Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
February 8, 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 Emergency Adoption

23-07 Amendment of Section 405.45 of Title 10 NYCRR
(Trauma Centers – Resources for Optimal Care of the Injured Patient)

For Adoption

23-07 Amendment of Section 405.45 of Title 10 NYCRR
(Trauma Centers – Resources for Optimal Care of the Injured Patient)

21-21 Amendment of Part 425 of Title 10 NYCRR (Adult Day Health Care)

20-22 Amendment of Sections 405.11 and 415.19 of Title 10 NYCRR
(Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements)

For Information

24-01 Amendment of Section 405.19 of Title 10 NYCRR (General Hospital Emergency Services Behavioral Health)

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

23-08 Amendment of Sections 405.4 & 405.6 of Title 10 NYCRR (General Hospital Medical Staff Recertification)

III. ADJOURNMENT

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

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 2803 of the Public Health Law, section 405.45 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon filing with the Secretary of State, to read as follows:

405.45 Trauma Centers

(a) *Definitions*. The following terms when used in this section shall have the following meanings:

* * *

(3) "Level I trauma center" means a facility verified by the American College of Surgeons Committee on Trauma (ACS-COT), or other entity determined by the Department, and designated by the Department as a facility that is capable of providing the full range of services required of trauma patients; conducts trauma research; and provides training to surgical residents that comports with the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022). The standards set forth in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) is available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago,

Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

* * *

(c) *Trauma Center Designation*

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

* * *

(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

* * *

(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022);

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) section 2803. Pursuant to PHL § 2803(2), the Public Health and Health Planning Council (PHHPC) is authorized to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services.

Needs and Benefits:

The criteria and standards in the *Resources for the Optimal Care of the Injured Patient* are used to ensure that trauma center applications are compliant with the most current standards and the ACS uses these standards to issue the verification of trauma center status. The current edition of the *Resources for Optimal Care of the Sick and Injured Patient* (2014) is out-of-date and the proposed rule change would update the edition of *Resources for Optimal Care of the Sick and Injured Patient* to the most current version dated 2022. This change is necessary because the American College of Surgeons (ACS) began using the updated edition to perform hospital trauma center verifications and re-verifications on September 1, 2023.

COSTS:

Costs to Regulated Parties:

The proposed rule change may impose additional costs on trauma center hospitals due to new education requirements, expansion of available surgical and medical experts, the addition of a performance improvement coordinator, and the number of trauma registrars required in the updated 2022 standards set forth in *Resources for Optimal Care of the Sick and Injured* compared to the 2014 standards. The Department cannot provide an accurate estimate of these costs because they will vary significantly depending on what actions each trauma center hospital will need to take, or may have already taken, to meet the updated 2022 standards.

Costs to State and Local Governments:

This regulation imposes no new costs or fees to state and local governments. General hospitals operated by local governments may be affected as regulated entities if they are also designated as trauma centers pursuant to 10 NYCRR section 405.45.

Costs to the Department of Health:

This regulation imposes no new costs or fees to the Department of Health.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation imposes no additional paperwork.

Duplication:

This regulation does not duplicate any State or federal rules.

Alternatives:

No alternatives to the proposed rule change were considered viable. The regulation needs to be updated since the ACS began using the updated edition of *Resources for Optimal Care of the Injured Patient* to perform hospital trauma center verifications and re-verifications on September 1, 2023.

Federal Standards:

There are no federal standards.

Compliance Schedule:

As of September 1, 2023, designated trauma center hospitals need to use the new 2022 edition of *Resources for Optimal Care of the Sick and Injured*.

Contact Person:

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

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

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

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

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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.

EMERGENCY JUSTIFICATION

State Administrative Procedure Act (SAPA) § 202(6) authorizes state agencies to adopt emergency regulations necessary for the preservation of public health, safety, or general welfare where compliance with routine administrative procedures would be contrary to public interest. In this case, compliance with SAPA for filing of this regulation on a non-emergency basis, including the requirement for a public comment period, cannot be met because to do so would be detrimental to the health and safety of the general public.

The proposed regulatory changes to Title 10 NYCRR section 405.45 will update the publication date of *Resources for Optimal Care of the Injured Patient* from 2014 to 2022. This change is immediately needed because the American College of Surgeons (ACS) began using the updated edition to perform hospital trauma center verifications and re-verifications on September 1, 2023. The Bureau of Emergency Medical Services and Trauma Systems (the Bureau) works in concert with the ACS to issue preliminary verification to hospitals seeking trauma center verification. The Bureau uses the criteria and standards in the *Resources for the Optimal Care of the Injured Patient* to ensure that trauma center applications are compliant with the most current standards. The ACS uses these standards to issue the verification of trauma center status and once received, the Bureau issues the trauma center designation.

Failure to adopt the emergency regulation will result in a delay of verification and designation of new and existing trauma centers in New York State (NYS). It may also negatively affect trauma centers that have received notices of deficiencies in their ability to timely correct those deficiencies. The Bureau uses the standards set forth by ACS to re-inspect and assist trauma centers in resolving any deficiencies found with re-verification by

the ACS. Any delays in trauma center designation may cause delays in appropriate patient care because of traumatic injury, especially in rural areas, because trauma center designation provides the guideline for emergency medical services for transport to the appropriate facility.

As such, an emergency rule is necessary to ensure that the most current standards for trauma centers are employed in preliminary and permanent trauma center designation. Updating this rule prior to September 1, 2023, was not feasible because the ACS was still conducting verifications and re-verifications of trauma centers using the 2014 version of the standards and was not prepared to incorporate the new version until now. Accordingly, current circumstances necessitate immediate action, and pursuant to SAPA § 202(6), a delay in the issuance of these emergency regulations would be contrary to public interest.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 2803 of the Public Health Law, section 405.45 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is amended, to be effective upon publication of a Notice of Adoption in the New York State Register to read as follows:

405.45 Trauma Centers

(a) *Definitions*. The following terms when used in this section shall have the following meanings:

* * *

(3) "Level I trauma center" means a facility verified by the American College of Surgeons Committee on Trauma (ACS-COT), or other entity determined by the Department, and designated by the Department as a facility that is capable of providing the full range of services required of trauma patients; conducts trauma research; and provides training to surgical residents that comports with the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022). The standards set forth in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) are hereby incorporated by reference with the same force and effect as if fully set forth herein. A copy of *Resources for Optimal Care of the Injured Patient* [(2014)] (2022) is available for inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the American College of Surgeons Committee on Trauma, 633 North Saint Clair Street, Chicago,

Illinois 60611. A Level I trauma center shall have a transfer agreement with at least one pediatric trauma center for trauma patients whose needs exceed the clinical capabilities of the facility.

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(c) *Trauma Center Designation*

(1) A hospital seeking designation as a trauma center must receive verification by the American College of Surgeons, Committee on Trauma (ACS-COT), or other entity determined by the Department. To receive verification, the hospital must undergo a consultation site visit and verification site visit by the ACS-COT, or other entity determined by the Department. During the verification site visit, the hospital must exhibit that it is capable of providing Level I, Level II, Level III, Level IV or pediatric trauma care in accordance with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

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(ii) Verification site visit.

A hospital seeking designation as a trauma center shall request an official verification site visit by the ACS-COT, or other entity determined by the Department, no later than two years following a hospital's receipt of its consultation site visit report. The hospital must receive confirmation from the ACS-COT, or other entity determined by the Department, that the hospital meets the criteria for trauma center verification in accordance with the criteria outlined in the ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022).

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(d) *Requirements for Operating a Trauma Center.*

(1) Upon designation, a hospital operating a trauma center shall:

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(ii) comply with the trauma care standards set forth in ACS-COT's publication entitled *Resources for Optimal Care of the Injured Patient* [(2014)] (2022);

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) section 2803. Pursuant to PHL § 2803(2), the Public Health and Health Planning Council (PHHPC) is authorized to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services.

Needs and Benefits:

The criteria and standards in the *Resources for the Optimal Care of the Injured Patient* are used to ensure that trauma center applications are compliant with the most current standards and the ACS uses these standards to issue the verification of trauma center status. The current edition of the *Resources for Optimal Care of the Sick and Injured Patient* (2014) is out-of-date and the proposed rule change would update the edition of *Resources for Optimal Care of the Sick and Injured Patient* to the most current version dated 2022. This change is necessary because the American College of Surgeons (ACS) will be using the updated edition to perform hospital trauma center verifications and re-verifications starting on September 1, 2023.

COSTS:

Costs to Regulated Parties:

The proposed rule change may impose additional costs on trauma center hospitals due to new education requirements, expansion of available surgical and medical experts, the addition of a performance improvement coordinator, and the number of trauma registrars required in the updated 2022 standards set forth in *Resources for Optimal Care of the Sick and Injured* compared to the 2014 standards. The Department cannot provide an accurate estimate of these costs because they will vary significantly depending on what actions each trauma center hospital will need to take, or may have already taken, to meet the updated 2022 standards.

Costs to State and Local Governments:

This regulation imposes no new costs or fees to state and local governments. General hospitals operated by local governments may be affected as regulated entities if they are also designated as trauma centers pursuant to 10 NYCRR section 405.45.

Costs to the Department of Health:

This regulation imposes no new costs or fees to the Department of Health.

Local Government Mandates:

This regulation imposes no new government mandates.

Paperwork:

This regulation imposes no additional paperwork.

Duplication:

This regulation does not duplicate any State or federal rules.

Alternatives:

No alternatives to the proposed rule change were considered viable. The regulation needs to be updated since the ACS will be using the updated edition of *Resources for Optimal Care of the Injured Patient* to perform hospital trauma center verifications and re-verifications started on September 1, 2023.

Federal Standards:

There are no federal standards.

Compliance Schedule:

Beginning September 1, 2023, designated trauma center hospitals started using the new 2022 edition of *Resources for Optimal Care of the Sick and Injured*.

Contact Person:

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STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

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

Summary of Express Terms

The proposed amendments concern sections of 10 NYCRR Part 425 that apply to adult day health care services for registrants in a non-residential health care facility with medical needs. The purpose of the amendments is to come into compliance with the Centers for Medicare and Medicaid Services (CMS) home and community-based services (HCBS) Final Rule.

The amendments also ensure that Medicaid's HCBS program, in this non-residential setting, provides full access to the benefits of community living, and offers services in the most integrated settings, in compliance with requirements for the Medicaid HCBS provided under section 1915(c) of the federal Medicaid Act and federal regulations applicable to HCBS at 42 CFR §441.301.

The amendments are made to ensure compliance with these federal regulatory requirements, which require that for individuals receiving Medicaid HCBS, the setting in which HCBS is provided is integrated into and supports full access to the greater community. This includes opportunities to seek employment and work in competitive integrated settings, engage in community life and events, control personal resources, and receive desired services in the community, to the same degree of access as individuals not receiving Medicaid.

Amendments are in the following areas:

The setting should be selected by the individual from among setting options including non-disability specific settings.

The settings options must be identified and documented in the person-centered plan and are based on the individual’s needs, preferences.

The setting should ensure an individual's rights of privacy, dignity, and respect, and freedom from coercion and restraint.

The setting should optimize, but does not regiment, individual initiative, autonomy, and independence in making life choices including but not limited to daily activities, physical environment, and with whom to interact.

The setting should facilitate individual choice regarding services and supports, and who provides them.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 363-a(2) of the Social Services Law and Section 2803(2) of the Public Health Law, Part 425 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: Part 425 Adult Day Health Care (Statutory Authority: Public Health Law, section 2803(2); Social Services Law, section 363-a(2))

Section 425.1 - Definitions

425.1 Definitions. As used in this Part:

(a) *Adult day health care* is a community-based model. It is defined as the health care services and activities provided in a non-residential group setting to a group of registrants with functional impairments to maintain their health status and enable them to remain in the community.

(b) *Registrant* is defined as a person:

(1) who is not a resident of a residential health care facility, is functionally impaired and not homebound, and requires supervision, monitoring, preventive, diagnostic, therapeutic, rehabilitative services or palliative care [or services] but does not require continuous 24-hour-a-day inpatient care and services, except that where reference is made to the requirements of Part 415 of this Subchapter, the term resident as used in Part 415 shall mean registrant;

(2) whose assessed social and health care needs can satisfactorily be met in whole or in part by the delivery of appropriate services in the community setting; and

(3) who has been accepted by an adult day health care program based on an authorized practitioner's order or a referral from a managed [long term]care plan [or care coordination model] and a comprehensive assessment conducted by the adult day health care program or by the managed [long term] care plan [or care coordination model].

(c) *Program* is defined as an approved adult day health care program listed on the operating certificate [located at] of a licensed residential health care facility or an approved extension site.

(d) *Operating hours for an adult day health care program* are defined as the period of time that the program must be open, operational, and providing services to registrants in accordance with the approval granted by the Department. Each approved adult day health care session must operate for a minimum of five hours duration, not including time spent in transportation, and must provide, at a minimum, nutritional services in the form of at least one meal and necessary supplemental nourishment in the form of snacks and hydration of choice, and [planned]activities at planned and at registrant desired times(s). In addition, an ongoing assessment must be made of each registrant's health status by the adult day health care program, or by the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, in order to provide coordinated person-centered care planning, case management and other health care services as determined by the registrant's needs.

(e) *Visit* is defined as an individual episode of attendance by a registrant at an adult day health care program during which the registrant receives adult day health care services in accordance with his/her person-centered care plan. A registrant's individual visit may be fewer than five hours or longer than five hours depending on the assessed needs of the

registrant. Registrants referred by an agency, physician or a managed [long term] care plan [or care coordination model] will receive services as ordered by those entities in conformance with those entities' comprehensive assessment after discussion and consultation with the adult day health care program.

(f*) Registrant capacity* is defined as the total number of registrants approved by the Department for each session in a 24 hour day.

(g) *Operator of an adult day health care program* is defined as the operator of the [a residential] health care facility that is approved by the Department to be responsible for all aspects of the adult day health care program.

(h) *Practitioner* is defined as a physician, nurse practitioner or a physician's assistant with physician oversight.

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

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

[(k) *Care coordination model* means a program model that meets guidelines specified by the Commissioner that supports coordination and integration of services pursuant to Section 4403-f of the Public Health Law.]

(k) [(l)] *Comprehensive assessment* means an interdisciplinary comprehensive assessment of a registrant completed in accordance with Section 425.[6]7 of this Part by the adult day health care program, or an interdisciplinary comprehensive assessment, approved by the Department, completed by the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program.

(l) [(m)] *Person-centered [C]care plan* means identifying goals and developing care plans [the care plan developed] in accordance with section 425.[7]8 of this Part by the

adult day health care program. *Person-centered care planning* is a process driven by the registrant that reflects the services and supports that are important to the registrant to meet their needs identified through an assessment of functional need, as well as what is important to the registrant with regard to the preference for the delivery of such services and supports 42 CFR 441.301(c)(2). Assists registrants in achieving their personally defined outcomes by integrating the registrant in, and supporting full access to, the community while providing registrant dignity and privacy.

(m [n]) *Unbundled Services/Payment Option* means the ability of an adult day health care program to provide less than the full range of adult day health care services to a functionally impaired individual [referred by a managed long term care plan or care coordination model] based on the registrant's comprehensive assessment. The full range of adult day health care services as described in Part 425 will be available to all registrants enrolled in the adult day health care program.

Section 425.2 - Application

425.2 Application. (a) Prior to operation of an adult day health care program, the proposed operator must apply for and receive Department approval in accordance with Part 710 of this Chapter. Such application must include a description of the proposed program, including but not limited to:

(1) the need for the program, including a statement on the philosophy and objectives of the program;

(2) the range of services to be provided;

(3) the method(s) of delivery of services;

(4) physical space to be utilized and planned use thereof;

(5) number and expected characteristics of registrants to be served;

(6) a description of a typical registrant's program;

(7) personnel to be employed in the program, including qualifications;

(8) intended use of and coordination with existing community resources;

(9) financial policies and procedures;

(10) program budget;

(11) methods for program evaluation; and

(12) proximity to an identified number of potential registrants.

(b) A residential health care facility operator that has been approved by the Department to operate an adult day health care program at its primary site may provide adult day health care services at an extension site only when such use of an extension site has first been approved by the Department under the provisions of Part 710 of this Chapter.

[(c) A residential health care facility operator that does not operate an adult day health care program at its primary site may provide such a program at an extension site approved by the Department for such use in accordance with section 710.1 of this Chapter if there is not sufficient suitable space within the residential health care facility to accommodate a full range of adult day health care program activities and services. The Department may conduct an on-site survey of the residential health care facility to determine whether the facility lacks suitable space for an adult day health care program.]

Section 425.3 - Changes in existing program

425.3 Changes in existing program.

(a) Applications for approval of changes in the program, including but not limited to substantial changes in the physical plant, space and utilization thereof, the extent and type of services provided, and the program's registrant capacity, must be submitted to the Department in writing and must conform with the provisions of Part 710 of this Chapter.

(b) Written requests for additional program sessions must be based on the number and needs of registrants and be approved by the Department.

(c) An operator may not discontinue operation of services to registrants without:

(1) notifying each registrant and making suitable plans for alternate services for each registrant; and

(2) receiving written approval from the commissioner in accordance with Part 710 of this Chapter. The application to discontinue services must set forth the specific intended date of discontinuance and the intended plans for alternate services to registrants.

(d) The operator of an approved adult day health care program must notify the Department of the program’s election of the Unbundled Services/Payment Option in writing thirty days before commencement of this option.

Section 425.4 - General requirements for operation

425.4 General requirements for operation.

(a) An operator must:

(1) provide services to registrants consistent with the requirements of this Title and Part and other applicable statutes and regulations;

(2) provide appropriate staff, equipment, supplies and space as needed for the administration of the adult day health care program in accordance with the requirements

of this Part; and

(3) provide each registrant with a copy of a Bill of Rights specific to operation of the adult day health care program.

These rights include, but are not limited to:

(i) rights of privacy, dignity, respect, and confidentiality, including confidential treatment of all registrant records;

(ii) freedom to voice grievances about care or treatment without discrimination or reprisal;

(iii) protection and freedom from physical and psychological abuse, coercion and restraint;

(iv)participation in developing the person-centered care plan;

(v) written notification by the program to the registrant at admission and following the continued-stay evaluation of the services the registrant shall receive while attending the adult day health care program; and

(vi) right to individual initiative, autonomy, and independence in making life choices, including freedom to decide whether or not to participate in any given activity.

(4) be selected from among options by the individual and be physically accessible to the individuals supported;

(5) be integrated in and support full access to the greater community;

(6) facilitate an individual's informed choice about their services and who provides them;

(7) provide freedom and support for individuals to control their own schedules and activities;

(8) provide individuals access to food (meals and/or snacks) and visitors at any time;

(9) offer individuals participation in developing the person-centered care plan; and

(10) provide written notification by the program to the registrant at admission and following the continued-stay evaluation of the services the registrant shall receive while attending the adult day health care program.

(b) Administration. Without limiting its responsibility for the operation and management of the program, the operator must designate a person responsible for:

(1) coordinating services for registrants with services provided by community or other agency programs, including but not limited to certified home health agencies, social services agencies, clinics and hospital outpatient departments and services; provided, however, with respect to registrants referred to the adult day health care program by a managed [long term] care plan [or care coordination model,] the coordination of such services shall be the responsibility of the managed [long term] care plan [or care coordination model]; and

(2) day-to-day direction, management and administration of the adult day health care services, including but not limited to:

(i) assigning adequate, consistent and appropriately licensed personnel to be on-duty at all times when the program is in operation to ensure safe care of the registrants;

(ii) assigning and supervising activities of all personnel to ensure that registrants receive assistance in accordance with their [plans of care] person-centered care plan;

(iii) ensuring supervision of direct care staff in accordance with state rules and regulation;

(iv) arranging for in-service orientation, training and staff development; and assuring that staff possess the competencies and skill sets necessary to meet the needs safely and in a manner that promotes each registrant's rights, and physical, mental and psychosocial

well-being; and

(v) maintaining records in accordance with provisions of sections 400.2 and 415.3(d)(1) of this Subchapter.

(c) Policies and procedures for service delivery. The operator must:

(1) establish and implement written policies and procedures, consistent with the approved application for operation of the adult day health care program, concerning the rights and responsibilities of registrants, the program of services provided to registrants, use of physical structures and equipment, and the number and qualifications of staff members and their job classifications and descriptions;

(2) ensure that written policies and procedures, consistent with current professional standards of practice, are developed and implemented for each service and are reviewed annually and revised as necessary;

(3) develop protocols for each involved professional discipline to indicate when the service of such discipline should be included in the registrant assessment;

(4) ensure that professional personnel are fully informed of, and encouraged to refer registrants to, other health and social community resources that may be needed to maintain the registrant in the community; provided, however, with respect to registrants referred to the adult day health care program by a managed [long term] care plan [or care coordination model], such referrals shall be the responsibility of the managed long term care plan [or care coordination model];

(5) establish and implement written policies for the storage, cleaning and disinfection of medical supplies, equipment and appliances;

(6) establish and implement written policies and procedures concerning refunds and

prepayment for basic services in accordance with existing rules and regulations;

(7) establish and implement written policies and procedures concerning transfer and affiliation agreements covering registrants that are consistent with the standards specified in section 400.9 of this Subchapter; and

(8) provide in such agreement(s) reasonable assurance of assistance to each registrant in transferring to inpatient or resident status in a residential health care facility whenever the registrant is deemed by a practitioner to be medically appropriate for such care.

Section 425.5 – General requirements for Adult day health care settings

425.5 General requirements for Adult day health care settings.

(a) the operator must assure that the adult day health care program has all the qualities of a Home and Community-Based Service (HCBS) setting:

(1) The setting is integrated in and supports full access of individuals receiving Medicaid HCBS to the greater community, including opportunities to seek employment and work in competitive integrated settings, engage in community life, control personal resources, and receive services in the community, to the same degree of access as individuals not receiving Medicaid HCBS.

(2) The setting is selected by the individual from among setting options including non-disability specific settings. The setting options are identified and documented in the person-centered care plan and are based on the individual's needs and preferences.

(3) The setting ensures an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint.

(4) The setting optimizes, but does not regiment, individual initiative, autonomy and independence in making life choices, including but not limited to, daily activities, physical environment, access to meals and snacks as desired at any time, and decisions concerning individuals with whom to interact. Visitors are not restricted.

(5) The setting facilitates individual choice regarding services and supports, and who provides them.

Section 425.6 - Adult day health care services

425.6 Adult day health care services.

(a) The operator must provide or arrange for services appropriate to each registrant in accordance with the comprehensive assessment conducted and person-centered care plan developed by the adult day health care program, or by the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program. At least the following program components must be available:

(1) case management;

(2) health education;

(3) interdisciplinary care planning;

(4) nursing services;

(5) nutrition;

(6) social services;

(7) assistance and supervision with the activities of daily living, such as toileting, feeding,

ambulation, bathing including routine skin care, care of hair and nails; oral hygiene; and supervision and monitoring of personal safety[,];

(8) restorative rehabilitative and maintenance therapy services;

[(8)] (9) planned therapeutic or recreational activities that reflect the interests, cultural backgrounds and the communities of the registrants and provide the registrants with choices, including access to offsite activities;

[(9)] (10) pharmaceutical services; and

[(10)] (11) referrals for necessary dental services and sub-specialty care.

(b) The following services may also be provided:

(1) specialized services for registrants with HIV or AIDS and other high-need populations; and

(2) religious services and pastoral counseling.

Section 425.[6]7 - Admission, continued stay and registrant assessment

425.[6]7 Admission, continued stay and registrant assessment.

(a) The operator must:

(1) select, admit and retain in the adult day health care program only those persons for whom adequate care and needed services can be provided and who, according to the comprehensive assessment conducted by the operator or by the managed [long term] care plan [or care coordination model] that referred the applicant to the adult day health care program, can benefit from the services and require a minimum of at least one (1) visit per week to the program;

(2) assess each applicant, unless the assessment was conducted by a managed [long term]

care plan [or care coordination model] that referred the applicant to the adult day health care program, utilizing an assessment instrument designated by the Department, with such assessment addressing, at a minimum:

(i) medical needs, including the determination of whether the applicant is expected to need continued services for a period of 30 or more days from the date of the assessment. An operator may request approval by the appropriate Department regional office for an exemption, based on special circumstances, to the requirement for determining whether there is a need for continued services for 30 days or more.

(ii) use of medication and required treatment;

(iii) nursing care needs;

(iv) functional status;

(v) mental/behavioral status;

(vi) sensory impairments;

(vii) rehabilitation therapy needs, including a determination of the specific need for physical therapy, occupational therapy, speech language pathology services, and rehabilitative, restorative or maintenance care;

(viii) family and other informal supports;

(ix) home environment;

(x) psycho-social needs, social history, preferences and interests;

(xi) nutritional status;

(xii) ability to tolerate the duration and method of transportation to the program; and

(xiii) evidence of any substance abuse problem.

(3) register an applicant only upon appropriate recommendation from the applicant's

practitioner or operator's medical director after completion of a personal interview by appropriate program personnel;

(4) register an applicant only after determining that the applicant is not [receiving the same services from another facility or agency.] enrolled in another adult day health care program.

(b) An individual may be registered in an adult day health care program only if his/her comprehensive assessment indicates that the program can adequately and appropriately care for the physical and emotional health needs of the individual.

(c) No individual suffering from a communicable disease that constitutes a danger to other registrants or staff may be registered or retained for services on the premises of the program.

(d) The operator may admit, on any given day, up to 10% over the approved capacity for that program. The average annual capacity, however, may not exceed the approved capacity of the operator's program.

Section 425.[7]8 - Registrant person-centered care plan

425.[7]8 Registrant person-centered care plan.

The operator must ensure that: (a) [An adult day health care program] A person-centered care plan based on the comprehensive assessment required by this Part, and, when applicable, a transfer or discharge plan, is developed for each registrant and is in place within five visits or within 30 days after registration, whichever is earlier. The adult day health care program and the referring managed [long term] care plan [or care coordination model] must be sure to coordinate with each other regarding the

development of a registrant’s person-centered care plan.

(b) Each registrant's person-centered care plan process must be commensurate with the level of need of the registrant, and the scope of services and supports available and must[include]:

(1) [designation of a professional person to be responsible for coordinating the care plan]include registrant led input and include people chosen by the registrant;

(2) provide necessary information and support to ensure the registrant directs the process to the maximum extent possible and is enabled to make informed choices and decisions, with the registrant's representative having a participatory role, as needed and as defined by the registrant, unless State law confers decision-making authority to the legal representative;

(3) be timely and occur at times and locations of convenience to the registrant;

(4) reflect cultural considerations of the registrant and be conducted by providing information in plain language and in a manner that is accessible to individuals with disabilities and persons who are limited English proficient;

(5) include strategies for solving conflict or disagreement within the process, including clear conflict of interest guidelines for all planning participants;

(6) offer choices to the registrant regarding the services and supports the registrant receives and from whom;

(7) include a method for the registrant to request updates to the care plan, as needed; and

(8) record the alternative home and community-based settings that were considered by the registrant.

(c) The person-centered care plan must reflect the services and supports that are important for the registrant to meet the clinical and support needs as identified through an assessment of functional need, as well as what is important to the registrant with regard to preferences for the delivery of such services and supports. The written plan must also:

(1) reflect [2] the registrant's pertinent diagnoses, including mental status, types of equipment and services required, case management, frequency of planned visits, prognosis, rehabilitation potential, functional limitations, planned activities, nutritional requirements, medications and treatments, necessary measures to protect against injury, instructions for discharge or referral if applicable, orders for therapy services, including the specific procedures and modalities to be used and the amount, frequency and duration of such services, and any other appropriate item.

[3](2) reflect the registrant's strengths and preferences, the medical and nursing goals and limitations anticipated for the registrant and, as appropriate, the nutritional, social, rehabilitative and leisure time goals and limitations;

[4](3) set forth the registrant's potential for remaining in the community; [and]

[5](4) include a description of all services to be provided to the registrant by the program, informal supports and other community resources pursuant to the person-centered care plan, and how such services will be coordinated;

(5) reflect that the setting in which the registrant receives services is chosen by the registrant;

(6) reflect risk factors and measures in place to minimize them, including individualized backup plans and strategies when needed;

(7) be understandable to the individual receiving services and supports, and the individuals important in supporting them. At a minimum, for the written plan to be understandable, it must be written in plain language and in a manner that is accessible to individuals with disabilities or with limited proficiency in English;

(8) identify the individual and/or entity responsible for monitoring the plan;

(9) be finalized and agreed to, with the informed consent of the registrant (and/or persons identified by the registrant) in writing and signed by all individuals and providers responsible for its implementation;

(10) be distributed to the registrant and other people involved in the plan;

(11) include those services, the purchase or control of which the registrant elects to self-direct; and

(12) prevent the provision of unnecessary or inappropriate services.

([c]d) Development and modification of the person-centered care plan is coordinated with other health care providers outside the program who are involved in the registrant's care.

([d]e) The responsible persons, with the appropriate participation of consultants in the medical, social, paramedical and related fields involved in the registrant's care, must:

(1) record in the clinical record changes in the registrant's status which require alterations in the registrant person-centered care plan;

(2) modify the person-centered care plan to reflect registrant physical and social changes accordingly;

(3) review the person-centered care plan at least once every six months and whenever the registrant's condition warrants and document each such review in the clinical record; and

(4) promptly alert the registrant's authorized practitioner of any significant changes in the registrant's condition which indicate a need to revise the person-centered care plan.

Section 425.[8]9 - Registrant continued-stay evaluation

425.[8]9 Registrant continued-stay evaluation. The operator, directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, must ensure that a written comprehensive assessment and evaluation is completed pursuant to section 425.[6]7 of this Part at least once every six months for each registrant, addressing the appropriateness of the registrant's continued stay in the program, such assessment and evaluation to address, at a minimum:

(a) a reassessment of the registrant's needs, including an interdisciplinary evaluation of the resident's need for continued services;

(b) the appropriateness of the registrant's continued stay in the program;

(c) the necessity and suitability of services provided; and

(d) the potential for transferring responsibility for or the care of the registrant to other more appropriate agencies or service providers.

Section 425.[9]10 - Medical services

425.[9]10 Medical services. The operator must, without limiting its responsibility for the operation and management of the program:

(a) assign to the operator's medical board, medical advisory committee, medical director or consulting practitioner the following responsibilities regarding registrants of the program:

(1) developing and amending clinical policies;

(2) supervising medical services;

(3) advising the operator regarding medical and medically related problems;

(4) establishing procedures for emergency practitioner coverage, records and consultants; and

(5) establishing professional relationships with other institutions and agencies, such as general hospitals, rehabilitation centers, residential health care facilities, home health agencies, hospital outpatient departments, clinics and laboratories;

(b) ensure that medical services, including arranging for necessary consultation services, are provided to registrants of the program in accordance with sections 415.15(b)(1), (2)(ix), (3) and (4) of this Subchapter;

(c) provide or arrange for the personal, staff or other designated practitioner to obtain a medical history and a physical examination of each registrant, including diagnostic laboratory and x-ray services, as medically indicated, within six weeks before or seven days after admission to the program;

(d) ensure that the practitioner record, date and authenticate significant findings of the medical history, physical examination, diagnostic services, diagnoses and orders for treatment in the registrant's clinical records; and

(e) ensure that orders for treatment include orders for medication, diet, permitted level of physical activity and, when indicated, special orders or recommendations for rehabilitative therapy services and other adult day health care services.

Section 425.[10]11 - Nursing services

425.[10]11 Nursing services. The operator, directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, must:

(a) evaluate the need of each registrant for nursing care on a periodic and continuing basis, but not less often than quarterly, and, when appropriate, provide or authorize such care;

(b) ensure that a registered professional nurse is on-site and performs a nursing evaluation of each registrant at the time of admission to the program, unless such nursing evaluation has been performed by the managed [long term] care plan [or care coordination model] prior to referring the registrant to the adult day health care program;

(c) ensure that for each registrant the findings of the nursing evaluation, the nursing care plan, and recommendations for nursing follow-up are documented, dated and signed in the registrant's clinical record;

(d) ensure that nursing services are provided to registrants under the direction of a registered professional nurse who is on-site in the adult day health care program during all hours of the program operation. Based on the care needs of the registrants, a licensed practical nurse may provide the on-site services under the supervision of a registered nurse;

[Based on the care needs of the registrants, for a program located at the sponsoring licensed residential health care facility, a licensed practical nurse may provide the on-site services when a registered professional nurse is available in the nursing home or on the campus to provide immediate direction or consultation;] and

(e) ensure that appropriate health education is provided to registrants, [and] family members and people chosen by the registrant to provide support [for the registrant and family] in understanding and dealing with the registrant's health condition as it relates to his/her continued ability to reside in the community. With respect to registrants referred to the adult day health care program by a managed [long term] care plan [or care coordination model,] the managed [long term] care plan [or care coordination mode] shall be responsible for compliance with the requirements of this section.

Section 425.[11]12 - Food and nutrition services

425.[11]12 Food and nutrition services. The operator must:

(a) provide nutritional services for each registrant;

(b) provide meals and nutritional supplements, including modified diets when medically prescribed, to registrants who are on the premises at scheduled and registrant desired meal/snack times and, where appropriate, to registrants in their homes in accordance with the identified needs included in registrant person-centered care plans;

(c) ensure that the quality and quantity of food and nutrition services provided to registrants are in conformance with section 415.14 of this Subchapter, exclusive of the requirements specified in section 415.14(f);

(d) ensure that nutrition services are under the direction of a qualified dietitian, as defined in section 415.14 of this Subchapter; and

(e) ensure that dietary service records for the adult day health care service are maintained in conformance with sections 415.14(c)(1) and (2) of this Subchapter.

(f) Provide individuals with access to snacks and meals at any time and obtain registrant

feedback on foods of preference.

Section 425.[12]13 - Social services

425.[12]13 Social services. The operator must:

(a) provide social services in conformance with section 415.5(g) of this Subchapter except that the use of a full or part time social worker in an adult day health care program must be in conformance with the approved application for operation and, with respect to section 415.5(g)(2)(ii) and (iii), regular access may be directly with a master's prepared or certified social worker or through a contract which meets the provisions of section 415.26(e);

(b) either directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, ensure that psycho-social needs are assessed, evaluated and recorded, and that services are provided to meet the identified needs as part of the coordinated care plan; and

(c) ensure that staff members arrange for the use of and/or access to other community resources as needed and coordinate the needs of the registrants with services provided by the adult day health care program and other health care providers, community social agencies and other resources provided, however, with respect to registrants referred to the adult day health care program by a managed [long term] care plan [or care coordination model], this shall be the responsibility of the managed [long term] care plan [or care coordination model].

Section 425.[13]14 - Rehabilitation therapy services

425.[13]14 Rehabilitation therapy services. The operator, either directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, must:

(a) provide or arrange for rehabilitation therapy services to registrants determined through the comprehensive assessment to need such services; and

(b) ensure that the rehabilitation therapy services provided are in conformance with section 415.16 of this Subchapter.

Section 425.[14]15 - Activities

425.[14]15 Activities. The operator, directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, must:

(a) ensure that activities are an integral part of the program, are age appropriate, and reflect the registrants' individual interests and cultural backgrounds in coordination with the registrant's person-centered care plan;

(b) ensure that activities involve integration in and full access of individuals to the greater community, control personal resources and ability to engage in community life to the same degree of access as individuals not receiving home and community-based services;

(c) ensure that activities are designed to enhance registrant participation in the program, home life and community;

([c]d) involve appropriate volunteers and volunteer groups in the program, unless prohibited by law;

([d]e) provide sufficient equipment and supplies for the operation of the activity program;

([e]f) provide or arrange for transportation to and from community events and outings; and

([f]g) ensure that activities are included as part of each person-centered care plan.

Section 425.[15]16 - Religious services and counseling

425.[15]16 Religious services and counseling.

If provided, religious services and counseling must be included in the registrant's person-centered care plan.

Section 425.[16]17 - Dental services

425.[16]17 Dental services. The operator, directly or through the managed [long term] care plan [or care coordination model] that referred the registrant to the adult day health care program, must, as appropriate:

(a) provide or refer registrants for dental services; and

(b) ensure that dental services provided to registrants or for which they are referred are in conformance with the needs identified during the comprehensive assessment.

Section 425.[17]18 - Pharmaceutical services

425.[17]18 Pharmaceutical services. The operator must:

(a) develop and implement written policies and procedures governing medications brought to the program site by registrants;

(b) ensure that pharmaceutical services, when provided for registrants, are in

conformance with section 415.18 of this Subchapter, exclusive of the requirements of section 415.18(c);

(c) ensure that each registrant's drug regimen is reviewed at least once every six months by a registered pharmacist in accordance with the registrant's person-centered care plan and otherwise modified as needed following consultation with the registrant's attending practitioner. Any modification to the drug regimen must be documented in the registrant's clinical record and included as a revision to the registrant's person-centered care plan; and

(d) ensure that written policies and procedures require the pharmacist to report any irregularity in a registrant's drug regimen and recommendations to the registrant's attending practitioner and to the program coordinator, with appropriate documentation in the registrant's clinical record and person-centered care plan.

Section 425.[18]19 - Services for registrants with Acquired Immune Deficiency Syndrome (AIDS) and other high-need populations

[425.18] 425.19 Services for registrants with Acquired Immune Deficiency Syndrome (AIDS) and other high-need populations.

(a) Applicability.

(1) This section applies to an adult day health care program approved by the commissioner pursuant to Part 710 of this Chapter as a provider of specialized services for registrants with AIDS and other high-need populations that in the discretion of the Commissioner would benefit from receiving adult day health care services.

(2) For purposes of these regulations, AIDS means acquired immune deficiency syndrome and other human immunodeficiency virus (HIV) related illness.

(b) General requirements. The program shall provide comprehensive and coordinated health services in accordance with this Article and requirements set forth in Part 759 of this Title and shall receive payment for such services in accordance with section 759.14 of this Title.

Section 425.[19]20 - General records

425.[19]20 General records. The operator must:

(a) maintain on the premises of the program or facility the following registrant written records including the person-centered care plan, which must be easily retrievable and must include, but not be limited to, the following:

(1) a chronological admission register consisting of a daily chronological listing of registrants admitted by name with relevant clinical and social information about each, including as a minimum, name, address, next of kin, attending practitioner, principal diagnosis, and the place from which each registrant was admitted;

(2) a chronological discharge register consisting of a daily chronological listing of registrants discharged by name, the reason for discharge and the place to which the registrant was discharged;

(3) a daily census record consisting of a summary report of the daily registrant census with cumulative figures for each month and each year; and

(4) general records in conformance with sections 415.30(e) - (o) of this Subchapter.

(b) ensure that each record includes non-medical information consisting of:

(1) all details of the referral and registration;

(2) identification of next of kin, family and sponsor;

(3) the person or persons to be contacted in the event of emergency;

(4) accident and incident reports;

(5) non-medical correspondence and papers pertinent to the registrant's participation in the program; and

(6) a fiscal record including copies of all agreements or contracts.

(c) Maintain as public information, available for public inspection, records containing copies of all financial and inspection reports pertaining to the adult day health care services that have been filed with or issued by any governmental agency for six years from the date such reports are filed or issued.

Section 425.[20]21 - Clinical records

425.[20]21 Clinical records. The operator must:

(a) provide a clinical record for each registrant in accordance with the clinical records requirements of section 415.22 of this Subchapter;

(b) ensure that all reports and information pertaining to registrant care and planning are entered promptly;

(c) ensure that all entries are dated and authenticated by the person making the entry or ordering the services;

(d) ensure that all clinical records for registrants referred by a managed [long term] care plan [or care coordination model] are made available to the referring managed [long term] care plan [or care coordination model];

(e) ensure that the record is kept in a place convenient for use by authorized staff; and

(f) retain intact clinical records and all other records of registrants and keep them readily

accessible in a safe and secure place. Such records shall be retained safely and securely for a period of six years following discharge or cessation of operation of services. In the case of a minor, retention shall be for three years after reaching majority (18 years of age).

Section 425.[21]22 - Confidentiality of records

425.[21]22 Confidentiality of records. The operator shall keep confidential and make available only to authorized persons all medical, social, personal and financial information relating to each registrant.

Section 425.[22]23 - Program evaluation

425.[22]23 Program evaluation.

(a) Quality improvement. The operator must develop and implement a quality improvement process that provides for an annual or more frequent review of the operator's program. Such evaluation must include a profile of the characteristics of the registrants admitted to the program, the services and degree of services most utilized, the length of stay and use rate, registrant need for care and services, and disposition upon discharge. The process must:

(1) include an evaluation of all services in order to enhance the quality of care and to identify actual or potential problems concerning service coordination and clinical performance;

(2) review accident and incident reports, registrant complaints and grievances and the actions taken to address problems identified by the process;

(3) develop and implement revised policies and practices to address problems found and the immediate and systematic causes of those problems; and

(4) assess the impact of the revisions implemented to determine if they were successful in preventing recurrence of past problems.

(b) The results of the quality improvement process must be reported to the chief executive officer, nursing home administrator or governing body.

Section 425.[23]24 - Payment

425.[23]24 Payment

(a) Payments to adult day health care program by State government agencies.

(1) A program may only bill for one visit per registrant per day.

(2) The majority of registrants for whom the program receives a payment made by a government agency must be in attendance for at least five hours.

(b) Payments to adult day health care programs by managed[long term]-care plans. [or care coordination models:]

(1) Payments shall be made in accordance with the negotiated agreement between the adult day health care program and the managed [long term] care plan [or care coordination model].

(2) The full range of adult day health care services shall be available to registrants with a medical need for such services. Based on a registrant's individual medical needs, as determined in the comprehensive assessment, the managed [long term] care plan [or care coordination model] may order less than the full range of adult day health care services. Nothing shall prohibit adult day health care programs and managed [long term] care

plans [or care coordination models] from agreeing to reimbursement terms that reflect a registrant's receipt of less than the full range of adult day health care services.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803(2) of the Public Health Law authorizes the Public Health and Health Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, that define standards and procedures relating to medical facilities. Section 201(1)(v) of the Public Health Law and section 363-a of the Social Services Law provide that the Department is the single state agency responsible for supervising the administration of the State's medical assistance ("Medicaid") program and for adopting such regulations, not inconsistent with law, as may be necessary to implement the State's Medicaid program.

Legislative Objective:

To implement programs beneficial to Medicaid recipients, including those persons who require health care services and activities in a non-residential group setting.

Needs and Benefits:

The legislature has determined that oversight of adult care facilities is in the interests of the state, as Adult Day Health Care (ADHC) programs provide medically supervised services, as well as personal care and socialization to individuals with physical and mental impairments or chronic illnesses who otherwise would require nursing home admission.

The proposed rule provides clear guidance to the operators of ADHC facilities, reflecting Centers for Medicare & Medicaid Services' (CMS) intent to ensure that individuals receiving services and supports through Medicaid's home and community-based services

(HCBS) programs have full access to the benefits of community living and are able to receive services in the most integrated setting.

With these proposed regulations, the Department seeks to assure the continued viability of these valued programs by permitting them to offer their services to elderly and disabled populations with functional impairments to maintain their health status and enable these persons to remain in the community.

CMS announced new rules that will potentially have a far-reaching and positive impact on the nature of day service settings funded through Medicaid as part of HCBS. The proposed regulations are needed as they can contribute to better quality services and more opportunities for individuals with disabilities who require less than institutional level of care, but still have a significant need to have access to greater number of services in the community which they might not otherwise qualify. The purpose of the amendments is to come into compliance with CMS' HCBS Final Rule. The proposed amendments provided will refer an enrollee to an ADHC program who will be responsible for meeting Part 425 Adult day health care requirements. It is the responsibility of the ADHC program operator to manage and coordinate the enrollee's health care needs and be guided by the requirements outlined in the HCBS rule.

The proposed amendments will ensure that all ADHC programs in a non-residential setting provide full access to the benefits of community living and offer services in the most integrated settings.

Lastly the proposed amendments aim to ensure that enrollees have a free choice of setting options, who provides services to them, and that individual rights and freedoms are not restricted, among other provisions.

Costs:

Costs to Regulated Entities:

There will be no costs incurred by regulated entities.

Costs to State Government:

There will be no costs incurred by state government.

Costs to Local Governments:

There will be no costs incurred by local governments.

Local Government Mandates:

There is no local government program, service, duty or responsibility imposed by the rule.

Paperwork:

There are no new reporting requirements imposed by the rule.

Duplication:

There are no other rules or other legal requirements of the state and federal governments that may duplicate, overlap or conflict with the rule.

Alternatives:

This rule is a necessary update to maintain the Department's oversight of the adult care facility program in compliance with federal Medicaid HCBS requirements. There were no significant alternatives to this rule.

Federal Standards:

CMS published a final rule that established new standards for approved settings for the provision of Medicaid-funded home and community-based services. Also established were new person-centered planning and conflict-of-interest requirements. The proposed change is to align with the Medicaid HCBS under Section 1915(c), 1915(i), and 1915(k) of the Social Security Act.

Small Business Guide:

A small business guide as required by section 102-a of the State Administrative Procedure Act is unnecessary at this time. The Department will provide educational webinars for all adult care facilities prior to promulgation.

Compliance Schedule:

Adult care facilities will be able to comply with this regulation upon publication of the Notice of Adoption in the 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 that applies to adult day health care services for registrants does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

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

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

A job impact statement is not being submitted with this rule because it is evident from the nature and purpose of these amendments that the regulation will not have a substantial adverse impact on jobs and/or employment opportunities.

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending sections 405.11 and 415.19, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 405.11 is amended by adding a new subdivision (g) as follows:

(g) (1) The hospital shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control and Prevention guidance, for at least 60 days, by August 31, 2021.

(2) The 60-day stockpile requirement set forth in paragraph (1) of this subdivision shall be determined by the Department as follows for each type of required PPE:

(i) for single gloves, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 550;

(ii) for gowns, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 41;

(iii) for surgical masks, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 21; and

(iv) for N95 respirator masks, fifteen percent, multiplied by the number of the hospital's staffed beds as determined by the Department, multiplied by 9.6.

(3) A hospital shall be considered to possess and maintain the required PPE if:

(i) it maintains all PPE on-site; or

(ii) it maintains PPE off-site, provided that the off-site storage location is within New York State, can be accessed by the hospital within at least 24 hours, and the hospital maintains at least a 10-day supply of all required PPE on-site, as determined by the calculations set forth in paragraph (2) of this subdivision. A hospital may enter into an agreement with a vendor to store off-site PPE, provided that such agreement requires the vendor to maintain unduplicated, facility-specific stockpiles; the vendor agrees to maintain at least a 60-day supply of all required PPE, or a 90-day supply in the event the Commissioner increases the required stockpile amount pursuant to this subdivision (less the amount that is stored on site at the facility); and the PPE is accessible by the facility 24 hours a day, 7 days a week, year round. In the event the Department finds a hospital has not maintained the required PPE stockpile, it shall not be a defense that the vendor failed to maintain the supply.

(iii) Any PPE stored outside of New York State shall not count toward the facility's required 60-day stockpile.

(4) The Commissioner shall have discretion to increase the stockpile requirement set forth in paragraph (1) of this subdivision from 60 days to 90 days where there is a State or local public health emergency declared pursuant to Section 24 or 28 of the Executive Law. Hospitals shall possess and maintain the necessary 90-day stockpile of PPE by the deadline set forth by the Commissioner.

(5) The Department shall periodically determine the number of staffed beds in each hospital. Hospitals shall have 90 days to come into compliance with the new PPE stockpile requirements, as set forth in paragraph (2) of this subdivision, following such determination by the Department. Provided further that the Commissioner shall have discretion to determine an applicable bed

calculation for a hospital which is different than the number of staffed beds, if circumstances so require.

(6) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers, and providers are strongly encouraged to rotate inventory through regular usage and replace what has been used in order to ensure a consistent readiness level and reduce waste. Expired products should be disposed of when their expiration date has passed. Expired products shall not be used to comply with the stockpile requirement set forth in paragraph (1) of this subdivision.

(7) Failure to possess and maintain the required supply of PPE may result in the revocation, limitation, or suspension of the hospital's license; provided, however, that no such revocation, limitation, or suspension shall be ordered unless the Department has provided the hospital with a fourteen-day grace period, solely for a hospital's first violation of this section, to achieve compliance with the requirement set forth herein.

(8) In the event a new methodology relating to PPE in hospitals is developed, including but not limited to a methodology by the U.S. Department of Health & Human Services, and the Commissioner determines that such alternative methodology is appropriate for New York hospitals and will adequately protect hospital staff and patients, the Commissioner shall amend this subdivision to reflect such new methodology.

Section 415.19 is amended by adding a new subdivision (f) as follows:

(f) (1) The nursing home shall possess and maintain a supply of all necessary items of personal protective equipment (PPE) sufficient to protect health care personnel, consistent with federal Centers for Disease Control and Prevention guidance, for at least 60 days, by August 31, 2021.

(2) The 60-day stockpile requirement set forth in paragraph (1) of this subdivision shall be determined by the Department as follows for each type of required PPE:

(i) for single gloves, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 24;

(ii) for gowns, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 3;

(iii) for surgical masks, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 1.5; and

(iv) for N95 respirator masks, the applicable positivity rate, multiplied by the nursing home's average census as determined annually by the Department, multiplied by 1.4.

(v) For the purposes of this paragraph, the term "applicable positivity rate" shall mean the greater of the following positivity rates:

(a) The nursing home's average COVID-19 positivity rate, based on reports made to the Department, during the period April 26, 2020 through May 20, 2020; or

(b) The nursing home's average COVID-19 positivity rate, based on reports made to the Department, during the period January 3, 2021 through January 31, 2021; or

(c) 20.15 percent, representing the highest Regional Economic Development Council average COVID-19 positivity rate, as reported to the Department, during the periods April 26, 2020 through May 20, 2020 and January 3, 2021 through January 31, 2021.

(d) In the case of nursing homes previously designated by the Department as a COVID-positive only facility, the term "applicable positivity rate" shall be as defined in clause *(c)* of this subparagraph.

(3) A nursing home shall be considered to possess and maintain the required PPE if:

(i) it maintains all PPE on-site; or

(ii) it maintains PPE off-site, provided that the off-site storage location is within New York State, can be accessed by the nursing home within at least 24 hours, and the nursing home maintains at least a 10-day supply of all required PPE on-site, as determined by the calculations set forth in paragraph (2) of this subdivision. A nursing home may enter into an agreement with a vendor to store off-site PPE, provided that such agreement requires the vendor to maintain unduplicated, facility-specific stockpiles, the vendor agrees to maintain at least a 60-day supply of all required PPE (less the amount that is stored on-site at the facility), and the PPE is accessible by the facility 24 hours a day, 7 days a week, year round. In the event the Department finds a nursing home has not maintained the required PPE stockpile, it shall not be a defense that the vendor failed to maintain the supply.

(iii) Any PPE stored outside of New York State shall not count toward the facility's required 60-day stockpile.

(4) The Department shall determine the nursing home's average census annually, by January 1st of each year, and shall communicate such determination to each facility. Nursing homes shall

have 90 days to come into compliance with the new PPE stockpile requirements, as set forth in paragraph (2) of this subdivision, following such determination by the Department.

(5) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers, and providers are strongly encouraged to rotate inventory through regular usage and replace what has been used in order to ensure a consistent readiness level and reduce waste. Expired products should be disposed of when their expiration date has passed. Expired products shall not be used to comply with the stockpile requirement set forth in paragraph (1) of this subdivision.

(6) Failure to possess and maintain the required supply of PPE may result in the revocation, limitation, or suspension of the nursing home's license; provided, however, that no such revocation, limitation, or suspension shall be ordered unless the Department has provided the nursing home with a fourteen day grace period, solely for a nursing home's first violation of this section, to achieve compliance with the requirement set forth herein.

(7) In the event a new methodology relating to PPE in Residential Health Care Facilities is developed, including but not limited to a methodology by the U.S. Department of Health & Human Services, and the Commissioner determines that such alternative methodology is appropriate for New York nursing homes and will adequately protect facility staff and patients, the Commissioner shall amend this subdivision to reflect such new methodology.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities, including hospitals and nursing homes.

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection and promotion of the health of the residents of the State by requiring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost.

Needs and Benefits:

The 2019 Coronavirus (COVID-19) is a disease that causes mild to severe respiratory symptoms, including fever, cough, and difficulty breathing. People infected with COVID-19 have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a general hospital and can be fatal, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

On January 30, 2020, the World Health Organization (WHO) designated the COVID-19 outbreak as a Public Health Emergency of International Concern. On a national level, the Secretary of Health and Human Services determined on January 31, 2020 that as a result of confirmed cases of COVID-19 in the United States, a public health emergency existed and had existed since January 27, 2020, nationwide. Thereafter, the situation rapidly evolved throughout

the world, with many countries, including the United States, quickly progressing from the identification of travel-associated cases to person-to-person transmission among close contacts of travel-associated cases, and finally to widespread community transmission of COVID-19.

In order for hospital and nursing home staff to safely provide care for COVID-19 positive patients and residents, or patients and residents infected with another communicable disease, while ensuring that they themselves do not become infected with COVID-19 or any other communicable disease, it is critically important that personal protective equipment (PPE), including masks, gloves, respirators, face shields and gowns, is readily available and are used. Therefore, as a result of global PPE shortages at the outset of the State of Emergency, New York State provided general hospitals, nursing homes, and other medical facilities with PPE from the State's emergency stockpile from the beginning of the COVID-19 outbreak. However, hospitals and nursing homes must ensure sufficient PPE stockpiles exist for any future communicable disease outbreaks to ensure each facility is adequately prepared to protect its staff and patients or residents, without needing to rely on the State's emergency stockpile.

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE to ensure that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak or another communicable disease outbreak.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each facility. However, the

Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are strongly encouraged to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby helping to balance facility expenditures over time and reduce waste. Further, in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). As such, this regulation imposes no long-term additional costs to regulated parties.

Costs to Local and State Governments:

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

Costs to the Department of Health:

This regulation will not result in any additional operational costs to the Department of Health.

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

General hospitals and nursing homes operated by local governments will be affected and will be subject to the same requirements as any other general hospital licensed under PHL Article 28.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

The Department believes that promulgation of this regulation is the most effective means of ensuring that general hospitals and nursing homes have adequate stockpiles of PPE necessary to protect hospital staff from communicable diseases, compared to any alternate course of action.

Federal Standards:

No federal standards apply to stockpiling of such equipment at hospitals.

Compliance Schedule:

The regulations will become effective upon publication of a Notice of Adoption in the New York State Register. These regulations are expected to be proposed for permanent adoption at a future meeting of the Public Health and Health Planning Council.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a general hospital or a nursing home. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses, and there are 79 nursing homes in New York qualify as small businesses given that they employ less than 100 staff.

Compliance Requirements:

These regulations require all general hospitals and nursing homes to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

Professional Services:

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

Compliance Costs:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each covered facility. However, the Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are strongly encouraged to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby

helping to balance facility expenditures over time and reduce waste. Further, in the event of an emergency need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). As such, this regulation imposes no long-term additional costs to regulated parties.

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 both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes. Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Small Business and Local Government Participation:

The Department contacted hospital and nursing home associations, individual hospitals and health systems, and health care labor unions for input regarding these regulations and the

underlying methodology. Input from these stakeholders has been incorporated into the regulations.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). Approximately 17% of small health care facilities are located in rural areas.

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

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

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

There are 47 general hospitals located in rural areas as well as several licensed nursing homes.

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

These regulations require all general hospitals and nursing homes, including those in rural areas, to purchase and maintain adequate stockpiles of PPE, including but not limited to masks, respirators, face shields and gowns.

Compliance Costs:

The purpose of this regulation is to require general hospitals and nursing homes to maintain adequate stockpiles of PPE. The initial cost to facilities as they establish stockpiles of PPE will vary depending on the number of staff working at each facility. However, the Department anticipates that hospitals and nursing homes will routinely use stockpiled PPE as part of their routine operations; while facilities must maintain the requisite stockpile at all times in the event of an emergency need, facilities are expected to rotate through their stockpiles routinely to ensure the PPE does not expire and is replaced with new PPE, thereby helping to balance facility expenditures over time and reduce waste. Further, in the event of an emergency

need, hospitals and nursing homes are expected to tap into their stockpiles; as such, hospitals and nursing homes will ultimately use equipment which would have been purchased had a stockpile not existed, thereby mitigating overall costs. Moreover, nursing homes are statutorily obligated to maintain or contract to have at least a two-month supply of PPE pursuant to Public Health Law section 2803(12). Therefore, this regulation imposes no long-term additional costs to regulated parties.

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 both hospitals and nursing homes have already mobilized their stockpiling efforts since early 2020, when the spread of the COVID-19 virus was first recognized in New York State, including through two surges of the COVID-19 pandemic. As such, the continuance of these stockpiling requirements is not expected to create any additional adverse impact on hospitals or nursing homes. Moreover, for nursing homes, these PPE regulations are consistent with the existing directive in Public Health Law section 2803(12) to maintain a two-month PPE supply.

Rural Area Participation:

The Department contacted hospital and nursing home associations, individual hospitals and health systems, and health care labor unions for input regarding these regulations and the

underlying methodology, including associations representing facilities in rural areas of the State. Input from these stakeholders has been incorporated into the regulations.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

A Job Impact Statement for these regulations 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 2803 of the Public Health Law, section 405.19 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (5) of subdivision (c) of section 405.19 is amended to read as follows:

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

(ii) The emergency service shall develop and implement policies and procedures for the identification, assessment and referral of patients with behavioral health presentations, including:

(*a*) The review of records, if any, in any available information network databases, including the Psychiatric Services and Clinical Knowledge Enhancement System (PSYCKES), the Statewide Health Information Network for New York (SHIN-NY), and the Prescription Monitoring Program (PMP).

(*b*) With the patient's consent, identifying and contacting the individual's family members or close friends who interact with the patient to obtain collateral information, including any psychiatric advance directive.

(*c*) Screening for suicide risk, which shall require positive screens be followed by a suicide risk assessment by a licensed professional trained in assessing suicide risk.

(*d*) Screening for violence risk, which shall include a process for subsequent assessment

and intervention in the case of a positive screen. As part of the screening, all patients must be asked about access to firearms or other weapons.

(*e*) Screening to determine whether an individual has complex needs. Social determinants must be considered in such discharge planning. For purposes of this paragraph, "individual with complex needs" shall have the meaning as determined by the Commissioner of Mental Health in Title 14 of the NYCRR.

(iii) In general hospitals with inpatient psychiatric units under 14 NYCRR Part 580, to accomplish adequate discharge planning for individuals with complex needs in need of post emergency treatment or services, the emergency service shall develop and implement policies and procedures for the discharge of an individual with complex needs, including:

(*a*) With the patient's consent, sending a discharge summary detailing the presenting mental health history, hospital course, and other relevant information to outpatient, residential, or long-term care treatment programs.

(*b*) Referring patients to care management programs or coordinating discharge planning with care managers in such programs.

(*c*) Confirming an appointment for psychiatric aftercare with an identified provider within seven calendar days following discharge. If, after making diligent efforts, a hospital cannot identify an aftercare provider with an available appointment within seven calendar days, the hospital shall document its efforts and schedule the appointment for as soon as possible thereafter. Individuals who are leaving the hospital against medical advice, or who state they do not wish to receive aftercare services, must be offered information about available treatment options.

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

The legislative objectives of PHL Article 28 include the protection of the health of the residents of the State by promoting the efficient provision and proper utilization of high-quality health services at a reasonable cost.

Current Requirements:

General hospital emergency services are required by 10 NYCRR § 405.19(c)(7), in conjunction with the discharge planning program of the hospital, to develop policies and procedures that specify the actions to be taken, and the appropriate contact agencies and individuals to accomplish adequate discharge planning for persons in need of post emergency treatment or services, but not in need of inpatient hospital care. A general hospital emergency department must refer emergency department patients for appropriate follow-up care after discharge from the hospital, including individuals with documented substance use disorders or who appear to have or be at risk for substance use disorders. However, the current regulations do not specifically reference discharges of patients with other behavioral health presentations and complex needs from the emergency department.

Needs and Benefits:

The proposed rule will require general hospital emergency services to develop policies and procedures for intake and discharge of patients with behavioral health presentations. The proposed rule will also add new screening requirements for risk of suicide and violence.

In addition, emergency departments in hospitals with inpatient psychiatric units must follow a more person-centered discharge plan for patients with complex needs. To accomplish adequate discharge planning for these individuals, general hospitals with inpatient psychiatric units must create and implement a discharge plan that addresses the patient's complex needs. These changes ensure that discharge plans will address the post-emergency needs of the patient, including confirmation of appointments for psychiatric follow-up after a hospital visit, moving clinicians away from treating only the medical emergency.

These new requirements for emergency departments will help improve patient outcomes, reduce the risk of post-discharge self-harm and violence, and reduce the risk of readmission and disconnection from care.

COSTS:

Costs to Private Regulated Parties:

The new screening requirements will increase staffing needs to accomplish this screening. Hospitals may need to hire more social workers, discharge planners, and administrative support staff to implement discharge plans that address the patient's complex needs. Cost to the regulated parties will be dependent upon the number of staff hired and the prevalent wages in the community where the regulated party is located. It is estimated that these costs will range from $500k per year for a small hospital, to up to $2.5M a year for a large

hospital. The Department will provide guidance to hospitals and will work with hospitals and hospital associations on the development of policies and procedures to implement the requirements of this regulation.

Costs to Local Government:

There are 13 hospitals owned by counties and municipalities which will be affected by this regulation and the costs associated with it. If the regulated party is owned by a local government, the costs will be comparable to the costs to private regulated parties.

Costs to the Department of Health:

It is estimated that at least 100 new complaints per year will be received after the implementation of this regulation. These complaints will result in approximately 75 onsite investigations at a cost of approximately $2.1M per year to the Department. This cost considers the number of hours that will be incurred by the surveillance team to investigate the complaint, collaborate with the Office of Mental Health (OMH) if needed, write up the statement of deficiency and review the plans of correction.

Costs to Other State Agencies:

OMH will also incur costs if they perform investigations into complaints and issues alleged or identified.

Local Government Mandate:

Hospitals owned by counties and municipalities are required to comply with the

requirements of this regulation.

Paperwork:

General hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. Therefore, the proposed regulations increase their paperwork to the extent that existing policies and procedures need to be updated to conform to these regulations.

Duplication:

While existing regulations require hospitals to make appropriate referrals, those regulations do not specifically reference patients with behavioral health presentations and complex needs. There otherwise are no relevant State regulations which duplicate, overlap, or conflict with the proposed regulations.

Alternatives:

The Office of Mental Health and the Department on Health, on October 20, 2023, issued joint guidance regarding evaluation and discharge practices for individuals who present with behavioral health conditions within psychiatric inpatient programs, emergency departments, and Comprehensive Psychiatric Emergency Programs (CPEPs). The Department opted to codify the guidance through these regulations, in part, for general hospitals with psychiatric inpatient programs to further strengthen evaluation and discharge requirements and to help improve patient outcomes, reduce the risk of post-discharge self-harm and violence, and reduce the risk of

readmission and disconnection from care. This regulation is necessary to turn provisions in the guidance into rules that general hospitals must follow.

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulatory provisions related to discharges from hospital emergency departments will apply to all general hospitals in New York State. This proposal will not impact local governments unless they operate one of the 13 general hospitals owned by counties and municipalities. Such local governments will be affected by this regulation and the costs associated with it. The general hospitals with emergency departments required to comply with these regulations are not small businesses.

Compliance Requirements:

These regulations will require general hospitals to develop new policies and procedures for intake and discharge of patients with behavioral health presentations and complex needs from emergency departments. Hospitals will be required to train their licensed and certified clinical staff members in such policies and procedures.

Professional Services:

While the current regulations do not specifically refer to intake and discharge of patients with behavioral health presentations or complex needs from hospital emergency departments, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. Hospitals are not likely to need outside professional services to comply with the requirements of this regulation.

Compliance Costs:

While the current regulations do not specifically refer to intake or discharge of patients with behavioral health presentations or complex needs from emergency departments, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training encompass the policies and procedures for patients who have behavioral health presentations or complex needs. However, these efforts are expected to assist individuals in obtaining treatment that will help them avoid future emergency room visits and hospital admissions. Costs to regulated parties will be dependent upon the number of staff hired and the prevalent wages in the community where the regulated party is located. It is estimated that these costs will range from $500k per year for a small hospital, to up to $2.5M a year for a large hospital. The Department will provide guidance to hospitals and will work with hospitals and hospital associations on the development of policies and procedures to implement the requirements of this regulation.

Economic and Technological Feasibility:

This proposal is economically and technically feasible. While existing regulations do not specifically refer to intake or discharge of patients with behavioral health presentations or complex needs from emergency departments, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care.

Minimizing Adverse Impact:

The regulations afford general hospitals flexibility to develop and implement their own policies and procedures that meet the minimum requirements of the regulations, which is expected to minimize the costs of compliance. In addition, if after making diligent efforts, a hospital cannot identify an aftercare provider with an available appointment within seven calendar days, the regulations provide flexibility to allow a hospital to document its efforts and schedule the appointment for as soon as possible thereafter.

Small Business and Local Government Participation:

Development of these regulations included input from organizations including those whose members include general hospitals that are operated by local governments or that constitute small businesses. The essential requirements of this regulation were announced in the Governor's State of the State address on January 9, 2024. This regulation was on the agenda of the meeting of the Public Health and Health Planning Council (PHHPC) that took place on February 8, 2024, in accordance with the Open Meetings Law. At that meeting, the regulation was reviewed and discussed by PHHPC members. In addition, the public, including the affected parties to this regulation, were afforded an opportunity to ask questions and provide comments.

In addition, there were conference calls made to associations representing the hospital industry to inform them of the regulation and to provide an opportunity to ask questions.

The regulation must be presented a second time at an open meeting of PHHPC, with another opportunity for public comment, and the regulation cannot be established unless and until PHHPC approves adoption of the regulation.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 44 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2020 (https://www.census.gov/quickfacts/). There are 55 general hospitals in rural areas.

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

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2020.

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

Reporting, Recordkeeping, Other Compliance Requirements and Professional Services:

The proposed regulation is applicable to those general hospitals located in rural areas and is expected to impose only minimal costs upon hospitals, which are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. However, the proposed regulatory requirements can be incorporated into existing processes, which should help to minimize the administrative burden on these entities.

Costs:

While the current regulations do not specifically refer to discharges of patients with behavioral health presentations or complex needs from hospitals emergency departments, hospitals are already required to establish written policies and procedures related to various operational requirements, train staff in such policies and procedures, and refer patients to appropriate follow-up care. The proposed regulations do require additional effort to ensure that the policies and training encompasses the policies and procedures for patients with behavioral health presentations or complex needs discharged from emergency departments. However, these efforts are expected to assist individuals in obtaining treatment that will help them avoid future emergency room visits and hospital admissions. Costs to regulated parties will be dependent upon the number of staff hired and the prevalent wages in the community where the regulated party is located. It is estimated that these costs will range from $500k per year for a small hospital, to up to $2.5M a year for a large hospital. The Department will provide guidance to hospitals and will work with hospitals and hospital associations on the development of policies and procedures to implement the requirements of this regulation.

Minimizing Adverse Impact:

The regulations afford general hospitals flexibility to develop and implement their own policies and procedures that meet the minimum requirements of the regulations, which is expected to minimize the costs of compliance. In addition, if after making diligent efforts, a hospital cannot identify an aftercare provider with an available appointment within seven calendar days, the regulations provide flexibility to allow a hospital to document its efforts and schedule the appointment for as soon as possible thereafter.

Rural Area Participation:

Development of these regulations included input from organizations including those that include as members general hospitals located in rural areas.

The essential requirements of this regulation were announced in the Governor's State of the State address on January 9, 2024. This regulation was on the agenda of the meeting of the Public Health and Health Planning Council (PHHPC) that took place on February 8, 2024, in accordance with the Open Meetings Law. At that meeting, the regulation was reviewed and discussed by PHHPC members. In addition, the public, including the affected parties to this regulation, were afforded an opportunity to ask questions and provide comments.

In addition, there were conference calls made to associations representing the hospital industry to inform them of the regulation and to provide an opportunity to ask questions.

The regulation must be presented a second time at an open meeting of PHHPC, with another opportunity for public comment, and the regulation cannot be established unless and until PHHPC approves adoption of the regulation.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

SUMMARY OF EXPRESS TERMS

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 surveillance and Medicaid purposes, to the extent authorized by law.

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 surveillance and Medicaid purposes, in accordance with SHIN-NY policy guidance.

(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 surveillance and Medicaid purposes, consistent with applicable law.

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 designated contractor 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 surveillance 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 surveillance 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 surveillance 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:

* * *

(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.

* * *

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.

* * *

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 surveillance and Medicaid purposes, in accordance with SHIN-NY policy guidance.

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 its Medicaid 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 further support such direct connection to the statewide data infrastructure, 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 Public Health Law section 2803, sections 405.4 and 405.6 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Paragraph (4) of subdivision (b) of Section 405.4 is amended to read as follows:

The hospital shall have an organized medical staff that operates under bylaws approved by the governing body.

* * *

(b) Organization.

* * *

(4) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates in accordance with the provisions of this Part and the New York State Public Health Law. Following the initial appointment of medical staff members, the medical staff shall conduct periodic reappraisals of its members, on at least[,] a [biennial] triennial basis.

Subparagraph (i) of paragraph (7) of subdivision (b) of Section 405.6 is amended to read as follows:

(b) The activities of the quality assurance committee shall involve all patient care services and shall include, as a minimum:

* * *

(7) the committee shall oversee and coordinate the following:

(i) the establishment of a medical, dental and podiatric staff privileges review procedure through which credentials, physical and mental capacity, and competence in delivering health care services are reviewed at least [biennially] triennially as part of an evaluation of staff privileges and in accordance with section 405.4 of this Part. These procedures shall include the collection of the following information from a physician, dentist or podiatrist prior to granting or renewing professional privileges or association in any capacity with the hospital:

* * *

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 2803 of the Public Health Law (PHL) authorizes the promulgation of such regulations as may be necessary to implement the purposes and provisions of PHL Article 28, including the establishment of minimum standards governing the operation of health care facilities, including hospitals.

Legislative Objectives:

PHL Article 28 assures the efficient provision and proper utilization of health services of the highest quality at a reasonable cost. Specifically, PHL section 2800 specifies that "hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health-related service shall be subject to the provisions of this article."

PHL section 2803(2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of health care facilities.

Needs and Benefits:

The proposed regulations will benefit Article 28 general hospitals by lengthening the requirement to review the credentials of medical staff from every two years to every three years, which will reduce administrative burdens and provide consistency by aligning with a recent revision by The Joint Commission to its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs.

Costs for Regulated Entities:

There are no anticipated costs to regulated parties (PHL Article 28 general hospitals), insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to State and Local Government:

There are no anticipated costs to regulated parties, including general hospitals owned and operated by State or Local governments, insofar as the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Cost to the Department of Health:

There are no anticipated costs to the Department of Health.

Local Government Mandates:

This regulation does not impose a local government mandate.

Paperwork:

Regulated entities will be required to maintain documentation that they have satisfied the minimum recredentialing review of medical staff as articulated in the proposed regulations.

However, the proposed regulations do not require new or additional paperwork requirements, insofar as existing regulations at 10 NYCRR sections 405.4 and 405.6 currently require Article 28 general hospitals to maintain records relating to their review of medical staff qualifications; the proposed regulations will reduce administrative burdens by requiring recredentialing every three years (triennially) instead of every two years (biannually).

Duplication:

The proposed regulation does not duplicate any federal, state, or local law.

Alternatives:

Alternatives include not amending the regulations or requiring a recredentialing period of a length other than every three years (triennially). However, the Department finds that neither alternative is viable. The proposed regulations align with a recent change by The Joint Commission to revise its credentialing and privileging standards applied to its Advanced Diagnostic Imaging, Ambulatory Surgical Center, Critical Access Hospital, and Hospital accreditation programs. Therefore, the Department finds that the triennial recredentialing timeframe proposed in these regulations—as opposed to the current (biannual) or an alternative timeframe—will provide consistency to regulated facilities, as it will align with standards applied by this national hospital accreditation organization to many of the Article 28 general hospitals in New York State.

Federal Requirements:

Federal Conditions of Participation at 42 CFR 482.22(a)(1) require medical staff to "periodically conduct appraisals of its members." The federal Centers for Medicare & Medicaid Services (CMS) has stated in a letter to The Joint Commission that "[p]eriodic review would be

consistent with local laws or national practice." Therefore, the proposed regulatory requirement for triennial reviews is consistent with existing federal regulation.

Compliance Schedule:

The regulations will become 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, nor does it require any new reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF
RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or new, 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

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