Public Health and Health Planning Council

Codes, Regulations and Legislation Committee Meeting Agenda
November 16, 2023
9:15 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 Information

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

23-20 Addition of Section 405.46 to Title 10 NYCRR (Hospital Cybersecurity Requirements)

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

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*.

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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 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.

SUMMARY OF EXPRESS TERMS

The proposed regulation would create a new section 405.46 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, to create cybersecurity requirements for all hospital facilities.

Section 405.46 (a) identifies all general hospitals in New York State as subject to the regulations.

Section 405.46 (b) defines certain terms and language for purposes of the section.

Section 405.46 (c) establishes the requirements for hospitals to have a cybersecurity program and defines protocols, procedures, and core functions of such program.

Section 405.46 (d) defines the cybersecurity policies that general hospitals will need to create and the topics that should be considered after a risk assessment has been performed.

Section 405.46 (e) requires general hospitals to designate a Chief Information Security Officer who will be responsible for cybersecurity program creation, implementation, and oversight.

Section 405.46 (f) sets forth the requirements for testing and vulnerability of a general hospital's cybersecurity program.

Section 405.46 (g) outlines the audit trails and records maintenance and retention requirements of a general hospital's cybersecurity program.

Section 405.46 (h) sets forth the requirements for cybersecurity risk assessments and the considerations for policies and procedures relative to those risk assessments.

Section 405.46 (i) sets forth the requirements for cybersecurity personnel general hospitals must utilize.

Section 405.46 (j) sets forth the policies for third-party service providers of cybersecurity programs.

Section 405.46 (k) sets forth the requirements for multi-factor authentication procedures.

Section 405.46 (l) sets forth the requirements for training and monitoring of the cybersecurity program.

Section 405.46 (m) defines the requirements for an incident response plan in the event of a cybersecurity incident.

Section 405.46 (n) defines the reporting requirements for a general hospital during a cybersecurity incident.

Section 405.46 (o) refers to confidentiality and the applicability of State and federal statutes.

Section 405.46 (p) provides general hospitals one (1) year from the date of adoption to comply with the new regulatory requirements, except that general hospitals must immediately begin reporting to the Department as required by subdivision (n) of this section.

Section 405.46 (q) states that if any provisions of the section are found to be invalid, it shall not affect or impair the validity of other provisions of the section.

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 adding a new section 405.46, to be effective upon publication of the Notice of Adoption in the State Register, to read as follows:

405.46 Hospital Cybersecurity Requirements

(a) Applicability. This section shall apply to all general hospitals licensed pursuant to article 28 of the Public Health Law, referred to throughout this section as "hospitals."

(b) Definitions. For the purposes of this section the following terms shall have the following meaning:

(1) "Authorized user" means any employee, contractor, agent or other person that participates in or operates on behalf of the operations of a hospital and is authorized to access and use any information systems and data of such hospital.

(2) "Control" means any mechanism, safeguard, policy or security measure that is put into place pursuant to implementation specification, to satisfy the requirement for a security measure.

(3) "Compensating Control" means any alternative measure that is put into place to satisfy the requirement for a security measure, where the implementation specification for that requirement is deemed not reasonable or appropriate to implement. The hospital must document why it would not be reasonable and appropriate to implement the implementation specification; and implement an equivalent alternative measure if reasonable and appropriate.

(4) “Cybersecurity event” means any act or attempt, successful or unsuccessful, to gain unauthorized access to, disrupt or misuse the hospital’s information system or information stored on such information system, including but not limited to health records.

(5) “Cybersecurity incident” means a cybersecurity event that:

(i) has a material adverse impact on the normal operations of the hospital, or;

(ii) has a reasonable likelihood of materially harming any material part of the normal operation(s) of the covered entity; or

(iii) results in the deployment of ransomware within a material part of the hospital’s information systems.

(6) “Information system” means a discrete set of electronic information resources organized for the collection, processing, storage, maintenance, use, sharing, dissemination or disposition of electronic information, as well as any specialized system such as industrial/process controls systems, telephone switching and private branch exchange systems, and environmental control systems. One such example is an electronic health records system.

(7) “Multi-factor authentication” means authentication through verification of at least two of the following types of authentication factors:

(i) knowledge factors such as a password

(ii) possession factors such as a token

(iii) inherence factors, such as a biometric characteristic

(8) “Nonpublic information” means all electronic information that is not publicly available information and is:

(i) a hospital's business-related information, the tampering with which, or unauthorized disclosure, access or use of which, would cause a material adverse impact to the business, operations or security of such hospital;

(ii) any information concerning a natural person which because of name, number, personal mark, or other identifier can be used to identify such natural person. This includes any information in combination with any one or more of the following data elements, when either the data element or the combination of personal information plus the data element is not encrypted, or is encrypted with an encryption key that has also been accessed or acquired, in combination with any one or more of the following data elements:

(*a*) social security number;

(*b*) drivers' license number or non-driver identification card number;

(*c*) account number, credit or debit card number in combination with any required security code or access code;

(*d*) password or other information that would permit access to an individual's financial account;

(*e*) account number, credit or debit card number, if circumstances exist wherein such number could be used to access an individual's financial account without additional identifying information, security code, access code or password;

(*f*) biometric information, meaning data generated by electronic measures of an individual's unique physical characteristics, such as a fingerprint, voice print, retina or iris image, or other unique physical representation or digital representation of biometric data which are used to authenticate or ascertain the individual's identity; or a username or email address in combination with a password or security question and answer that would permit access to an online account; or

(*g*) any information or data, in any form or medium created by, held by, transmitted by, or derived from a health care provider or an individual and that relates to:

(1) the past, present or future physical, mental or behavioral health, or condition of any individual or a member of the individual's family;

(2) the provision of health care to any individual; or

(3) payment for the provision of health care to any individual.

(9) "Penetration testing" is a test methodology in which assessors attempt to circumvent or defeat the security features of an information system from outside or inside the hospital's information systems.

(10) "Publicly available information" means any information that a hospital has a reasonable basis to believe is lawfully made available to the general public from widely distributed media; or disclosures to the general public that are required to be made by Federal, State or local law. For the purposes of this paragraph, a hospital has a reasonable basis to believe that information is lawfully made available to the general public if the hospital has taken steps to determine that:

(i) the information is of the type that is available to the general public;

(ii) no individual who could have lawfully objected to the information being disclosed to the general public, has made such a request; and

(iii) disclosure to the general public would not violate other Federal, State, or local government laws, including but not limited to the Health Insurance Portability and Accountability Act (HIPAA).

(11) "Risk assessment" means the risk assessment that each hospital must conduct under subdivision (h) of this section.

(c) Cybersecurity Program Requirements.

(1) Each hospital shall establish within its policies and procedures a cybersecurity program based on the hospital's risk assessment.

(2) The cybersecurity program shall be designed to supplement HIPAA and shall not replace any provisions of the HIPAA Security Rule (45 CFR part 160 and subparts A and C of part 164), or any existing patient protections afforded and mandated under HIPAA. Hospitals are expected to comply with this section and HIPAA.

(3) The cybersecurity program shall be designed to perform the following core functions:

(i) identify and assess internal and external cybersecurity risks that may threaten the security or integrity of nonpublic information stored on the hospital's information systems;

(ii) use defensive infrastructure and the implementation of policies and procedures to protect the hospital's information systems, and the nonpublic information stored on those information systems, from unauthorized access, use or other malicious acts;

(iii) detect cybersecurity events;

(iv) respond to identified or detected cybersecurity events to mitigate any negative effects;

(v) recover from cybersecurity events and incidents and restore normal operations and services; and

(vi) fulfill applicable statutory and regulatory reporting obligations.

(4) Each hospital's cybersecurity program shall include policies and protocols to limit user access privileges to information systems that provide access to nonpublic information. Each hospital shall periodically review such access privileges, and such access privileges shall be based on the hospital's risk assessment, and other State and Federal laws, including but not limited to the administrative, physical and technical safeguards under HIPAA.

(5) Each hospital's cybersecurity program shall include written procedures, guidelines and standards designed to ensure the use of secure development practices for in-house developed applications utilized by the hospital, and procedures for evaluating, assessing and testing the security of externally developed applications utilized by the hospital. All such procedures, guidelines and standards shall be annually reviewed, assessed, updated and attested as such by the chief information security officer (CISO) (or a qualified designee) of the hospital.

(6) Each hospital's cybersecurity program shall include policies and procedures for the secure disposal, on a periodic basis, of any nonpublic information identified that is no longer necessary for business operations or for other legitimate business purposes of the hospital, except where such information is otherwise required to be retained by law or regulation, or where targeted disposal is not reasonably feasible due to the manner in which the information is maintained.

(7) Each hospital's cybersecurity program shall implement security measures and controls, including encryption, to protect nonpublic information held or transmitted by the hospital, both in transit over external networks and at rest, which takes into account necessary controls identified in the hospital's risk assessment.

(i) To the extent a hospital determines that encryption of nonpublic information in transit over external networks is infeasible, the hospital shall instead secure such nonpublic information using effective compensating controls reviewed and approved by the hospital's CISO.

(ii) To the extent a hospital determines that encryption of nonpublic information at rest is infeasible, the hospital shall instead secure such nonpublic information using effective alternative compensating controls reviewed and approved by the hospital's CISO.

(iii) To the extent that a hospital is utilizing compensating controls under this paragraph, the feasibility of encryption and effectiveness of the compensating controls shall be reviewed and

documented by the CISO as needed to continue securing nonpublic information. Such reviews and associated documentation shall be completed at minimum on an annual basis.

(d) Cybersecurity policy.

(1) Each hospital shall maintain and implement policies and procedures for the protection of its information systems and nonpublic information stored on those information systems, in accordance with State and Federal law. These policies shall be developed by the CISO and hospital information security/information technology staff.

(2) The hospital's cybersecurity policy, upon recommendation by the CISO shall be approved by the hospital's governing body, established pursuant to section 405.2 of this Part. If a committee is established for the specific purpose of supervising the hospital's cybersecurity measures, the committee shall present the cybersecurity policy to the governing body for full approval and implementation.

(3) The cybersecurity policies shall be based on the hospital's risk assessment and address, at a minimum, the following topics:

(i) information security;

(ii) data governance and classification;

(iii) asset inventory and device management;

(iv) access controls and identity management;

(v) business continuity and disaster recovery planning and resources;

(vi) systems operations and availability concerns;

(vii) systems and network security;

(viii) systems and network monitoring;

(ix) systems and application development and quality assurance;

(x) physical security and environmental controls;

(xi) patient data privacy;

(xii) vendor and third-party service provider management;

(xiii) risk assessment as defined in subdivision (h) of this section;

(xiv) training and monitoring as defined in subdivision (l) of this section; and

(xv) overall incident response as defined in subdivision (m) of this section;

(e) Chief Information Security Officer.

(1) Each hospital shall designate an individual from senior- or executive-level staff, qualified in training, experience, and expertise, to serve as the hospital's Chief Information Security Officer, or "CISO."

(2) Notwithstanding the provisions set forth in subdivision (i) of this section, the hospital's CISO may be an employee of the facility, or an employee of a third-party or contract vendor. If the CISO is an employee of a third-party or contract vendor, the governing body, as defined under section 405.2 of this Part, shall approve the contract on an annual basis.

(3) The hospital's CISO shall be responsible for developing and enforcing the hospital's cybersecurity policy, established pursuant to subdivision (d) of this section, and overseeing and implementing the hospital's cybersecurity program, established pursuant to subdivision (c) of this section.

(4) The CISO of each hospital shall report in writing, at least annually to the hospital's governing body, on the hospital's cybersecurity program and material cybersecurity risks. Such report shall, at minimum include:

(i) the confidentiality of nonpublic information and the integrity and security of the hospital's information systems;

(ii) the hospital's cybersecurity policies and procedures, including their implementation status and any recommendations for revisions;

(iii) material cybersecurity risks to the hospital;

(iv) overall effectiveness of the hospital's cybersecurity program; and

(v) any cybersecurity incidents as defined herein involving the hospital during the time period addressed by the report, as well as steps taken to mitigate future events.

(f) Testing and vulnerability assessments.

(1) The cybersecurity program for each hospital shall include monitoring and testing, developed in accordance with the hospital's risk assessment, designed to assess the effectiveness of the hospital's cybersecurity program and assess changes in information systems that may create or indicate vulnerabilities.

(2) The monitoring and testing shall include at a minimum:

(i) penetration testing of the hospital's information systems by a qualified internal or external party at least annually; and

(ii) automated scans or manual or automated reviews of information systems reasonably designed to identify publicly known cybersecurity vulnerabilities in the hospital's information systems based on the risk assessment.

(g) Audit Trails and Records Maintenance.

(1) Each hospital shall securely maintain systems that are designed to support normal operations and obligations of the hospital. Records pertaining to systems design, security, and maintenance supporting such normal operations shall be maintained for a minimum of six years.

(2) Each hospital shall also securely maintain systems to include audit trails designed to detect and respond to cybersecurity events that have a reasonable likelihood of materially harming any

material part of the normal operations of the hospital, and cybersecurity incidents as defined herein. Records pertaining to such audit trail systems shall be maintained for a minimum of six years.

(3) Designs for the security systems and audit trails required pursuant to paragraphs (1) and (2) of this subdivision shall be based on the hospital's risk assessment.

(h) Risk assessment.

(1) Each hospital shall conduct an accurate and thorough annual risk assessment of the hospital's potential risks and vulnerabilities to the confidentiality, integrity, and availability of nonpublic information, such as electronic protected health information, held by the hospital, as well as information systems sufficient to inform the design of the cybersecurity program as required by this section. Such risk assessment shall be updated as reasonably necessary, and no less than annually, and address changes to the hospital's information systems, nonpublic information or business operations. The risk assessment shall allow for revision of controls to respond to technological developments and evolving threats and shall consider the particular risks of the hospital's business operations, nonpublic information collected or stored, information systems utilized and the availability and effectiveness of controls to protect nonpublic information and information systems. Risk assessments performed for other regulatory purposes, such as HIPAA, shall be acceptable under this provision provided they comport with the requirements herein. Other risk assessments performed for other regulatory purposes, such as HIPAA, may be extended to comply this section and incorporate other risk assessments performed by qualified internal or external parties.

(2) The risk assessment shall be carried out in accordance with written policies and procedures and shall be documented. Such policies and procedures shall, at a minimum include:

(i) criteria for the evaluation and categorization of identified cybersecurity risks, vulnerabilities, and threats facing the hospital;

(ii) criteria for the assessment of the confidentiality, integrity, security and availability of the hospital's information systems and nonpublic information, including the identification and adequacy of existing controls in the context of identified risks, the determination of the likelihood of threat occurrence and the determination of the potential impact on threat occurrence, and the determination of the level of risk; and

(iii) requirements describing how identified risks and threats will be mitigated or accepted based on the risk assessment and how the cybersecurity policies and programs will address the risks.

(i) Cybersecurity personnel.

(1) Each hospital shall:

(i) utilize qualified cybersecurity personnel of the hospital, an affiliate or a third-party service provider sufficient to manage the hospital's cybersecurity risks and to perform or oversee the performance of the core cybersecurity functions specified in subdivision (c) of this section and in accordance with the hospital's risk assessment;

(2) Each hospital may utilize an affiliate or qualified third-party service provider to assist in complying with the requirements set forth in this section.

(j) Security policies for third-party service providers.

(1) Each hospital shall implement written policies and procedures designed to ensure the security of information systems and nonpublic information that are accessible to, or held by, third-party service providers. Such policies and procedures shall be based upon the hospital's risk assessment and shall, at a minimum, address the following:

(i) the identification and baseline assessment (if applicable) of third-party service providers; and

(ii) minimum cybersecurity practices required to be met by such third-party service providers in order for them to do business with the hospital.

(2) Such policies and procedures shall include relevant guidelines for due diligence and contractual protections relating to third-party service providers, including, at a minimum, guidelines addressing:

(i) ensuring third-party service provider's policies and procedures for access controls are consistent with industry standards;

(ii) the third-party service provider's policies and procedures for use of encryption or another method to protect nonpublic information in transit and at rest;

(iii) notice to be provided to the hospital in the event of a cybersecurity incident directly impacting the hospital's information systems or the hospital's nonpublic information being held by the third-party service provider; and

(iv) representations and warranties addressing the third-party service provider's cybersecurity policies and procedures that relate to the security of the hospital's information systems or nonpublic information.

(k) Risk-Based authentication.

(1) Each hospital shall use multi-factor authentication, risk-based authentication, or other compensating control to protect against unauthorized access to nonpublic information or information systems.

(2) Multi-factor authentication shall be utilized for any individual accessing the hospital's internal networks from an external network, unless the hospital's CISO has approved in writing the use of compensating controls.

(l) Training and monitoring.

As part of its cybersecurity program, each hospital shall, at a minimum:

(1) Implement risk-based policies, procedures and controls designed to monitor the activity of authorized users and detect unauthorized access or use of, or tampering with, nonpublic information by such authorized users.

(2) Provide regular cybersecurity awareness training for all personnel that is updated to reflect risks identified by the hospital in its risk assessment, which may include annual phishing exercises and training/remediation for employees.

(m) Incident response plan.

(1) As part of its cybersecurity program, each hospital shall establish a written incident response plan designed to promptly respond to, and recover from, any cybersecurity incident materially affecting the confidentiality, integrity or availability of the hospital's information systems or the continuing functionality of any aspect of the hospital's business or operations.

(2) Such incident response plan shall, at a minimum, address the following areas:

(i) the goals of the incident response plan;

(ii) the definition of clear roles and responsibilities, a list of actual personnel and both business hour and off-business hour contact information with levels of decision-making authority;

(iii) external and internal communications and information sharing about any incidents;

(iv) identification of requirements for the remediation of any identified weaknesses in information systems and associated controls;

(v) the internal processes for responding to a cybersecurity event including, at a minimum, mitigation, downtime procedures and contingency plan, and process for determining if a cybersecurity event becomes a cybersecurity incident, and processes for determining if a cybersecurity incident has a material adverse impact on the hospital;

(vi) documentation and reporting regarding cybersecurity events and related incident response activities; and

(vii) the evaluation and revision as necessary of the incident response plan following a cybersecurity event.

(n) Department Reporting.

(1) The hospital CISO or their designee shall notify the department within two hours of a determination that a cybersecurity incident, as defined herein, has occurred and has had a material adverse impact on the hospital, in a manner prescribed by the department. All notifications to the department under this section does not replace any other notifications required under State or Federal law.

(2) Each hospital shall maintain and submit for examination, in such time and manner and containing such information, as the department determines to be necessary, including but not limited to any and all documentation, such as records, schedules, reports, and data required and supporting the required documentation by this section. All such documentation must be maintained for a minimum of six years.

(3) To the extent a hospital has identified areas, systems or processes that require material improvement, updating or redesign, the hospital shall document the identification and the remedial efforts planned, and underway, to address such areas, systems or processes. Such documentation must be available for inspection by the department, in such time and manner as prescribed by the department, and must be maintained for a minimum of six years.

(o) Confidentiality.

Information provided by a hospital pursuant to this Part shall be subject to the applicable provisions of the Public Health Law, Mental Hygiene Law, Education Law, and the Public Officers Law or any other applicable State or Federal law in relation to disclosure.

(p) Compliance period.

(1) Covered entities shall have one year from the effective date of this section to comply with the requirements set forth herein, provided, however, subdivision (n) of this section shall be effective immediately upon adoption.

(q) Severability.

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

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.

These regulations fulfill this legislative objective by ensuring that general hospitals within New York State implement minimum cybersecurity controls to safeguard protected health information (PHI) and personally identifying information (PII) from being publicly disclosed or used for identity theft.

Needs and Benefits:

The healthcare industry is one of the most targeted communities for cybersecurity scams and breaches due to the significant amount of sensitive and financially lucrative information healthcare facilities collect. Currently in New York State there are no cybersecurity requirements for the safeguarding and security of patients' protected health information (PHI) and personally identifying information (PII). As a result, New Yorkers seeking medical care

have no guaranteed minimum levels of protection of their information. As a result of this, there have been several high-profile cybersecurity breaches at facilities across the state which have resulted in not only a loss of patient financial and health data, but in some cases has also delayed care.

Additionally, cybersecurity events at hospitals can have significant, far-reaching, and long-term impacts to the provision of patient care and operation of the facility. Governor Hochul has been focusing on cybersecurity and ensuring that New Yorkers data stays safe no matter where they go. The promulgation and implementation of cybersecurity focused regulations supports this initiative. These regulations will ensure all hospitals develop, implement, and maintain minimum cybersecurity standards, including cybersecurity staffing, network monitoring and testing, policy and program development, employee training and remediation, incident response, appropriate reporting protocols and records retention.

There will be multiple benefits to the adoption of these regulations. Given the significant differences in preparedness statewide against cybersecurity attacks, these regulations will ensure hospitals are required to maintain a minimum level of readiness to prepare for, respond to, and quickly recover from cybersecurity incidents.

Costs:

Costs to Regulated Parties:

The costs associated with the implementation by regulated facilities will vary significantly due to the varying levels of cybersecurity programs and policies hospitals currently have in place. Some facilities may have mature monitoring, training and response programs, whereas others may not. Therefore, the costs could vary from tens of thousands to tens of millions. Hospitals will be allowed to sub-contract for cybersecurity services and this may reduce

the overall cost of program implementation. It is estimated that effective cybersecurity programs can cost between $250,000 and $10 Million to develop and implement initially and anywhere from $50,000 - $2 Million or more to maintain on a yearly basis depending on the facility size. For small hospitals (of which there are 15 and are defined as less than 10 acute care or ICU beds), ongoing annual costs are estimated to be $50,000-$200,000. For medium sized hospitals (of which there are 62 and are defined as those with between 10 and 100 beds), ongoing costs are estimated to be $200,000-$500,000. For large hospitals (of which there are 114 and are defined as those with more than 100 beds), ongoing annual costs are estimated to be $2 million.

Costs to Local and State Governments:

There are currently fifteen facilities which would be subject to these proposed regulations which are operated by local municipalities. As such, they would be subject to the same regulations as those operated by private entities. The estimated costs they would incur would depend on their size, as noted above.

Local Government Mandates:

These regulations do impose a program, service, duty or other responsibility upon 4 separate city, county and State governments to the extent they do not already comply with the proposed regulations.

Paperwork:

These regulations impose additional paperwork in the form of procedures, policies, guidelines, and reporting documents. These requirements are necessary to ensure the efficacy of a cybersecurity program and also provide accountability and transparency for hospitals.

Duplication:

There is no duplication of this initiative in existing State law. The Heath Insurance Portability and Accountability Act (HIPAA) Security Rule does provide broad requirements for safeguarding PHI, but the regulations contained herein are intended to supplement HIPAA.

Alternatives:

The alternative to the proposed regulation would be not enacting the cybersecurity requirements. This option is not appropriate due to the demonstrated need to protect PHI and PII at hospitals within the State. The Department in 2023 has responded to more than 1 cybersecurity incident per month, several of which have forced hospitals to go on diversion, stopped their billing procedures, and required facilities to operate on downtime procedures which can severely hamper the care delivery process. Over 225,000 patients had data possibly compromised in one breach alone.

In order to respond to comments received by facilities, the proposed regulations were modified to lengthen and simplify the compliance period in order to maximize the ability for facilities to come into compliance. Furthermore, the Department removed the requirement for a Chief Information Security Officer to be employed directly by the facility, and instead allow them to be a virtual or 3rd party vendor upon approval by the facilities' governing body.

Federal Standards:

Federal regulations governing protection of PHI and PII are contained within HIPAA, however they are overly vague and provide limited guidance on cybersecurity and the protection of PHI and PII.

Compliance Schedule:

General hospitals will have one year from the effective date of the regulation to comply with the requirements set forth herein. However, subdivision (n) of the regulation, requiring general hospitals to notify the department within two hours of a determination that a cybersecurity incident has occurred, will be effective upon adoption in the State Register. The schedule as proposed was modified as a direct result of outreach to facilities by the Department who provided feedback on the difficulty in developing cybersecurity programs.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

The proposed regulations will affect all general hospitals licensed pursuant to Article 28 of the Public Health Law, regardless of size or location. There are currently 226 hospitals in New York State, including Veteran's Affairs facilities (which would not be affected by these proposed regulations). These regulations will not affect local governments unless they operate a general hospital. In NYS, there are 15 hospitals operated by municipalities; Lewis County Hospital in Lewis County, NY, Wyoming County Hospital in Wyoming County, 12 facilities operated by New York City Health and Hospitals Corporation, and Helen Hayes hospital operated by the State of New York.

Currently in New York State there are no cybersecurity requirements for the safeguarding and security of patients' protected health information (PHI) and personally identifying information (PII). As a result, New Yorkers seeking medical care have no guaranteed minimum levels of protection of their information. As a result of this, there have been several high-profile cybersecurity breaches at facilities across the state which have resulted in not only a loss of patient financial and health data, but in some cases has also delayed care. Additionally, cybersecurity events at hospitals can have significant, far-reaching, and long-term impacts to the provision of patient care and operation of the facility. These regulations will ensure all hospitals develop, implement, and maintain minimum cybersecurity standards, including cybersecurity staffing, network monitoring and testing, policy and program development, employee training and remediation, incident response and appropriate reporting protocols and records retention.

Compliance Requirements:

The proposed regulations require that hospitals develop, implement and maintain minimum cybersecurity standards and programs, including information technology (IT) staffing, network monitoring and testing, policy and program development, employee training and remediation, incident response, appropriate reporting protocols and records retention.

Professional Services:

Depending on the current state of an existing cybersecurity program, a facility or system may need to contract with a third-party service provider for anything from staffing, network monitoring, incident response, or staff training. Facilities will be required to hire or appoint a Chief Information Security Officer (CISO) to design and implement their cybersecurity program. The draft regulations currently allow for the CISO to be a direct employee of the facility, or an employee of a virtual or third-party contractor upon consent and approval of the governing body. Facilities may also need to hire or contract additional information technology staff to ensure compliance with the new regulations. Additionally, the facilities may need to purchase information security programs or contract with third-party vendors to monitor for malicious network traffic, perform compliance testing with authorized users and ensure protected health information and personally identifying information is kept secure.

Compliance Costs:

Given the variability in cybersecurity preparedness and current programs at facilities, the initial startup and ongoing costs could vary significantly. After initial conversations with facilities to gain a basic understanding of costs, it is estimated that effective cybersecurity

programs can cost millions to develop and implement initially, and anywhere from $50,000-$2 million or more to maintain on a yearly basis depending on the facility size. For small hospitals (of which there are 15 and are defined as less than 10 acute care or ICU beds), ongoing annual costs are estimated to be $50,000-$200,000. For medium sized hospitals (of which there are 62 and are defined as those with between 10 and 100 beds), ongoing costs are estimated to be $200,000-$500,000. For large hospitals (of which there are 114 and are defined as those with more than 100 beds), ongoing annual costs are estimated to be $2 million.

Economic and Technological Feasibility:

It is both economically and technologically feasible for hospitals to become compliant with the proposed regulations. There currently exists a significant amount of technology and software which can be licensed or purchased to provide network monitoring, notification, staff training and exercises and multifactor or risk-based authentication, among others. Economically, it will be easier for hospitals which are part of large healthcare systems or located in more urban areas to comply with these regulations than it may be for smaller or more rural facilities. This is due to the fact that the larger facilities and systems may already have aspects of the regulations already functioning as part of a mature cybersecurity program, or may have access to more capital and resources than smaller, more rural or standalone facilities. While several facilities voiced concerns related to the cost of implementation, the consequences of what can occur as a result of a cyber-attack far outweigh those costs. Days or weeks of downtime with an inability to bill for services can cost tens of millions of dollars (at a minimum), as well as the unknown cost of lost productivity, cancellation of elective surgeries, purchase of new computers, etc, can well exceed the yearly maintenance program costs.

Minimizing Adverse Impact:

The Department of Health conducted several rounds of outreach to affected healthcare facilities and healthcare associations as part of the regulatory drafting process, to understand what makes a successful cybersecurity program, what things should be avoided or be flexible, and how the Department can work with them to enhance preparedness in New York State. As a result of those discussions, the Department took significant steps to ensure that no specific references to technology, programs or software were included into the regulations. In this way, it allows for facilities to become compliant with the regulations however they may be able to, without the regulation becoming too prescriptive, or requiring use of overly expensive or specific software. These regulations establish truly baseline, general requirements that allow maximum flexibility to healthcare facilities to comply based on their operations. While other approaches to cybersecurity programs were considered, as required under SAPA § 202-b(1), there are unfortunately no alternatives to cybersecurity, as the health and welfare of patients both current and former at a facility can be adversely affected by a network breach. Facilities will have one year from implementation to come into compliance with the regulations except for event reporting. The compliance period as proposed will not only maximize the ability for facilities to come into compliance, but was modified as a result of feedback received from those facilities. While these regulation will result in some cost to facilities, the Department will be taking action to mitigate these impacts. The Department will soon be issuing a request for application for a new $500M Health Care Technology Capital program. Funding for this program was appropriated in the FY24 budget, with the intention of supporting facilities' technological needs, including for cybersecurity purposes. This funding will help facilities to come into compliance with these regulations.

Small Business and Local Government Participation:

During the drafting process, the Department conducted several rounds of outreach to over 25 different hospitals and hospital/healthcare associations to understand the current state of the industry, cybersecurity program best practices and areas to avoid.

Parties the Department reached out to:
University of Rochester MC
Kaleida Health
Northwell Health
NY Presbyterian
Elizabethtown Hospital
Arnot Ogden MC
Geneva General Hospital
Soldiers and Sailors Memorial Hospital
Rochester General Hospital
Unity Hospital
Wyoming County Hospital
Richmond University Medical Center
Healthcare Association of NYS
Iroquois Healthcare Association
Healthcare Association of Central and Western NY
Suburban Hospital Alliance of NYS
Greater NY Healthcare Association

As there are facilities run by city, county and state municipalities, a cross section of them was invited to participate in the roundtable discussion related to cybersecurity programs and proposed regulations. The Department has some direct communication methods through the

Health Commerce system which will be utilized to reach out to C Suite executives at each facility after the regulations are publicly posted and available for comment.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

Rural areas as defined by Executive Law § 418(7) are counties with a population less than 200,000 and towns with a population density less than 150 people per square mile. For the purposes of this regulation, there are 44 counties with a population of less than 200,000, which have a total of 76 regulated facilities. The proposed rule will apply statewide to all general hospitals regulated under Article 28 of the Public Health Law.

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

1. Recordkeeping- Article 28 facilities will be required to develop cybersecurity policies, protocols and procedures within one year of the adoption of the proposed regulations. Facilities will be required to maintain records of program compliance by employees, security breaches by outside entities (both successful and unsuccessful), and other program documentation for at least 6 years.
2. Reporting: Article 28 facilities will be required to report any cybersecurity incidents as defined in the proposed regulation within 2 hours of discovery. Facilities will also be required to provide a report to the Department upon request of all cybersecurity incidents within the previous reporting period.
3. Professional services- Facilities will be required to hire or appoint a Chief Information Security Officer (CISO) to design and implement their cybersecurity program. The draft regulations currently allow for the CISO to be a direct employee of the facility, or an employee of a virtual or third-party contractor upon consent and approval of the

governing body. Facilities may also need to hire or contract additional information technology staff to ensure compliance with the new regulations. Additionally, the facilities may need to purchase information security programs or contract with third-party vendors to monitor for malicious network traffic, perform compliance testing with authorized users and ensure protected health information and personally identifying information is kept secure.

Costs:

The costs for this program will vary depending on the level of preparedness of each facility. For less mature programs which require significant development, the initial funding required could range from $250,000 to $10 million. For small hospitals (of which there are 15 and are defined as less than 10 acute care or ICU beds), ongoing annual costs are estimated to be $50,000-$200,000. For medium sized hospitals (of which there are 62 and are defined as those with between 10 and 100 beds), ongoing costs are estimated to be $200,000-$500,000. For large hospitals (of which there are 114 and are defined as those with more than 100 beds), ongoing annual costs are estimated to be $2 million. Facilities may be able to purchase equipment or services from State Contract lists where appropriate and applicable. Facilities will also be able to contract with appropriate third-party vendors or contractors to help ensure compliance with the proposed regulations.

Minimizing Adverse Impact:

The Department has included flexibility within the regulations for facilities to ensure they are compliant with the requirements, including allowing for third-party or vendor contractors to

complete compliance reporting and measures on behalf of them. Additionally, facilities will have one year from the adoption of the proposed regulations to implement the requirements and ensure compliance. While these regulations will result in some cost to facilities, the Department will be taking action to mitigate these impacts. The Department will soon be issuing a request for application for a new $500M Health Care Technology Capital program. Funding for this program was appropriated in the FY24 budget, with the intention of supporting facilities' technological needs, including for cybersecurity purposes. This funding will help facilities to come into compliance with these regulations.

Rural Area Participation:

In consideration of SAPA § 202-bb(7), the Department conducted multiple rounds of outreach with facilities of a diversity of sizes, including those located in rural areas such as Ellenville Regional Hospital and Arnot Ogden Medical Center. This outreach consisted of one-on-one conference calls with specific facilities, which occurred June 12-22, 2023, as well as a roundtable in August 2023 where over 25 facilities, healthcare associations and Department of Health staff were invited to discuss the current state of cybersecurity programs, best practices and required elements of a good cybersecurity program. While many facilities agreed about the need for mature cybersecurity program amid increasing cybersecurity threats, many voiced concerns about the costs of these programs. The Department listened to all of the feedback provided and modified some of the language in the proposed regulations. For example, the Department simplified and lengthened the compliance period to allow facilities the maximum amount of time to be in compliance.

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 purpose 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 Medicaid's HCBS program in a non-residential setting, provide full access to the benefits of community living and offer services in the most integrated settings. This also establishes requirements that are eligible for reimbursement for the Medicaid home and community-based services (HCBS) provided under sections 1915 of the Medicaid statute.

The amendments are made to the setting requirements, where in 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 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.