associate contracts required for certain entities"). Under 42 USC § 17938: "Each organization, with respect to a [HIPAA-]covered entity, that provides data transmission of protected health information to such entity (or its business associate) and that requires access on a routine basis to such protected health information, such as a Health Information Exchange Organization, Regional Health Information Organization, E-prescribing Gateway, or each vendor that contracts with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section 164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this title [enacted Feb. 17, 2009]."

Prior to the enactment of HITECH, on December 15, 2008, ONC had already published a guidance document called "The HIPAA Privacy Rule and Electronic Health Information Exchange in a Networked Environment." That guidance made clear the federal government's view that under HIPAA, RHIO participants may disclose health information to RHIOs without any authorization from patients provided that the RHIOs

enter into appropriate "business associate" agreements with the RHIO participants. http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/; http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/introduction.pdf; 45 CFR § 164.502(e). 42 USC § 17938 codified this guidance into law.

In 2010, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) likewise issued guidance (which was supplemented on December 8, 2011) explaining that under 42 CFR Part 2, RHIO participants may disclose alcohol and substance abuse patient records to RHIOs without patient consent provided that the RHIOs enter into appropriate Qualified Service Organization agreements with the RHIO participants. http://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf; December 8, 2011, FAQs (available upon request); 2 CFR § 2.12(c)(4).

This regulation implements federal policies, including the federal policies effected by the HITECH provisions of ARRA to enable widespread interoperability among disparate health information systems, while protecting patient privacy and ensuring data security. These regulations include the requirements for organizations such as RHIOs, which under 42 USC § 17938 make it possible, without patient authorization, to exchange patient information among disparate health care providers so long as those organizations comply with federal requirements for business associates and qualified service organizations.

Public Health Law Sections 201, 206(1), 2800, 2803, 2816, 3600, 3612, 4000, 4010, 4400, 4403, 4700 and 4712 authorize the Commissioner to make such rules and regulations as may be necessary to effectuate the provisions and purposes of Public

Health Law Articles 28, 36, 40, 44 and 47 and provide additional authority for the Commissioner to create and make use of the SHIN-NY.

Legislative Objectives:

This regulation will establish formal requirements for operation of the SHIN-NY in order to advance health information technology adoption and use statewide for the public good. The Department would regulate people and entities in New York that exchange health information using the SHIN-NY, including Regional Health Information Organizations (RHIOs) and other such health IT entities.

Needs and Benefits:

This regulation facilitates the operation of a statewide interoperable health information infrastructure that will provide clinicians and consumers with access to health information in a timely, secure, efficient, and effective way.

Benefits of consistent policy implementation:

As the use of health information technology expands, the regulation will formalize a common policy framework across the entire health care system to maximize the use and benefits of the SHIN-NY. The SHIN-NY enables delivery of appropriate care at the appropriate time in a coordinated, patient-centered manner. RHIOs and QEs facilitate access to the SHIN-NY through participation agreements and technical services to connect health care providers to the network. A certification process has been established by the State Department of Health for QE designation. In order to qualify to

become a QE, a set of minimum criteria must be met. Consistent implementation of statewide policies through the regulatory process leads to a common approach to education and training of providers and consumers and can lead to reduction in costs and creation of efficiencies across the state. The regulation will further promote adoption, usage and sustainability of health information exchange organizations and the SHIN-NY by:

- Increasing patient record availability on a statewide basis
- Establishing the core set of HIE services that provide clinical and administrative value to the healthcare system
- Reducing barriers for EHR integration with HIE services
- Increasing participation of all stakeholders including payers
- Creating opportunities for emerging health care payment, delivery and access reforms through new models of care such as health homes, patient centered medical homes and Accountable Care Organizations, among others.

In addition, HITECH established a program for incentive payments to Medicaid providers who demonstrate "meaningful use" of certified EHR technology with the ultimate goal of promoting health care quality and care coordination through state health information exchange (HIE) activities. Providers that achieve NCQA Patient Centered Medical Home designation qualify for meaningful use incentive payments. This regulation will expand access to and use of the SHIN-NY to additional segments of the broader health care system (e.g., mental health, alcohol and substance abuse and social services agencies) to improve health, improve health care and reduce costs. The

Department of Health needs clear regulatory authority to apply these policies more broadly.

State and Local Cost:

To date, the development of the SHIN-NY and expansion of EHR adoption has been funded through a combination of federal and state funds distributed through grant programs, as well as private contributions from participating health plans, providers and other stakeholders. Currently, over 170 hospitals and over 8200 primary care providers qualify for "meaningful use" incentives under Medicaid and Medicare. In addition, through HEAL NY funding, it is expected that over 7800 primary and specialty care providers were supported to have adopted EHRs and be connected to the SHIN-NY by the end of 2013. Over 80% of hospitals and over 75% of Federally Qualified Health Centers (FQHCs) in New York State participate in RHIOs.

Investment in the operation of the SHIN-NY will generate a substantial return through the elimination of wasted expenditures and promoting better quality health care at a lower cost. Three studies conducted in Rochester by the Health Information Technology Evaluation Collaborative (HITEC), an academic research consortium under contract with the State Department of Health to perform evaluation activities for the HEAL NY Program, identified improved quality and reduction in duplicative testing and in readmission rates for a two year study period for events in 2009-2010. Use of the Rochester RHIO by five Emergency Departments (EDs) resulted in 6 averted admissions per 100 patients who came to the ED, resulting in $9 million projected savings annually across the adult community. Extrapolating the cost savings across the state would result

in an annual savings of $52 million. During the same study period, image exchange use through the Rochester RHIO within 90 days following an initial imaging procedure reduced the probability of repeat imaging by 35%. Finally, use of the Rochester RHIO after hospital discharge resulted in a 55% reduction in readmission within 30 days. These highly significant findings with important financial implications further demonstrate the value of the SHIN-NY.

An 18-month study in the Buffalo region looked at the number of multiple CT scans ordered for the same body part, for the same patient, over a six-month period. During the period, 2,763 CT scans were deemed to be potentially unnecessary, duplicative tests. 90% of the potentially duplicative tests were ordered by physicians who never or infrequently access the local health information exchange. By local calculations, that amounts to a potential additional cost of $1.3 million over a six-month period for one test in one region of the state.

Across the country, states have used similar studies to project the value of statewide HIE. Based on estimates of 85% provider and patient participation in its statewide HIE, Rhode Island forecasted an annual savings of $95 per person.[1] In a similar study of fully operational statewide HIE in Maine that factored in the total operational costs, researchers projected significant, but more modest net savings of $35 per person per year.[2]

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[1] Boston Consulting Group. *Rhode Island Quality Institute Business case for Health Information Exchange*. December 5, 2009.
[2] Center for Health Policy and Research. *The Impact of Electronic Health Information Exchange (HIE) Services in Maine: Avoidable Service and Productivity Savings Estimates Related to HealthInfoNet Services*. November 2008.

In addition to savings associated with reduction in unnecessary and duplicative testing, readmissions, and adverse drug events, participation in the SHIN-NY will also generate savings by minimizing the number of interfaces health care organizations need to access data. Currently, physician practices, hospitals, laboratories, public health agencies, and others must create and maintain costly and complex interfaces with every organization they wish to exchange data. In this point-to-point data exchange environment, a typical hospital with 10 interfaces can spend as much as $200,000 in one-time development fees, and $40,000 per year in maintenance fees.[3] The SHIN-NY and its QEs, serving as utilities and consolidating services and interfaces, have been and will continue to reduce the per unit connectivity cost for all participants.

The proposed regulation will require that health care facilities defined in PHL Section 18 that utilize certified EHRs, connect to the SHIN-NY through a QE and allow private and secure bi-directional access to patient information by other QE participants authorized by law to access such patient information.

Costs for facilities operated by State and local governments will be equivalent to costs for other regulated facilities.

Costs to Regulated Entities:

The proposed regulation will require that health care facilities defined in PHL Section 18 that utilize certified EHRs, including urgent care centers, connect to the

[3] Delaware Health Information Network. *Final Report: Delaware Health Information Network Evaluation Analysis*. August 2011.

SHIN-NY through a QE and allow private and secure bi-directional access to patient information by other QE participants authorized by law to access such patient information.

Average interface costs for hospitals are $75,000 while interface costs for physician practices vary but generally average $5000 – $10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Some RHIOs have established this functionality for their participants, thereby reducing associated interface costs for their participants, which include physician practices. In some regions of the State, health plans have absorbed the interface costs for their network providers because they see the value of having their physicians connected to the SHIN-NY. Only health care providers using certified EHR technology need to comply with these requirements. Currently, adoption of certified EHR technology for health care facilities outside of hospitals and FQHCs is low because they are not eligible to receive meaningful use incentive payments.

This requirement, to connect a certified EHR to the SHIN-NY, may be waived for health care facilities that meet criteria established by the commissioner, such as economic hardship, technological limitations that are not reasonably in the control of the provider or other exceptional circumstances demonstrated by the provider to the department.

The Department will develop a fair process for health care providers to demonstrate that they meet waiver criteria and for the Department to give such providers a waiver or extension of time to connect to the SHIN-NY.

The regulation is being put forth as a "public good" model. That is, a certain set of baseline services, both technical and administrative, will be made available to all providers within New York State, at no charge. The basic technical services will include: patient record look-up; provider and public health clinical viewer; secure messaging; consent management; notifications and alerts; identity management and security; public health reporting integration; and results delivery.

Local Government Mandates:

Health facilities operated by local governments will be required to comply with these regulations in the same manner as other facilities. Should local health departments need to make expenditures to comply with the regulatory requirements, they have opportunities to request funding through the Public Health Law Article 6 Local Assistance Grant Program, and possibly other sources.

Only health care providers using certified EHR technology need to comply with these requirements. This requirement, to connect a certified EHR to the SHIN-NY, may be waived for health care facilities that meet certain criteria, such as economic hardship, technological limitations that are not reasonably in the control of the provider or other exceptional circumstances demonstrated by the provider to the department.

Paperwork:

Entities that wish to become QEs will need to submit an application for review by DOH to determine if the criteria outlined in the regulation have been met as well as meeting other criteria as may be required under the QE certification process.

Any entity seeking certification as a QE, regardless the entity's organizational structure, origin or type, will be subject to the full certification process. This certification process incorporates criteria that fall into four broad categories including: organizational characteristics; operational requirements; policies and procedures; and technical requirements. QEs would be subject to recertification and would also be subject to ongoing monitoring and enforcement activities between full certifications. This will ensure that patient information is made available to all providers participating in a patient's care in a secure and confidential manner.

Duplication:

This regulation will not conflict with any state or federal rules.

Alternatives:

The Department used the statewide collaborative process to solicit comments from a variety of stakeholders to develop recommendations on regulations and its policy guidance. A series of summits and input opportunities were incorporated into the development process. In January of 2013 a summit of stakeholders, which included RHIO Executive Directors, Members of RHIO Board of Directors, the Board of Directors of the New York eHealth Collaborative, representatives for NYS DOH, NYC DOHMH and other stakeholders was conducted. The goal of the session was to establish the roles and responsibilities of Qualified Entities. Subsequent to the summit, a series of workgroups were launched to further define requirements and responsibilities.

While other states have different models for health information exchange, and NY considered the approaches and models used in other states through its statewide collaborative process, based on the size, complexity and diversity of New York and the resources that were available, the State Department of Health determined that the current model was the best approach. The State Department of Health has convened and considered the recommendations of the workgroup established by Public Health Law § 206(18-a)(b), including the workgroup's interim report under § 206(18-a)(b)(iii). To date, the State Department of Health has acted in a manner that is consistent with the recommendations of the workgroup; however, in the event that the Department acts in a manner inconsistent with the recommendations of the workgroup, it shall provide the reasons therefor, as required by § 206(18-a)(d).

Federal Standards:

This rule aligns with current federal laws and regulations governing the adoption of interoperable exchange of health information and meaningful use requirements under the HITECH provisions of ARRA including the Electronic Health Record Incentive program. This rule also aligns with the SAMHSA federal standards regarding the exchange of certain alcohol and drug abuse patient records under 42 CFR Part 2.

Compliance Schedule:

Two years from the effective date of this regulation (or one year for general hospitals), health care facilities utilizing certified electronic health record technology under HITECH must become qualified entity participants in order to connect to the

SHIN-NY through a qualified entity. Since RHIOs or QEs are largely operational in NYS and the majority of hospitals and federally qualified health centers are already participants, and the number of physician practices participating continues to grow and the infrastructure for the SHIN-NY is already in development, the estimated time period needed for regulated persons or entities to achieve compliance with the rule is two years (one year for general hospitals) from the time the rule becomes effective. Two years from the time the rule becomes effective (one year for general hospitals), health care facilities utilizing certified health record technology under HITECH must allow private and secure bi-directional access to patient information by other QE Participants authorized by law to access such patient information.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

The proposed rule will not have a substantial adverse impact on small businesses or local governments. Small businesses such as physician practices, that are not regulated by the Department, that adopt certified electronic record technology in order to qualify for meaningful use incentives, would not be required to exchange patient health information among disparate providers to facilitate care coordination and appropriate follow up. Although this exchange is encouraged, it is strictly optional for these practitioners in private practice.

Local health departments that operate health facilities including Article 28 facilities, including outpatient departments of hospitals, diagnostic and treatment centers, free-standing ambulatory surgery centers and nursing homes, as well as home care services agencies, hospices and health maintenance organizations would be required to connect to the SHIN-NY would be impacted by the regulation if those facilities use certified electronic health record technology. Average interface costs for hospitals are $75,000 while interface costs for physician practices vary but generally average $5000 – $10,000 per practice. Interface costs for other types of facilities, such as nursing homes, home care agencies and hospice would fall in between physician practices and hospitals, depending on the size and complexity. Costs of connecting the SHIN-NY could be offset by funds from the meaningful use incentive program. A connection to the SHIN-NY satisfies one requirement of the meaningful use incentive program and will allow providers at these facilities to access Medicaid or Medicare Meaningful Use incentive payments. The meaningful use incentive program allows all individual eligible

professionals who meet meaningful use requirements to apply for incentive payments of up $43,720 over a five year period. The Department of Health, with the New York eHealth Collaborative, has implemented an additional incentive program, with support from the Centers for Medicare and Medicaid Services (CMS), to allow meaningful use providers to receive an additional incentive payment of up to $30,000 to help defray the cost of connecting to the SHIN-NY. It is anticipated that the incentive program will continue with additional funding from CMS. Additionally, any facility that is required to connect to the SHIN-NY under this regulation may request that this requirement be waived for its facilities based on economic or technical constraints.

Accessing the SHIN-NY to perform required local health department surveillance and case investigation activities has actually been documented to result in increased efficiency and decreased costs for the local health department. Through the statewide collaboration process, local governments have the opportunity to participate in SHIN-NY policy development including providing input on draft regulations. The SHIN-NY policy committee includes representatives from the local public health agencies.

Ensuring that clinical data are available in safe, secure way supports the goals of increasing the quality of care, increasing population health and reducing healthcare costs. Hospitals that connect to the SHIN-NY have been show to decrease the number of tests and imaging studies thus reducing costs.

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 the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not required.

RURAL AREA FLEXIBILITY ANALYSIS

The proposed rule will not have a direct adverse impact on rural areas. Operation of the SHIN-NY and expanded use of certified EHR technology should improve health care, increase efficiency, reduce duplicative testing and reduce overall costs for underserved populations in the state, including rural areas.

JOB IMPACT STATEMENT

The proposed rule should not have any adverse impact on jobs and employment opportunities, but may increase the number of health IT jobs available in the state. The development and operation of the SHIN-NY will most likely result in opportunities for the development of new applications of health IT tools and services and may result in new health IT jobs in New York State. It has been estimated that the SHIN-NY, and related initiatives that use the data from the SHIN-NY has the potential to create 1,500 health technology jobs across New York State over the next five years.

Summary of Express Terms

The following summarizes the proposed regulations pertaining to children with disabilities attending a children's camp.

Pursuant to the proposed amendments, the following requirements, which previously pertained only to camps with 20 percent or more campers with a developmental disability, will now apply to any camp enrolling campers with a disability, beginning October 1, 2016:

- For campers who cannot independently manipulate a wheelchair or adaptive equipment, camps must provide at least 1:2 supervision;
- Staff that have direct care responsibilities of campers with disabilities must receive training relevant to the specific needs of the campers in their charge;
- Camps must obtain and implement, as appropriate, care and treatment plans for campers with disabilities that have such plans as well as obtain other available information relevant to the care and specific needs of a camper with disabilities including pre-existing medical conditions, allergies, modified diets, and activity restrictions;
- During swimming activities, camps must provide one counselor for each camper who is non-ambulatory or has a disability that may result in an increased risk for an emergency in the water;
- For campers with developmental disabilities, camps must provide one counselor for every five campers during swimming activities;

- Camps must obtain parent/guardian's written permission to allow campers with developmentally disabilities to participate in swimming activities;
- Camps must develop procedures and training for handling seizures or aspiration of water by campers with developmental disabilities that may occur during swimming activities;
- All lavatories and showers used by campers with physical disabilities must be equipped with specialized features and grab bars;
- Lavatories and showers used by campers with a disability, who are unable to moderate water temperature safely, shall have a water temperature not greater than 110 degrees Fahrenheit;
- Buildings housing non-ambulatory campers shall have ramps to facilitate access.
- Non-ambulatory campers may not have housing above ground level; and
- Exterior paths must be constructed and maintained, as appropriate for the camp population served, to provide for safe travel during inclement weather.

The amendments also define a "Camp for Children with Developmental Disabilities." Such camps would be immediately required to adhere to the following additional requirements, pursuant to the legislation that established the Justice Center, in addition to immediately complying with the provisions above:

- Reportable incident is defined to include abuse, neglect and other significant incidents specified in section 488 of Social Services Law. Camp staff must report all reportable

incidents to the Justice Center Vulnerable Persons' Central Registry and the permit-issuing official;

- A definition of a personal representative was added to be consistent with section 488 of Social Services Law;
- Prior to hiring camp staff, camps must verify that candidates are not on the Justice Center's staff exclusion list or on the Office of Children and Family Services State Central Registry of Child Abuse and Maltreatment;
- All camp staff must obtain mandated reporter training and review and acknowledge an understanding of the Justice Center's code of conduct;
- Camps must ensure that immediate protections are in place following an incident to prevent further risk or harm to campers;
- Camps must notify the victim, any potential witnesses, and each camper's personnel representative (as appropriate) that the camper may be interviewed as part an abuse or neglect investigation;
- Camps must cooperate fully with reportable incident investigations and provide/disclose all necessary information and access to conduct investigations;
- Reportable incident investigations procedures are established;
- Camps must promptly obtain an appropriate medical examination of a physically injured camper with a developmental disability;

- Unless a waiver is granted, camps must convene a Facility Incident Review Committee to review the camp's responses to a reportable incident including making recommendations for improvement, reviewing incident trends, and making recommendations to reduce reportable incidents;
- Camps must implement any corrective actions identified as the result of a reportable incident investigation.

Note that, for organizational reasons, these amendments repeal section 7-2.25 in its entirety, and replace it with a new section 7-2.25. Although reorganized, some provisions have been left substantially unchanged, including certain provisions relating to camp directors and health directors.

Pursuant to the authority vested in the New York State Department of Health by Public Health Law Section 225, Subpart 7-2 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective immediately upon publication in the New York State Register, to read as follows:

Subdivision (b)(2)(ix) of section 7-2.1 is amended to read as follows:

(ix) implementation of the medical requirements of the camp safety plan not under the supervision of a camp health director; at [camps for the developmentally disabled] Camps for Children with Developmental Disabilities, as defined in section 7-2.2(d-1) of this Subpart, medication is not under the supervision of licensed or certified personnel;

Subdivision (d-1) of section 7-2.2 is added to read as follows:

(d-1) Camp for Children with Developmental Disabilities shall mean a children's camp with 20% or more enrollment of campers with a developmental disability as defined by subdivision (d) of this section.

Subdivision (c) of section 7-2.9 is amended to read as follows:

(c) Showers with water under pressure heated to between [90 and 100] 110 and 120 degrees Fahrenheit, and one shower head for each 20 occupants or less, shall be provided.

Subdivisions (a) and (b) of section 7-2.24 are amended to read as follows:

(a) Variance. [-] In order to allow time to comply with certain provisions of this Subpart, an operator may submit a written request to the permit-issuing official for a variance from a specific provision(s) when the health and safety of the children attending the camp and the public will not be prejudiced by the variance, and where there are practical difficulties or unnecessary hardships in immediate compliance with the provision. An operator must meet all terms of an approved variance(s) including the effective date, the time period for which the variance is granted, the requirements being varied and any special conditions the permit-issuing official specifies. For any variance request relating to the requirements of section 7-2.25(b) of this Subpart, the permit-issuing official shall consult with and obtain approval from the State Department of Health, prior to granting or denying the variance.

(b) Waiver. [-] In order to accept alternative arrangements that do not meet certain provisions of this Subpart but do protect the safety and health of the campers and the public, an operator may submit a written request to the permit-issuing official for a waiver from a specific provision of this Subpart. Such request shall indicate justification that circumstances exist that are beyond the control of the operator, compliance with the provision would present unnecessary hardship and that the public and camper health and safety will not be endangered by granting such a waiver. The permit-issuing official shall consult with a representative of the State Department of Health prior to granting or denying a waiver request. An operator must meet all terms of an approved waiver(s), including the condition that it will remain in effect indefinitely unless revoked by the permit-issuing official or the facility changes operators. For any waiver request relating to the

requirements of section 7-2.25(b) of this Subpart, the permit-issuing official shall consult with and obtain approval from the State Department of Health, prior to granting or denying the variance.

Section 7-2.25 (Additional requirements for camper with camper enrollments of 20 percent or more developmentally disabled campers) is repealed and replaced to read as follows:

7-2.25 Additional requirements for camps enrolling campers with disabilities.

(a) Effective October 1, 2016, the following requirements shall apply to all camps enrolling a child with a physical or developmental disability, except that any Camp for Children with Developmental Disabilities as defined in section 7-2.2 of this Subpart shall comply with this section upon the effective date of this Subpart:

(1) Personnel and Supervision.

(i) The ratio of counselors to campers who use a wheelchair, adaptive equipment or bracing to achieve ambulation, but who do not possess, for whatever reason, the ability to fit, secure or independently manipulate such devices satisfactorily to achieve ambulation, shall be 1:2.

(ii) Camp staff providing direct care of a camper with a disability shall be trained on the specific needs of the campers in their charge.

(2) Medical Requirements.

(i) A camp operator shall obtain existing individual treatment, care, and behavioral plans for campers with a disability. Camp staff shall implement adequate procedures to protect the health and safety of a camper based on the plan provided and, when necessary, in consultation with an individual's parent, guardian and/or clinical team.

(ii) The confidential medical history for a camper with a disability shall, in addition to the requirements of section 7-2.8(c)(1) of this Subpart, include:

(a) Any restrictions, allergies, medications, special dietary needs, and other pre-existing medical, physical or psychological conditions and illnesses.

(b) The camper's physician's name, address and telephone number.

(iii) Modified diets and other special needs related to a camper's disability shall be identified for each camper prior to arrival at camp, planned for, provided for in accordance with supplied directions, and reviewed by the designated camp health director.

(3) Recreational Safety.

(i) The minimum counselor-to-camper ratio during swimming pool and bathing beach activities shall be one counselor for each camper who is non-ambulatory or has a disability identified by the camper's parents, guardian, physician or residential care

provider that may result in an increased risk of an emergency in the water, such as uncontrolled epilepsy.

(ii) The minimum counselor-to-camper ratio during swimming pool and bathing beach activities shall be one staff member for every five (5) campers with a developmental disability not designated in subparagraph (i) of this paragraph.

(iii) No camper with a developmental disability can participate in swimming activities unless a written permission statement signed by the camper's parent, guardian or residential care provider is on file at the camp.

(iv) The camp safety plan approved under section 7-2.5(n) of this Subpart shall contain a procedure to address the handling of seizures and aspiration of water for campers with developmental disabilities. All bathing beach and swimming pool staff shall be trained to implement the procedure prior to the date the camp begins operation. In-service training using this procedure shall be conducted and documented every two weeks after the commencement of the camp's operation or as otherwise approved by the permit-issuing official in the camp's safety plan.

(4) Toilets, privies, lavatories, showers. All lavatories and showers used by a camper with a physical disability shall be equipped with specialized fixtures, grab bars or other controls appropriate for the camper's disability. Lavatories and showers used by campers with physical, intellectual or developmental disabilities, who are unable to moderate

water temperature safely, shall have a water temperature not greater than 110 degrees Fahrenheit.

(5) Sleeping Quarters.

(i) Buildings housing campers who are non-ambulatory or use a wheelchair shall have ramps constructed in accordance with the Uniform Code to facilitate access and egress.

(ii) Non-ambulatory campers shall not have their sleeping accommodations above the ground floor.

(6) Location; grounds. Exterior paths of travel shall be free of encumbrances and provide an appropriate surface for movement during inclement weather as appropriate for the camp population being served.

(b) Children's Camps for Children with Developmental Disabilities. In addition to the requirements listed in subdivision (a), the following requirements shall apply to all Children's Camps for Children with Developmental Disabilities, as defined as defined in section 7-2.2 of this Subpart:

(1) Definitions. The following definitions apply to this subdivision:

(i) *Camp staff* shall mean a director, operator, employee or volunteer of a children's camp; or a consultant, employee or volunteer of a corporation,

partnership, organization or government entity which provides good or services to a children's camp pursuant to contract or other arrangement that permits such person to have regular or substantial contact with individuals who are cared for by the children's camp.

(ii) *Department* shall mean the New York State Department of Health.

(iii) *Justice Center* shall mean the Justice Center for the Protection of People with Special Needs, as established pursuant to section 551 of the Executive Law.

(iv) *Reportable incidents* shall include the following:

(*a*) *Abuse and Neglect* shall mean those actions by camp staff that satisfies the definitions of "physical abuse", "sexual abuse", "psychological abuse", "deliberate use of restraints", "use of aversive conditioning", "obstruction of reports of reportable incidents", "unlawful use or administration of controlled substance" and "neglect" all as defined in section 488 of Social Services Law.

(*b*) *Significant Incident* shall mean an incident, other than an incident of abuse or neglect as defined by subparagraph (*a*) of this section that because of its severity or the sensitivity of the situation may result in, or has the reasonably foreseeable potential to result in, harm to the health, safety, or welfare of a camper with a developmental disability. A significant incident shall include but not limited to: (1) conduct between campers with developmental disabilities that would constitute abuse, as defined in this

Section, if it had been conducted by a camp staff member; or (2) conduct by a camp staff member which is inconsistent with the individual treatment plan for a camper with a developmental disability, generally accepted treatment practices and/or applicable federal or state laws, regulations or policies, and impairs or creates a reasonably foreseeable potential to impair the health, safety or welfare of a camper with a developmental disability. Such conduct shall include but is not limited to: actions incorporated within the definitions of "unauthorized seclusion," "unauthorized use of time-out," "administration of a prescribed or over-the-counter medication, which is inconsistent with a prescription or order issued by a licensed, qualified health care practitioner, and which has an adverse effect," and "inappropriate use of restraints," as defined in section 488 of the Social Services Law.

(v) Personal Representative shall mean a camper's parent, guardian, or person authorized under state, tribal, military or other applicable law to act on behalf of a camper with a developmental disability in making health care decisions.

(2) Personnel and Supervision.

(i) The camp director, who may also be the camp operator, shall possess a Bachelor's Degree from an accredited program in the field of physical education, recreation, education, social work, psychology, rehabilitation or related human services fields and shall present evidence of specialized training or one year of

experience in treating or working with individuals with a developmental disability.

(ii) A camp director does not have to meet the minimum requirements of paragraph (i) of this subdivision if:

(a) the individual was a camp director for a camp for children with developmental disabilities during each of the three camping seasons preceding the 1986 camping season;

(b) conditions at the camp did not threaten the health or safety of campers during that person's tenure as camp director; and

(c) the individual otherwise meets the minimum qualifications for a camp director, as set forth in section 7-2.5 of this Subpart.

(iii) The camp director shall not be on the Justice Center Staff Exclusion List (SEL) consistent with paragraph 6 of subdivision b of this section.

(iv) The camp director shall develop a written staff training program appropriate to the specific needs of the campers with developmental disabilities enrolled in the camp.

(v) There shall be at least one counselor in addition to the driver in any vehicle transporting campers with developmental disabilities or as provided in the camp safety plan approved under section 7-2.5(n) of this Subpart.

(3) Medical Requirements. The camp health director shall be a physician, physician's assistant, registered nurse or licensed practical nurse and shall be on-site for the period the camp is in operation.

(4) Reporting. In addition to reporting incidents as required by Part 5 of this Title and by sections 7-2.8(d), 7-2.5(n)(3) and 7-2.6(f)(4) of this Subpart, all camp staff shall immediately report any reportable incident, as defined in section 7-2.25(b)(1)(iv) of this Subpart, involving a camper with a developmental disability, to the permit-issuing official and to the Justice Center's Vulnerable Person's Central Register (VPCR). Such report shall be provided in a form and manner as required by the Department and Justice Center.

(5) Immediate Protections and Notifications.

(i) Immediately upon notification of abuse, neglect or significant incident as defined by section 7-2.25(b)(1)(iv), the camp operator or designee shall ensure appropriate actions are taken to address the immediate physical and psychological needs of the camper(s), implement protections to ensure the safety and mitigate further risk to campers, and document such actions and implementations.

(ii) The camp director or designee shall notify a camper with a developmental disability and the camper’s personal representative that the camper is an alleged victim or potential witness of an incident of abuse or neglect. Alleged victims

shall be notified within 24 hours and potential witnesses shall be notified within 48 hours of the permit-issuing official reporting, to the camp director or designee, that an incident of abuse or neglect has been accepted by the Justice Center for investigation. There shall be no notification of a personal representative if the alleged victim or potential witness objects to such notification or if providing such notification would compromise the investigation, violate relevant confidentiality laws, be contrary to court order, or otherwise contrary to the best interests of the alleged victim or the potential witness.

(iii) Camp staff shall document in writing that notice was given or that a diligent effort to make such notification was made for each camper.

(6) Camp Staff Screening, Training, and Code of Conduct.

(i) Prior to hiring anyone who will or may have direct contact with campers, or approving credentials for any camp staff, the operator shall follow the procedures established by the Justice Center in regulations or policy, to verify that such person is not on the Justice Center's Staff Exclusion List (SEL) established pursuant to section 495 of the Social Services Law. If such person is not on the Justice Center's Staff Exclusion List (SEL), the operator shall also consult the Office of Children and Family Services State Central Registry of Child Abuse and Maltreatment as required by section 424-a of the Social Services Law. Such screening is in addition to the requirement that the operator similarly verify that a

prospective camp staff is not on the sexual abuse registry, as required by section 7-2.5(l) of this Subpart.

(ii) A camp operator shall ensure that camp staff receive training regarding mandated reporting and their obligations as mandated reporters as defined by Article 11 of Social Services Law. A camp operator shall ensure that the telephone number for the Justice Center's VPCR hotline for the reporting of reportable incidents is conspicuously displayed in areas accessible to mandated reporters and campers.

(iii) The camp operator shall ensure that all camp staff are provided with a copy of the code of conduct established by the Justice Center pursuant to section 554 of Executive Law. Such code of conduct shall be provided at the time of initial employment, and at least annually thereafter during the term of employment. Receipt of the code of conduct shall be acknowledged and the recipient shall further acknowledge that he or she has read and understands such code of conduct.

(7) Disclosure of Information.

(i) Except to the extent otherwise prohibited by law, the camp operator shall be obliged to share information relevant to the investigation of any incident subject to the reporting requirements of this Subpart with the permit-issuing official, the Department, and the Justice Center. The permit-issuing official, the Department

and the Justice Center shall, when required by law, or when so directed by the Department or the Justice Center and except as otherwise prohibited by law, be permitted to share information obtained in their respective investigations of incidents subject to the reporting requirements of section 7-2.25 (b)(4) of this Subpart.

(ii) Except as otherwise prohibited by law, the operator of a camp not otherwise subject to Article Six of the Public Officers Law shall make records available for public inspection and copying to the extent required by subdivision six of section 490 of the Social Services Law.

(8) Incident Management.

(i) The camp operator shall cooperate fully with the investigation of reportable incidents involving campers with developmental disabilities and shall provide all necessary information and access to conduct the investigation. The camp operator shall promptly obtain an appropriate medical examination of a physically injured camper with a developmental disability. The camp operator shall provide information, whether obtained pursuant to the investigation or otherwise, to the Justice Center and permit-issuing official upon request, in the form and manner requested. Such information shall be provided in a timely manner so as to support completion of the investigation subject to the time limits set forth in this subdivision.

(ii) Unless delegated by the Justice Center to the Department, an allegation of abuse or neglect as defined in section 7-2.25(b)(1)(iv)(*a*) of this Subpart, shall be investigated by the Justice Center. With regard to an alleged significant incident, as defined in section 7-2.25(b)(1)(iv)(*b*) of this Subpart, the permit-issuing official shall initiate a prompt investigation of the allegation, unless the Justice Center agrees that it will undertake such investigation. An investigation conducted by the permit-issuing official shall commence no later than five business days after notification of such an incident. Additional time for completion of the investigation may be allowed, subject to the approval of the department, upon a showing of good cause for such extension. At a minimum, the investigation of any reportable incident shall comply with the following:

(a) Investigations shall include a review of medical records and reports, witness interviews and statements, expert assessments, and the collection of physical evidence, observations and information from care providers and any other information that is relevant to the incident. Interviews should be conducted by qualified, objective individuals in a private area which does not allow those not participating in the interview to overhear. Interviews must be conducted of each party or witness individually, not in the presence of other parties or witnesses or under circumstances in which other parties or witnesses may perceive any aspect of the interview. The person alleging the incident, or who is the subject of the incident, must be offered the opportunity to give

his/her version of the event. At least one of the persons conducting the interview must have an understanding of, and be able to accommodate, the unique needs or capabilities of the person being interviewed. The procedures required by this clause may be altered if, and only to the extent necessary to, comply with an applicable collective bargaining agreement.

(b) All evidence must be adequately protected and preserved.

(c) Any information, including but not limited to documents and other materials, obtained during or resulting from any investigation shall be kept confidential, except as otherwise permissible under law or regulation, including but not limited to Article 11 of the Social Services Law.

(d) Upon completion of the investigation, a written report shall be prepared which shall include all relevant findings and information obtained in the investigation and details of steps taken to investigate the incident. The results of the investigation shall be promptly reported to the department, if the investigation was not performed by the department.

(e) If any remedial action is necessary, the permit-issuing official shall establish a plan in writing with the camp operator. The plan shall indicate the camp operator's agreement to the remediation and identify a follow-up date

and person responsible for monitoring the remedial action. The plan shall be provided, and any measures taken in response to such plan shall be reported to the department.

(f) The investigation and written report shall be completed and provided to the department within 45 days of when the incident was first reported to the Justice Center.

(iii) At the conclusion of an investigation of an alleged reportable incident, the camp operator shall:

(a) Assess the need for corrective actions;

(b) Report corrective actions plans to the permit-issuing official within 45 days of the conclusion of an investigation from the Justice Center or permit-issuing official; and

(c) Implement corrective actions identified by the camp, or required by the permit issuing official or the Justice Center. Corrective action plans shall be implemented as soon as possible but within ninety (90) days of the completion of an investigation unless the camp has closed for the season. If closed for the season, corrective action plans shall be implemented when the camp reopens.

(iv) Incident Review Committee.

(a) The camp shall maintain a facility incident review committee, in accordance with 14 NYCRR Part 704. The incident review committee shall be composed of members of the governing body of the children's camp and other persons identified by the camp operator, including some members of the following: camp administrative staff, direct support staff, licensed health care practitioners, service recipients, the permit-issuing official or designee and representatives of family, consumer and other advocacy organizations, but not the camp director. The camp operator shall convene a facility incident review committee to review the timeliness, thoroughness and appropriateness of the camp's responses to reportable incidents; recommend additional opportunities for improvement to the camp operator, if appropriate; review incident trends and patterns concerning reportable incidents; and make recommendations to the camp operator to assist in reducing reportable incidents. The facility incident review committee shall meet each year in which there is a reportable incident. When the incident review committee is responsible for approving or developing corrective action plans, the committee shall meet within 45 days of the conclusion of an investigation, unless an extension for such plans has been granted by the Justice Center.

(b) Pursuant to paragraph (f) of subdivision one of section 490 of the Social Services Law and 14 NYCRR Part 704, a camp operator may seek an exemption from the requirement to establish and maintain an incident review committee. In order to obtain an exemption, the camp operator shall file an application with the permit-issuing official and provide sufficient documentation and information to demonstrate that compliance would present undue hardship, that granting an exemption would not create an undue risk of harm to campers' health and safety and specify an alternative process to ensure appropriate review and evaluation of reportable incidents. The permit-issuing official shall consult with the Department and shall not grant or deny an application for an exemption unless it first obtains department approval for the proposed decision. An operator shall meet all terms of an approved exemption(s). An exemption shall remain in effect until revoked by the permit-issuing official. A camp operator shall immediately notify the permit-issuing official when conditions, upon which the incident review committee exemption was granted, have changed.

(9) In addition to the requirements specified by subdivisions (d) and (g) of the section 7-2.4 of this Subpart, a permit may be denied, revoked, or suspended if the children's camp fails to comply with regulations, policies, or other requirements of the Justice Center. In considering

whether to issue a permit to a children's camp, the permit-issuing official shall consider the children's camp's past and current compliance with the regulations, policies, or other requirements of the Justice Center.

Summary of Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council (PHHPC) is authorized by section 225(4) of the Public Health Law (PHL) to establish, amend and repeal sanitary regulations known as the State Sanitary Code (SSC), subject to the approval of the Commissioner of Health. Article 13-B of the PHL authorizes the PHHPC to prescribe standards and establish regulations for children's camps. PHL sections 225 and 201(1)(m) authorize SSC regulation of the sanitary aspects of businesses and activities affecting public health including children's camps.

Legislative Objectives:

In enacting Chapter 501 of the Laws of 2012, the Legislature established the New York State Justice Center for the Protection of People with Special Needs (Justice Center). This legislation amended Article 11 of Social Service Law to include children's camps for children with developmental disabilities, and it required the Department of Health to promulgate regulations pertaining to incident management.

Needs and Benefits:

The following requirements, which previously pertained only to camps with 20 percent or more campers with a developmental disability, will now apply to any camper with a disability, as of October 1, 2016:

- For campers who cannot independently manipulate a wheelchair or adaptive equipment,

camps must provide at least 1:2 supervision;

- Staff providing direct care of campers with disabilities must be trained on the needs of the campers in their charge;
- Camps must obtain health information and existing care/treatment plans and implement adequate procedures to protect the safety and health of camper with disabilities;
- During swimming activities, camps must provide one counselor for each camper who is non-ambulatory or has a disability that might result in unusual emergencies in the water. For campers with developmental disabilities, camps must provide one counselor for every five campers and obtain parent/guardian's written permission to allow for swimming participation;
- Non-ambulatory campers cannot have housing above ground level.
- Provisions for adaptive equipment, ramps and accessible design are included for lavatories, showers, and buildings. A maximum water temperature is established lavatories and showers.

To implement Article 11, the Department of Health proposes these amendments to 10 NYCRR Subpart 7-2, relating to "Children's Camp for Children with Developmental Disabilities". The amendments define a Children's Camp for the Developmentally Disabled as a children's camp with camper enrollments of 20 percent or more campers with a developmental disability. In addition to immediately complying with the requirements above, the amended regulations would immediately require these camps to comply with the following:

- Reportable incidents are defined and required to be reported by camp staff to the Justice Center and permit-issuing official;
- Camps must implement immediate protections following an incident to prevent further risk or harm to campers;
- Camps must notify the victim, potential witnesses, and each camper's personnel representative that the camper may be interviewed as part of an abuse or neglect investigation;
- Camps must verify staff are not on the Justice Center's Staff Exclusion List (SEL) prior to hiring. After this verification, the operator must consult the Office of Children and Family Services (OFCS) State Central Registry of Child Abuse and Maltreatment (SCR);
- Camp staff must receive mandated reporter training and acknowledge an understanding of the Justice Center's code of conduct;
- Camps need to cooperate with investigations, including providing access and disclosing necessary information;
- Camps must convene a Facility Incident Review Committee to review the camp's response to a reportable incident and make recommendations to reduce reportable incidents.

Compliance Costs:

Cost to Regulated Parties:

Costs to Camps for Children with Developmental Disabilities:

Costs to regulated parties are difficult to estimate due to variation in staff salaries and time needed to investigate incidents. Reporting incidents should take less than half an hour; assisting with investigations will range from several hours to two staff days. The Department estimates that the total staff costs range from $120 to $1600 for each investigation. Expenses should be minimal statewide as less than 55 Camps for Children with Developmental Disabilities operate each year, with an average of six camps reporting a total of 18 incidents per year.

There will be minimal expense for determining if potential employees are on the SEL and SCR. An entry level staff person earning the minimum wage of $8.75/hour should be able to compile the information for 100 employees within six to eight hours. OCFS requires a $25.00 screening fee for new or prospective employees and no fee for volunteers.

Camps will be required to: disclose certain information to the Justice Center and to the permit issuing official charged with investigating reportable incidents; ensure immediate protections are in place for victims; and notify the victims and any witnesses that they may be interviewed as part of an investigation. Costs associated with these activities include staff time for locating information, contacting camper's parent/guardians and expenses for copying materials. The typical cost should be under $100 per incident.

Costs associated with mandated reporting training are minimal as training materials will be provided to the camps and will take about one hour to review during routine staff training. The telephone number for the Justice Center reporting hotline must be conspicuously posted for campers and staff. Costs associated with posting is limited to making and posting copies in appropriate locations.

Camp operators must provide each camp staff member or volunteer with the code of conduct established by the Justice Center. The code must be provided at the time of initial employment and annually thereafter. The employee must acknowledge they received, read, and understand the code. The cost of providing the code, and obtaining and filing the required employee acknowledgment should be minimal. Staff should need less than 30 minutes to review the code.

Camps will be required to establish and maintain a facility incident review committee to review the camp's responses to reportable incidents. The cost to maintain a facility incident review committee is difficult to estimate due to the variations in salaries and the amount of time needed for the committee to meet. An incident review committee will be required to meet to fulfill its duties if any reportable incidents occur. Because most camps only operate during the summer season, it is expected that the incident review committee will meet no more than once a year. The cost is estimated to be $450.00 dollars per meeting. The regulations provide

opportunity for a camp to seek an exemption, which may be granted based on the duration of the camp season and other factors.

Camps are now required to obtain a medical examination of any camper physically injured during a reportable incident. Because a medical examination is an expected standard of care in response to such injuries, there will be no additional cost.

Costs to camps enrolling campers with a disability:

Certain regulations, which previously pertained only to camps with 20 percent or more campers with a developmental disability, will now apply to any camp that enrolls one or more campers with a disability. The cost to affected parties is difficult to estimate due to variation in salaries and the unknown number of campers with a disability attending camps.

Camps will be required to provide at least: 1:2 supervision for campers who cannot independently manipulate a wheelchair or other adaptive equipment; 1:1 supervision during swimming for each camper who is non-ambulatory or has a disability that may result in an increased risk of an emergency in the water; and 1:5 supervision for campers with a developmental disability during swimming. Entry level staff person earning the minimum wage of $8.75/hour should be able to comply with the supervision requirements. The expense for camps will vary depending on the number of campers with these disabilities and the length of time the campers are in attendance.

Camps will be required to obtain and follow existing care/treatment plans and other available information relevant to the care of a camper with disabilities, such as pre-existing medical conditions, allergies, modified diets, and activity restrictions. Staff providing direct care of these campers must be trained on the specific needs of each camper. Costs to obtain existing health and care information are expect to be minimal, since camps currently collect health information. Costs to provide staff training will vary based on needs of individual campers, but are expected to be a minimal as they currently provide staff training in other areas.

Camps will need to obtain parent or guardian's written permission to allow campers with developmental disabilities to participate in swimming activities. The cost of obtaining permission slips should be minimal, as it is limited to copying, distributing, and filing with other materials from parents/guardians.

Cost to State and Local Government:

State agencies and local governments operating camps will have the same costs described in the section entitled "Cost to Regulated Parties."

The regulation imposes requirements on local health departments (LHDs) for receiving incident reports, investigating incidents, and oversight of corrective actions. The total cost for these services is difficult to estimate because of the variation in the number of incidents and amount of time to investigate an incident. The cost to investigate an incident, including report

completion, is estimated to range from $400 to $1600.

Cost to the Department of Health:

There will be costs associated with printing and distributing the amended Code. There will be minimal costs for printing and distributing training materials, as most information will be distributed electronically. LHDs will likely include copies of training materials in routine correspondence to camps.

Local Government Mandates:

Camps operated by local governments must comply with the requirements imposed on camps operated by other entities, as described in the section entitled "Cost to Regulated Parties." Local governments serving as permit issuing officials will face additional reporting and investigation requirements, as described in the section entitled "Cost to State and Local Government." The proposed amendments otherwise do not impose new responsibilities on local governments.

Paperwork:

The paperwork associated with the amendment includes the completion and submission of incident report forms to the LHD and Justice Center. Camps will be required to provide records necessary for LHD investigation of incidents, and to retain documentation regarding whether prospective employees were found on the SEL or SCR. Camps enrolling campers with a disability will be required to obtain health care related documents/information and permission

slips for swimming and document in-service training for aquatic staff.

Duplication:

This regulation does not duplicate any existing federal, state, or local regulation.

Alternatives Considered:

The amendments to the code that relate to Camps for Children with Developmental Disabilities are mandated by law. No alternatives were considered for these requirements.

The Department considered not imposing additional requirements on camps that enroll less than 20% of campers with a disability; however, this option was rejected because the requirements are viewed as necessary to protect campers with disabilities attending camp.

The Department also considered imposing all of the requirements for Camps for Children with Development Disabilities on all children's camps with one or more qualifying campers; however, this option was rejected due to the burdensome costs associated with implementing the requirements. The State Camp Safety Advisory Council also expressed concern that applying the regulations to all camps enrolling a child with a developmental disability could be burdensome and have unintended consequences. The Department received correspondences from two State Senators, who expressed concern that expanding the regulations to all children's camps would have unintended financial consequences that could impact access.

Public comments were delivered by municipal organizations, children's camps and camp organizations, all of which argued in favor of keeping the 20 percent threshold. The Justice Center conveyed agreement with the Department's application of the additional requirements to camps serving a population of 20 percent or more children with developmental disabilities.

Federal Standards:

No current federal law governs the operation of children's camps.

Compliance Schedule:

The proposed amendments will be effective upon publication of the Notice of Adoption in the State Register. For Camps for Children with Developmental Disabilities, compliance with all requirements will be immediately required. For camps serving a population of less than 20 percent of children with developmental disabilities, the requirements pertaining to such camps will be effective October 1, 2016.

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Regulatory Impact Statement

Statutory Authority:

The Public Health and Health Planning Council is authorized by section 225(4) 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. Article 13-B of the PHL authorizes the PHHPC to prescribe standards and establish regulations for children's camps sets forth sanitary and safety requirements for children's camps. PHL sections 225 and 201(1)(m) authorize SSC regulation of the sanitary aspects of businesses and activities affecting public health including children's camps.

Legislative Objectives:

In enacting Chapter 501 of the Laws of 2012, the Legislature established the New York State Justice Center for the Protection of People with Special Needs (Justice Center) to strengthen and standardize the safety net for vulnerable people that receive care from New York's Human Services Agencies and Programs. The legislation amended Article 11 of Social Service Law to include children's camps for children with developmental disabilities, and it required the Department of Health to promulgate regulations approved by the Justice Center pertaining to incident management. The proposed amendments further the legislative objective of protecting the health and safety of vulnerable children attending camps in New York State.

Needs and Benefits:

In order to better protect and provide for the needs of campers with disabilities that attend

children's camps with less than 20 percent of the population having a developmental disability, the following requirements now apply to any camp that enrolls a camper with a disability:

- For campers who cannot independently manipulate a wheelchair or adaptive equipment, camps must provide at least 1:2 supervision;
- Staff that have direct care responsibilities of campers with disabilities must receive training relevant to the specific needs of the campers in their charge;
- Camps must obtain and implement, as appropriate, care and treatment plans for campers with a disability that have such plans as well as obtain other available information relevant to the care and specific needs of a camper with disabilities including pre-existing medical conditions, allergies, modified diets, and activity restrictions;
- During swimming activities, camps must provide one counselor for each camper who is non-ambulatory or has a disability that may result in an increased risk for an emergency in the water;
- For campers with developmental disabilities, camps must provide one counselor for every five campers during swimming activities;
- Camps must obtain parent/guardian's written permission to allow campers with developmentally disabilities to participate in swimming activities;
- Camps must develop procedures and training for handling seizures or aspiration of water by campers with developmental disabilities that may occur during swimming activities;
- All lavatories and showers used by campers with a physical disability must be equipped with specialized features and grab bars;

- Lavatories and showers used by campers with disabilities, who are unable to moderate water temperature safely, shall have a water temperature not greater than 110 degrees Fahrenheit.

- Buildings housing non-ambulatory campers shall have ramps to facilitate access.
- Non-ambulatory campers may not have housing above ground level; and
- Exterior paths must be constructed and maintained, as appropriate for the camp population served, to provide for safe travel during inclement weather.

The Justice Center legislation amended Article 11 of Social Services Law to include overnight, summer day and traveling summer day camps for children with developmental disabilities as facilities that must comply with the Justice Center requirements. This included mandating regulations regarding incident management procedures and other requirements consistent with Justice Center guidelines and standards.

To implement Article 11 of Social Services Law, the Department of Health defined "Children's Camp for Children with Developmental Disabilities" in Subpart 7-2 of the State Sanitary Code. The amendment defines a Children's Camp for Children with Developmental Disabilities as a children's camp with enrollment of 20 percent or more campers with a developmental disability. The amendments further require these camps to comply with staff screening, staff training and incident management procedures mandated by the Justice Center legislation. The Department's proposal includes the following:

- Reportable incident is defined to include abuse, neglect and other significant incidents

specified in section 488 of Social Services Law. Camp staff must report all reportable incidents to the Justice Center Vulnerable Persons' Central Registry and the permit-issuing official;

- A definition of a personal representative was added to be consistent with section 488 of Social Services Law;
- Prior to hiring camp staff, camps must verify that candidates are not on the Justice Center's staff exclusion list or on the Office of Children and Family Services State Central Registry of Child Abuse and Maltreatment;
- All camp staff must obtain mandated reporter training and review and acknowledge an understanding of the Justice Center's code of conduct;
- Camps must ensure that immediate protections are in place following an incident to prevent further risk or harm to campers;
- Camps must notify the victim, any potential witnesses, and each camper's personnel representative (as appropriate) that the camper may be interviewed as part an abuse or neglect investigation;
- Camps must cooperate fully with reportable incident investigations and provide/disclose all necessary information and access to conduct investigations;
- Camps must promptly obtain an appropriate medical examination of a physically injured camper with a developmental disability;
- Unless a waiver is granted, camps must convene a Facility Incident Review Committee to review the camp's responses to a reportable incident including making recommendations

for improvement, reviewing incident trends, and making recommendations to reduce reportable incidents;

- Camps must implement any corrective actions identified as the result of a reportable incident investigation.

Additionally, unrelated to requirements for camps with children with disabilities, the requirement for shower water temperature at children's camps is made consistent with Part 1226 (Property Maintenance Code) of 19 NYCRR Chapter XXXIII.

Compliance Costs:

Cost to Regulated Parties:

Costs to Camps for Children with Developmental Disabilities:

The amendments impose additional requirements on children's camp operators for reporting and cooperating with Department of Health and Justice Center investigations at Camps for Children with Developmental Disabilities. The cost to affected parties is difficult to estimate due to variation in salaries for camp staff and the amount of time needed to investigate each reported incident. Reporting an incident is expected to take less than half an hour; assisting with the investigation will range from several hours to two staff days. Using a high estimate of staff salary of $30.00 an hour, total staff cost would range from $120 to $1600 for each investigation. Expenses are nonetheless expected to be minimal statewide as between 45 and 55 Camps for Children with Developmental Disabilities operate each year, with a three-year average of six camps reporting 18 incidents per year. Accordingly, any individual camp will be very unlikely to

experience costs related to reporting or investigation.

Each Camp for Children with Developmental Disabilities will incur expenses for contacting the Justice Center to verify that potential employees, volunteers or others falling within the definition of "custodian" under section 488 of the Social Services Law (collectively "employees"), are not on the Staff Exclusion List (SEL). The effect of adding this consultation should be minimal. An entry level staff person earning the minimum wage of $8.75/hour should be able to compile the necessary information for 100 employees, and complete the consultation with the Justice Center, within a few hours.

Similarly, each Camp for Children with Developmental Disabilities will incur expenses for contacting the Office of Children and Family Services (OCFS) to determine whether potential employees are on the State Central Registry of Child Abuse and Maltreatment (SCR) when consultation with the Justice Center shows that the prospective employee is not on the SEL. An entry level staff person earning the minimum wage of $8.75/hour should be able to compile the necessary information for 100 employees, and complete the consultation with the OCFS, within a few hours. Assuming that each employee is subject to both screens, aggregate staff time required should not be more than six to eight hours. Additionally, OCFS imposes a $25.00 screening fee for new or prospective employees. There is no charge for volunteers.

For each reportable incident, Camps for Children with Developmental Disabilities will be

required to disclose information pertaining to reportable incidents to the Justice Center and to the permit issuing official investigating the incident. They will also be required to ensure immediate protections are in place for the victim and notify the victim and any witnesses that they may interviewed as part of the investigation. Costs associated with this include staff time for locating information, contacting camper's parent/guardians and expenses for copying materials. Using a high estimate of staff salary of $30.00 an hour, and assuming that staff may take up to two hours to locate and copy the records, the typical cost should be under $100.

Camps for Children with Developmental Disabilities must also assure that camp staff, and certain others, who fall within the definition of mandated reporters under section 488 of the Social Services Law receive training related to mandated reporting to the Justice Center, and the obligations of those staff who are required to report incidents to the Justice Center. The costs associated with such training should be minimal as it is expected that the training material will be provided to the camps and will take about one hour to review during routine staff training. Camps for Children with Developmental Disabilities must also ensure that the telephone number for the Justice Center reporting hotline is conspicuously posted for campers and staff. Cost associated with such posting is limited, related to making and posting a copy of such notice in appropriate locations.

The operator of a Camp for Children with Developmental Disabilities must also provide each camp staff member, and others who may have contact with campers, with a copy of a code

of conduct established by the Justice Center pursuant to section 554 of the Executive Law. The code must be provided at the time of initial employment, and at least annually thereafter during the term of employment. Receipt of the code of conduct must be acknowledged, and the recipient must further acknowledge that he or she has read and understands it. The cost of providing the code, and obtaining and filing the required employee acknowledgment, should be minimal, as it would be limited to copying and distributing the code, and to obtaining and filing the acknowledgments. Staff should need less than 30 minutes to review the code.

Camps for Children with Developmental Disabilities will also be required to establish and maintain a facility incident review committee to review and guide the camp's responses to reportable incidents. The cost to maintain a facility incident review committee is difficult to estimate due to the variations in salaries for camp staff and the amount of time needed for the committee to do its business. An incident review committee will be required to meet to fulfill its duties if any reportable incidents occur. Because most camps only operate during the summer season, it is expected that the incident review committee will meet no more than once a year. Assuming the camp will have several staff members participate on the committee, an average salary of $50.00 an hour and a three hour meeting, the cost is estimated to be $450.00 dollars per meeting. However, the regulations also provide the opportunity for a camp to seek an exemption, which may be granted subject to Department approval based on the duration of the camp season and other factors.

Camps for Children with Developmental Disabilities are now explicitly required to obtain an appropriate medical examination of a camper physically injured from a reportable incident. A medical examination has always been required for such injuries; therefore, this will not be an increased cost.

Costs to camps enrolling campers with a disability:

Certain regulations which previously only pertained to camps with 20 percent or more campers with a developmental disability will now apply to camps that enroll one or more campers with a disability. The cost to affected parties is difficult to estimate due to variation in salaries for camp staff and the unknown and varying number of campers with a disability attending camps.

Camps will be required to provide at least one staff for ever two campers who cannot independently manipulate a wheelchair or other adaptive equipment. Camps will also be required to provide one on one supervision during swimming for each camper who is non-ambulatory or has a disability identified by the camper's parent, guardian, physician or residential care provider that may result in an increased risk of an emergency in the water. One camp staff person will be required for each five campers swimming with a developmental disability. Entry level staff person earning the minimum wage of $8.75/hour should be able to meet the minimum counselor qualification to provide supervision. The expense for camps will vary depending on the number of campers with these types of disabilities and the length of time the campers are in attendance.

Camps will be required to obtain and follow care and treatment plans for campers when they exist, and obtain other available information relevant to the care and specific needs of a camper with disabilities such as information on pre-existing medical conditions, allergies, modified diets, and activity restrictions. Staff providing direct care of these campers will be required to receive any relevant training to provide for the safe care of such campers. The cost to obtain existing health and care information is expected to be minimal, since camps currently collect health information. The cost to provide staff training will vary based on the needs of individual campers, but is expected to be a minimal additional cost to camp operators, as they are currently required to provide staff training in other areas.

Camps will need to obtain parent's or guardian's written permission to allow campers with developmentally disabilities to participate in swimming activities. The cost of obtaining permission slips should be minimal, as it would be limited to copying, distributing, and filing with other materials sent to and received from parents or guardians.

Cost to State and Local Government:

State agencies and local governments that operate Camps for Children with Developmental Disabilities and camps enrolling campers with a disability will have the same costs described in the section entitled "Cost to Regulated Parties." Currently, it is estimated that municipalities operate nine summer day camps that meet the definition of a Camp for Children with Developmental Disabilities.

The regulation includes additional requirements on local health departments for receiving incident reports, investigations of reportable incidents, oversight of corrective actions and providing a copy of the resulting report to the Department. The total cost for these services is difficult to estimate because of the variation in the number of incidents and amount of time to investigate an incident. However, assuming the typical estimate of $50 an hour for health department staff conducting these tasks, an investigation lasting between one and four staff days, and an eight hour day, the cost to investigate an incident will range from $400 to $1600. Since the inception of the Justice Center, an average of 18 incidents per year have been reported within an average of six different local health departments.

Cost to the Department of Health:

There will be routine costs associated with printing and distributing the amended Code. The estimated cost to print revised code books for each regulated children's camp in NYS is approximately $1600. There will be additional cost for printing and distributing training materials. The expenses will be minimal, as most information will be distributed electronically. Local health departments will likely include paper copies of training materials in routine correspondence to camps that is sent each year.

Local Government Mandates:

Camps for Children with Developmental Disabilities and camps enrolling campers with a disability operated by local governments must comply with the same requirements imposed on camps operated by other entities, as described in the "Cost to Regulated Parties" section of this

Regulatory Impact Statement. Local governments serving as permit issuing officials will face minimal additional reporting and investigation requirements, as described in the "Cost to State and Local Government" section of this Regulatory Impact Statement. The proposed amendments do not otherwise impose a new program or responsibilities on local governments. City and county health departments continue to be responsible for enforcing the amended regulations as part of their existing program responsibilities.

Paperwork:

The paperwork associated with the amendment includes the completion and submission of an incident report form to the local health department and Justice Center. Camps for Children with Developmental Disabilities will be required to provide the records and information necessary for LHD investigation of reportable incidents, and to retain documentation of the results of their consultation with the Justice Center regarding whether any given prospective employee was found to be on the SEL or the SCR. Camps enrolling campers with a disability will be required to obtain health care related documents/information and permission slips for swimming. Camps will also be required to document in-service training for aquatic staff that oversee swimming pertaining to seizures and aspiration of water.

Duplication:

This regulation does not duplicate any existing federal, state, or local regulation for children's camps.

Alternatives Considered:

The amendments relating to Camps for Children with Developmental Disabilities are mandated by law. No alternatives were considered for these requirements.

The Department considered not imposing additional requirements on camps that have less than 20 percent of the children enrolled with a developmental disability; however, this option was rejected because the additional requirements are viewed as necessary to protect campers with disabilities attending camp.

The Department also considered applying all of the requirements for Camps for Children with Developmental Disabilities to all children's camps with one or more qualifying campers; however, this option was rejected due to the costs associated with implementing the requirements. The New York State Camp Safety Advisory Council expressed concern that applying the regulations to all camps with a child with a developmental disability could be burdensome and have unintended consequences such as a camp not admitting a child into the program. The Department also received correspondences from two State Senators, who indicated that expanding the emergency regulations to all children's camps, in addition to those that meet the 20 percent threshold, would have unintended financial consequences that could impact access.

Similarly, public comments were delivered by municipal organizations, children's camps and camp organizations, all of which argued in favor of keeping the 20 percent threshold for Camps for Children with Developmental Disabilities. Finally, the Justice Center conveyed

agreement with the Department's application of the additional requirements to camps serving a population of 20 percent or more children with developmental disabilities.

Federal Standards:

Currently, no federal law governs the operation of children's camps.

Compliance Schedule:

The proposed amendments are to be effective upon publication of the Notice of Adoption in the State Register. For Camps for Children with Developmental Disabilities, compliance with all requirements will be immediately required. For camps serving a population of less than 20 percent of children with developmental disabilities, the requirements pertaining to such camps will be effective October 1, 2016.

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Regulatory Flexibility Analysis

for Small Business and Local Government

Types and Estimated Number of Small Businesses and Local Governments:

There are approximately 2,510 regulated children's camps (533 overnight and 1977 summer day camps) operating in New York State. Any such camp that enrolls a camper with a disability will be affected by the proposed rule. Municipalities (towns, villages, cities and school districts) operate approximately 295 summer day camps and no overnight camp. Most of the remaining camps are believed to be small businesses.

Of the estimated 49 Children's Camps for Children with Development Disabilities (21 overnight camps and 28 summer day camps) that will be affected by the proposed rule, approximately nine summer day camps and none of the overnight camps are operated by municipalities (towns, villages, and cities). Most of the remaining Children's Camps for Children with Development Disabilities are believed to be small businesses.

Regulated children's camps representing small business include those owned or operated by corporations, hotels, motels and bungalow colonies, non-profit organizations (e.g., Girl/Boy Scouts of America, Cooperative Extension, YMCA) and others. The proposed amendments would affect these camps if they enroll children with disabilities. None of the proposed amendments will apply solely to camps operated by small businesses or local governments.

Compliance Requirements:

Reporting and Recordkeeping:

The obligations imposed on small business and local government as camp operators are no different from those imposed on camps generally, as described in "Cost to Regulated Parties," "Local Government Mandates," and "Paperwork" sections of the Regulatory Impact Statement. The obligations imposed on local government as the permit issuing official is described in "Cost to State and Local Government" and "Local Government Mandates" portions of the Regulatory Impact Statement.

Other Affirmative Acts:

The obligations imposed on small business and local government as camp operators are no different from those imposed on camps generally, as described in "Cost to Regulated Parties", "Local Government Mandates," and "Paperwork" sections of the Regulatory Impact Statement.

Professional Services:

Camps for Children with Developmental Disabilities are now explicitly required to obtain an appropriate medical examination of a camper physically injured from a reportable incident; however, a medical examination has always been expected for such injuries, so this is not a new required service.

Compliance Costs:

Cost to Regulated Parties:

The obligations imposed on small business and local government as camp operators are no different from those imposed on camps generally, as described in "Cost to Regulated Parties" and "Paperwork" sections of the Regulatory Impact Statement.

Cost to Small Businesses and State and Local Government:

The obligations imposed on small business and local government as camp operators are no different from those imposed on camps generally, as described in the "Cost to Regulated Parties" and "Paperwork" section of the Regulatory Impact Statement. The obligations imposed on local government as the permit issuing official is described in "Cost to State and Local Government" and "Local Government Mandates" portions of the Regulatory Impact Statement.

Economic and Technological Feasibility:

There are no changes requiring the use of technology.

The proposal is believed to be economically feasible for impacted parties. The amendments impose additional reporting and investigation requirements that will use existing staff that already have similar job responsibilities. There are no requirements that that involve capital improvements.

Minimizing Adverse Economic Impact:

The amendments for Camps for Children with Developmental Disabilities are mandated by law. No alternatives were considered.

Amendments for camps that have less than 20 percent of the campers with developmental disabilities are believed to be what is minimally necessary to protect this vulnerable population. Requirements for camps serving a population of less than 20 percent of children with developmental disabilities will be effective October 1, 2016. This will allow camps to adequately prepare for and implement these requirements.

Small Business and Local Government Participation:

The regulations were discussed at several State Camp Safety Advisory Council meetings which are open to the public and attended by camp operators, local health department staff and other local government officials. However, due to the need to have regulations in place by the 2016 camping season with adequate time for camps to prepare for the new requirements, no formal outreach was conducted.

Rural Area Flexibility Analysis

Types and Estimated Number of Rural Areas:

There are approximately 2,510 regulated children's camps (533 overnight and 1,977 summer day camps) operating in New York State. Any of these camps that enrolls a camper with a disability will be affected by the proposed rule. There are an estimated 412 day camps and 402 overnight camps operating in the 44 counties that have population less than 200,000. There are an additional 395 day camps and 97 overnight camps in the nine counties identified to have townships with a population density of 150 persons or less per square mile.

Of the approximate 814 camps operating in the 44 counties that have populations less than 200,000, there are 9 summer day and 13 overnight Camps for Children with Development Disabilities. There are an additional 5 day camps and 4 overnight camps in the 9 counties identified as having townships with a population density of 150 persons or less per square mile.

Reporting and Recordkeeping and Other Compliance Requirements:

Reporting and Recordkeeping:

The obligations imposed on camps operators in rural areas are no different from those imposed on camps generally, as described in "Cost to Regulated Parties" and "Paperwork" sections of the Regulatory Impact Statement.

Other Compliance Requirements:

The obligations imposed on camps in rural areas are no different from those imposed on camps generally, as described in "Cost to Regulated Parties" and "Paperwork" sections of the Regulatory Impact Statement.

Professional Services:

Camps for the Children with Development Disabilities are now explicitly required to obtain an appropriate medical examination of a camper physically injured from a reportable incident; however a medical examination has always been expected for such injuries, so this is not an additional service.

Compliance Costs:

Cost to Regulated Parties:

The costs imposed on camps in rural areas are no different from those imposed on camps generally, as described in "Cost to Regulated Parties" and "Paperwork" sections of the Regulatory Impact Statement.

Economic and Technological Feasibility:

There are no changes requiring the use of technology.

The proposal is believed to be economically feasible for impacted parties. The amendments impose additional reporting and investigation requirements that will use existing

staff that already have similar job responsibilities. There are no requirements that involve capital improvements beyond requirements already imposed by the Americans with Disabilities Act.

Minimizing Adverse Economic Impact on Rural Area:

The amendments for Camps for Children with Developmental Disabilities are mandated by law. No alternatives were considered. No impacts are expected to be unique to rural areas.

Amendments for camps that have less than 20 percent of the campers with developmental disabilities are necessary to protect this vulnerable population. The Department has sought to strike a balance between protecting this vulnerable population and ensuring that costs are feasible. Amendments for camps that have less than 20 percent of the campers with developmental disabilities are believed to be what is minimally necessary to protect this vulnerable population.

Requirements for camps serving a population of less than 20 percent of children with developmental disabilities will be effective October 1, 2016. This will allow camps to adequately prepare for and implement these requirements.

Rural Area Participation:

The regulations were discussed at several State Camp Safety Advisory Council meetings which are open to the public and attended by camp operators from rural areas However, due to the need to have regulations in place by the 2016 camping season with adequate time for camps to prepare for the new requirements, no formal outreach was conducted.

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 have no adverse impact on the number of jobs and employment opportunities at children's camps, because it does not result in a decrease in current staffing level requirements.