Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
June 20, 2024
9:30 a.m.

90 Church Street, 4th Floor CR 4 A/B, New York, New York 10007

I. WELCOME AND INTRODUCTION

Thomas Holt, Chair of the Committee on Codes, Regulations and Legislation

II. REGULATIONS

For Adoption

23-21 Amendment of Part 300 of Title 10 NYCRR (Statewide Health Information Network for New York (SHIN-NY))

For Information

24-03 Amendment of Part 12 of Title 10 NYCRR and Section 505.2(e) of Title 18 NYCRR (Reproductive Health Care Standards)

24-02 Amendment of Section 2.6 of Title 10 NYCRR (Disease Outbreak Investigation and Response Clarifications

23-24 Addition of Subpart 98-5 to Title 10 NYCRR (Program for All-Inclusive Care for the Elderly (PACE) Licensure)

III. ADJOURNMENT

******Agenda items may be called in an order that differs from above******

SUMMARY OF EXPRESS TERMS

Public Health Law sections 206(18-a)(d) and 2816 give the Department broad authority to promulgate regulations, consistent with federal law and policies, that govern the Statewide Health Information Network for New York (SHIN-NY).

These amendments support the development of the statewide data infrastructure, thereby increasing interoperability and providing the flexibility necessary for the SHIN-NY to adapt in a constantly evolving technological environment. The goal of these amendments is to ensure consistency across the SHIN-NY in how SHIN-NY participants connect and exchange data, to support public health during emergencies and to assist with Medicaid reporting in support of the Medicaid program's Social Security Act section 1115 waiver (see 42 USC § 1315).

In order to promote efficiency through the development of network-wide policies, processes, and solutions, these amendments create a process to develop the statewide data infrastructure that will facilitate the exchange of data among SHIN-NY participants. Relevant activities required of the Department or its contracted vendor under the amendments include enhancement of the data matching process for patient demographic information submitted by SHIN-NY participants, creation of a statewide provider directory to serve as a standardized resource for resolving provider and facility identities, development of a statewide patient consent management system, and the aggregation of data from SHIN-NY participants in a secure statewide repository.

In addition, under these regulations, the Department will create a statewide common participation agreement to be used by each qualified entity and which will allow SHIN-NY participants to connect to the statewide data infrastructure by agreeing to participate in the SHIN-NY and adhering to SHIN-NY policy guidance. This will allow patient data to be

contributed to the statewide data infrastructure and used for statewide reporting and analytics for public health activities and Medicaid purposes, to the extent authorized by law. Any disclosure of data from the statewide data repository, a component of the statewide data infrastructure, will be in accordance with the SHIN-NY policy guidance reviewed and approved by relevant stakeholders through the statewide collaboration process.

This will further promote consistency and efficiency across the SHIN-NY by requiring the qualified entities to use and accept network-wide agreements and patient consent decisions. The statewide common participation agreement will eliminate the current variation in the terms and conditions applicable to participating in the SHIN-NY through one qualified entity versus another. The amendments also reduce ambiguity by requiring qualified entities to honor and implement patient consent decisions that authorize data access by treating providers across the network, regardless of which qualified entity such providers have contracted with, to participate in the SHIN-NY.

This amendment will further the Legislature's intent under chapter 54 of the Laws of 2023, which appropriated an additional $2.5 million "for modernizing health reporting systems." By clarifying the data reporting and aggregation responsibilities applicable to the qualified entities, the proposed amendments will transform the SHIN-NY into a functional resource for the analysis and reporting of statewide health information for authorized public health and health oversight purposes.

Pursuant to the authority vested in the Commissioner of Health and the Public Health and Health Planning Council by sections 201, 206(1) and (18-a)(d), 2803, 2816, 3612, 4010, 4403, and 4712 of the Public Health Law, Part 300 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to read as follows:

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

(a) "*Statewide Health Information Network for New York*" or "*SHIN-NY*" means the technical infrastructure and the supportive policies and agreements that:

(i) make possible the electronic exchange of clinical information among [qualified entities and qualified entity] SHIN-NY participants for authorized purposes to improve the quality, coordination and efficiency of patient care, reduce medical errors and carry out public health and health oversight activities, while protecting patient privacy and ensuring data security; and

(ii) enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data, and public health information systems, while protecting patient privacy and ensuring data security.

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

(c) "[*Qualified entity*] *SHIN-NY participant*" means any health care provider, health

plan, governmental agency or other type of entity or person that has executed a statewide common participation agreement with a qualified entity or with the entity that facilitates their connection to the SHIN-NY statewide data infrastructure, pursuant to which it has agreed to participate in the SHIN-NY.

* * *

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

* * *

(m) "*Statewide common participation agreement*" means a common agreement, developed using a statewide collaboration process, consistent with any minimum standards set forth in the SHIN-NY policy guidance and approved by the New York State Department of Health, that is used statewide by each qualified entity or by SHIN-NY participants, allowing them to connect to the SHINY-NY statewide data infrastructure either directly or through a contractor, and pursuant to which SHIN-NY participants agree to participate in the SHIN-NY and adhere to SHIN-NY policy guidance, including but not limited to causing patient data to be contributed to the statewide data infrastructure and authorizing the use of patient data for statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law.

(n) "*Statewide data infrastructure*" means the information technology infrastructure provided by the New York State Department of Health, either directly or through contract, to support the aggregation of data provided by qualified entities and SHIN-NY participants, statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law.

(o) "*Public health activities*" means purposes for which a SHIN-NY participant is permitted to disclose protected health information to a public health authority without an authorization or opportunity to agree or object under federal standards for uses and disclosures for public health activities.

(p) "*Medicaid purposes*" means purposes related to the administration of the Medicaid program, including but not limited to reporting to support any Social Security Act section 1115 waiver approved by the Centers for Medicare and Medicaid Services.

Section 300.2 Establishing the SHIN-NY. The New York State Department of Health shall:

(a) oversee the implementation and ongoing operation of the SHIN-NY;

(b) implement the infrastructure and services to support the private and secure exchange of health information among [qualified entities and qualified entity] SHIN-NY participants;

(c) provide, either directly or through contract, statewide data infrastructure and any other SHIN-NY services that the New York State Department of Health deems necessary to effectuate the purposes of this Part;

(d) administer the statewide collaboration process and facilitate the development, regular review and [update] amendment of SHIN-NY policy guidance;

[(d)](e) perform regular audits, either directly or through contract, of qualified entity and SHIN-NY participant functions and activities as necessary to ensure the quality, security and confidentiality of data in the SHIN-NY;

[(e)](f) provide [technical services], either directly or through contract, [to ensure the quality, security and confidentiality of data in the SHIN-NY;] strategic leadership on the use of the statewide data infrastructure to ensure health information exchange services are efficiently deployed in the SHIN-NY to support:

(1) the exchange of data among SHIN-NY participants;

(2) the matching of patient demographic information submitted by SHIN-NY participants;

(3) a statewide provider directory;

(4) a statewide consent management system; and

(5) aggregation of data from SHIN-NY participants in a statewide repository;

[(f)](g) assess qualified entity and SHIN-NY participant participation in the SHIN-NY and, if necessary, suspend a qualified [entity's] entity or SHINY-NY participant's access to or use of the SHIN-NY, as provided in the statewide common participation agreement, or when it reasonably determines that the qualified entity or SHINY-NY participant has created, or is likely to create, an immediate threat of irreparable harm to the SHIN-NY, to any person accessing or using the SHIN-NY, or to any person whose information is accessed or transmitted through the SHIN-NY;

[(g)](h) publish reports on health care provider participation and usage, system performance, data quality, the qualified entity certification process, and SHIN-NY security;

[(h)](i) take such other actions, including but not limited to the convening of appropriate advisory and stakeholder workgroups, as may be needed to promote development of the SHIN-NY;

(j) approve the statewide common participation agreement under which SHIN-NY participants supply patient information to the SHIN-NY using qualified entities or the entity that facilitates their connection to the statewide data infrastructure, and qualified entities supply patient information using the statewide data infrastructure. Any such qualified entity or third-party entity that facilitates a SHIN-NY participant's connection must be the "business associate," as defined in 42 USC § 17921, of any SHIN-NY participant that supplies patient information and is a health care provider, and must be a qualified service organization of any SHIN-NY participant that supplies patient information and is an alcohol or drug abuse program required to comply with federal regulations regarding the confidentiality of alcohol and substance abuse patient records. 42 USC § 17921, effective February 17, 2009, which has been incorporated by reference in this Part, has been filed in the Office of the Secretary of State of the State of New York. The section of the United States Code incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Office of the Law Revision Counsel of the United States House of Representatives.

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

(a) SHIN-NY policy guidance. The New York State Department of Health shall

establish SHIN-NY policy guidance as set forth below:

(1) The New York State Department of Health shall establish [or designate a policy committee] a statewide collaboration process, which may include the designation of committees, representing qualified entities, SHIN-NY participants, relevant stakeholders, and healthcare consumers to make recommendations on SHIN-NY policy guidance and standards.

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

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

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

(1) privacy and security;

(2) monitoring and enforcement;

(3) [minimum] core service requirements;

(4) organizational characteristics of qualified entities; [and]

(5) qualified entity certification;

(6) technical standards for interoperability and data sharing among SHIN-NY participants, qualified entities, and the New York State Department of Health or its designated contractor; and

(7) requirements and procedures for the disclosure of data, using the statewide

data infrastructure, to the New York State Department of Health or its designated contractor, and for the use and re-disclosure of such data to support statewide reporting and analytics for public health activities and Medicaid purposes.

Section 300.4 Qualified entities.

(a) Each qualified entity shall:

(1) maintain and operate a network of [qualified entity] SHIN-NY participants seeking to securely exchange patient information;

(2) connect to the statewide data infrastructure to allow [qualified entity] SHIN-NY participants to exchange information with [qualified entity] SHIN-NY participants of other qualified entities and with the New York State Department of Health or its designated contractor to support statewide reporting and analytics for public health activities and Medicaid purposes;

(3) submit to regular audits of qualified entity functions and activities by the New York State Department of Health or its designated contractor as necessary to ensure the quality, security, and confidentiality of data in the SHIN-NY;

(4) ensure that data from [qualified entity] SHIN-NY participants is only made available through the SHIN-NY in accordance with applicable law;

(5) enter into agreements, including the statewide common participation agreement, with [qualified entity] SHIN-NY participants that supply patient information to, or access patient information from, the qualified entity. A

qualified entity must be the "business associate," as defined in 42 USC § 17921, of any [qualified entity] SHIN-NY participant that supplies patient information and is a health care provider, and must be a qualified service organization of any [qualified entity] SHIN-NY participant that supplies patient information and is an alcohol or drug abuse program required to comply with Federal regulations regarding the confidentiality of alcohol and substance abuse patient records;

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

(7) submit data, including patient information, using the statewide data infrastructure, to the New York State Department of Health or its designated contractor, according to specifications provided by the New York State Department of Health;

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

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

[(9)](10) implement policies and procedures to provide patients with information

identifying [qualified entity] SHIN-NY participants that have obtained access to their patient information using the qualified entity, except as otherwise prohibited by law.

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

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

(2) to allow patients to approve and deny access to [specific qualified entity] SHIN-NY participants; and

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

(c) Each qualified entity shall provide [the following minimum set of] such core services to [qualified entity] SHIN-NY participants as required by the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part. Such core services shall include, but not be limited to:

(1) allow [qualified entity] SHIN-NY participants to search existing patient records on the network;

(2) make available to [qualified entity] SHIN-NY participants and public health authorities a clinical viewer to securely access patient information;

(3) [permit secure messaging among health care providers;

(4)] provide tracking of patient consent;

[(5) provide notification services to establish subscriptions to pre-defined events and receive notifications when those events occur;

(6)](4) provide identity management services to authorize and authenticate users in a

manner that ensures secure access;

(5) submit data using the statewide data infrastructure, to the New York State Department of Health or its designated contractor, to support the aggregation of data, statewide reporting and analytics for public health activities and Medicaid, consistent with applicable law;

[(7)](6)support Medicaid and public health reporting to public health authorities;

[(8) deliver diagnostic results and reports to health care providers.]

(7) provide SHIN-NY participants with appropriate access to data using the statewide data infrastructure.

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

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(3) The qualified entity has technical infrastructure, privacy and security policies and processes in place to: manage patient consent for access to health information consistent with section 300.5 of this Part and the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part; support the authorization and authentication of users who access the

system; audit system use; and implement remedies for breaches of patient information.

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Section 300.5 Sharing of Patient Information.

(a) General standard. [Qualified entity] SHIN-NY participants may only exchange patient information as authorized by law and consistent with their statewide common participation agreements [with qualified entity participants]. Under section 18(6) of the Public Health Law, individuals who work for a qualified entity or the entity that facilitates SHIN-NY participants' connection to the statewide data infrastructure are deemed personnel under contract with a health care provider that is a [qualified entity] SHIN-NY participant. As such, a [qualified entity] SHIN-NY participant may disclose to such a qualified entity necessary patient information without a written authorization from the patient of the [qualified entity] SHIN-NY participant. [Qualified entity] SHIN-NY participants may, but shall not be required to, provide patients the option to withhold patient information, including minor consent patient information, from the SHIN-NY. Except as set forth in paragraph (b)(2) or subdivision (c) of this section, a qualified entity shall only allow access to patient information by [qualified entity] SHIN-NY participants with a written authorization from:

(1) the patient; or

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

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

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

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

(b) Written authorization.

(1) Written authorizations must [specify to whom disclosure is authorized] be obtained using a statewide form of consent, approved by the New York State Department of Health, that allows patients to approve and deny access to information in the SHIN-NY by SHIN-NY participants.

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

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

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

(ii) Any written authorization shall remain in effect until it is revoked in writing or explicitly superseded by a subsequent written authorization. A patient may revoke a written authorization in writing at any time by following procedures established by the qualified entity consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.

(2) Qualified entities shall permit access to all of a patient's information by all persons or entities authorized to access information in the SHIN-NY, or any other general designation of who may access such information, after consent is obtained.

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

[(3)](4) Minor consent patient information.

(i) In general, a minor's minor consent patient information may be disclosed to a [qualified entity] SHIN-NY participant if the minor's parent or legal guardian has provided authorization for that [qualified entity] SHIN-NY participant to access the minor's patient information through the SHIN-NY. Such access shall be deemed necessary to provide appropriate care or treatment to the minor. However, if federal law or regulation requires the minor's authorization for disclosure of minor consent patient information or if the minor is the parent of a child, has married or is otherwise emancipated, the disclosure may not be made without the minor's

authorization.

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

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

* * *

(x) emergency care as provided in section 2504(4) of the Public Health Law[.];

(xi) treatment provided with the consent of no person other than the minor patient, where the patient is a homeless youth as defined in section 532-A of the executive law, or receives services at an approved runaway and homeless youth crisis services program or transitional independent living support program as defined in section 532-A of the executive law.

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Section 300.6 Participation of health care facilities.

(a) [One year from the effective date of this regulation, general hospitals as defined in subdivision ten of section two thousand eight hundred one of the Public Health Law, and two years from the effective date of this regulation, all health] Health care facilities as defined in section 18(c)(1) of the Public Health Law, including those who hold themselves out as urgent care providers[, utilizing certified electronic health record technology under the federal Health Information Technology for

Economic and Clinical Health Act (HITECH),] must become [qualified entity] SHIN-NY participants in order to connect to the SHIN-NY through a qualified entity, and must allow private and secure bi-directional access to patient information by other [qualified entity] SHIN-NY participants authorized by law to access such patient information. [Bi-directional] As used in this subdivision, bi-directional access means that a [qualified entity] SHIN-NY participant has the technical capacity to upload its patient information to the qualified entity so that it is accessible to other [qualified entity] SHIN-NY participants authorized to access the patient information and that the [qualified entity] SHIN-NY participant has the technical capacity to access the patient information of other [qualified entity] SHIN-NY participants from the qualified entity when authorized to do so, consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.

(b) All health care facilities required to become SHIN-NY participants pursuant to subdivision (a) of this section must supply patient information to the statewide data infrastructure.

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

(1) economic hardship;

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

(3) other exceptional circumstances demonstrated by the health care provider to

the New York State Department of Health as the Commissioner may deem appropriate; or

(4) the facility has the technical capacity for private and secure bi-directional access, executes a statewide common participation agreement, connects to the SHIN-NY and supplies patient information to the statewide data infrastructure in accordance with this Part and the SHIN-NY policy guidance. As used in this paragraph, bi-directional access means that a SHIN-NY participant has the technical capacity to upload its patient information to the SHIN-NY so that it is accessible to other SHIN-NY participants authorized to access the patient information and that the SHIN-NY participant has the technical capacity to access the patient information of other SHIN-NY participants when authorized to do so, consistent with the SHIN-NY policy guidance under subdivision (b) of section 300.3 of this Part.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) § 206(18-a)(d) authorizes the Commissioner to make such rules and regulations as may be necessary to enable widespread, non-duplicative interoperability among disparate health information systems, including electronic health records, personal health records, health care claims, payment and other administrative data and public health information systems, while protecting patient privacy and ensuring data security. In addition, PHL sections 201, 206(1), 2803, 2816, 3612, 4010, 4403, and 4712 authorize the Commissioner to make such rules and regulations as may be necessary to effectuate the provisions and purposes of PHL Articles 28 (hospitals), 36 (home care services), 40 (hospice), 44 (health maintenance organizations) and 47 (shared health facilities) and provide additional authority for the Commissioner to create and make use of the Statewide Health Information Network for New York (SHIN-NY).

Legislative Objectives:

The explicit legislative objective of PHL § 206(18-a) is the promotion of widespread, non-duplicative interoperability among disparate health information systems and data types, including electronic health records, personal health records, health care claims, payment and other administrative data and public health information systems, while protecting patient privacy and ensuring data security. Such interoperability is intended to improve patient outcomes, minimize unnecessary service utilization, and reduce health care costs by fostering efficiency and supporting care coordination.

Existing regulations at 10 NYCRR Part 300 advanced these legislative objectives by establishing requirements for the regional health information organizations (RHIOs) that

were created as health information exchanges in New York State. Under the provisions of Part 300, the RHIOs became the qualified entities (QEs) that facilitate the exchange of health information in the SHIN-NY. These regulatory amendments will further the legislative intent by making it easier for health care providers, health plans, and governmental agencies to become SHIN-NY participants and access the SHIN-NY through the use of a statewide common participation agreement, while ensuring patient privacy and data security.

Needs and Benefits:

Pursuant to the current regulation, responsibility for the development and maintenance of SHIN-NY policies and technical infrastructure is divided between the QEs and the Department. In practice, this division of oversight and operational responsibilities has resulted in the deployment of disparate forms, processes, and technology solutions across the network. The proposed amendments are necessary to support the development of the statewide data infrastructure, thereby increasing interoperability and providing the flexibility necessary for the SHIN-NY to adapt in a constantly evolving technological environment. The goal of these amendments is to ensure consistency across the SHIN-NY in how SHIN-NY participants connect and exchange data, and to support the sharing of information for public health purposes, such as the Medicaid program's Social Security Act section 1115 waiver (see 42 USC § 1315).

In order to promote efficiency through the development of network-wide policies, processes, and solutions, these amendments create a process to develop the statewide data infrastructure that will facilitate the exchange of data among SHIN-NY participants by enhancing the matching of patient demographic information submitted by SHIN-NY

participants, with a statewide provider directory, and statewide consent management system.

In addition, under these regulations, the Department will create a statewide common participation agreement to be used statewide by each qualified entity whether the participant connects through a qualified entity or directly through the statewide infrastructure. This will enable SHIN-NY participants to connect with the statewide data infrastructure and contribute patient data. Furthermore, the statewide common participation agreement will allow the use of such data for statewide reporting and analytics for public health activities and Medicaid purposes, consistent with applicable law. The regulations define the terms "public health activities" and "Medicaid purposes" and the SHIN-NY policy guidance sets forth the instances in which a participant may disclose protected health information to the Department, without affirmative consent of the patient.

The regulations will further promote consistency and efficiency across the SHIN-NY by requiring the QEs to use and accept network-wide agreements and patient consent decisions. The statewide common participation agreement will eliminate the current variation in the terms and conditions applicable to participating in the network through one QE versus another. The regulatory amendments will also reduce ambiguity by requiring QEs to honor and implement patient consent decisions that authorize data access by treating providers across the network, regardless of which QE such providers have contracted with to participate in the SHIN-NY.

These amendments will also further the Legislature's intent under chapter 54 of the Laws of 2023, which appropriated an additional $2.5 million "for modernizing health reporting systems." As the COVID-19 and requirement to use the Hospital Emergency

Reporting Data System (HERDS) for crucial public health reporting pandemic demonstrated, the current framework for SHIN-NY data collection and reporting is insufficient to enable timely analysis and decision making in situations involving an emergent public health concern. By providing for a statewide data infrastructure and explicitly requiring all SHIN-NY participants to submit data for aggregation, these amendments will ensure that facilities and the Department are not required to navigate and implement an ad-hoc or emergency data collection procedure during future public health scenarios of urgent concern. Additionally, it will enable more efficient reporting for healthcare facilities.

Moreover, interoperability and analytics based on data from the SHIN-NY will be a key component of the Department's mandatory reporting in relation to the Medicaid program's Social Security Act section 1115 demonstration project and associated waiver. Whereas the current regulation merely authorizes the QEs to disclose patient information without written consent to a public health authority or health oversight agency, the proposed amendments will require the QEs and SHIN-NY participants to submit data using the statewide data infrastructure, both on a regular basis and in response to ad-hoc requests from the Department or its designated contractor. By clarifying the data reporting and aggregation responsibilities applicable to the QEs and the permissible uses of such data by the Department or its designated contractor, the proposed amendments will transform the SHIN-NY into a functional resource for the analysis and reporting of statewide health information for authorized public health and health oversight purposes.

Beyond supporting interoperability and consistency across the network for QEs and SHIN-NY participants and clarifying the data reporting obligations of both, these

regulations also address the need to allow for providers to connect directly to the statewide data infrastructure and participate in SHIN-NY data exchange and data reporting without a qualified entity acting as intermediary. To that end, the definition of "qualified entity participant" has been changed to refer to "SHIN-NY participants," which will account for the possibility that provider organizations may participate in the SHIN-NY without contracting with one of the qualified entities. In such circumstances, the provider organization would enter into the statewide common participation agreement with the Department or its designated contractor, under which the organization would agree to adhere to applicable SHIN-NY policies and provide data to other SHIN-NY participants and the Department for data reporting and aggregation. To create an option for such direct connection to the statewide data infrastructure as an alternative to connecting through one of the qualified entities, subdivision 300.6(c)(4) is amended to exempt a health care facility that demonstrates "the technical capacity for private and secure bi-directional access, executes a statewide common participation agreement, and connects to the SHIN-NY using the statewide data infrastructure" from the requirement to enter into a participation agreement with a qualified entity. These changes reflect the fact that health information technology has rapidly advanced since the inception of the SHIN-NY, to the point where most larger health systems now possess the technical capacity to connect to and retrieve data from a statewide network without the assistance of a dedicated health information exchange partner or may exchange through electronic health record networks established at the national level.

These regulations account for the possibility that the Department, its designated contractor, and/or other types of health care organizations or other national networks might

provide data and/or services through the SHIN-NY in the future. Data and services may be provided through the SHIN-NY by the Department, by its designated contractor, or by other SHIN-NY participants that meet the minimum technical, security, privacy, organizational and other requirements set forth by the Department. Along with the provisions that authorize providers to connect directly to the SHIN-NY, this change will support the shift to an ecosystem model for New York's health information system in favor of the current system under which participation is restricted to those organizations that contract and follow the policies of the certified QEs.

Finally, these amendments will promote the development of a statewide provider directory and consent management system, both of which have been longstanding goals for the Department and will contribute substantially to the modernization of New York's health reporting system once implemented.

COSTS

Costs to Private Regulated Parties:

The private parties subject to the proposed amendments are the QEs and SHIN-NY participants. To the extent that any expenditures are necessary by QEs in order to comply with these amendments, such expenditures are expected to continue to be reimbursed using money appropriated to the Department's designated contractor. It is not anticipated that SHIN-NY participants will incur any costs as a result of these amendments. Most regulated facilities are currently connected to the SHIN-NY via a qualified entity. The amendments are also intended to allow the alignment of SHIN-NY interoperability requirements with interoperability requirements from the federal Department of Health and Human Services. By aligning with federal interoperability requirements, this should create more efficiency

by leveraging interoperability standards currently built into electronic health records.

Costs to Local Government:

This proposal will not impact local governments unless they operate a health care facility, in which case the impact would be the same as outlined above for private parties.

Costs to the Department of Health:

While there will be costs to build the statewide data infrastructure initially, those costs have already been budgeted. It is anticipated there will be greater efficiency in how technology is deployed in the SHIN-NY. Initial outlays will be funded through a $2.5million increase in the budget appropriation that occurred in the SFY 2023-2024 budget.

Costs to Other State Agencies:

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

Local Government Mandates:

Health facilities operated by local governments will be required to comply with these amendments in the same manner as other facilities. The regulation is not anticipated to impose any direct costs on SHIN-NY participants, including local health departments.

Paperwork:

No new paperwork requirements would be imposed under the proposed amendments. Any consent forms that are developed will replace current consent forms and deployed can be done electronically. Additionally, there will be less variation in consent forms because of a consistent consent form developed by the Department.

Duplication:

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

Alternatives:

An alternative to the proposed regulation would be not to make any amendments to 10 NYCRR Part 300 regulations. However, these amendments are necessary to fulfill the legislature's objective of creating an efficient statewide health information network that serves as a resource for patients, providers, and public health officials across the State. These regulations are essential to improve the long-term efficacy of the SHIN-NY and therefore the alternative of not making any amendments to the regulation was not considered viable.

Federal Standards:

The proposed amendments do not duplicate or conflict with any federal regulations. These amendments will complement the Office of the National Coordinator for Health Information Technology (ONC) Final Rule implementing certain provisions of the 21st Century Cures Act (85 Fed. Reg. 25642, May 1, 2020), which requires patient information to be accessible under application programming interface (API) requirements and prohibits actions that constitute information blocking. See 42 USC § 300jj–11 et seq.

Compliance Schedule:

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

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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. By having a standard participation agreement across the state, SHIN-NY participants will have a consistent participation agreements that will not vary by region. This should result lower costs compared to current variation across the state.

STATEMENT IN LIEU OF RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for this amendment is not being submitted because the amendment will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. By having a standard participation agreement across the state, SHIN-NY participants will have a consistent participation agreements that will not vary by region. This should result lower costs compared to current variation across the state. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for the proposed regulatory amendments is not being submitted because it is apparent from the nature and purposes of the amendment that it 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 the Commissioner of Health by sections 201, 206 and 225 of the Public Health Law, Part 12 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 12.13 is REPEALED.

Section 12.20 is REPEALED.

A new section 12.21 is added, under the new title "REPRODUCTIVE HEALTHCARE STANDARDS," to read as follows:

Section 12.21. Determination of blood group and Rh type and administration of Rh immune globulin.

(a) It shall be the duty of the physician, licensed midwife or nurse practitioner attending a pregnant person to take or cause to be taken a sample of their blood to determine blood group and Rh type in accordance with evidence based clinical guidelines.

(b) It shall further be the duty of the attending physician, licensed midwife or nurse practitioner to evaluate every such patient for the risk of sensitization to Rho (D) antigen in accordance with evidence based clinical guidelines and if the use of Rh immune globulin is indicated, and the patient consents, to cause an appropriate dosage thereof to be administered as clinically indicated.

Pursuant to the authority vested in the Commissioner of Health by sections 363-a(2) and 365-a(2) of the Social Services Law, subdivision (e) of section 505.2 of Title 18 (Social Services) 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:

505.2 Physicians' services.

* * *

(e) Abortion.

(1) Definition. [An abortional act is the procedure or procedures by which an abortion is induced and completed; this being either medical, surgical or both, the words abortional act refer to either or both.] <u>For purposes of this section, an abortion shall include medication and procedural abortion that both a pregnant person and provider agree are needed.</u>

[(2) Where care may be provided. An abortional act shall be performed subject to the requisites set forth in 10 NYCRR 12.20.]

[(3)]<u>(2)</u> Who may provide service. [(i)] <u>Abortion may be performed by a health care practitioner licensed, certified, or authorized under title eight of the Education Law, acting within their lawful scope of practice.</u> [An abortional act is an obstetrical procedure and shall be performed only by a physician with a currently valid license to practice medicine and surgery in the State of New York and in accordance with the medical staff rules of the hospital or qualifying facility where the abortional act is performed.

(ii) No physician or other person shall be required to perform or participate in a medical procedure which may result in the termination of a pregnancy.]

[(4)] (3) Establishment of diagnosis of pregnancy. Prior to the performance of an abortion[al act], the health care practitioner must determine and document the estimated duration of the pregnancy in accordance with evidence based clinical guidelines and section 2599-bb of the Public Health Law. [positive evidence of pregnancy by test result, history and physical examination or other reliable means shall be recorded on the patient's medical chart, with an estimate of the duration of the pregnancy.]

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the proposed revisions is set forth in Public Health Law (PHL) sections 201, 206 and 225, as well as Social Services Law (SSL) sections 363-a(2) and 365-a(2). Section 201(1)(l) of the PHL establishes the powers and duties of the New York State Department of Health (Department), which include promoting diagnostic and therapeutic services for maternal health, as well as acting as the single state agency for the provision of the medical assistance program, also known as Medicaid. Section 206 of the PHL requires the Commissioner of Health to establish rules and regulations for the determination of asymptomatic conditions including Rh sensitivity, and establishes the Commissioner's authority to enforce the PHL, the State Sanitary Code and the requirements of the medical assistance program. Section 225 of the PHL sets forth the powers and duties of the Public Health and Health Planning Council (PHHPC), which include the authority to establish, amend and repeal the regulations known as the State Sanitary Code, subject to the approval of the Commissioner of Health. Further, section 225(5)(a) of the PHL allows the State Sanitary Code to address any matter affecting the security of life or health, or the preservation or improvement of public health, in New York State.

Additionally, SSL section 363-a(2) establishes the Department's authority to promulgate regulations needed to implement the medical assistance program, and SSL section 365-a(2) requires the Department to determine the scope of standard coverage under the medical assistance program.

Legislative Objective:

The legislative objective of sections 201, 206 and 225 of the PHL are to ensure that the Department of Health, through the Commissioner of Health and PHHPC, protect public health by adopting regulations in the State Sanitary Code (SSC) that effectively promote diagnostic and therapeutic services for maternal health and establish rules for the determination of asymptomatic conditions such as Rh sensitivity. In accordance with that objective, this regulation amends the SSC by revising Title 10 of New York Codes, Rules and Regulations (NYCRR) Part 12 to accord with provisions of the Reproductive Health Act of 2019.

Additionally, SSL section 363-a(2) establishes the Department's authority to promulgate regulations needed to implement the medical assistance program, and SSL section 365-a(2) requires the Department to determine the scope of standard coverage under the medical assistance program.

Needs and Benefits:

Neither Part 12 of Title 10 nor Part 505 of Title 18 has been modified since the passage of the Reproductive Health Act of 2019, and the provisions subject to amendment in this proposal derived their authority from PHL, section 4164, which was repealed by the Reproductive Health Act. Consequently, the proposed amendments are necessary to reconcile the regulations with the statute in its current form.

The Reproductive Health Act added a new Article 25-A to the PHL that expanded the types of otherwise qualified health care practitioners who may perform abortions, enshrined a fundamental right to carry a pregnancy to term, give birth to a child, or have an abortion, and explicitly stated that it was "the intent of the legislature to prevent the enforcement of laws or regulations that are not in furtherance of a legitimate state interest in protecting a woman's health

that burden abortion access." As such, it is necessary to repeal section 12.20 of Title 10 and the corresponding provisions of subdivision 505.2(e) of Title 18.

What is now compartmentalized as section 12.13 of Title 10 contains two provisions applicable to abortion care that are inconsistent with both current standards of clinical care and recent changes to the abortion provisions in regulations authorized by Article 28 of the PHL. Moreover, it is both legally inaccurate and medically inappropriate that regulations governing abortion care be organized under a heading entitled "Protection of Infants and Children Against Hazards," when in fact these provisions are meant to protect the health and lives of people of childbearing age. For that reason, the proposal will create a new subject heading under Part 12 entitled "Reproductive Healthcare Standards," to clarify the regulation's relevance and better facilitate public access to its contents.

Additionally, the rulemaking will amend subdivision of 505.2(e) of Title 18 to modernize the definition of abortion to expressly include medication and procedural services as deemed appropriate by patient and physician; to clarify that abortion services may be provided by any healthcare practitioner licensed in New York State and acting within their lawful scope of practice; and to clarify that said practitioners should determine a patient's estimated duration of pregnancy in accordance with the requirements of PHL section 2599-bb and evidence-based clinical guidelines.

COSTS:

Costs to Private Regulated Parties:

There are no anticipated costs to regulated parties, including physicians, licensed midwifes and nurse practitioners attending a pregnant person, because the current regulations already require these individuals to take or cause to be taken a sample of blood to determine blood group and Rh type. In addition, the changes to Title 18 modernize and clarify the

definition of abortion but make no actual changes to current provision of services or scope of practice. Therefore, there are no anticipated costs to regulated parties.

Cost to Local Government:

There are no anticipated costs to local governments associated with this regulation.

Cost to the Department of Health:

There are no anticipated costs to the Department of Health associated with this regulation.

Cost to Other State Agencies:

There are no anticipated costs to other state agencies associated with this regulation.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation does not impose any new paperwork requirements.

Duplication:

This regulation does not duplicate, overlap, or conflict with relevant rules or other legal requirements of the State or federal government.

Alternatives:

An alternative to these regulatory amendments would be not to make any changes and to keep the regulations as written. However, these amendments are needed to bring the regulations into compliance with Article 25-A of the PHL, and therefore this was not considered a viable alternative.

Federal Standards:

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

Compliance Schedule:

This regulation will be effective immediately upon publication of a Notice of Adoption in the New York State Register. These proposed rules conform current regulation to existing State statutes.

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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 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.

There was no small business or local government participation in the development of these regulations. Local government should not be impacted by these proposed regulations.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to section 202-bb of the State Administration Procedure Act (SAPA). It is apparent from the nature of the proposed amendment that it will not impose any adverse impact on rural areas, and the rule does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas. These provisions apply uniformly throughout New York State, including all rural areas.

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 the Commissioner of Health by Section 225 of the Public Health Law, Section 2.6 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:

2.6 Investigations and Response Activities.

(a) Except where other procedures are specifically provided in law and consistent with any direction that the State Commissioner of Health may issue, every local health authority, either personally or through a qualified representative, shall, with all due speed [immediately] upon receiving a report of a case, suspected case, outbreak, or unusual disease[,] and as the circumstances may require, investigate the circumstances of such report at any and all public and private places in which the local health authority has reason to believe, based on epidemiological or other relevant information available, that such places are associated with such disease. Except as consistent with any direction that the State Commissioner of Health may issue, s[S]uch investigations and response activities shall[, consistent with any direction that the State Commissioner of Health may issue]:

* * *

(6) With the training or assistance of the State Department of Health as necessary, examine the processes, structures, conditions, machines, apparatus, devices, equipment, records, and material within such places that may be relevant to the investigation of disease or condition;

* * *

(c) Investigation Updates and Reports.

(1) Upon request of the State Department of Health, the local health authority shall submit updates and reports on outbreak investigations to the State Department of Health. The content, timeframe, and manner of submission of such updates shall be determined by the State Department of Health in consultation with the local health authority.

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the regulatory amendments to Part 2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is section 225 of the Public Health Law (PHL), which authorizes the Public Health and Health Planning Council (PHHPC), subject to the approval of the Commissioner of Health (Commissioner), to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York. Additionally, section 2103 of the PHL requires all local health officers to report cases of communicable disease to the New York State Department of Health (the "Department").

Legislative Objectives:

The legislative objective of section 225 of the PHL is, in part, to protect the public health by authorizing the PHHPC, with the approval of the Commissioner, to amend the SSC to address public health issues related to communicable disease.

Needs and Benefits:

These regulations update and clarify the Department's authority as well as that of local health departments (LHDs) to take specific actions to monitor the spread of disease, including actions related to investigation and response for a disease outbreak.

Specifically, the proposed regulatory amendments would add language to clarify and make explicit that the Commissioner may issue guidance that impacts investigation and response activities. For example, guidance may be issued instructing LHDs to prioritize full

investigations of varicella cases to those known to involve congregate residential settings and conduct investigations of other varicella cases only to the extent that resources allow, or guidance may provide details about the extent of investigation for a case of chlamydia in a pregnant individual. Regarding the timing for when investigation must commence, the regulation would change "immediately" to "with all due speed" to account for the fact that there is a range of appropriate response times depending on the condition and situation. In addition, the regulation would add "as necessary" to the provision requiring the local health authority to examine various factors associated with places related to an investigation "with the training or assistance of the State Department of Health", to acknowledge that local health authorities will not always need training or assistance. Finally, the regulation would add "in consultation with the local health authority" to the provision stating that the Department shall determine the content and other characteristics of investigation updates, to acknowledge that the local health authority can provide valuable input.

COSTS:

Costs to Regulated Parties:

Although there are costs associated with disease investigation and response for any outbreak, these amendments merely clarify the existing authorities and responsibilities of local governments. As such, these amendments do not impose any substantial additional costs beyond what LHDs would incur in the absence of these amendments.

Further, making explicit the Department's authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments by reducing unnecessary investigatory

activities and allowing resources to be focused on investigations likely to have the greatest public health impact.

Costs to Local and State Governments:

Although there are costs associated with disease investigation and response for any outbreak, these regulations merely clarify the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what local health departments would incur in the absence of these regulations.

Further, making explicit the Department's authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments.

Paperwork:

These amendments do not require any additional paperwork.

Local Government Mandates:

Under existing regulation, LHDs already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments clarify these existing authorities and duties.

Duplication:

There is no duplication in existing State or federal law.

Alternatives:

The alternative would be to leave in place the current regulations on disease investigation. However, these regulatory provisions clarify the regulation and provide additional flexibility to LHDs, while ensuring appropriate responses are taken for communicable disease outbreaks.

Federal Standards:

States and local governments have primary authority for controlling disease within their respective jurisdictions. Accordingly, there are no federal statutes or regulations that apply to disease control within New York State.

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

Under existing regulation, local health departments (LHDs) already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments merely clarify these existing authorities and duties.

Compliance Requirements:

Under existing regulation, LHDs already have the authority and responsibility to take actions to control the spread of disease within their jurisdictions. The proposed amendments merely clarify these existing authorities and duties.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

Although there are costs associated with disease investigation and response for any outbreak, these regulations merely clarify the existing authorities and responsibilities of local governments. As such, these regulations do not impose any substantial additional costs beyond what LHDs would incur in the absence of these regulations being amended.

Further, making explicit the New York State Department of Health's ("the Department") authority to issue guidance that impacts investigation activities will result in a more appropriate allocation of resources, possibly resulting in a cost-savings for State and local governments.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

As the proposed amendments clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with regulated entities to ensure they are aware of the new regulations and have the information necessary to comply.

Small Business and Local Government Participation:

These proposed amendments to the regulation were previously discussed with the New York State Association of Counties Health Officials (NYSACHO) on three occasions and participants included both NYSACHO and LHD representatives. Discussions involved a detailed review of each of the submitted comments to the prior amendments adopted effective December 20, 2023 and a proposed approach to prioritize the initial scope of the regulatory amendments to incorporate the requested flexibility to prioritize investigation and response efforts at the local level, which is reflective of current practice and supported by both the Department and NYSACHO. These proposed amendments to the regulation are being proposed for permanent adoption, so all parties will have an opportunity to provide comments during the notice and comment period.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Estimated Numbers of Rural Areas:

While this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population, 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein."

The following 44 counties have a population of less than 200,000 based upon 2020 United States Census data:

Allegany County
Broome 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 10 counties have populations of 200,000 or greater, and towns with population densities of 150 persons or fewer per square mile, based upon the United States Census estimated county populations for 2020:

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

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

As the proposed regulations clarify existing responsibilities and duties among regulated entities and individuals, no additional recordkeeping, compliance requirements, or professional services are expected.

Compliance Costs:

As the proposed regulations clarify existing responsibility and duties among regulated entities and individuals, no initial or annual capital costs of compliance are expected above and beyond the cost of compliance for the requirements currently in 10 NYCRR Part 2.

Minimizing Adverse Impact:

As the proposed amendments to the regulations clarify existing responsibility and duties among regulated entities and individuals, any adverse impacts are expected to be minimal. The Department, however, will work with local health departments (LHDs) to ensure they are aware of the new regulations and have the information necessary to comply.

Rural Area Participation:

These proposed amendments to the regulations are being proposed for permanent adoption, so all parties will have an opportunity to provide comments during the notice and comment period.

JOB IMPACT STATEMENT

The Department of Health has determined that this regulatory change will not have a substantial adverse impact on jobs and employment, based upon its nature and purpose.

SUMMARY OF EXPRESS TERMS

This regulation amends Title 10 of the Codes, Rules, and Regulations of the State of New York by adding a new Subpart 98-5 and will be effective upon publication of a Notice for Adoption in the New York State Register.

The proposed regulations implement a new licensure requirement for the Program of All-Inclusive Care for the Elderly (PACE) program under Article 29-EE of the Public Health Law requiring the Commissioner of Health to develop regulations for a unified licensure process for PACE organizations that includes the applicable program requirements of this article and Articles 28, 36 and 44 of the Public Health Law.

The regulations specifically provide the criteria for the establishment application process for the newly developed Article 29-EE PACE program including: the criteria needed to submit or make amendments or modifications to PACE applications, the criteria for an applicant withdrawing and abandoning a PACE application, the criteria for revocation, limitation or annulment of approvals of establishment and decision-making process, the criteria for determining if a PACE program is operating a Diagnostic and Treatment Center, and the responsibilities of the governing authority of a PACE program.

The following is a summary of the amendments to the Department's regulations which creates a new Subpart: 98.5 – Programs of All Inclusive Care for the Elderly (PACE):

- **Section 98-5.1** establishes the new PACE program. A PACE organization lawfully operating at the time this Subpart takes effect may continue to operate while the PACE organization transitions into full compliance with Articles 29-EE and this Subpart. All pending applications for PACE-related programs currently under review by the

Department under Article 29-EE, Article 28, Article 36 and Article 44 shall automatically be reviewed for compliance with this section at the time this Subpart is adopted.

Further, this section lists the criteria that PACE programs must comply with and provides the Commissioner of Health the authority to establish a uniform licensure process for the newly formed PACE organizations and that any license granted requires the approval of the Public Health and Health Planning Council (PHHPC).

- **Section 98-5.2** defines certain terms in the Subpart.
- **Section 98-5.3** outlines the criteria for the application process for Article 29-EE PACE licenses.
- **Section 98-5.4** outlines the requirements for approval of a PACE license.
- **Section 98-5.5** outlines the requirements to revise, amend, or modify a PACE licensure application.
- **Section 98-5-6** outlines the requirements to withdraw or abandon a PACE licensure application and what processes will be taken if an applicant fails to satisfy contingencies.
- **Section 98-5.7** outlines the procedures for the revocation, limitation, or annulment of approvals for establishment of PACE licenses.
- **Section 98-5.8** outlines the procedures for necessary hearings conducted by PHHPC, a committee of the Council, a person designated by the Council, or the Department related to PACE licenses.
- **Section 95-5.9** outlines how decisions of PHHPC on PACE licensure applications will be disseminated.
- **Section 98-5.10** outlines the criteria for determining the operation of a diagnostic and treatment center for PACE programs.

- **Section 98-5.11** outlines the criteria for the governing authority or operator of a PACE program licensed under Article 29 EE.
- **Section 98-5.12** outlines the procedures for agents, nominees, and fiduciaries for the new PACE program.
- **Section 98-5.13** outlines the procedures for name-of-purpose changes of operators and medical facilities related to PACE programs.

Pursuant to the authority vested in the Commissioner of Health by Section 2999-u of the Public Health Law, and the authority vested in PHHPC, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Subpart 98-5 within Subchapter R, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Subpart 98-5 is added to read as follows:

SUBPART 98-5. Program of All-Inclusive Care for the Elderly (PACE)

Section 98-5.1 PACE Program Established.

(a) The program of all-inclusive care for the elderly (PACE) is established in the department to provide community-based, risk-based, and capitated long-term care services as optional services under Medicaid and, where applicable, under Medicare, as well as under contracts among Centers for Medicare and Medicaid Services (CMS), the department, and PACE organizations.

(b) A PACE organization lawfully operating at the time this Subpart takes effect may continue to operate while the organization transitions into full compliance with this section under a process and requirements established by the department. Such requirements will take effect 180 days after the effective date of this Subpart.

(c) For purposes of existing contractual obligations of PACE organizations currently established under articles 28, article 36 and article 44 of the Public Health Law, a PACE program may continue to be established if the organization notifies the department of its intention to do so in writing within 30 days following the effective date of this section. Such approval is at the discretion of the department based on criteria set forth by the commissioner. Any material change (such as, but not limited to, change in current PACE-related services, current location, or change in any of the established operators) to the makeup and composition of the PACE program

under this section will automatically trigger requirements for licensure of the PACE organization under article 29-ee of the Public Health Law.

(d) All pending applications for PACE-related programs currently under review under article 28, article 36 and article 44 of the Public Health Law shall automatically be reviewed for compliance with this section at the time this Subpart is adopted for licensure under article 29-ee of the Public Health Law.

(e) Any new PACE program pursuant to article 29-ee of the Public Health Law or a PACE program currently established (prior to enactment of article 29-ee of the Public Health Law) shall comply with this section except for those PACE programs that qualify under section 98-5.1(c) of this Subpart.

(f) A PACE organization under this section must:

(1) Comply with applicable federal law and regulations, 42 USC §1396u-4 and 42 CFR part 460, respectively. The statute at 42 USC §1396u-4 is contained Title 42 of Supplement 4 of the United States Code, the 2006 Edition. The regulations at 42 CFR part 460 are contained in volume 42 of the Code of Federal Regulations, Public Health, at part 460 (42 CFR part 460), 1984 edition. Both are published by the Office of the Federal Register National Archives and Records Service, General Services Administration. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office Washington, DC 20402. Both 42 USC §1396u-4 and 42 CFR part 460 are available for public inspection and copying at the Records Access Office, New York State Department of Health, Corning Tower Building, Empire State Plaza, Albany, NY 12237.

(2) Provide a PACE program or facilities at which primary care and other services are furnished to enrollees.

(3) Provide an interdisciplinary team approach to care management, care delivery, and care planning.

(4) Unless specifically enumerated in this section, comply with this section and the applicable provisions of articles 29-ee, and if relevant, articles 28, 36 (if not already contracted with an article 36 licensed entity for home care services), and 44 of the Public Health Law.

(5) Enter into a PACE organization contract and agreement with the department and CMS.

(g) (1) A PACE organization shall serve an approved geographic service area as determined by the department.

(2) (i) A PACE organization and its incorporators, directors, sponsors, stockholders, members, and operators shall have the experience, competence, and standing in the community as to give reasonable assurance of their ability to operate the organization to provide a consistently high level of care for enrollees and comply with this section.

(ii) A PACE organization shall demonstrate that where any incorporator, director, sponsor, stockholder, member, or operator of the organization holds, or within the past 10 years has held, a controlling interest or been a controlling person in a PACE program licensed under this Chapter or outside the State of New York, a consistently high level of care has been rendered in each such organization.

(iii*)* A PACE organization shall demonstrate that where any incorporator, director, sponsor, stockholder, member, or operator of the organization facility holds, or within the

past 10 years has held, a controlling interest in any other entity providing health-related or senior services inside or outside the State of New York, a consistently high level of care has been rendered in each such organization or facility.

(3) A PACE organization shall meet requirements for financial solvency under paragraph (c) of subdivision 1 of section 4403 of the Public Health Law, including a contingent reserve requirement as developed by the commissioner.

(4) A PACE organization shall be deemed to be a health maintenance organization under article 44 of the Public Health Law for purposes of subdivision 1 of section 6527 of the Education Law.

(h) (1) A unified licensure process for PACE organizations is hereby established that includes the applicable program requirements of article 29-ee of the Public Health Law, and, if not noted in this section, the provisions found in articles 28, 36 and 44 of the Public Health Law shall apply.

(2) A license under this Subpart shall require approval of the Public Health and Health Planning Council (PHHPC) and CMS.

(3) Any part of the PACE application that is approved by PHHPC is considered contingently approved until such time as all components of the PACE application are finally approved in writing by CMS which confers the final approval to become a PACE organization.

(4) A PACE application can be submitted at any time to the department during a calendar year. The separately required CMS application may only be submitted based on the quarterly submission schedule, or any other scheduled timeframes, issued by CMS and only after the department has officially issued the *State Attestation and Assurances*. An

applicant that has received an executed *State Attestation and Assurances* document must notify the department within 10 business days upon filing their CMS application.

Section 98-5.2 Definitions.

(a) *Application* shall mean all or a part of the application for PACE licensure as defined in section 29-ee of the Public Health Law.

(b) *Council* shall mean the New York State Public Health and Health Planning Council or PHHPC, the body set forth in section 225 of the Public Health Law.

(c) *CMS* shall mean the federal Centers for Medicare and Medicaid Services

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

(e) *Health maintenance organization* or *HMO* shall have the same meaning as defined in article 44 of the Public Health Law unless otherwise noted in this section.

(f) *Hospital* shall have the same meaning as defined in article 28 of the Public Health Law unless otherwise noted in this section.

(g) *Interdisciplinary team* shall have the same meaning as found in section 42 CFR 460.102 unless otherwise noted.

(h) *Medicaid* shall mean the program established pursuant to title 11 of article 5 of the Social Services Law and the program thereunder.

(i) *Medicare* shall mean the program established by the federal government pursuant to title XVIII of the Federal Social Security Act and the programs thereunder.

(j) *PACE services* shall mean those services defined by CMS as all Medicare Part A, Part B, and Part D services along with all Medicaid state plan covered services as determined appropriate by the Interdisciplinary Team.

Section 98-5.3 Applications for uniform licensure to the PACE program.

(a) The department will develop a unified PACE license application which will consist of three parts:

(1) health maintenance organization, newly licensed under this Subpart;

(2) hospital, newly licensed under this section; and

(3) proof that a home care agency licensed or certified pursuant with defined criteria under article 36 of the Public Health Law is either newly licensed under this Subpart for the proposed PACE program, or the proposed PACE program plans to contract with an already existing home care provider currently licensed under article 36 of the Public Health Law.

(b) An application to CMS must be accompanied by a fully executed *State Attestation and Assurance*s document indicating that the council considers the entity qualified to be a PACE organization and is willing to enter into a three-way agreement with the PACE program upon final approval of the application by both the council and CMS. This document will also clearly define the applicant's proposed geographic service area, consistent with both the applicant's State and CMS applications.

(c) (1) An application shall be in writing on forms provided by the department and subscribed by the chief executive officer (or other officer duly authorized by the applicant) of the proposed PACE program or, where an application is to be submitted by a local governmental applicant, the president or chairperson of the board of the proposed PACE program or the chief executive officer if there is no board; and accompanied by a certified copy of a resolution of the board of a corporate applicant authorizing the undertaking which is the subject of the application, and the subscribing and submission thereof by an appropriate designated individual. In the event that an

application is to be submitted by an entity which necessarily remains to be legally incorporated it shall be subscribed and submitted by one of the proposed stockholders or directors. If a local governmental applicant submitting an application has not designated a president, chairperson or chief executive officer for the proposed facility, the application shall be subscribed by the chairperson or president of the local legislature or board of supervisors having jurisdiction, or other appropriate executive officer. An original application and two copies thereof shall be prepared. The original shall be filed with the council through submission to the PACE project management unit in the department's Office of Aging and Long Term Care in Albany, New York, or by such means as determined by the commissioner.

(2) Applications shall contain information and data with reference to:

(i) the justification for the existence of the proposed PACE program at the time and place and under the circumstances proposed for use in a specific PACE program;

(ii) the character, experience, competency, and standing in the community of the proposed incorporators, directors, stockholders, sponsors, individual operators, or partners;

(iii) the financial resources and sources of future revenue of the proposed PACE program to be operated by the applicant as defined in article 29-ee of the Public Health Law;

(iv) the fitness and adequacy of the premises and equipment to be used by the applicant for the proposed facility;

(v) the following documents shall be filed:

(a) a certified copy of the applicant's certificate of doing business;

(b) where the applicant is a partnership, full and true copies of all partnership agreements, which shall include the following language:

"By signing this agreement, each member of the partnership created by the terms of this agreement acknowledges that the partnership and each member thereof has a duty to report to the New York State Department of Health any proposed change in the membership of the partnership. The partners also acknowledge that the prior written approval of the Public Health and Health Planning Council and the New York State Department of Health is necessary for such change before such change is made, except that a change resulting from an emergency caused by the severe illness, incompetency or death of a member of the partnership shall require immediate notification to the New York State Department of Health of such fact and application shall be made for the approval by both the Public Health and Health Planning Council and the New York State Department of Health of such change within 30 days of the commencement of such emergency. The partners also acknowledge that they shall be individually and severally liable for failure to make the aforementioned reports and/or applications."; and

(c) any additional information or documents which may be requested by the council.

(3) Each application shall include an application fee of $2,000 in addition to the fee described in section 2802 of the Public Health Law due upon submission of application. All fees pursuant to this paragraph shall be payable to the Department of Health for deposit into the Special Revenue Funds - Other, Miscellaneous Special Revenue Fund - 339, Certificate of Need Account.

(4) Any person filing a proposed certificate of incorporation or an application for licensure shall file with the commissioner information regarding the property interests in such facility, including the following:

(i) the name, address, and a description of the interest held, or proposed to be held, by each of the following persons:

(a) any person who, directly or indirectly, beneficially owns an interest in the land on which the proposed PACE program premises is located;

(b) any person who, directly or indirectly, beneficially owns any interest in the building in which the proposed PACE program is located;

(c) any person who, directly or indirectly, beneficially owns any interest in any mortgage, note, deed of trust or other obligation secured in whole or in part by the equipment used in the facility, or by the land on which or the building in which the proposed PACE program is located;

(d) any person who, directly or indirectly, has any interest as lessor or lessee in any lease or sublease of the land on which or the building in which the proposed PACE program is located; and

(e) any person who, directly or indirectly has any interest as a lessor or lessee in any lease or sublease of the equipment used in the building in which the proposed PACE program is located;

(ii) if any person named in response to subparagraph (i) of this paragraph is a partnership, then the name and address of each partner;

(iii) if any person named in response to subparagraph (i) of this paragraph is a corporation, other than a corporation whose shares are traded on a national securities

exchange or are regularly quoted in an over-the-counter market or which is a commercial bank, savings bank or savings and loan association, then the name and address of each officer, director, stockholder and, if known, each principal stockholder and controlling person of such corporation;

(iv) any additional information and documents which may be requested by the council.

Section 98-5.4 Requirements for Approval.

(a) The application must be complete and in proper form. It shall provide all the scope and organization of services defined by CMS for a PACE plan and all information essential for the council's and the department's consideration.

(b) The applicant must satisfactorily demonstrate to the council:

(1) that there is a justification for the proposed PACE program. All applicants must demonstrate in their application that the PACE services provided by the proposed PACE program will be an organized and comprehensive program. The department may exclude from designation an application's proposed geographic service area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing PACE program;

(2) (i) if a nonprofit corporation, that the members of the board of directors and the officers of the corporation are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation in its best interests and in the public interest and so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(ii) if a proprietary business, that the owner, or all the partners, if a partnership, are persons of good moral character with the experience, competence and standing as to give reasonable assurance of their ability to operate the business so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(iii) if a business corporation, that the members of the board of directors, the officers and the stockholders of the corporation are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the corporation so as to provide proper care for the patients or residents to be served by the proposed PACE program;

(iv) if a limited liability company, that the members, managers, and officers of the company, are of such character, experience, competence, and standing as to give reasonable assurance of their ability to conduct the affairs of the company so as to provide proper care for the patient or residents to be served by the proposed PACE program;

(3) that there are adequate finances to properly establish and conduct the proposed PACE program for purposes of this section, including:

(i) all sources of capital;

(ii) all audited financial statements of all holding companies, related parties, and principals;

(iii) financial projections that identify the medical loss ratio and administrative overhead in line with industry standards;

(iv) the ability of the applicant to project financial viability;

(v) the ability of the applicant to meet reserved requirements defined in Part 98 of this Title; and

(vi) templates or contracts to meet all administrative and management services requirements;

(4) that with respect to an applicant who is already, or within the past 10 years has been, an incorporator, director, sponsor, stockholder, member, controlling person, principal stockholder, principal member, or operator of any PACE program or other entity providing health-related or senior services in New York as specified in paragraph (b) of subdivision (3) of section 2801-a of the Public Health Law or any other jurisdiction outside the State of New York, a substantially consistent high level of care has been rendered in each such PACE program or other entity providing health-related or senior services, with which the applicant is or has been affiliated.

(i) In reaching this determination, the council shall consider findings of PACE program or any other heath facility related inspections, including but not limited to title XVIII and XIX of the Social Security Act and any relevant article 28, article 36, or article 29-ee survey findings that pertain to violations of this Chapter, routine and patient abuse complaint investigation results, and other available information. The council's determination that a substantially consistent high level of care has been rendered shall be made after evaluating such information, with the following criteria: the gravity of any violation, the manner in which the applicant/operator exercised supervisory responsibility over the proposed PACE program operation, or other entity providing health-related or senior services, and the remedial action, if any, taken after the violation was discovered.

(a) In evaluating the gravity of the violation, the council shall consider whether the violation threatened, or resulted in direct, significant harm to the health, safety or welfare of patients/residents.

(b) In evaluating the manner in which the applicant/operator exercised supervisory responsibility over the proposed PACE program operation, or other entity providing health-related or senior services, the council shall consider whether a reasonably prudent individual of the applicant/operator should have been aware of the conditions which resulted in the violation and/or was notified about the conditions which resulted in the violation.

(c) In evaluating any remedial action taken, the council shall consider whether the applicant/operator investigated the circumstances surrounding the violation and took steps which a reasonably prudent applicant/operator would take to prevent the reoccurrence of the violation.

(ii) When violations were found which either threatened to directly affect patient/resident health, safety, or welfare, or resulted in direct, significant harm to the health, safety or welfare of patients/residents, there shall not be a determination of a substantially consistent high level of care if the violations were recurrent or were not promptly corrected.

(a) A violation is recurrent if it has the same root cause as a violation previously cited within the last 10 years.

(b) A violation is not promptly corrected if a plan of correction has not been submitted to the department within 10 calendar days of the issuance of the *Statement of Deficiencies (Form CMS-2567),* and the PACE program, or other entity providing

health-related or senior services has failed to provide an acceptable date of compliance based on the violation(s) requiring correction.

(c)(1) The applicant must supply any additional documentation or information requested by the council or the department within 30 days of such request, or must obtain from the council or the department, an extension of the time to provide such documentation or information which is requested during the review of the application. Any request for an extension of time shall set forth reasons why such documentation or information could not be obtained within the prescribed time. The granting of a request for an extension shall be at the discretion of the council or the department. Failure to provide such documentation or information within the time prescribed or as extended by the council or the department, shall constitute an abandonment or withdrawal of the application without any further action by the council or department.

(2) The applicant must supply any authorization the council or the department requests in order to verify any documentation or information contained in the application or to obtain any additional documentation or information which the council or department finds is pertinent to the application. Failure to provide such authorization shall constitute an abandonment or withdrawal of the application without any further action by the council or department.

(d) Whenever any applicant proposes to lease premises in which the operation of a hospital as defined in section 2801 of the Public Health Law is to be conducted, the lease agreement shall include the following language:

"The landlord acknowledges that their rights of reentry into the premises set forth in this lease do not confer on them the authority to select or install an operator or to operate a hospital as defined in article twenty-eight or article twenty-nine-ee of the Public Health Law on the premises and agrees that they will give the New York State Department of Health, Center for Long Term Care

Licensure, Planning and Finance, Office of Aging and Long Term Care, New York State Department of Health, Empire State Plaza, Albany, N.Y. 12237, notification by certified mail of their intent to reenter the premises or to initiate dispossess proceedings or that the lease is due to expire, at least 30 days prior to the date on which the landlord intends to exercise a right of reentry or to initiate such proceedings or at least 60 days before expiration of the lease.

Upon receipt of notice from the landlord of their intent to exercise his right of reentry or upon the service of process in dispossess proceedings and 60 days prior to the expiration of the lease, the tenant shall immediately notify by certified mail to the Center for Long Term Care Licensure, Planning and Finance, New York State Department of Health, Office of Aging and Long Term Care, Empire State Plaza, Albany, NY 12237, of the receipt of such notice or service of such process or that the lease is due to expire."

(e) No lease covering the premises in which the operation of a hospital as defined in article 29-ee or, if relevant, 28 of the Public Health Law may contain any provision whereby rent, or any increase therein, is based upon the Consumer Price Index, or any other cost-of-living index, except:

(1) Leases for outpatient facilities and premises leased solely for administrative purposes may contain cost-of-living index rent determination or adjustment provisions, provided the following conditions are met:

(i) the lease is reviewed and approved by the department;

(ii) the space rented is in a multi-purpose, multi-use building not constructed specifically for the purpose of housing an outpatient proposed PACE program;

(iii) the rental, if the lease is a sublease, is the same or less than the rental in the overlease;

(iv) the applicant has no interest, direct or indirect, beneficial or of record, in the ownership of the building or any overlease; and

(v) the rental per square foot, in the judgement of the department, is the same as or is comparable to other rentals in the building in which the outpatient service or administrative space is to be located, and the rental per square foot is comparable to the rental of similar space in other comparable buildings in the area when such comparisons can be made.

(2) In addition to the exception set forth in paragraph (1) of this subdivision, in the event the lease covering hospital premises contains provisions whereby it is the lessor's responsibility to pay necessary expenses associated with such premises, such as real estate taxes, utilities, heat, insurance, maintenance and operating supplies, such lease may contain provisions which allow adjustments to the rent only to the extent necessary to compensate for changes in such expenses.

Section 98-5.5 Revisions, Amendments, and Modifications to Applications.

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

(1) *Amendment* shall mean a change to an application which has been approved or contingently approved by the council but for which an operating certificate has not been issued, and meets the criteria contained in subdivision (c) of this section.

(2) *Modification* shall mean a change to an application which has been approved or contingently approved by the council for which an operating certificate has not been issued and does not meet the criteria contained in subdivision (c) and is approvable pursuant to subdivision (e) or meets the criteria in subdivision (d) of this section.

(3) *Revision* shall mean a change to an application which has not been approved or contingently approved before the council.

(4) *Total basic cost of construction* means total project costs less the capitalized amount of construction loan interest and financing fees.

(5) *Total project cost* means total costs for construction, including but not limited to costs for demolition work, site preparation, design and construction contingencies, total costs for real property, for fixed and movable equipment, architectural and/or engineering fees, legal fees, construction manager and/or cost consultant fees, construction loan interest costs, and other financing, professional and ancillary fees and charges. If any asset is to be acquired through a leasing arrangement, the relevant cost shall be the cost of the asset as if purchased for cash, not the lease amount.

(b) Revisions: changes prior to council approval. An application made to the council pursuant to this Subpart, may be changed before the council has approved or contingently approved the application, which shall constitute a revision as defined in this section. Such revisions shall be made on appropriate forms supplied by the department and submitted to the council through the PACE project management unit in the department's Office of Aging and Long Term Care in Albany and shall be governed by the following:

(1) any change in the information contained in the original application must be accompanied by a satisfactory written explanation as to the reason such information was not contained in the original application;

(2) when reviewing a competitive batch of applications, the department, acting on behalf of the council, may establish deadlines pursuant to written notification for the submission of any change to an application; and

(3) if a change is submitted after any such deadline(s), the application shall be removed from consideration within the competitive batch being reviewed.

(c) Amendments. An application made to the council pursuant to this Subpart may be changed after the council has approved or contingently approved an application but prior to the issuance of an operating certificate. For any amendment which changes the information set forth in paragraphs (1) through (3) of this subdivision, the applicant shall submit the proposed amendment, to the council, with appropriate documentation explaining the reason(s) for the amendment and such additional documentation as may be required in support of such amendment to the council for their reevaluation and recommendations. The approval of the council must be obtained for any such amendment including the following:

(1) a change in the number and/or type of services, other than a reduction in service which would be subject to an administrative review;

(2) a change in the location of the site of the construction if outside the facility's service area or adjacent service areas; and

(3) any change in the applicant.

(d)(1) If the commissioner, acting on behalf of the council determines that increases in total project costs or total basic costs of construction are due to factors of an emergency nature such as labor strikes, fires, floods, or other natural disasters or factors beyond the control of the applicant, or modifications to the architectural aspects of the application which are made on the recommendation of the department, the applicant may proceed without the need for the application to be referred back to the council and the department.

(2) If the applicant can document by evidence acceptable to the commissioner, acting on behalf of the council, that increases in total project cost or total basic cost of construction were caused by delays in obtaining zoning or planning approvals which were beyond its control, the commissioner may permit review of the application to proceed without the need

for the application to be referred back to the council and the department pursuant to this Subpart. The evidence shall demonstrate clearly that the applicant had timely pursued the zoning or planning permits, has now obtained all such required permits and approvals, and is prepared to proceed with the project.

(3) If the applicant can document by evidence acceptable to the commissioner, acting on behalf of the council, that increases in the total basic cost of construction were caused by inflation in excess of that estimated and approved in the application and that such inflation has affected the total basic cost of construction as a result of delays which were beyond the applicant's control, the commissioner may permit review of the application to proceed without the need for the application to be referred back to the council and the department, pursuant to this Subpart. The evidence shall demonstrate clearly that the increase in inflation exceeds that estimated and approved in the application, and that any delays resulting in such inflationary cost increases were beyond the applicant's control.

(e) Any modification submitted subsequent to the issuance of any approval by the council, which does not constitute an amendment pursuant to subdivision (c) of this section shall require only the prior approval of the commissioner.

(f) Failure to disclose an amendment as described in subdivision (c) of this section prior to the issuance of an operating certificate shall constitute sufficient grounds for the revocation, limitation, or annulment of the approval of licensure.

Section 98-5.6 Withdrawals or abandonment of applications and failure to satisfy contingencies.

(a) An application made to the council and the department in accordance with this Subpart may, on written request of the applicant, be withdrawn prior to decision by the council at any time without prejudice to resubmission. Such resubmission shall be considered a new application.

(b) The failure, neglect, or refusal of an applicant to submit documentation or information, within the stated time frame, to satisfy a contingency imposed by the council and the department in conjunction with the council's or the department's proposal to approve an application shall constitute and be deemed an abandonment or withdrawal of the application by the applicant without the need for further action by the council and the department.

(c) When an applicant submits documentation or information, within the stated time frame, in an attempt to satisfy a contingency imposed by the council but the department, on behalf of the council, does not consider the documentation or information sufficient to satisfy the contingency, the application may be returned to the council for whatever action the council deems appropriate.

Section 98-5.7 Revocation, limitation, or annulment of approvals of licensure.

(a) An approval of licensure may be revoked, limited, or annulled by the council or the department if the council or the department finds:

(1) that the licensed operator employed fraud or deceit, as determined by the department (such as, but not limited to, information from a conviction, civil suit, or an investigation by a government agency), in procuring such approval of licensure or has made statements or furnished information in support of the application which were not true, accurate, or complete in any material respect;

(2) that the operating certificate of a hospital or PACE program has been revoked, limited, or annulled pursuant to the applicable provisions of law;

(3) that a PACE program or hospital caused or allowed a patient to be subjected to violence or abuse by an employee, consultant, volunteer, or other person serving in any capacity in the hospital or that a hospital has failed to comply with the relevant provisions of article 29-ee, article 28, article 36, or article 44 of the Public Health Law or the rules and regulations promulgated thereunder;

(4) that the licensed operator has had such a change in his financial condition or in the fiscal aspects of the proposed institution since the approval of licensure as to render the project economically unfeasible or render unsatisfactory the financial resources of the proposed institution and its sources of future revenue;

(5) that the licensed operator has been convicted in a court of competent jurisdiction, of a relevant crime, as determined by the commissioner. Such crimes may entail fraud, theft, falsifying an instrument, or any crime that affects patient safety;

(6) that the licensed operator has transferred his ownership interest in the operation of the PACE program without council approval and department approval, and that such person has terminated his participation in the operation of the PACE program;

(7) that there has been a violation of section 610.4(a) of this Title;

(8) that the licensed operator has granted any person convicted of a crime relating to PACE program, hospital, Medicaid, Medicare, or HMO activities the authority to direct or cause the direction of the operations, management, or policies of the PACE program;

(9) that the licensed operator has failed to comply fully with any condition, limitation, or other requirement imposed as part of, or in conjunction with, the approval of licensure; or

(10) that the applicant has failed to commence and complete construction within the time period determined under Part 710 of this Title.

(b) For purposes of this section, licensed operator shall include any person, partnership, or partner thereof, company and its members, and any corporation or stockholder, officer or director thereof, actual or proposed, whose application for licensure has been approved, regardless of whether an operating certificate has been issued.

Section 98-5.8 Decisions.

Copies of the resolution of the council approving or disapproving an application shall be transmitted to the commissioner.

Section 98-5.9 Governing authority or operator.

(a) The governing authority or operator is the party responsible for the operation of a medical facility.

(b) The governing authority or operator shall mean:

(1) the policy making body of a government agency;

(2) the board of directors or trustees of a not-for-profit corporation;

(3) the officers, directors and stockholders of a business corporation;

(4) the proprietor or proprietors of a proprietary medical facility; and

(5) the members of a limited liability company.

(c) An individual, partnership or corporation which has not received establishment approval pursuant to articles 28, 36, and 44 of the Public Health Law or licensure pursuant to article 29-ee of the Public Health Law, may not participate in the total gross income or net revenue of a medical facility.

(d)(1) Except as provided in section 405.3 of this Title, the governing authority or operator may not contract for management services with a party which has not received establishment or licensure approval.

(2) The criteria set forth in this paragraph shall be used in determining whether there has been an improper delegation to a contracting entity or individual by the governing authority or operator of its responsibilities. The governing authority shall not delegate the following elements of management authority:

(i) authority to hire or fire the administrator or other key management employees;

(ii) maintenance and control of the books and records;

(iii) authority over the disposition of assets and the incurring of liabilities on behalf of the PACE program;

(iv) the adoption and enforcement of policies regarding the operation of the facility; or

(v) regular review and oversight of the contracting entity or individual activities.

(3) The criteria set forth in paragraph (2) of this subdivision shall not be the sole determining factors of an improper delegation, but indicators to be considered with such other factors that may be pertinent in particular instances.

(4) Professional expertise shall be exercised in the utilization and analysis of the criteria. All of the listed criteria need not be present in a given instance for there to be an improper delegation of authority.

Section 98-5.10 Agents, nominees, and fiduciaries.

(a) Agents, nominees, and fiduciaries, whether testamentary or inter vivos, shall not be considered proper applicants for licensure, transfer of interest, or transfer of stock of a PACE program except that the following persons may apply for licensure approval in accordance with and subject to the requirements and conditions set forth in relevant portions outlined in article 29-ee, and if relevant, article 28, article 36, and article 44 of the Public Health Law:

(1) a natural person appointed as trustee of an express testamentary trust created by a deceased sole proprietor, partner, or shareholder in the operation of a hospital for the benefit of a person less than 25 years of age; or

(2) a natural person appointed conservator pursuant to article 77 of the Mental Hygiene Law or a natural person appointed committee of the property of an incompetent pursuant to article 78 of the Mental Hygiene Law or a sole proprietor, partner, or shareholder of a hospital, with respect to a hospital owned by a conservatee or incompetent person.

Section 98-5.11 Name changes or purpose changes of operators and medical facilities.

(a) Any change in the following shall require the prior approval of the council and the department, in accordance with the requirements of this section, section 98-5.5 of this Subpart, and any other applicable requirements of law:

(1) the name of a not-for-profit corporation operating a PACE program under article 29-ee, or, if relevant, article 28 of the Public Health Law or the not-for-profits purposes thereof;

(2) the name of a not-for-profit corporation authorized to solicit contributions for the establishment, licensure, or maintenance of any hospital pursuant to article 29-ee or article 28 of the Public Health Law;

(3) the assumed name of a sole proprietor or a not-for-profit corporation operating a PACE program under article 29-ee or, if relevant, article 28 or article 36 of the Public Health Law or of a not-for-profit corporation authorized to solicit contributions for the establishment, licensure, or maintenance of any hospital pursuant to article 28 of the Public Health Law, whenever the prior assumed name was approved by the council or its predecessor; and the department and;

(4) the name or assumed name of a business corporation, partnership, or governmental subdivision operating a PACE program under article 29-ee and, if relevant article 28, article 36, and article 44 of the Public Health Law whenever the prior name or prior assumed name was approved by the council and the department.

(b) Applicants requesting council and the department approval of a change of name or assumed name shall submit a written request to the executive secretary of the council, and the Office of Aging and Long Term Care at the department's central office in Albany, which shall include the following information and documentation as appropriate:

(1) a letter specifying the current and proposed names and explaining the nature of and the reasons for the requested name or purpose of change;

(2) a photocopy of the executed proposed certificate of amendment for the certificate of incorporation or articles of organization, as appropriate, certificate of authority to conduct business in the State of New York, or certificate of conducting business under an assumed name; and,

(3) such other pertinent information and documents necessary for the council's and department’s consideration, as requested.

(c) Whenever the name of a business corporation, partnership, limited liability company, or governmental subdivision, or the assumed name of a business corporation, not-for-profit corporation, partnership, limited liability company, governmental subdivision, or sole proprietor operating a PACE program or fundraiser under article 29-ee or, if relevant, article 28, and article 36, of the Public Health Law was not specifically approved by the council and the department, any proposed change in said name or assumed name or initial use of an assumed name shall not

require the approval of the council but shall require the approval of the department in accordance with section 401.3 of this Title.

(d) The approval of the council and the department of a proposed name or assumed name or purposes may be withheld if the proposed name or assumed name or purposes indicates or implies that the corporation, partnership, limited liability company, governmental subdivision, or individual is authorized to engage in activities for which it is not authorized, provide a level of care it is not authorized to provide, is misleading, causes confusion with the identity of another facility, or violates any provision of the law.

(e) An approved name change under this Subpart is deemed a material change under 98-5.1(c) of this Subpart.

(f) Nothing contained within this section shall limit the authority of the council and the department to approve or disapprove the initial use of a name or assumed name for a not-for-profit corporation, business corporation, partnership, limited liability company, governmental subdivision, or sole proprietor when such name or assumed name is before the council and the department as part of an application for the establishment or licensure of a PACE program or fundraiser.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority for the new Subpart 98-5 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York is Article 29-EE of the Public Health Law which authorizes the Department of Health (Department), subject to approval of the Commissioner to develop regulations for the new Program of All-Inclusive Care of the Elderly (PACE) licensure process.

Legislative Objectives:

The legislative objective of Article 29-EE is to create a streamlined single application process for the Program of All-Inclusive Care of the Elderly (PACE) programs.

PACE is a federally recognized model of provider-sponsored, comprehensive care for persons 55 years of age or older who are otherwise eligible for nursing home admission. The PACE program fully integrates, coordinates, and pays for the continuum of Medicare and Medicaid-covered services to enable individuals with long-term care needs to live safely in the community.

This legislative objective is to streamline the regulation of PACE programs by developing a consolidated and uniform authorization process, encompassing all program requirements into singular licensure, and improve oversight of PACE organizations.

These changes maintain the same level of oversight of all PACE programs that exist today across all program areas.

Needs and Benefits:

The regulations are needed to comply with a new statutory provision, Article 29-EE of the Public Health Law, which creates a new licensure category for the Program of All-Inclusive Care of the Elderly (PACE) program. PACE programs are established to provide community-based, risk-based, and capitated long-term care services as optional services under Medicaid and, when applicable, under Medicare as well as under contracts among CMS, the Department, and PACE organizations.

Specifically, these regulations are required under Section 2999-u of the Public Health Law which states that the Commissioner of Health "shall establish in regulation" a unified licensure process for PACE organizations that includes the applicable program requirements of Article 29-EE, Articles 28, 36, and 44 of the Public Health Law.

PACE programs directly provide medical care, home health care, and social support services (typically at a PACE Center), unlike partially capitated managed long-term care (MLTC) plans that only provide certain Medicaid-covered long-term services and supports. PACE programs provide over 5,900 New Yorkers with the opportunity to remain safely in their communities and improve their quality of life, while also effectively controlling healthcare expenditures. Nationwide, PACE participants have shown reduced hospitalizations, readmissions, and reliance on emergency medical services, along with improved quality of life and higher satisfaction with their care. Yet, New York pays PACE programs less than the cost of caring for a comparable population through other Medicaid services, including nursing homes and MLTC programs.

However, PACE organizations operate in a confusing and complicated regulatory structure which hinders their ability to expand and further development of PACE programs in

New York. Statutory reforms were made to eliminate barriers to the development, expansion, and efficient operation of PACE programs in New York while preserving vitally important protections to those receiving services.

Currently, PACE organizations in New York must be licensed as MLTC plans, clinics, and licensed home care agencies (under Articles 44, 28, and 36 of New York's Public Health Law, respectively). This has created an administratively burdensome authorization process, which has limited the expansion of this critical product and does not reflect its unique role in the healthcare system.

There are several benefits to creating a uniform PACE licensure structure within the Department. The regulation will streamline the licensure and establishment of PACE programs by developing a uniform authorization process, encompassing all program requirements into a singular licensure which will assist in improving oversight of PACE organizations.

These changes maintain the same level of oversight of all PACE programs that exist today across all program areas.

Both nationally and here in New York, PACE programs have demonstrated the ability to allow individuals to reside safely in their communities for longer, improve their quality of life and deliver a high satisfaction with their care. Contrary to costing the State money, PACE programs deliver this desired level of care for elderly individuals for less than the cost of caring for a comparable population through other Medicaid services.

COSTS:

Costs to regulated parties:

This regulation will reduce the costs for regulated parties. Instead of three separate application fees, there will only be a single application to prepare and submit in addition to the

capital construction fee in Section 2802 of the Public Health Law. Outside of the unified and reduced standard application processing fee of $2000 dollars, it is not expected that any new compliance costs will be associated with this rule. Under the current three license tier structure there is an Article 28 Diagnostic and Treatment Center Certificate of Need filing fee of $2,000 and an additional $2,000 filing fee for any Article 36 Licensed Home Care Agency Certificate of Need. There is no filing fee associated for an Article 44 Managed Long Term Care application.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a PACE program, in which case the costs will be the same as costs for private entities. Currently, there are no PACE programs run by local governments in New York State.

Costs to the Department of Health:

Costs associated are the implementation of ten new staff within the Office of Aging and Long-Term Care to administer the licensure process and surveillance and operations of the new PACE licensure developed under the new statute and regulations. The Department is prepared to absorb the cost of the new hires in existing staff allocation but is seeking an additional staff package that is pending.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

This regulation imposes no local government mandates.

Duplication:

There is no duplication in State or federal law.

Alternatives:

An alternative would be to leave in place the current structure which consists of three different licenses. Any alternative short of full unification would fail to accomplish the directives of the statute and the goals of the program. The current structure is burdensome, confusing, and unnecessarily bureaucratic, and the statute requires a new regulation.

Federal Standards:

PACE programs must adhere to all federal PACE requirements. Currently, all PACE programs must be reviewed and approved by the federal Centers for Medicare and Medicaid Services (CMS) and nothing in this regulation will affect federal laws, rules and regulations regarding federal compliance with PACE programs.

Compliance Schedule:

These regulations will become 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:

This regulation will not impact local governments or small businesses unless they operate a PACE program. Currently, there are only nine New York State PACE Plans and they currently enroll 5,800 members.

Compliance Requirements:

These regulations are required for all new PACE programs to be established under a new licensure category as defined in Article 29-EE of the New York State Public Health Law. As such the regulations mostly apply to only new PACE program applications after these regulations take effect. The regulations set up the framework and the requirements needed to apply under an Article 29-EE PACE program.

Professional Services:

It is not expected that any professional services will be needed to comply with this rule.

Compliance Costs:

Outside of the standard application processing fee of $5,000 dollars, it is not expected that any new compliance costs will be associated with this rule.

Economic and Technological Feasibility:

There are no economic or technological impediments to the rule changes.

Minimizing Adverse Impact:

The Department anticipates that any adverse impacts will be minimal as the purpose of this regulation is to streamline the current three individual licenses approval process (currently an Article 28 Diagnostic and Treatment Center license, an Article 36 Home Care license, and an

Article 44 Health Maintenance Organization license) into one, streamlined PACE application and licensure process under Article 29-EE of the Public Health Law.

Small Business and Local Government Participation:

Those interested in expanding the PACE program in New York State have offered input at the statutory bill drafting and at various public forums including the legislative process that resulted in the requirement of these regulations. Further, all stakeholders will have the opportunity to present their ideas for improvement and enhancements during the public comment period. Further, the Department anticipates holding a public committee meeting of the Public Health and Health Planning Council (PHHPC) to discuss these new regulations. The public, consumers of PACE programs, and industry stakeholders will be invited to present testimony at the PHHPC meeting.

For Rules That Either Establish or Modify a Violation or Penalties Associated with a Violation:

Not applicable to the proposed regulation.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

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

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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