Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting
Agenda and Informational Announcements

Thursday, December 13, 2018
10:00 AM
Location: Meeting Room 6, Concourse, Empire State Plaza, Albany, New York

A. Agenda

For Adoption	**Program Area**	**Unit Representative**
Amendment of Sections 405.7 and 751.9 of Title 10 NYCRR – Patients' Bill of Rights	Division of Hospitals and Diagnostic & Treatment Centers	Deirdre Astin
Amendment of Section 400.18 of Title 10 NYCRR – Statewide Planning and Research Cooperative System (SPARCS)	Office of Quality and Patient Safety	Scott Franko
For Information	**Program Area**	**Unit Representative**
Addition of Section 415.32 to Title 10 NYCRR – Nursing Home Weekly Bed Census	Division of Nursing Home and Intermediate Care Facilities	James Tardy
Amendments to Part 766 of Title 10 NYCRR – New Requirements for Annual Registration of Licensed Home Care Services Agencies	Division of Home and Community Based Services	Rebecca Fuller Gray
Amendments to 10 NYCRR Part 405 and Section 751.5 – Hospital Policies for Victims of Human Trafficking	Division of Hospitals and Diagnostic & Treatment Centers	Deirdre Astin
Amendment of Part 14 of Title 10 NYCRR – Food Service Establishments	Center for Environmental Health	Brian Miner
Amendments to 10 NYCRR Part 19 – Clinical Laboratory Directors	Wadsworth Laboratory	Beverly Rauch

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, December 12, at (212) 417-6218 to arrange for placement on the speakers' list. Please give your name, affiliation, if any and the agenda item(s) you wish to address. To ensure that all commenters have an opportunity to address the Committee, speakers should limit their comments to 3-4 minutes maximum.

2. All meeting attendees including Committee members are requested to sign the Attendance Sheet, which will be circulated in the meeting room.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803 of the Public Health Law, sections 405.7 and 751.9 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register:

Paragraph (2) of subdivision (b) of section 405.7 of Title 10 is amended to read as follows:
(2) treatment without discrimination as to race, color, religion, sex, gender identity, national origin, disability, sexual orientation, age, or source of payment;

Subdivision (c) of section 405.7 of Title 10 is amended to read as follows:
(c) Patients' Bill of Rights. For purposes of subdivision (a) of this section, the hospital shall utilize the following Patients' Bill of Rights:

Patients' Bill of Rights

As a patient in a hospital in New York State, you have the right, consistent with law, to:

(1) Understand and use these rights. If for any reason you do not understand or you need help, the hospital must provide assistance, including an interpreter.

(2) Receive treatment without discrimination as to race, color, religion, sex, gender identity, national origin, disability, sexual orientation, age, or source of payment.

(3) Receive considerate and respectful care in a clean and safe environment free of unnecessary restraints.

(4) Receive emergency care if you need it.

(5) Be informed of the name and position of the doctor who will be in charge of your care in the hospital.

(6) Know the names, positions, and functions of any hospital staff involved in your care and refuse their treatment, examination or observation.

(7) [A no smoking room.] Identify a caregiver who will be included in your discharge planning and sharing of post-discharge care information or instruction.

(8) Receive complete information about your diagnosis, treatment and prognosis.

(9) Receive all the information that you need to give informed consent for any proposed procedure or treatment. This information shall include the possible risks and benefits of the procedure or treatment.

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

(11) Refuse treatment and be told what effect this may have on your health.

(12) Refuse to take part in research. In deciding whether or not to participate, you have the right to a full explanation.

(13) Privacy while in the hospital and confidentiality of all information and records regarding your care.

(14) Participate in all decisions about your treatment and discharge from the hospital. The hospital must provide you with a written discharge plan and written description of how you can appeal your discharge.

(15) Review your medical record without charge and obtain a copy of your medical record for which the hospital can charge a reasonable fee. You cannot be denied a copy solely because you cannot afford to pay.

(16) Receive an itemized bill and explanation of all charges.

(17) View a list of the hospital's standard charges for items and services and the health plans the hospital participates with.

(18) Challenge an unexpected bill through the Independent Dispute Resolution process.

[(17)] (19) Complain without fear of reprisals about the care and services you are receiving and to have the hospital respond to you and if you request it, a written response. If you are not satisfied with the hospital's response, you can complain to the New York State Health Department. The hospital must provide you with the Health Department telephone number.

[(18)] (20) Authorize those family members and other adults who will be given priority to visit consistent with your ability to receive visitors.

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

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

(a) receive service(s) without regard to age, race, color, sexual orientation, religion, marital status, sex, gender identity, national origin or sponsor;

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803 authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to implement the purposes and provisions of PHL Article 28 and to establish minimum standards governing the operation of health care facilities. Under PHL § 2803(1)(g), the Commissioner shall require that every general hospital adopt and make public an identical statement of the rights and responsibilities of patients.

Legislative Objectives:

The statement of rights of patients under PHL § 2803(1)(g) is intended to include the right to receive treatment without discrimination based on characteristics defined by Article 15 of New York Executive Law (the Human Rights Law), as well as other rights afforded to patients by statute. These include the right to have a caregiver involved in discharge planning, the right to receive information regarding the hospital's standard charges, the right to challenge unexpected bills through an independent dispute resolution process, and the right to make known a patient's wishes with regard to consenting to organ donation in the hospital setting.

Current Requirements:

General hospitals are required by § 405.7 of Title 10 of the New York Compilation of Codes, Rules and Regulations of New York (NYCRR) to provide treatment without discrimination as to race, color, religion, sex, national origin, disability, sexual orientation, age, or source of payment and to adopt and make public a Patients' Bill of Rights that informs

patients of the right to receive treatment absent from such discrimination.

The Caregiver Advise, Record and Enable (CARE) Act, enacted as PHL Article 29-CCCC, gives hospital patients the right to have a caregiver involved in discharge planning. The Surprise Bill Law (Part H of Chapter 60 of the Laws of 2014) enacted PHL § 24 to give hospital patients the right to receive information regarding the hospital's standard charges and enacted Article 6 of the Financial Services Law to give them the right to challenge unexpected bills through an independent dispute resolution process.

PHL § 2803(1)(g) requires hospitals to inform patients of their right to make anatomical gifts and the means by which the patient may make such a donation. PHL §§ 4301, 4303, and 4310 include various ways that an individual who is 16 years of age or older may consent to organ donation, including through enrollment in the New York State Donate Life Registry.

Needs and Benefits:

The New York State Division of Human Rights implements the Human Rights Law and establishes regulations thereunder. Part 466 of Title 9 of the NYCRR contains the general regulations of the Division of Human Rights. The statement of rights of patients under PHL § 2803(1)(g) includes the right to receive treatment without discrimination based on characteristics defined by the Human Rights Law and the regulations of the Division of Human Rights. On January 20, 2016, the Division of Human Rights adopted a regulation adding 9 NYCRR § 466.13. Section 466.13 clarifies that discrimination on the basis of gender identity is sex discrimination and further defines "gender identity" as:

> having or being perceived as having a gender identity, self-image, appearance, behavior or expression whether or not that gender identity, self-image, appearance, behavior or expression is different from that traditionally associated with the sex assigned to that person at birth.

The proposed amendments to 10 NYCRR §§ 405.7 and 751.9 with respect to gender identity will conform the Patient's Bill of Rights to New York's Human Rights Law.

Under the CARE Act, hospital patients have the right to have a caregiver involved in discharge planning. Under the Surprise Bill Law, hospital patients have the right to receive information regarding the hospital's standard charges and to challenge unexpected bills through an independent dispute resolution process. This proposed regulatory amendment conforms the Patient's Bill of Rights to these statutory requirements.

PHL § 2803(1)(g) requires hospitals to inform patients of his or her right to make anatomical gifts and the means by which the patient may make such a donation. PHL §§ 4301, 4303, and 4310 provide for the right of an individual who is 16 years of age or older to document their consent to make an anatomical gift by a variety of mechanisms in New York State (*i.e.*, the New York State Donate Life Registry, health care proxy, wills, donor cards or a signed paper). This proposal updates the Patients' Bill of Rights to clarify that patients not only have the right to express their wish or intent to donate their organs, but have the right to consent to donation and to document such consent through various mechanisms including enrollment in the NYS Donate Life Registry.

COSTS:

Costs to Private Regulated Parties:

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

Costs to Local Government:

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

Costs to the Department of Health:

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

Costs to Other State Agencies:

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

Local Government Mandate:

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

Paperwork:

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

Duplication:

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

Alternatives:

The alternative would be to take no action, which would result in a lack of consistency between the Human Rights Law and the Patients' Bill of Rights. Similarly, the Patient's Bill of Rights would be inconsistent with the PHL provisions related to the CARE Act, the Surprise Bill Law, and organ donation.

Federal Standards:

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

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

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

Compliance Requirements:

These regulations will require general hospitals and D&TCs to change their patients' bill of rights.

Professional Services:

General hospitals and D&TCs are already required to make the Patients' Bill of Rights available to patients.

Compliance Costs:

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

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

The anticipated impact of the proposal is minimal. General hospitals and D&TCs are already required to make the Patients' Bill of Rights available to patients.

Small Business and Local Government Participation:

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

Cure Period:

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

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 17% of small health care facilities are located in rural areas.

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

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

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

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

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to those general hospitals located in rural areas and is expected to impose minimal costs upon hospitals, which are already required to make the Patient's Bill of Rights available to patients. Because the proposed regulatory requirements can be incorporated into existing processes, they are not expected to increase the administrative burden on these entities.

Costs:

Hospitals are already required to make the Patients' Bill of Rights available to patients. The cost of the small wording change to the Patients' Bill of Rights will be insubstantial.

Minimizing Adverse Impact:

The impact is minimal.

Rural Area Participation:

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to approval by the Commissioner of Health by Section 2816 of the Public Health Law, Section 400.18 of Title 10 (Health) 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, to read as follows:

Section 400.18 is amended to read as follows:

10 NYCRR § 400.18 Statewide Planning and Research Cooperative System (SPARCS).

(a) Definitions. For the purposes of this section, these terms shall have the following meanings:

(1) Health care facilities shall mean facilities licensed under Article 28 of the Public Health Law.

(2) Identifying data elements shall mean those SPARCS [and Patient Review Instrument (PRI)] data elements that, if disclosed without any restrictions on use or re-disclosure would constitute an unwarranted invasion of personal privacy. A list of identifying data elements shall be specified by the Commissioner and will be made available publicly.

(3) Inpatient hospitalization data shall mean SPARCS data submitted by hospitals for patients receiving inpatient services at a general hospital that is licensed under Article 28 of the Public Health Law and that provides inpatient medical services.

(4) Outpatient data shall mean emergency department data, ambulatory surgery data, and outpatient services data.

(i) Emergency department data shall mean SPARCS data submitted by a facility licensed to provide emergency department services under Article 28 of the Public Health Law.

(ii) Ambulatory surgery data shall mean SPARCS data submitted by a facility licensed to

provide ambulatory surgery services under Article 28 of the Public Health Law.

(iii) Outpatient services data shall mean all data submitted by licensed Article 28 facilities excluding inpatient hospitalization data, emergency department data, and ambulatory surgery data.

(5) [Patient Review Instrument (PRI) data shall mean the data submitted on PRI forms by residential health care facilities, pursuant to section 86-2.30 of this Title.

(6)] SPARCS Administrator shall mean a person in the SPARCS program designated by the Commissioner to act as administrator for all SPARCS activities.

[(7)] (6) SPARCS data shall mean the data collected by the Commissioner under section 2816 of the Public Health Law and this section, including inpatient hospitalization data and outpatient data.

[(8)] (7) SPARCS program shall mean the program in the New York State Department of Health (NYSDOH) that collects and maintains SPARCS data and discloses SPARCS [and Patient Review Instrument (PRI)] data.

(b) Reporting SPARCS data.

(1) Health care facilities shall report data as follows:

(i) Health care facilities shall submit, or cause to have submitted, SPARCS data in an electronic, computer-readable format through [NYSDOH's] a secure electronic network [according to the requirements of section 400.10 of this Part and the] designated by the Department according to specifications provided by the Commissioner.

(ii) All SPARCS data must be supported by documentation in the patient's medical and billing records.

(iii) Health care facilities must submit on a monthly basis to the SPARCS program, or cause to have submitted on a monthly basis to the SPARCS program, data for all

inpatient discharges and outpatient visits. Health care facilities must submit, or cause to have submitted, at least 95 percent of data for all inpatient discharges and outpatient visits within sixty (60) days from the end of the month of a patient's discharge or visit. Health care facilities must submit, or cause to have submitted, 100 percent of data for all inpatient discharges and outpatient visits within one hundred eighty (180) days from the end of the month of a patient's discharge or visit.

(iv) The SPARCS program may conduct an audit evaluating the quality of submitted SPARCS data and issue an audit report to a health care facility listing any inadequacies or inconsistencies in the data. Any health care facility so audited must submit corrected data to the SPARCS program within 90 days of the receipt of the audit report.

(2) Content of the SPARCS data.

(i) Health care facilities shall submit, or cause to have submitted, uniform bill data elements as required by the Commissioner. The data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website <u>to the extent allowed by copyright law</u>.

(ii) Health care facilities shall submit, or cause to have submitted, additional data elements as required by the Commissioner. Such additional data elements shall be from medical records or demographic information maintained by the health care facilities.

(iii) The list of specific SPARCS data elements and their definitions shall be maintained by the Commissioner, will be made available publicly, and may be modified by the Commissioner.

(c) Maintenance of SPARCS data.

The Commissioner shall be responsible for protecting the privacy and security of the health care information reported to the SPARCS program.

(d) Requests for SPARCS [and PRI] data.

(1) SPARCS [and PRI] data may be used for medical or scientific research or statistical or epidemiological purposes approved by the Commissioner.

(2) The Commissioner may determine that additional purposes are proper uses of SPARCS [and PRI] data.

(3) In determining the purpose of a request for SPARCS [and PRI] data, the SPARCS program shall not be limited to information contained in the data request form and may request supplemental information from the applicant.

(4) The Commissioner shall charge a reasonable fee to all persons and organizations receiving SPARCS [and PRI] data based upon costs incurred and recurring for data processing, platform/data center and software. The Commissioner may discount the base fee or waive the fee upon request to the SPARCS program. The fee may be waived in the following circumstances:

(i) Use by a health care facility of the data it submitted to the SPARCS program.

(ii) Use by a health care facility that is licensed under Article 28 of the Public Health Law for the purpose of rate determinations or rate appeals and for health care-related research.

(iii) Use by a Federal, New York State, county or local government agency for health care-related purposes.

(5) The SPARCS program shall follow applicable federal and state laws when determining whether SPARCS [and PRI] data contain identifying data elements may be

shared and whether a disclosure of SPARCS [and PRI] data constitutes an unwarranted invasion of personal privacy.

(6) All entities seeking SPARCS [and PRI] data must submit a request to the SPARCS program using standard data request forms specified by the SPARCS program. Data users shall take all necessary precautions to prevent unwarranted invasions of personal privacy resulting from any data analysis or release. Data users may not release any information that could be used, alone or in combination with other reasonably available information, to identify an individual who is a subject of the information. Data users bear full responsibility for breaches or unauthorized disclosures of personal information resulting from use of SPARCS [or PRI] data. Applications for SPARCS [or PRI] data must provide an explicit plan for preventing breaches or unauthorized disclosures of personal information of any individual who is a subject of the information.

(7) Each data request form must include an executed data use agreement in a form prescribed by the SPARCS program. Data use agreements are required of: a representative of the requesting organization; a representative of each other organization associated with the project; and all individuals who will have access to any data including identifying data elements.

(8) The SPARCS program shall publish and make publicly available the name of the project director, the organization, and the title of approved projects.

(9) The SPARCS Administrator shall review and make recommendations on requests for SPARCS [and PRI] data containing identifying data elements to a data release committee established by the Commissioner. The data release committee shall have at least three members, including at least one member not otherwise affiliated with NYSDOH. The members of the data release committee shall be posted on the NYSDOH website. Requests will be granted only upon formal, written approval for access by a majority of

the members of the data release committee. The Commissioner has the final authority over the approval, or disapproval, of all requests. Requests for identifying data elements shall be approved only if:

(i) The purpose of the request is consistent with the purposes for which SPARCS [and PRI] data may be used;

(ii) The applicant is qualified to undertake the project; and

(iii) The applicant requires such identifying data elements for the intended project and is able to ensure that patient privacy will be protected.

(10) The SPARCS Administrator may recommend approval of a request in which future SPARCS data is to be supplied on a periodic basis under the following conditions:

(i) SPARCS data may be requested for a predetermined time not to exceed three years beyond the current year provided that the organization and uses of the data remain as indicated in the data request form submitted to the SPARCS program.

(ii) During the period of retention of SPARCS [or PRI] data, no additional individuals may access SPARCS [or PRI] data without an executed data use agreement on file with the SPARCS program.

(11) The Commissioner may rescind for cause, at any time, approval of a data request.

(e) Penalties.

(1) Any person or entity that violates the provisions of this section or any data use agreement may be liable pursuant to the provisions of the Public Health Law, including, but not limited to, sections 12 and 12-d of the Public Health Law.

(2) Any person or entity that violates the provisions of this section or any data use agreement may be denied access to SPARCS [or PRI] data.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The Statewide Planning and Research Cooperative System (SPARCS) is a comprehensive health care data reporting system established in 1979 through cooperation between the health care industry and government. The enabling legislation for SPARCS is Section 2816 of the Public Health Law (PHL). The regulations pertaining to SPARCS are under Section 400.18 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR).

Legislative Objectives:

In 2001, the Legislature codified the Department's authority to collect SPARCS data by adding PHL § 2816. In 2011, the Legislature expanded this authority by authorizing the Department to develop and implement an All Payer Database for New York State. In doing so, the Legislature referenced the Department's need for greater flexibility in the forms of data submission.

The enactment of Public Health Law § 2816(6) authorized the Department to describe data elements by reference to information reasonably available to regulated parties, as such material may be amended in the future. This provision recognizes the Department's need for flexibility when determining data elements by authorizing the Department to adjust such data elements administratively.

Needs and Benefits:

The current regulation directs data to be submitted to SPARCS through the Health Commerce System (HCS). This rule making revises Section 400.18 to grant the SPARCS program the flexibility to explore other data intake options, consistent with Public Health

Law § 2816. This rule making also removes all references to Patient Review Instrument (PRI) data, which is an obsolete data source.

This rule making clarifies that input data dictionary elements are protected by copyright law. The Department will continue to precisely identify and publish a description of what data elements must be submitted to the extent it may do so under copyright law.

The proposed regulation changes will enhance the SPARCS program by modernizing the program's technology and functionality. Currently, HCS users regularly experience bandwidth issues, poor network performance, and slow data transfer speeds. These issues hinder the ability of data submitters to submit SPARCS data in a timely fashion. By leveraging new technology for SPARCS data intake, the SPARCS program will operate more efficiently.

Lastly, the proposed regulation specifies that data elements required by the Commissioner shall be based on those approved by the National Uniform Billing Committee (NUBC) or required under national electronic data interchange (EDI) standards for health care transactions and shall be published on the NYSDOH website to the extent allowed by copyright law. The SPARCS program is in the process of changing its data format to require data to be submitted in the X12 837R ("X12") format, which is to some extent proprietary intellectual property owned by X12 Incorporated. See http://www.x12.org/, http://members.x12.org/policies-procedures/cap01v3-bylaws.pdf, http://store.x12.org/store/ip-use. Consistent with past practice, the Department will publish the data elements with specificity so that regulated parties will know exactly what data elements must be submitted, with the caveat that the Department will not publish intellectual property that it does not have a right to publish.

Costs:

Costs to Regulated Parties:

The rule change levies minor additional costs to health care facilities licensed under Article 28 of the PHL that may need to, in some cases, change their existing contracts with vendors to submit data, if they utilize a vendor. These minor additional costs would be solely related to changes needed to submit data to the Department's contractor rather than submitting data directly to the Department using the HCS. Data will continue to be submitted in the standard claims data format that all Article 28 facilities have already adopted under federal regulations in 42 CFR Part 162 as authorized by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Costs to the NYSDOH:

The costs associated with this change will be offset by savings from no longer having to finance a mainframe system and changes needed to the HCS maintained by the NYS Office of Information Technology Services. This change will also allow for the reallocation of NYSDOH staff to areas needing additional resources.

Costs to State and Local Governments:

There are no anticipated costs to local governments as a result of this rule change, except that any PHL Article 28 facilities that are operated by local governments will incur the same costs as any other Article 28 facilities subject to this regulation.

Local Government Mandates:

This rule change imposes no mandates upon any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The rule change imposes no significant reporting requirements, forms, or other paperwork upon regulated parties.

Duplication:

There will be no duplication of reporting efforts to New York State for health care facilities licensed under Article 28 of the PHL.

Alternatives:

There are no reasonable alternatives that could serve as a substitute, because the Department will no longer be able to collect data using the HCS. The Department's mainframe system for SPARCS was scheduled to sunset when key staff retired. The Office of Information Technology Services would no longer support COBOL/mainframe SPARCS translation. Likewise, the Office of Information Technology Services was sunsetting support for a key technology used to support the SPARCS application on the HCS.

Federal Standards:

The rule change does not exceed any minimum standards of the federal government for the same or similar subject area, as the federal government does not operate a national program like SPARCS.

Compliance Schedule:

The rule change will not alter SPARCS compliance schedules. Health care facilities licensed under Article 28 of the PHL will continue to submit data to SPARCS at the same frequency and levels they currently do.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

The rule change will have no impact on jobs and employment opportunities on the part of regulated parties (health care facilities licensed under Article 28 of the Public Health Law). The regulated health care facilities already have an existing data reporting infrastructure and are required to report SPARCS data. The way facilities submit data to SPARCS would not change. It would not be more burdensome or costly for data submitters as their data submission process would be very similar to what currently is in place. There will be no job impacts in any other segments or sectors of the job market. With regards to adverse employment effects, there is no expectation of job losses as a result of the rule.

Pursuant to the authority vested in the Public Health and Health Planning Council, subject to the approval of the Commissioner of Health, by section 2803(2) of the Public Health Law, a new section 415.32 is added to Part 415 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, to be effective upon publication of a Notice of Adoption in the New York State Register:

415.32 Weekly bed census data survey.

(a) Definitions. As used in this section, the following terms shall have the following meanings:

(1) "Communications Directory" (Directory) shall mean a listing of all organizations with access to the HCS, ordered by type, and including the identity of and contact information for individuals at each organization who: (i) perform specific job functions identified by the Department; and/or (ii) have access to perform certain data exchange functions on the HCS.

(2) "HCS Coordinator" shall mean the individual designated by each organization with access to the HCS to be responsible for authorizing and managing accounts and maintaining other key information about the organization's HCS users.

(3) "Health Commerce System" (HCS) shall mean the Department's secure Internet portal used for communications and information exchange with organizations including nursing homes and other health care providers or any successor system used for such information exchange as required by the Department.

(4) "Health Electronic Reporting Data System" (HERDS) shall mean the data reporting application on the HCS that houses the Survey or any successor system used for such

reporting as required by the Department.

(5) “Nursing Home Data Reporter” shall mean the name of the role in the Directory that provides access to an individual designated by a nursing home to use HERDS.

(6) “Nursing Home Weekly Bed Census Survey” (Survey) shall mean an electronic survey used by each nursing home to report its bed census to the Department using HERDS.

(7) “Role” shall mean the term used to indicate in the Directory the specific job functions and HCS data exchange functions assigned to individuals by each organization.

(b) Submission of Surveys.

(1) Each nursing home shall complete the Survey on HERDS on a weekly basis by indicating, for each category of bed, the total number of certified or approved beds and the number of those beds that are available. The Survey shall be submitted on a weekly basis by individuals at the nursing home who are assigned to the Nursing Home Data Reporter role within the Directory.

(2) Nursing homes shall report bed census data reflecting the weekly census taken every Wednesday at 12:00 a.m. The nursing home’s designated Nursing Home Data Reporter shall enter and transmit the survey census data to the Department between Wednesday at 12:01 a.m. and the following Tuesday at 11:59 p.m. Instructions for the Survey will be available on the HCS.

(c) Designation of Nursing Home Data Reporters. Nursing homes shall, through their HCS Coordinators, designate a sufficient number of Nursing Home Data Reporters to ensure that the Survey is submitted to the Department in a timely manner.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 2803(2)(a)(v) provides that the Public Health and Health Planning Council shall adopt rules and regulations, subject to the approval of the Commissioner of Health, governing the standards and procedures followed by nursing homes which, at a minimum, must meet federal standards.

Legislative Objectives:

The legislative objective of PHL Article 28, as set forth in PHL section 2800, includes the protection of the health of the residents of New York State through the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. This proposal, which requires nursing homes to submit weekly bed census data to the Department of Health (Department) through the Department's Health Commerce System, is consistent with that objective. Having current and accurate nursing home bed occupancy data is important in the event of natural disasters and to alert the Department to significant changes in nursing home occupancy, improving the Department's ability to take appropriate action. While facilities have already been advised administratively that they must submit this data, including the requirement in regulation will improve compliance.

Current Requirements:

The Health Commerce System (HCS), previously known as the Health Provider Network (HPN), is a highly secure, Internet-based, electronic portal for communications and critical data sharing with organizations including nursing homes and other health care providers. Section 400.10 of Title 10 (Health) of the New York Compilation of Codes, Rules and Regulations (NYCRR) requires providers, including nursing homes, to maintain and keep updated an active HPN account.

DAL #09-02, effective April 8, 2009, was issued by the Department to require nursing homes to report weekly bed census data electronically to the Department through the HPN. The DAL provided for such data to be reported each week between Wednesday 8:00 a.m. and Friday 5:00 p.m. In 2013, via a notice sent through the HCS, the Department informed nursing homes that such data should be reported between Wednesday 12:01 a.m. and the following Tuesday at 11:59 p.m.

Needs and Benefits:

It is critical that the Department have accurate nursing home census data including occupancy and availability data by bed type. Natural events such as hurricanes and floods and other emergency events such as extended power outages could cause situations in which some nursing homes may have to transfer their residents to other facilities to ensure their safety. In those situations, the Department must be able to quickly assess the number and location of nursing home residents across the affected area, as well as the number of available beds. Furthermore, the ability to monitor a facility's current occupancy data

improves the Department's ability to identify a declining census and proactively take appropriate action.

Despite the current requirement for bed census data reporting, communicated via a DAL and a subsequent HCS notice, the Department often finds itself in the position of having to call some nursing homes repeatedly to obtain this information. This proposed regulation will add a new section 415.32 to Title 10 of the NYCRR to require that nursing homes submit bed census data on a weekly basis by electronically filing the Nursing Home Weekly Bed Census Survey (Survey). This will promote compliance and ensure that the Department has access to essential, current occupancy data as necessary to protect residents.

Accordingly, the proposed regulation provides that the Survey must be submitted via the HCS Health Electronic Response Data System (HERDS) application by a facility staff person assigned a Nursing Home Data Reporter role within the HCS Communications Directory. Nursing homes shall report bed census data reflecting the weekly census taken every Wednesday at 12:00 a.m. The facility's designated Nursing Home Data Reporter shall enter and transmit the survey census data to the Department between Wednesday at 12:01 a.m. and the following Tuesday at 11:59 p.m. Instructions for the Survey will be available on the HCS. The proposal further requires nursing homes, through their HCS Coordinators, to designate enough Nursing Home Data Reporters to ensure that the facility can submit surveys to the Department as required.

COSTS:

Costs to Private Regulated Parties:

New York State health care facilities are already required by section 400.10 of the NYCRR to have an HCS account to exchange electronic information with the Department. Moreover, nursing homes are already expected to send bed census information to the Department as communicated in the DAL. Therefore, nursing homes should not incur any additional costs related to the electronic submission of bed census information to comply with the proposed regulation.

Costs to Local Government:

This proposal will not impact local governments unless they operate a nursing home, in which case they will be impacted to the same extent as other nursing homes. As previously noted, nursing homes are not expected to incur any additional costs related to the electronic submission of bed census information.

Costs to the Department of Health:

The Department is not expected to incur any additional administrative costs as a result of the proposed regulation. The statewide HCS infrastructure and the mechanisms for nursing home bed census data collection are already in place.

Costs to Other State Agencies:

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

Local Government Mandates:

This proposed regulation does not impose any new mandates on local governments.

Paperwork:

Nursing homes are already expected to submit bed census information via the HCS. Accordingly, the proposal should not increase paperwork.

Duplication:

This proposed regulation reiterates and strengthens the existing requirement, set forth in the DAL, that nursing homes report census data on a weekly basis to the Department. Moreover, while federal regulations require submission of bed census data to the federal Centers for Medicare and Medicaid Services (CMS) on a quarterly basis, this regulation will ensure that the Department receive this information directly and more frequently.

Alternatives:

There are no other alternatives for the Department to reliably secure current bed census data from nursing homes.

Federal Standards:

Federal regulations require nursing homes to submit quarterly census data to CMS.

Compliance Schedule:

These regulations will be effective upon publication of a Notice of Adoption in the New York State Register. The statewide HCS infrastructure and the mechanisms for bed census reporting for nursing homes are already in place. Consequently, regulated parties should be able to comply with the proposed regulation as of its effective date.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed rule will not have a substantial adverse impact on small businesses or local governments. Nursing homes that constitute small businesses and local health departments that operate nursing homes, like all other nursing homes, are already required to have an HCS account to exchange electronic information with the Department and report bed census data.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed rule will not have an impact on nursing homes located in rural areas any differently than in any other areas. Such nursing homes are already required to have an HCS account to exchange electronic information with the Department and report bed census data.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of this proposed regulation.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 3605(7) of the Public Health Law, sections 766.9 and 766.12 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register.

Subdivision (n) of § 766.9 is amended to read as follows:

(n) ensure that any franchise agreement complies with the following:

* * *

(4) An agreement which contains elements of both a franchise agreement and a management contract shall be subject to the applicable provisions of this subdivision and subdivision (m) of this section[.]; and

A new subdivision (o) is added to § 766.9 to read as follows and existing subdivision (o) re-lettered (p):

(o) ensure registration of the licensed home care services agency with the commissioner through submission of annual registration forms included in the annual statistical report;

(1) no licensed home care services agency shall be operated, provide nursing services, home health aide services, or personal care services, or receive reimbursement from any source for the provision of such services during any period of time on or after January 1, 2019, unless it has registered for the current period;

(2) a licensed home care services agency that fails to submit a complete and accurate set of all required registration materials by the annual deadline of November 16th is required to pay a fee of $500 for each month or part thereof that the licensed home care services agency is not registered;

(3) a licensed home care services agency that fails to register in the prior year by the deadline of the current year shall not be permitted to register for the upcoming registration period unless it submits any and all unpaid late fees;

(4) the department shall publish a listing of all licensed home care services agencies and their current registration status on its public website;

(5) the department shall institute proceedings to revoke the license of any licensed home care services agency that fails to register for two annual registration periods, whether or not such periods are consecutive; and

(6) the department shall pursue revocation of the license of a licensed home care services agency if it evidences a pattern of late registration over the course of multiple years without justification acceptable to the commissioner.

Subdivision (c) of § 766.12 is amended to read as follows:

(c) The home care services agency shall furnish annually to the department a copy of:

(1) statistical summaries of all health care services, including the type, frequency and reimbursement for services provided, including reimbursement from federal and state governmental agencies, on forms provided by the department;

(2) if a for-profit corporation, a list of the principal stockholders and the number and percent of the total issued and outstanding shares of the corporation held by each, duly certified by the

secretary of the corporation as to completeness and accuracy;

(3) if a not-for-profit corporation, a list of directors, officers and corporate members, if such members number 10 or fewer;

(4) the agency's registration in a manner prescribed by the department; and

(5) other such records and reports as may be legally required by the department.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

This proposal will implement amendments to Public Health Law (PHL) §§ 3605-a and 3605-b requiring registration of licensed home care services agencies pursuant to Article 36.

Legislative Objective:

Public Health Law Article 36 was intended to promote the quality of home care services provided to residents of New York State and to assure adequate availability as a viable alternative to institutional care. The proposed regulation furthers this objective by developing a system for the Department of Health (Department) to identify agencies that are non-operational and aligns state regulations with the Department's strategic plan.

Needs and Benefits:

The proposed changes to 10 NYCRR §§ 766.9 and 766.12(c)(4) implement amendments to PHL §§ 3605-a and 3605-b made by Chapter 57 of the Laws of 2018, Part B, §§ 9-c and 9-d, requiring registration of licensed home care services agencies pursuant to PHL.

Annual registration of licensed home care services agencies will allow the Department, on an annual basis, to confirm operational entities in all regions of the state. The registration will confirm the number of agencies providing services in the defined services area and the types of services provided. The information will assist the Department in identifying potential gaps in provider capacity and consumer access to services, and is important as the Department develops a need methodology for licensed home care services agencies. It will also be useful to the Department's oversight and surveillance functions.

This will be integral in improving the overall quality of services provided to individuals who are receiving home care services.

Just as important, the information obtained from the licensed home care services agency registration will improve consumer access to information about licensed home care services agency availability. The information collected from the registration process will improve the currency and accuracy of provider-related information on the DOH public website, giving consumers meaningful information that can help them identify available options for home care services. Additionally, the public website will identify those agencies who are registered with the Department and those agencies who are not registered with the department, indicating their compliance with 10 NYCRR § 766.9.

To comply with the registration requirement, licensed home care services agencies will need to complete a section that will be added to the existing annual statistical report. These must be submitted during the annual data collection period, which commences in August of the preceding year of the registration deadline and ends by November 16th.

The proposed changes will provide a benefit to current licensed home care services agencies who complete the registration as required, as they will be listed on the public website as being currently registered and active.

Costs to Regulated Parties:

The regulated parties (providers) are not expected to incur any additional costs as a result of the proposed rule change. There are no additional costs to local governments for the implementation of and continuing compliance with this amendment. There are no additional costs to the Department of Health as a result of the proposed rule change.

Local Government Mandates:

The proposed amendment does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district. The registration will be incorporated as part of the annual statistical reports already required to be submitted by licensed home care services agencies. Therefore, the new state regulation will require county operated agencies to complete one additional form.

Paperwork:

The registration will be incorporated as part of the annual statistical reports already required to be submitted by licensed home care services agencies. Therefore, the new state regulation will require one additional form to be completed.

Duplication:

The proposed rule is not duplicative of any known rules or regulations.

Alternatives:

There are no alternatives to this proposal, which is necessary to implement a legislative enactment requiring licensed home care services agencies to register annually with the Department.

Federal Standards:

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

Compliance Schedule:

There are no significant actions which are required by the affected providers to comply with the amendments, as the amendments ensure conformance with expectations that were already in effect. Those licensed home care services agencies who are operational should already be in compliance with the required annual statistical reports and should be readily able to comply. The registration will be incorporated as part of the annual statistical reports already required to be submitted by licensed home care services agencies. Therefore, the new state regulation will require one additional form to be completed. A licensed home care services agency that fails to submit a complete and accurate set of all required registration materials by the annual deadline of November 16th, established by the Commissioner of Health, is required to pay a fee of $500 for each month or part thereof that the licensed home care services agency is not registered. No licensed home care services agency shall be operated, provide nursing services, home health aide services, or personal care services, or receive reimbursement from any source for the provision of such services during any period of time on or after January 1, 2019, unless it has registered for the current period. The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

Licensed home care services agencies, including those operated by county health departments, provide health services in the home pursuant to Public Health Law Article 36. There are currently 1,083 licensed operators providing home care services at 1,475 licensed sites. Local governments will not be affected by this rule except to the extent that they operate licensed home care services agencies; nor will small businesses be impacted in their routine cost of conducting business.

Compliance Requirements:

Regulated parties are expected to be in compliance beginning on and after January 1, 2019. The proposed regulations will implement the new registration requirement for licensed home care services agencies, which will be carried out through existing reporting mechanisms. The registration process is a new requirement; however; the registration process will be incorporated with existing statistical data collection requirements for licensed home care services agencies which are required annually. Therefore, compliance requirements are minimal.

The Department does not intend to publish a small business regulation guide in connection with this regulation. Although a number of licensed home care services agencies are small businesses, the impact is expected to be minimal. Additional guidance will be posted on the web as needed after the regulation is promulgated.

Professional Services:

No additional professional staff are expected to be needed as a result of the regulations. Record keeping and compliance requirements could be handled by existing staff, as it is the expectation that the administrator complete the registration.

Compliance Costs:

There are no capital costs associated with these proposed rules. Any costs are already incurred by agencies under the existing regulations.

Economic and Technological Feasibility:

The Department has considered feasibility and believes there will be minimal, if any, economic and technological impact. The registration will be incorporated as part of the annual statistical reports already required to be submitted by licensed home care services agencies. Therefore, the new state regulation should not affect the routine cost of doing business, unless agencies have been non-compliant with existing requirements.

Minimizing Adverse Impact:

While the Department has considered the options of State Administrative Procedure Act (SAPA) § 202-b(1) in developing this rule, flexibility does not exist for any particular entity since the new requirements are consistent with requirements that are already in effect.

Small Business and Local Government Participations:

The Department will meet the requirements of SAPA § 202-b(6) in part by publishing a

notice of proposed rulemaking in the State register with a comment period. The Department has not solicited input prior to publication as the proposed amendments are required by statute, do not change existing procedures in any substantive manner and will, therefore, have no deleterious effect on small businesses and local governments.

Rules that Either Establish or Modify a Violation or Penalties Associated with a Violation:

A licensed home care services agency which fails to submit a complete and accurate set of all required registration materials by the deadline established by the Commissioner shall be required to pay a fee of $500 for each month or part thereof that the licensed home care services agency is in default. The statute allows for the LHCSA to register at any time, however, the fines will continue to be incurred.

A licensed home care services agency that failed to register in the prior year by the deadline of the current year shall not be permitted to register for the upcoming registration period unless it submits any unpaid late fees.

A licensed home care services agency is prohibited from providing nursing services, home health aide services, or personal care services, or receive reimbursement from any source for the provision of such services during any period of time on or after January 1, 2019, unless it has registered with the Department.

The Department shall institute proceedings to revoke the license of any licensed home care services agency that fails to register for two annual registration periods, whether or not such periods are consecutive. The Department shall have the discretion to pursue revocation of the license of a licensed home care services agency on grounds that it evidences a pattern of late registration over the course of multiple years.

The registration will be incorporated as part of the annual statistical reports already required to be submitted by licensed home care services agencies. Therefore, the new state regulation will require one additional form to be completed. A licensed home care services agency that fails to submit a complete and accurate set of all required registration materials by the annual deadline of November 16th is required to pay a fee of $500 for each month or part thereof that the licensed home care services agency is not registered. No licensed home care services agency shall be operated, provide nursing services, home health aide services, or personal care services, or receive reimbursement from any source for the provision of such services during any period of time on or after January 1, 2019, unless it has registered for the current period.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

All counties in New York State (NYS) have rural areas with the exception of seven (7) downstate counties. Approximately 80% of licensed home care services agencies are licensed to serve counties with rural areas. No rural area flexibility analysis is required pursuant to § 202-bb(4)(a) of SAPA. The proposed amendment does not impose an adverse impact on facilities in rural areas and it does not impose additional reporting, record keeping or other compliance requirements on facilities in rural areas. The proposed amendment to require licensed home care agencies to complete registration seeks information regarding operational agencies and to assure home care availability in rural areas as an alternative to institutional care.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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

Pursuant to the authority vested in the Public Health and Health Planning Council and Commissioner of Health by sections 2803(2)(a) and 2805-y(4) of the Public Health Law, sections 405.9, 405.18, 405.19, 405.20, 407.5, and 751.5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) are hereby amended, to be effective upon filing of a Notice of Adoption in the New York State Register:

Subparagraph (ii) of paragraph (11) of subdivision (b) of section 405.9 of Title 10 is amended to read as follows:

(ii) If a patient eligible for transfer to a hospital operated by the Veteran's Administration requests such transfer, hospital staff shall make such arrangements. Transfer shall be effected in accordance with paragraph [(g)(7)] (h)(7) of this section.

Subdivision (g) is relettered as (h) and a new subdivision (g) is added to section 405.9 of Title 10 to read as follows:

(g) Human Trafficking. The hospital shall provide for the identification, assessment, and appropriate treatment or referral of individuals who are suspected to be human trafficking victims, as that term is defined in section 483-aa of the Social Services Law and used in Article 10-D of the Social Services Law. The hospital shall establish and implement written policies and procedures, which shall apply to all service units of the hospital and, at a minimum, shall meet the following requirements:

(1) Policies and procedures shall provide for the identification, assessment, and appropriate treatment or referral of individuals who are suspected to be human trafficking victims;

(2) In the case of individuals who are suspected to be human trafficking victims and are under eighteen years old, policies and procedures shall provide for the reporting of such persons as an abused or maltreated child if required under Title 6 of Article 6 of the Social Services Law;

(3) The hospital shall inform individuals who are suspected to be human trafficking victims of services that may be available, including those referenced in Article 10-D of the Social Services Law. Referrals also may be made to other health care providers, appropriate state agencies, and/or other providers of services as appropriate. Such information may be provided verbally and/or in writing as appropriate;

(4) The hospital shall post the human trafficking hotline poster issued by the National Human Trafficking Resources Center, or a variation of such poster created by the Office of Temporary and Disability Assistance (OTDA) consistent with section 483-ff of the Social Services Law, whichever OTDA makes available on its website. Posters shall be placed in conspicuous locations near primary public entrances and where other posters and notices are posted; and

(5) The hospital shall establish and implement training, which may be incorporated into current training programs, for all individuals licensed or certified pursuant to Title 8 of the Education Law who provide direct patient care, and for all security personnel, regarding the policies and procedures established pursuant to this subdivision. Such training shall include training in the

recognition of indicators of a human trafficking victim and the responsibilities of such personnel in dealing with persons suspected as human trafficking victims.

Subdivision (h) of section 405.9 of Title 10 is relettered as (i) and subparagraph (ii) of paragraph (7) of the former subdivision (g), now relettered as subdivision (h), of section 405.9 of Title 10 is amended to read as follows:

(ii) Patients discharged from the hospital by their attending practitioner shall not be permitted to remain in the hospital without the consent of the chief executive officer of the hospital except in accordance with provisions of subdivision [(h)] (i) of this section.

Subparagraph (vi) of paragraph (2) of subdivision (b) of section 405.18 of Title 10 is amended to read as follows:

(vi) In accordance with the provisions of section [405.9(g)] 405.9(h) of this Part, rehabilitation therapy staff shall work with the attending practitioner, the nursing staff, other health care providers and agencies as well as the patient and the family, to the extent possible, to assure that all appropriate discharge planning arrangements have been made prior to discharge to meet the patient's identified needs.

New paragraph (6) is added to subdivision (c) of section 405.19 of Title 10 to read as follows, and existing paragraphs (6) through (10) are renumbered (7) through (11):

(6) The emergency service shall provide for the identification, assessment, and appropriate treatment or referral of individuals who are suspected to be human trafficking victims, as described in subdivision (g) of section 405.9 of this Part.

Paragraph (5) of subdivision (c) of section 405.20 of Title 10 is amended, paragraph (6) is renumbered (7) and a new paragraph (6) is added to read as follows:

(5) identification, assessment, and referral of individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders, as that term is defined in section 1.03 of the Mental Hygiene Law, as described in subdivision (f) of section 405.9 of this Part; [and]

(6) compliance with the human trafficking provisions pertaining to the identification, assessment, and appropriate treatment or referral of individuals who are suspected to be human trafficking victims, as described in subdivision (g) of section 405.9 of this Part; and

Paragraph (6) of subdivision (b) of section 407.5 of Title 10 is amended to read as follows:

(6) Discharge/transfer. Hospitals shall comply with the provisions of paragraph (1) of subdivision [(h)](i) of section 405.9 of this Title concerning discharge/transfer. In addition, PCHs and CAHs shall comply with the following:

* * *

A new paragraph (8) is added to subdivision (a) of section 751.5 of Title 10, and paragraphs (8) through (16) are renumbered (9) through (17), to read as follows:

(8) the identification, assessment, and appropriate treatment or referral of individuals who are suspected to be human trafficking victims, as that term is defined in section 483-aa of the Social Services Law and used in Article 10-D of the Social Services Law; training in the recognition of indicators of a human trafficking victim and the responsibilities of such personnel in dealing with persons suspected as human trafficking victims, the reporting of individuals who are suspected to be human trafficking victims and are under eighteen years old as abused or maltreated children if required under Title 6 of Article 6 of the Social Services Law; and the posting of the human trafficking hotline poster issued by the National Human Trafficking Resources Center, or a variation of such poster created by the Office of Temporary and Disability Assistance (OTDA) consistent with section 483-ff of the Social Services Law, whichever OTDA makes available on its website, in conspicuous locations near primary public entrances and where other posters and notices are posted;

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 2803(2)(a) authorizes the Public Health and Health Planning Council (PHHPC) to adopt and amend rules and regulations, subject to the approval of the Commissioner of Health (Commissioner), to implement PHL Article 28 and establish minimum standards for health care facilities.

PHL § 2805-y(4) authorizes the Commissioner to issue regulations, in consultation with the Office of Temporary and Disability Assistance (OTDA) and the Office of Children and Family Services (OCFS), to implement the section, which requires "subject facilities" (general hospitals, public health centers, diagnostic centers, treatment centers, or outpatient departments) to develop, maintain, and train staff in policies and procedures for the identification, assessment, treatment, and referral of human trafficking victims.

Legislative Objectives:

This proposal will implement PHL § 2805-y, added by Chapter 408 of the Laws of 2016, to require general hospitals and diagnostic and treatment centers (D&TCs), which encompass the entities referenced as "subject facilities" in the statute, to establish policies and procedures for the identification, assessment, treatment, and referral of human trafficking victims and to train staff in such policies and procedures. The policies and procedures must include the posting of a human trafficking hotline poster consistent with the objectives of Social Services Law (SSL) § 483-ff, added by Chapter 311 of the Laws of 2016.

As explained below, a 2007 law established new crimes related to human trafficking and made various health and social services available to victims. More recent enactments reflect a

legislative desire to combat this growing issue by requiring that general hospitals and D&TCs adopt procedures to identify victims, treat and/or refer them for other services as appropriate, and post a hotline number in public areas where victims may be present.

Needs and Benefits:

The scale of the human trafficking problem constitutes a public health crisis impacting people and their families throughout New York. Legislation enacted in 2007 greatly expanded the tools available to address the issue, but human trafficking nevertheless remains prevalent. A recent study found that 69 percent of survivors surveyed indicated they had accessed health care services at some point during their trafficking. Chapter 408 of the Laws of 2016 recognized this additional opportunity to support human trafficking victims by requiring general hospitals and D&TCs to establish and implement policies to identify, assess, and treat or refer individuals suspected of being victims. Similarly, Chapter 311 of the Laws of 2016 sought to publicize information about resources for human trafficking victims in public areas where victims are likely to be present, including hospitals and clinics.

The New York State Anti-Trafficking Statute, Chapter 74 of the Laws of 2007, was enacted in light of the growing problem of human trafficking for "forced labor, involuntary domestic servitude, or sexual exploitation." The sponsor's memorandum noted that victims – frequently children – may be trafficked within or into the United States and New York often serves as a hub of such activity. Among other things, the law added Penal Law §§ 135.35 and 230.34 to establish the crimes of labor trafficking and sex trafficking, respectively.

The 2007 enactment, as amended in 2015, also added SSL Article 10-D providing for services to human trafficking victims. SSL § 483-aa(a) defines a "human trafficking victim" as a

victim of sex trafficking or labor trafficking under the above-referenced Penal Law sections. SSL § 483-bb provides that OTDA may contract with non-governmental entities to make available services, including case management, emergency temporary housing, health care, mental health counseling, and drug addiction screening and treatment, to "pre-certified" human trafficking victims. SSL § 483-aa(b) defines "pre-certified victim of human trafficking" as a person with a pending application for federal certification as a victim of a severe form of trafficking in persons as defined in section 7105 of title 22 of the United States Code (Trafficking Victims Protection) but has not yet obtained such certification, or a person who has reported a crime to law enforcement and it reasonably appears to law enforcement that the person is such a victim.

SSL § 483-cc sets forth procedures for confirming an individual's status as a human trafficking victim. Under that section, a law enforcement agency or district attorney's office that encounters a person who reasonably appears to be a human trafficking victim must notify OTDA and the Division of Criminal Justice Services (DCJS) that the individual may be eligible for services under SSL Article 10-D. To activate this process, a law enforcement agency or district attorney's office must use the *New York State Referral of Human Trafficking Victim Form* available on the OTDA website at http://otda.ny.gov/programs/bria/trafficking.asp. Providers of social or legal services designated by an applicable state agency (OTDA, the Office for the Prevention of Domestic Violence, or the Office of Victim Services) that encounter a person who reasonably appears to be a human trafficking victim may submit the form if the individual consents.

Upon receipt of the form, DCJS, in consultation with OTDA and the referring agency or office, assesses whether the person meets the criteria for certification as a victim of a severe form

of trafficking in persons as defined in 22 U.S.C. § 7105 or appears to be otherwise eligible for any federal, state or local benefits and services. If so, OTDA reports such finding to the victim and the referring entity and may assist the victim in receiving services. This finding is referred to as "confirmation" as a victim of human trafficking.

Chapter 311 of the Laws of 2016 added a new SSL § 483-ff requiring OTDA to make available on its website the hotline poster issued by the National Human Trafficking Resources Center (NHTRC) or a version created by OTDA. The section provides for OTDA to consult with other state agencies to encourage that the posters be placed where human trafficking victims may be present, including hospitals and urgent care centers, in conspicuous places near primary public entrances or where posters and notices are customarily placed.

Chapter 408 of the Laws of 2016 added new PHL § 2805-y to require "subject facilities" to establish and implement policies and procedures pertaining to victims of human trafficking. New PHL § 2805-y(1) defines key terms such as "subject facilities," defined to mean general hospitals, public health centers, diagnostic centers, treatment centers or outpatient departments, and provides that the requirements of PHL § 2805-y applies to all service units that include emergency services, pediatrics, obstetrics and gynecology, orthopedics, internal medicine, family medicine, radiology, surgery, psychiatry and dental services to the extent the facility maintains a dental clinic, center, or department on site of the facility.

New PHL § 2805-y(2) requires subject facilities to establish and implement written policies and procedures for the identification, assessment, and appropriate treatment or referral of persons suspected of being human trafficking victims, as that term is defined by SSL § 483-aa. Further, policies and procedures must provide for referral of human trafficking victims under the

age of 18 to the Statewide Central Register of Child Abuse and Maltreatment (SCR) established pursuant to SSL Title 6, Article 6 if required by that law.

New PHL § 2805-y(3) also requires subject facilities to require all "subject facility personnel" – defined as nursing, medical, social work and other clinical care personnel as well as security personnel – to complete training regarding such policies and procedures. This must include training in the recognition of indicators of a human trafficking victim and the responsibilities of such personnel in dealing with persons suspected of being victims.

Finally, new PHL § 2805-y(4) authorizes the Commissioner to identify organizations or providers that could provide training for general hospitals consistent with the new provisions. The subdivision also authorizes the issuance of regulations, in consultation with OTDA and OCFS, as necessary to carry out the new section.

Consistent with these requirements, this proposal will amend 10 NYCRR §§ 405.9, 405.19, 405.20, and 751.5 to require general hospitals and D&TCs to establish written policies and procedures for the identification, assessment, and appropriate treatment or referral of individuals who are or appear to be a human trafficking victim and train staff in such policies and procedures. Referrals may be provided verbally and/or in writing as appropriate. Policies, procedures and training must include information about the referral process overseen by OTDA and DCJS. While the proposed regulations do not mandate that hospitals and D&TCs use the *New York State Referral of Human Trafficking Victim Form*, they are strongly encouraged to do so when they can secure the victim's consent.

In addition, there are other sources of assistance that the victim can be referred to, such as the NHTRC hotline, that provide confidential assistance to those victims who do not feel comfortable being referred to OTDA and DCJS. Further, the proposed regulation requires

posting of the NHTRC hotline poster or other variation developed by OTDA in conspicuous locations, which is consistent with the objectives of SSL § 483-ff. The poster designated for such purpose by OTDA is available at http://otda.ny.gov/programs/bria/trafficking.asp.

Under the law, policies and procedures and training must also include the reporting of human trafficking victims under 18 years of age to the SCR if required under SSL Title 6, Article 6. Medical and hospital personnel already serve as mandated reporters who are required to make reports to the SCR if they suspect child abuse or maltreatment. As reiterated by Chapter 408, if an individual appears to be a human trafficking victim under the age of 18, mandated reporters in hospitals and D&TCs must make a report if required under SSL Title 6, Article 6.

COSTS:

Costs to Private Regulated Parties:

While current regulations do not specifically refer to individuals who are human trafficking victims, general hospitals and D&TCs are already required to have written policies and procedures for various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training include the identification, assessment, and appropriate treatment or referral of individuals who are suspected victims of human trafficking, consistent with PHL § 2805-y. However, the additional costs are expected to be minimal given the existing training infrastructure in general hospitals and D&TC's. In addition, these efforts are expected to assist individuals in obtaining treatment critical for their overall health and well-being and could help such individuals avoid future emergency room visits and hospital admissions. Therefore, the cost of implementing the proposed regulations is likely to be offset

by a reduction in care provided at no, or low, cost to victims of human trafficking.

Costs to Local Government:

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

Costs to the Department of Health:

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

Costs to Other State Agencies:

The proposed regulatory changes may result in additional costs to other state agencies if referrals increase and more victims access available services, but this would be consistent with the objectives of the statute. OTDA, OCFS, and DCJS have existing materials related to human trafficking available on their websites.

Local Government Mandate:

The proposed regulations do not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district, unless such local government operates a hospital or D&TC.

Paperwork:

General hospitals and D&TCs are already required to establish written policies and procedures related to various operational requirements, train staff, and refer patients. Therefore, the proposed regulations should not significantly increase their paperwork.

Duplication:

Existing regulations require hospitals to make appropriate referrals for patients to a variety of services, but do not specifically reference human trafficking victims. There otherwise are no relevant State or federal regulations which duplicate, overlap or conflict with the proposed regulations.

Alternatives:

There are no alternatives to the proposed regulations related to hospital policies and procedures, which are necessary to implement the provisions of PHL § 2805-y, added by Chapter 408 of the Laws of 2016, and SSL § 483-ff, added by Chapter 311 of the Laws of 2016.

Federal Standards:

There are currently no federal requirements for hospitals to adopt policies and procedures for the identification, assessment, treatment, and referral of human trafficking victims.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulatory provisions related to human trafficking will apply to all general hospitals and diagnostic and treatment centers (D&TCs) in New York State. This proposal will not impact local governments or small business unless they operate a general hospital or D&TC, in which case the requirements will be the same as for those entities.

Compliance Requirements:

These regulations will require general hospitals and D&TCs to develop, maintain and disseminate written policies and procedures for the identification, assessment, and appropriate treatment or referral of victims of human trafficking. These facilities will be required to train their licensed and certified clinical staff members as well as security staff members in such policies and procedures. In addition, the policies must incorporate the posting of a poster with human trafficking hotline information, available on the Office of Temporary and Disability Assistance website, in conspicuous places.

Professional Services:

While the current regulations do not specifically refer to individuals who are human trafficking victims, general hospitals and D&TCs are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. As such, the Department

anticipates that no additional professional services will be required for general hospitals and D&TCs to comply with this proposed regulation.

Compliance Costs:

While the current regulations do not specifically refer to individuals who are or may be victims of human trafficking, general hospitals and D&TCs are already required to have written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training include the identification, assessment and referral of individuals who are suspected victims of human trafficking, consistent with the requirements of PHL § 2805-y. However, the additional costs are expected to be minimal given the existing training infrastructure in general hospitals and D&TC's. In addition, these efforts are expected to assist individuals in obtaining treatment critical for their overall health and well-being and could help such individuals avoid future emergency room visits and hospital admissions. Therefore, the cost of implementing the proposed regulations is likely to be offset by a reduction in care provided at no, or low, cost to victims of human trafficking.

Economic and Technological Feasibility:

This proposal is economically and technically feasible. Although existing regulations do not specifically refer to human trafficking victims, general hospitals and diagnostic and treatment centers are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care.

Minimizing Adverse Impact:

The impact of this proposal is expected to be minimal as general hospitals and D&TCs are already required to have written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care.

To assist hospitals and D&TCs with the development of their policies, procedures and training materials, several state agencies have provided resources that are free of charge to the public. For example:

- A course entitled "NYSDOH Human Trafficking Awareness Training," available on the Department's NYLearnsPH.com Learning Management System at https://www.nylearnsph.com/public;
- Materials on human trafficking on the OTDA website at https://otda.ny.gov/programs/bria/trafficking.asp;
- Materials on human trafficking on the OCFS website at http://ocfs.ny.gov/main/humantrafficking/default.asp;
- Materials on human trafficking on the website of the Division of Criminal Justice Services http://www.criminaljustice.ny.gov/pio/humantrafficking/humantrafficking.htm

In addition, these efforts are expected to assist individuals in obtaining treatment critical for their overall health and well-being and could help such individuals avoid future emergency room visits and hospital admissions. Therefore, the cost of implementing the proposed regulations is likely to be offset by a reduction in care provided at no, or low, cost to victims of human trafficking.

Small Business and Local Government Participation:

Organizations representing health care providers and other stakeholders, including organizations whose members include general hospitals or diagnostic and treatment centers that

are operated by local governments or that constitute small businesses, were consulted on the proposed regulations.

Cure Period:

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

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (http://quickfacts.census.gov). Approximately 17% of small health care facilities are located in rural areas.

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

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

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

There are 47 general hospitals, approximately 90 diagnostic and treatment centers, 159 nursing homes, and 92 certified home health agencies in rural areas.

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to those general hospitals and diagnostic and treatment centers located in rural areas and is expected to impose only minimal costs upon hospitals, which are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. Because the proposed regulatory requirements can be incorporated into existing processes, they are not expected to substantially increase the administrative burden on these entities.

Costs:

While the current regulations do not specifically refer to individuals who may be victims of human trafficking, general hospitals and diagnostic and treatment centers (D&TCs) are already required to have written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training include the identification, assessment and referral of individuals who are suspected victims of human trafficking, as well as the provision of information related to appropriate services, consistent with the requirements of the statute. However, the additional costs are expected to be minimal given the existing training infrastructure in general hospitals and D&TC's. In addition, these efforts are expected to assist individuals in obtaining treatment

critical for their overall health and well-being and could help such individuals avoid future emergency room visits and hospital admissions. Therefore, the cost of implementing the proposed regulations is likely to be offset by a reduction in care provided at no, or low, cost to victims of human trafficking.

Minimizing Adverse Impact:

The impact of this proposal is expected to be minimal as general hospitals and D&TCs are already required to have written policies and procedures related to various operational requirements, train staff in such policies and procedures and refer patients to appropriate follow-up care.

To assist hospitals and D&TCs with the development of their policies, procedures and training materials, several state agencies have provided resources that are free of charge to the public. For example:

- A course entitled "NYSDOH Human Trafficking Awareness Training," available on the Department's NYLearnsPH.com Learning Management System at https://www.nylearnsph.com/public;
- Materials on human trafficking on the OTDA website at https://otda.ny.gov/programs/bria/trafficking.asp;
- Materials on human trafficking on the OCFS website at http://ocfs.ny.gov/main/humantrafficking/default.asp;
- Materials on human trafficking on the website of the Division of Criminal Justice Services http://www.criminaljustice.ny.gov/pio/humantrafficking/humantrafficking.htm

In addition, these efforts are expected to assist individuals in obtaining treatment critical for their overall health and well-being and could help such individuals avoid future emergency room visits and hospital admissions. Therefore, the cost of implementing the proposed regulations is likely to be offset by a reduction in care provided at no, or low, cost to victims of

human trafficking.

Rural Area Participation:

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.

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

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

14-1.89 Use of Liquid Nitrogen and Dry Ice.

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

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

(b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.

(c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.

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

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

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

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

(2) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.

(3) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.

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

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

14-4.96 Use of Liquid Nitrogen and Dry Ice.

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

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

(b) Liquid Nitrogen, used in the preparation of food, shall be evaporated completely or the operator shall ensure that all residual liquid Nitrogen is drained prior to service.

(c) Dry Ice, used in the preparation of food, shall be sublimated completely prior to service or the operator shall ensure no residual Dry Ice is served to the patrons.

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

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

14-5.46 Use of Liquid Nitrogen and Dry Ice.

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

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

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

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

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

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

Costs:

Cost to Regulated Parties:

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

Cost to State and Local Governments:

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

Local Government Mandates:

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

Paperwork:

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

Duplication:

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

Alternatives:

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

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

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

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENT

Effect on Small Business and Local Government:

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

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

Cost to State and Local Governments:

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

Economic and Technological Feasibility:

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

Minimizing Adverse Economic Impact:

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

Small Business and Local Government Participation:

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

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to Section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact on facilities in rural areas, and it does not impose reporting, record keeping or other compliance requirements on facilities in rural areas.

JOB IMPACT STATEMENT

Nature of the Impact:

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

Categories and Numbers Affected:

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

Regions of Adverse Impact:

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

Minimizing Adverse Impact:

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

SUMMARY OF EXPRESS TERMS

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 573 of the Public Health Law, Part 19 of Title 10 (Health) 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, as follows:

Section 19.1 is amended to include definitions for "assistant director," "board certified," "earned doctoral degree," "training," and "experience." The definitions of "acceptable laboratory" and "category" are also revised and clarified. Section 19.1 is further revised to expressly recognize physicians and dentists who are licensed in the countries in which they practice as being able to qualify as directors or assistant directors of clinical laboratories or blood banks.

Section 19.2 is amended to recognize additional accrediting boards for purposes of certifying that applicants meet the educational and training requirements needed to be a director or assistant director of a clinical laboratory or blood bank.

Section 19.3 is amended to provide the Department more flexibility in updating the certificate of qualification categories. Amendments to this section will also allow the Department to issue certificates of qualification with limitations based on an applicant's specific experience. In addition, this section is amended to include additional director responsibilities, such as ensuring staff competency, specifying in writing the responsibilities and duties of all laboratory personnel, having standard operating procedure manuals, and participating in acceptable proficiency testing.

Section 19.4 is amended for clarity and to remove references to New York City laboratory permits, which are obsolete.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by section 573 of the Public Health Law, Part 19 of Title 10 (Health) 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, as follows:

19.1 Definitions.

(a) [Clinical laboratory director] Director means the individual responsible for administration of the technical and scientific operation of a clinical laboratory or blood bank, including supervision of test procedures, the reporting of results, and the duties and responsibilities specified in section 19.3 of this Part. If a clinical laboratory or blood bank employs more than one director, the laboratory owner(s) shall designate in writing one such individual as the director of record for the laboratory.

(b) Assistant director means a director who has been designated by the owner(s) of the laboratory as having shared responsibility with a director for the technical and scientific operation of the clinical laboratory or blood bank in one or more categories and/or subcategories.

[(b)] (c) Acceptable laboratory means [a clinical laboratory or blood bank of a hospital, health department, university, medical research institution, independent clinical laboratory or blood bank, or other facility providing equivalent training and/or experience in patient specimen testing, which has a director who meets or would meet the requirements of this Part and which meets or would meet the commissioner's standard as outlined in Part 58 of this Title.] a facility, operating lawfully, that meets the definition of a clinical laboratory or blood bank as defined in Section 571 of the Public Health Law and which has a director who meets or would meet the

requirements of this Part, including the anatomic and clinical pathology facilities of a hospital or health department, a clinical testing unit of a university or medical research institution, an independent clinical laboratory or blood bank, a privately operated forensic testing laboratory, or a facility providing training and/or experience in the testing of human specimens.

[(c)] (d) Accredited means having the approval (accreditation) conferred on schools, institutions or programs by an accrediting agency or association recognized by the United States Secretary of Education and verified as such by the [commissioner] department.

[(d)] (e) Physician means a physician who is licensed and currently registered to practice medicine in New York State or in the state or the country in which he or she practices and is not subject to any disciplinary or non-disciplinary order by the applicable state or country except as otherwise allowed by the department.

[(e)] (f) Dentist means a dentist who is licensed and currently registered to practice dentistry in New York State or in the state or the country in which he or she practices and is not subject to any disciplinary or non-disciplinary order by the applicable state or country except as otherwise allowed by the department.

[(f)] (g) Certificate of qualification means a credential issued by the department to applicants [meeting] determined by the department to meet the requirements set forth in this Part.

[(g)] (h) Grandfathered laboratory director means a laboratory director who qualified for and received a certificate of qualification in one or more categories of testing prior to the amendment of this regulation which became effective January 25, 1988.

[(h)] (i) Category means an area, [procedure, or specialty of laboratory medicine specified in section 19.3(d) of this Part.] field, or discipline of laboratory medicine or laboratory science in

which a certificate of qualification is issued. The department may issue certificates of qualification in a specified subpart of a category, including, but not limited to, a subcategory, technology, method, or specific procedure, based on the applicant's education, training, and experience and the applicant's ability to demonstrate that tests performed under their direction generate reliable results. The department shall make available a list of: categories and subcategories in which certificates of qualification are issued; minimum qualifications for each category; and the corresponding categories of testing authorized by a laboratory permit.

[(i) Blood banking-collection means collection of blood or blood components, or processing of blood or blood products.

(j) Referring physician means a physician or other person authorized by law to order laboratory tests and receive reports, as specified in Subpart 58-1 of this Title.

(k) Virology means isolation and other characterization of virus.

(l) Diagnostic immunology means application of immunologic techniques to detect the presence of antigens in biologic fluids and determine host-antibody responses.

(m) Transfusion service means a service which issues blood or blood components for administration into a person, but does not include a limited transfusion service, as defined in section 58-2.1(k) of this Title.

(n) Genetic testing means enzyme, substrate, and DNA-based analyses, or qualitative and/or quantitative measurement of other body analytes, undertaken to determine the genetic status (carrier or disease) of a person.]

(j) Department means the New York State Department of Health.

(k) Board certified means having completed all requirements set forth by an accrediting board

acceptable to the department, including a passing score on any qualifying examination and completion of all the requirements for recertification whenever the certifying board mandates recertification, provided such requirements are determined by the department to provide the applicant with the ability to effectively discharge the responsibilities described in Parts 10 and 58 of this title.

(l) Earned doctoral degree means a doctor of philosophy, doctor of science, or equivalent degree as determined by the department.

(m) Training includes participation in a residency, fellowship, or post-doctoral position, or participation in a training course approved by a board acceptable to the department.

(n) Experience includes post-doctoral employment or voluntary participation in an acceptable laboratory where the applicant performed, supervised or directed testing of human clinical specimens. Teaching experience directly related to a medical technology program, clinical laboratory sciences program, or a clinical laboratory section of a residency program is also considered acceptable experience.

19.2 Clinical laboratory or blood bank; qualifications of laboratory director.

[The] A director and any assistant director of a clinical laboratory or blood bank [must] shall possess training and/or experience acceptable to the department, obtained within the previous six years, [in generally accepted and currently used methods and techniques] in one or more categories. [listed in section 19.3(d) of this Part, and] Additionally, the applicant must meet one of the following requirements:

(a) be a physician who is currently certified by [the American Board of Pathology in]:

(1) the American Board of Pathology in:

[(1)](i) clinical pathology; or

[(2)](ii) anatomic pathology; or

[(3) An area of special competence relevant to the certificate of qualification sought; or] (iii) dermatopathology; or

(2) the American Osteopathic Board of Pathology in:

(i) laboratory medicine; or

(ii) anatomic pathology; or

(iii) dermatopathology; or

(b) be a physician in the State of New York who:

(1) is currently certified by the American Board of Pathology in Blood Banking and Transfusion Medicine; or

(2) is currently certified by the American Board of Pathology in Clinical Pathology or the American Board of Internal Medicine in Hematology, and possesses six months of training and/or experience in transfusion services; or

(3) possesses four years of training and/or experience in an acceptable laboratory including two or more years of training and/or experience in transfusion services and in general laboratory management.

[(b)](c) be a dentist who is currently certified by the American Board of Oral and Maxillofacial Pathology; or

[(c)](d) be a physician, or hold an earned doctoral degree from an accredited institution with a relevant chemical, physical or biological science major, and:

(1) is currently certified by one of the following boards and meets any supplemental requirements for experience as specified by the department:

(i) [the American Board of Medical Microbiology] the American Board of Bioanalysis as a High Complexity Laboratory Director, provided the applicant has obtained a minimum of four years of post-doctoral experience equivalent to paragraph (2) of this subdivision; or

(ii) the American Board of Clinical Chemistry in clinical chemistry; or

(iii) the American Board of Clinical Chemistry in toxicological chemistry; or

(iv) the American Board of Dermatology; or

[(iv)](v) the American Board of Forensic Toxicology, provided the applicant has an earned doctoral degree; or

[(v) the American Board of Medical Laboratory Immunology; or]

(vi) the American Board of Internal Medicine in hematology or hematology and medical oncology; or

(vii) the American Board of Medical Laboratory Immunology; or

(viii) the American Board of Medical Microbiology; or

(ix) dual certification by the American Board of Pathology in either Anatomic Pathology or Clinical Pathology, and Molecular Genetic Pathology; or

(x) the American Board of Pathology in Medical Microbiology; or

(xi) the National Registry for Certified Chemists, provided the applicant has obtained a minimum of four years of post-doctoral experience equivalent to paragraph (2) of this subdivision; or

(2) subsequent to receiving a doctor of medicine, doctor of osteopathy or earned doctoral degree has had, and has documented to the department, four years of training and/or experience in an acceptable laboratory, including two or more years of training and/or experience in methods and techniques currently in use in the certificate category or categories sought and in general

laboratory management, or an equivalent combination of training and/or experience as verified by the [commissioner] department.

[(d) A transfusion facility director shall be a physician licensed to practice medicine in the State of New York.]

19.3 Director of a clinical laboratory or blood bank; certificate of qualification issuance, duties and responsibilities.

(a) Certificate required. [A]An individual serving as a director or assistant director of a clinical laboratory or blood bank must hold a certificate of qualification issued after the [commissioner] department has determined that the applicant meets the requirements specified in sections 19.2 and 19.3[(e)] of this Part, and has demonstrated, in accordance with subdivision (c) of this section and section 19.4(a) of this Part, that he or she possesses the character, competence, training, and ability to direct the technical and scientific operation of a clinical laboratory or blood bank, and ensure the proper supervision or performance of test procedures, adherence to the department's quality control standards, and accurate reporting of findings of tests.

(b) An applicant for a certificate of qualification must submit a complete, original, signed, and sworn application in such form and manner as may be required by the department, and must supply such additional information as may be required by the department. An individual seeking renewal of a certificate of qualification must submit an application no later than 90 days prior to expiration of the current certificate.

(c) [To function effectively in fulfilling his or her duties and responsibilities,] To qualify for, and maintain, a certificate of qualification, a laboratory director and any assistant director [should

possess a] shall demonstrate that he or she possesses knowledge of basic clinical laboratory sciences and operations, and [should] shall have the training and/or experience and physical capability to discharge the following responsibilities:

(1) provide advice to referring [physicians] health care providers regarding the significance of laboratory findings and ensure that reports of test results include pertinent information required for the interpretation of laboratory data;

* * *

(3) define, implement, and monitor standards of performance [in quality control and quality assurance] for the laboratory and for other ancillary laboratory testing programs in conformance with the department's clinical laboratory standards of practice;

* * *

(5) assure that the laboratory participates in monitoring and evaluating the quality and appropriateness of services rendered, within the context of [the quality assurance program] a quality management system, regardless of where the testing is performed;

* * *

(7) [set goals and develop and allocate resources within the laboratory] ensure that policies and procedures are established for monitoring staff to assess competency and, whenever necessary, to provide remedial training to improve skills;

(8) [provide effective and efficient administrative direction of the laboratory, including budget planning and controls in conjunction with the individual(s) responsible for financial management of the laboratory] specify in writing the responsibilities and duties of all laboratory personnel;

(9) provide [educational direction] continuing education to laboratory staff;

(10) [select all reference laboratories; and] ensure that a current and complete procedure manual

is available to all personnel;

(11) [promote a safe laboratory environment for personnel and the public.] set goals, develop and allocate resources within the laboratory;

(12) provide effective administrative direction of the laboratory, in conjunction with the individual(s) responsible for financial management of the laboratory, to ensure adequate resources are available to operate the laboratory in a manner consistent with all state and federal requirements;

(13) select all reference laboratories for services not offered by the laboratory;

(14) promote a safe laboratory environment for personnel and the public; and

(15) ensure that the laboratory, when applicable, is enrolled in a proficiency testing program acceptable to the department for the testing performed and that the laboratory adheres to the proficiency testing program's administrative and technical requirements.

[(d) Certification. Certificates of qualification are issued in one or more of the following categories, procedures or specialties:

(1) one or more of the subspecialties of microbiology: bacteriology, virology, mycology, mycobacteriology, diagnostic immunology, and parasitology;

(2) hematology;

(3) immunohematology, excluding testing performed solely for transfusion purposes;

(4) one or more of the subspecialties of clinical biochemistry: clinical chemistry, blood pH and gases, endocrinology, and therapeutic substance monitoring/quantitative toxicology;

(5) histopathology, and/or the subspecialties: oral pathology and dermatopathology;

(6) cytopathology;

(7) cytogenetics;

(8) histocompatibility;

(9) cellular immunology;

(10) oncofetal antigens, and/or the subspecialties: tumor markers, maternal serum, and amniotic fluid;

(11) genetic testing;

(12) transfusion services, including all pre-transfusion testing;

(13) blood banking collection-comprehensive, including all tests required in Subpart 58-2 of this Title;

(14) blood banking collection-limited, including collection of autologous blood for transfusion and excluding testing for transmissible disease markers;

(15) one or more of the subspecialties of clinical toxicology: drug analysis, blood lead, erythrocyte protoporphyrin, and chlorinated hydrocarbons;

(16) forensic toxicology; or

(17) other specific categories, procedures, or specialties designated by the department.]

[(e)](d) Required qualifications.

(1) Applicants for a certificate of qualification in bacteriology, mycobacteriology, mycology, and/or parasitology must qualify under section 19.2[(a)(1), (c)(1)(i), or (c)(2)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(viii), (d)(1)(x) or (d)(2) of this Part.

(2) Applicants for a certificate of qualification in virology must qualify under section 19.2[(c)(1)(i) or (c)(2)](d)(1)(viii), (d)(1)(x) or (d)(2) of this Part. Applicants for a certificate of qualification in virology limited to antigen detection and molecular methods must qualify under

section 19.2(a)(1)(i), (a)(2)(i) or (d)(1)(i) of this Part.

(3) Applicants for a certificate of qualification in diagnostic immunology must qualify under section 19.2[(a)(1), (c)(1)(i), (c)(2), or (c)(1)(v)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(vii), (d)(1)(viii), (d)(1)(x) or (d)(2) of this Part.

(4) Applicants for certificate of qualification in hematology must qualify under section 19.2[(a)(1), (c)(1)(vi), or (c)(2)](a)(1)(i), (a)(2)(i), (d)(1)(vi) or (d)(2) of this Part. Applicants qualifying under section 19.2[(c)(1)(vi)](d)(1)(vi) of this Part must document that the required training and/or experience includes or is supplemented by six months' training and/or experience in an acceptable laboratory.

(5) Applicants for a certificate of qualification in immunohematology must qualify under section 19.2[(a)(1) or (c)(2)](a)(1)(i), (a)(2)(i), or (d)(2) of this Part.

(6) Applicants for a certificate of qualification in [one or more of the subspecialties of clinical biochemistry] clinical chemistry, blood pH and gases, endocrinology, or therapeutic substance monitoring - quantitative toxicology must qualify under section 19.2[(a)(1), (c)(1)(ii), or (c)(2)](a)(1)(i), (a)(2)(i), (d)(1)(i), (d)(1)(ii), (d)(1)(xi) or (d)(2) of this Part.

(7) Applicants for a certificate of qualification in histopathology and/or cytopathology must qualify under section 19.2[(a)(2)](a)(1)(ii) or (a)(2)(ii) of this Part.

(8) Applicants for a certificate of qualification in oral pathology must qualify under section 19.2[(a)(2) or (b)](a)(1)(ii), (a)(2)(ii), or (c) of this Part.

(9) Applicants for a certificate of qualification in dermatopathology must qualify under section 19.2[(a)(2) or (a)(3)](a)(1)(ii), (a)(1)(iii), (a)(2)(ii), (a)(2)(iii) or (d)(1)(iv) of this Part.

(10) Applicants for a certificate of qualification in cytogenetics, histocompatibility, cellular immunology, [oncofetal antigens, and/or] genetic testing, fetal defect markers, forensic identity,

oncology, parentage/identity testing, trace elements, and/or transplant monitoring must qualify under section 19.2[(c)(2)](d)(2) of this Part.

(11) Applicants for a certificate of qualification in transfusion services must be physicians and must qualify under section 19.2[(a)(3) or (c)(2)](b)(1), (b)(2) or (b)(3) of this Part[, or under section 19.2(a)(1) or (c)(1)(vi) of this Part including or supplemented by at least six months' training and/or experience in transfusion services].

(12) Applicants for a certificate of qualification in blood banking collection-comprehensive must qualify under section 19.2[(c)(2)](d)(2) of this Part. Required experience in blood services must include at least one year's training and/or experience in collection and testing of blood for [homologous]allogenic transfusion.

(13) Applicants for a certificate of qualification in blood banking collection-limited must qualify under section 19.2[(a)(1), (c)(1)(vi) or (c)(2)](a)(1)(i), (b)(1)(i), or (d)(1)(vi) of this Part.

(14) Applicants for a certificate of qualification in [one or more of the subspecialties of] clinical toxicology must qualify under section 19.2[(a)(1), (c)(1)(iii), (c)(1)(iv), or (c)(2)](a)(1)(i), (b)(1)(i), (d)(1)(i), (d)(1)(ii), (d)(1)(iii), (d)(1)(xi), or (d)(2) of this Part.

(15) Applicants for a certificate of qualification in forensic toxicology must qualify under section 19.2[(c)(1)(iii), (c)(1)(iv), or (c)(2)](d)(1)(iii), (d)(1)(v), or (d)(2) of this Part.

(16) Applicants for a certificate of qualification in andrology must qualify under section 19.2(d)(1)(i) or (d)(2) of this Part; or under section 19.2(a)(1)(i) or (b)(1)(i) of this Part including or supplemented by at least six months' training and/or experience in andrology.

(17) Applicants for a certificate of qualification in blood lead must qualify under section 19.2(a)(1)(i), (b)(1)(i), (d)(1)(i), (d)(1)(iii), (d)(1)(v), (d)(1)(xi), or (d)(2) of this Part.

[(f)] (e) Scope and limitations.

(1) The requirements for qualification set forth in section 19.2 of this Part shall apply to all laboratory directors, regardless of prior grandfathered status, upon expiration of current certificates of qualification[,] if the laboratory director is no longer employed in a laboratory or in the field of laboratory medicine.

(2) Additional categories of testing may not be added to a certificate of qualification issued on a grandfathered basis. Such a certificate [may] will not be renewed if allowed to lapse[, unless extenuating circumstances prevent timely reapplication and specific departmental approval is obtained].

19.4 Denial of an application for a certificate of qualification.

(a) In determining whether to deny an application for a certificate of qualification in whole or in part, the department shall consider: the applicant's education, experience, and licensure as required in sections 19.2 and 19.3 of this Part; the applicant's demonstrated ability to discharge the responsibilities set forth in section 19.3(c) of this Part; the character and competence of the applicant and the laboratory or laboratories directed; and any other factors the department considers relevant, including, but not limited to:

* * *

(3) false representation or omission of any material fact in making an application in any state or city of the United States for any license, permit, certificate, or registration related to a profession or business, or in making an application for a certificate of qualification or laboratory permit to New York State [or New York City];

* * *

(6) on the part of any laboratory, category, or subcategory directed by the applicant, a pattern of

repetitive failures of required proficiency testing performance in one or more proficiency testing categories, excluding failure for administrative reasons such as late result submission;

(7) on the part of any laboratory, category, or subcategory directed by the applicant, a pattern of deficiencies on onsite inspection, especially in areas of quality control, quality assurance, laboratory management, and handling of regulated medical waste and radioactive materials, including refusal or inability to produce records as requested by department employees, which deficiencies are not corrected from inspection to inspection or which recur at each [annual] inspection despite written notice of violations by a state or Federal licensing or auditing agency and which jeopardize the quality of test results and resulting patient care, even if interim corrections have occurred;

(8) on the part of any laboratory, category, or subcategory directed by the applicant, performance of any laboratory procedures not authorized by the laboratory permit issued pursuant to article 5, Title V of the Public Health Law; or operation or direction of a laboratory without a permit; or continuing operation or failure to notify the department after a change in director, ownership, or location has voided the permit;

[(9) unless the laboratory is owned and operated by the State of New York, performance of tests on specimens collected in New York City while the laboratory directed by the applicant lacks a New York City permit to perform such tests;]

[(10)](9) on the part of any laboratory, category, or subcategory directed by the applicant, referral of specimens collected in New York State [outside of New York City] to laboratories which do not possess a New York State permit;

[(11)](10) on the part of any laboratory, category, or subcategory directed by the applicant, knowing acceptance of specimens or requisitions for laboratory examination from, or issuance of

reports to, a person or persons not authorized by law to submit such specimens or requisitions, or receive such reports;

[(12)](11) on the part of any laboratory, category, or subcategory directed by the applicant, issuance of reports on laboratory work, including both patient samples and proficiency testing, actually performed in another laboratory, without designating the fact that the examinations or procedures were performed in another laboratory; and/or testing and reporting results on unsatisfactory specimens as defined by the department, including unlabeled specimens or specimens of insufficient quantity to conduct the analyses requested;

[(13)](12) on the part of any laboratory, category, or subcategory directed by the applicant, failure to establish and ensure that employees follow procedures for disposal or handling of specimens or infectious or radioactive medical waste, in violation of applicable state and Federal laws, rules and regulations, or in a manner which endangers the public, the laboratory's employees, or the environment;

[(14)](13) employment of unqualified or unlicensed technical personnel or an insufficient number of such personnel;

[(15)](14) failure of the [laboratory director] applicant to be responsible for adequately supervising laboratory personnel to ensure the proper performance of all tests conducted in the laboratory; and

[(16)](15) any other factor having a direct bearing on the applicant's ability to provide or supervise the provision of high quality laboratory services, or to ensure compliance with statutory and regulatory requirements.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 573 establishes the authority of the Department to promulgate criteria for the issuance of a certificates of qualification. PHL section 573(2) specifically states that the Department shall issue a certificate of qualification to any person who meets such minimum qualifications and who otherwise demonstrates to the Department that he or she possesses the character, competence, training and ability to administer properly the technical and scientific operation of a clinical laboratory or blood bank, including supervision of procedures and reporting of findings of tests.

Legislative Objectives:

The legislature enacted PHL section 573 to protect the health and safety of the public by requiring that only properly educated and experienced individuals be issued certificates of qualification and subsequently assigned responsibility as clinical laboratory directors. Such directors are responsible for the proper operation of clinical laboratories to ensure accurate and reliable results for clinical testing. Part 19 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR), in its original adoption and all subsequent revisions, has been crafted to ensure that applicants have the necessary education, training and experience to effectively direct a laboratory. The proposed amendment is consistent with this legislative objective as it will include the recognition of additional accrediting boards that have been developed since the last regulatory amendment, in response to changes and advances in clinical laboratory testing.

Needs and Benefits:

Part 19 regulates the issuance of certificates of qualification. An individual must hold such certificate to be a clinical laboratory director or assistant director at a clinical laboratory or blood bank permitted by New York under the authority of PHL section 572. The intent of these regulations is to ensure that individuals who are granted certificates of qualification have the necessary education, experience, and training to effectively operate a clinical laboratory. Successful applicants for a certificate of qualification must demonstrate both experience in laboratory management, such as management of resources (e.g. budget allocation, staffing), implementation of a quality management system, development of standard operating procedures; and experience specific to a category of testing defined in Part 19.

Several revisions to the regulatory definitions are proposed. Most notable are the inclusion of a definition for assistant director and revision to the definition of category. Assistant directors are jointly accountable with the laboratory director for the categories of testing on the laboratory permit. In many instances, however, the assistant director may be the only individual qualified to supervise testing in a specific category on the laboratory permit.

Language is proposed in sections 19.2 and 19.3 that clarifies the role and responsibilities of assistant directors of clinical laboratories. With these revisions, assistant directors will be held to the same standards as laboratory directors.

The definition of "category" was revised to strengthen the Department's authority to limit the approval of a certificate of qualification to a subcategory, technology, method or specific

procedure based on the applicant's documented experience. Extensive experience in a single method of testing does not necessarily translate to breadth of knowledge across an entire category of testing. Indeed, as innovations in laboratory medicine continue, an individual's experience in a proven technology may quickly become obsolete without continued education and training. The proposed revisions to the definition of category allow the Department to ascertain an individual's specific breadth of experience upon each application and re-application for a certificate of qualification.

The definitions of the following terms are being proposed for the first time; board certified, earned doctoral degree, training, and experience.

A review of the accrediting boards currently recognized in Part 19 and those included in the proposed revisions was performed to ensure that the requirements for each board were consistent with the rules set forth in federal regulation. This included a review of both the educational and training requirements for the accrediting board. As noted in the proposed revisions, certain boards mandate the appropriate educational requirement of a doctoral degree, but do not specify that the candidate for the board demonstrate the required four years of post-doctoral experience. Therefore, language clarifying the post-doctoral degree experience required by the Department has been proposed for these boards (American Board of Bioanalysts High Complexity Laboratory Director and the National Registry of Clinical Chemists) to ensure that the requirements for all applicants are consistent.

The duties and responsibilities of laboratory directors and assistant directors set forth in subdivision 19.3(c) were revised to provide clarity and introduce new responsibilities. Of note are the added responsibilities of ensuring the availability of procedures for monitoring staff competency and improvement of skills. These new responsibilities are currently included in the New York State Clinical Laboratory Standards of Practice; however, formal codification in regulation is desired.

Finally, subdivision 19.3(d) has been removed since the certificate of qualification categories are repeated in the current subdivision 19.3(e), and therefore 19.3(d) was considered redundant. The Department currently maintains a list of certificate of qualification categories on its publicly accessible website, and revisions were made in proposed subdivision 19.1(i) to outline the necessary contents of this list.

Costs:

Costs to Regulated Parties:

The proposed amendment will not impose costs on regulated parties. The current regulation already requires clinical laboratories and blood banks to have directors who hold certificates of qualification.

Costs to the Agency, State and Local Governments:

The proposed amendment will not impose additional costs to the New York State Department of Health, the program responsible for oversight of clinical laboratories, or to local governments. The program responsible for the oversight of clinical laboratories is a well-established program

operated at the State level and the new language does not impact the costs of the oversight program.

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The proposed revisions to Part 19 do not require any additional forms or paperwork from applicants. All candidates are required under the current rule to provide a complete application, a curriculum vitae, and proof of licensure for physicians or granting of an earned doctoral degree. Additionally, candidates must submit proof of any accreditation by a recognized board and/or letters from third parties attesting to the candidate's training and experience. The proposed revisions expand the list of recognized accrediting boards, which may in fact reduce the paperwork needed for candidates holding those accreditations.

Duplication:

The federal government also recognizes clinical laboratory directors. The Department has applied and been approved for an exemption from the federal government continuously since 1995 that grants the Department the authority to act as the primary accrediting body for clinical laboratories and clinical laboratory directors operating in New York.

Alternatives:

The alternative to this proposal would be to maintain the existing regulatory requirements. However, the proposed amendments are necessary to update the regulations to include new definitions, update the list of acceptable accrediting boards, and clarify and expand the responsibilities of laboratory directors and assistant directors.

Federal Standards:

The Federal Code of Regulations (CFR) sets forth rules for the education and experience of clinical laboratory directors (CFR 493.1443). The proposed revisions to Part 19 will incorporate several of the accrediting boards that are already recognized under the federal rule.

Compliance Schedule:

Regulated parties are expected to comply with the proposed regulation by its effective date.

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STATEMENT IN LIEU OF REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

No regulatory flexibility analysis is required. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments. At present the regulations require clinical laboratories and blood banks to be directed by individuals who hold a certificate of qualification. This proposed amendment would update and expand the list of acceptable accrediting boards for obtaining a certificate of qualification and is therefore anticipated to have a positive impact by increasing the number of individuals who may qualify for a certificate of qualification.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

No rural area flexibility analysis is required pursuant to § 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendments will not impose an adverse impact on facilities in rural areas, and will not impose any significant new reporting, record keeping or other compliance requirements on facilities in rural areas.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

No job impact statement is required pursuant to § 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of these proposed regulations.