Section 103.8(c)(4)(i) is amended as follows:

(i) the amount determined in section 103.7(b)(1) or section [103.8(c)(1)] *103.7(c)(1)* of this Part, as applicable, reduced by the credit for reinsurance determined pursuant to the Insurance Law and this Title, including Insurance Law section 1308, Part 79 (Insurance Regulation 133), Part 125 (Insurance Regulation 20), Part 126 (Insurance Regulation 114), Part 83 (Insurance Regulation 172), and Part 127 (Insurance Regulation 102) of this Title, and any other applicable regulations, as applicable; and

Text of proposed rule and any required statements and analyses may be obtained from: Amanda Fenwick, New York State Department of Financial Services, One Commerce Plaza, Albany, New York 12257, (518) 474-7929, email: Amanda.Fenwick@dfs.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

Consensus Rule Making Determination

No person is likely to object to this amendment, which adopts the most recent (2022) edition of the Valuation Manual published by the National Association of Insurance Commissioners ("NAIC"), replacing the rule's current reference to the 2021 Valuation Manual; expands the scope of Section 103.4 to include individual certificates issued under a group term life contract; and makes technical corrections by fixing certain citations in subdivision (c) of Section 103.8.

Insurance Law Section 4217 sets forth rules for the valuation of insurance policies and contracts and Insurance Law Section 4217(g) requires principle-based reserving ("PBR") for certain individual and group life insurance policies and annuity contracts. The minimum standard for the valuation of all such policies and contracts is the standard prescribed in the NAIC's Valuation Manual as adopted by the Superintendent of Financial Services by regulation.

PBR is also an NAIC accreditation standard. Thus, this amendment is necessary for the Department of Financial Services ("Department") to maintain its accreditation status with the NAIC.

The Department determines this rule to be a consensus rule, as defined in State Administrative Procedure Act Section 102(11) ("SAPA"), and the rule is proposed pursuant to SAPA Section 202(1)(b)(i). Accordingly, this rulemaking is exempt from the requirement to file a Regulatory Impact Statement, Regulatory Flexibility Analysis for Small Businesses and Local Governments, or a Rural Area Flexibility Analysis.

Job Impact Statement

This amendment should not adversely impact jobs or employment opportunities in New York State. Insurance Law Section 4217(g) requires principle-based reserving ("PBR") for certain individual and group life insurance policies and annuity contracts. The minimum standard for the valuation of all such policies and contracts must be the standard prescribed in the National Association of Insurance Commissioners ("NAIC") valuation manual (the "Manual") as adopted by the Superintendent of Financial Services by regulation. PBR is also an NAIC accreditation standard. This amendment to the regulation makes technical corrections by fixing certain citations in subdivision (c) of Section 103.8, expands the scope of section 103.4 to include individual certificates issued under a group term life contract, and adopts the NAIC's 2022 edition of the Manual, which also ensures continued compliance with the NAIC's accreditation standards.

Department of Health

EMERGENCY RULE MAKING

Surge and Flex Health Coordination System

I.D. No. HLT-07-22-00011-E
Filing No. 954
Filing Date: 2022-11-18
Effective Date: 2022-11-18

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of sections 1.2, 700.5, Part 360; amendment of sections 400.1, 405.24, 1001.6 of Title 10 NYCRR; amendment of sections 487.3, 488.3 and 490.3 of Title 18 NYCRR.

Statutory authority: Public Health Law, sections 225, 576, 2800, 2803, 4662; Social Services Law, section 461

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: During a State disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as has been the case with COVID-19, these proposed regulations will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

The Surge and Flex Health Care Coordination System was activated during the COVID-19 State disaster emergency which was declared by Governor Cuomo under Executive Orders No. 202 through 202.111 (March 7, 2020 to June 15, 2021; see 9 NYCRR §§ 8.202 through 8.202.111), the State disaster emergency which was declared by Governor Hochul under Executive Orders No. 4 through 4.14 (September 27, 2021 to November 26, 2022; see 9 NYCRR §§ 9.4 through 9.4.14), and the State disaster emergency which was declared by Governor Hochul under Executive Orders No. 11 through 11.9 (November 26, 2021 to September 12, 2022; see 9 NYCRR §§ 9.11 through 9.11.9).

Of note, a Notice of Proposed Rule Making was published in the State Register on February 16, 2022, with a public comment period that ended on April 18, 2022. The Department intends these emergency regulations to be in effect only until such time as the Notice of Adoption is published in the State Register, which will make the Proposed Rule permanent.

Subject: Surge and Flex Health Coordination System

Purpose: Provides authority to the Commissioner to direct certain actions and waive certain regulations in an emergency.

Substance of emergency rule (Full text is posted at the following State website: https://regs.health.ny.gov/regulations/emergency): Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these regulatory amendments provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The regulatory amendments permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These amendments also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The regulatory amendments also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously submitted to the Department of State a notice of proposed rule making, I.D. No. HLT-07-22-00011-P, Issue of February 16, 2022. The emergency rule will expire January 16, 2023.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

Regulatory Impact Statement

Statutory Authority:

The authority for the promulgation of these regulations with respect to facilities subject to Article 28 of the Public Health Law (PHL) is contained in PHL sections 2800 and 2803(2). PHL Article 28 (Hospitals), section 2800, specifies: "Hospital and related services including health-related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state, pursuant to section three of article seventeen of the constitution, the department of health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal, incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the

rendering of health-related service shall be subject to the provisions of this article." PHL section 2801 defines the term "hospital" as also including residential health care facilities (nursing homes) and diagnostic and treatment centers (D&TCs). PHL section 2803 (2) authorizes PHHPC to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of PHL Article 28, and to establish minimum standards governing the operation of such health care facilities.

PHL section 4662 authorizes the Commissioner to issue regulations governing assisted living residences. Social Services Law (SSL) section 461(1) authorizes the Commissioner to promulgate regulations establishing standards applicable to adult care facilities. PHL section 576 authorizes the Commissioner to regulate clinical laboratories.

PHL section 225 authorizes the Public Health and Health Planning Council (PHHPC) and the Commissioner to establish and amend the State Sanitary Code (SSC) provisions related to any matters affecting the security of life or health or the preservation and improvement of public health in the State of New York.

Upon the future declaration of any disaster emergency, any further authorization by the Governor pursuant to article 2-B of the Executive Law, if it should suspend any statutes which otherwise conflict with these regulations, will establish the immediate effectiveness of these provisions.

Legislative Objectives:

The objectives of PHL Article 28 include protecting the health of New York State residents by ensuring that they have access to safe, high-quality health services in medical facilities, while also protecting the health and safety of healthcare workers. Similarly, PHL Articles 36 and 40 ensure that the Department has the tools needed to achieve these goals in the home care and hospice spaces, and PHL section 4662 and SSL section 461 likewise ensure that the Department has appropriate regulatory authority with respect to assisted living residences and adult care facilities. PHL section 576 ensures that the Commissioner has appropriate regulatory authority over clinical laboratories. Finally, PHL section 225 ensures that the State Sanitary Code includes appropriate regulations in the areas of communicable disease control and environmental health, among others.

By permitting the Commissioner to temporarily suspend or modify regulatory provisions in each these areas, where not required by state statute or federal law, or where authorized by a gubernatorial Executive Order, these amendments provide crucial flexibility for this and future emergency response efforts.

Needs and Benefits:

During a state disaster emergency, Section 29-a of the Executive Law permits the Governor to, among other things, "temporarily suspend specific provisions of any statute, local law, ordinance, or orders, rules or regulations, or parts thereof, of any agency during a state disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster."

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions or modifications. The proposed regulatory amendments would permit the State Commissioner of Health or designee to take specific actions, as well as to temporarily suspend or modify certain regulatory provisions (or parts thereof) in Titles 10 and 18 of the NYCRR during a state disaster emergency, where such provisions are not required by statute or federal law. These proposed amendments would also permit the Commissioner to take certain actions, where consistent with any Executive Order (EO) issued by the Governor during a declared state disaster emergency. Examples include issuing directives to authorize and require clinical laboratories or hospitals to take certain actions consistent with any such EOs, as well as the temporary suspension or modification of additional regulatory provisions when the Governor temporarily suspends or modifies a controlling state statute.

The proposed regulatory amendments would also require hospitals to: develop disaster emergency response plans; maintain a 60-day supply of personal protective equipment (PPE); ensure that staff capable of working remotely are equipped and trained to do so; and report data as requested by the Commissioner.

During a state disaster emergency with significant public health impact, and where compliance with certain regulations may prevent, hinder or delay action necessary to cope with the disaster, as is the case with COVID-19, this authority will ensure that the State has the most efficient regulatory tools to facilitate the State's and regulated parties' response efforts to Surge and Flex the healthcare system statewide. Additionally, this authority will also ensure that the Department has the flexibility to impose additional requirements, where necessary, to ensure effective response to a declared state disaster emergency. Accordingly, these tools will help ensure the health and safety of patients and residents in New York State.

Costs:

Costs to Regulated Parties:

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within, and as part of, a coordinated response to a specific situation.

To the extent that additional requirements are imposed on regulated parties by these proposed regulatory amendments, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

Costs to Local Governments:

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on local governments that operate facilities regulated by the Department, most requirements would be in effect only for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible.

Cost to State Government:

The administration and oversight of these planning and response activities will be managed within the Department's existing resources.

Paperwork:

It is not anticipated that the proposed regulatory amendments will impose any significant paperwork requirements. Although these proposed amendments require additional reporting, these reports can be submitted electronically using the current platforms that facilities are already using. Moreover, such reporting requirements would only be activated during a declared state disaster emergency, thereby limiting the burden.

Local Government Mandates:

Facilities operated by local governments will subject to the same requirements as any other regulated facility, as described above.

Duplication:

These proposed regulatory amendments do not duplicate state or federal rules.

Alternatives:

The alternative would be to not promulgate the regulation. However, this alternative was rejected, as the Department believes that these regulatory amendments are necessary to facilitate response to a state disaster emergency.

Federal Standards:

42 CFR 482.15 establishes emergency preparedness minimum standards in four core areas including emergency planning, development of applicable policies and procedures, communications plan, and training and testing. These proposed amendments would complement the federal regulation and further strengthen hospitals' emergency preparedness and response programs.

Compliance Schedule:

These regulatory amendments will become effective upon filing with the Department of State.

Regulatory Flexibility Analysis

Effect of Rule:

The proposed regulatory amendments would primarily affect health care professionals, licensed health care facilities, permitted clinical laboratories, emergency medical service personnel, providers, and agencies, and pharmacies.

Compliance Requirements:

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, as well as hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, which would apply regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans.

Professional Services:

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

Compliance Costs:

As demonstrated during the COVID-19 pandemic emergency, significant provider costs, as well as local, regional and state costs, were incurred as a result of the need to respond to the demand for urgent healthcare and related services. These costs had significant impact throughout the state. It is anticipated there would be similar types of costs in a widespread emergency that would need to be addressed through both appropriate preparedness as well as within and as part of a coordinated response to a specific situation.

To the extent additional requirements are imposed on small businesses and local governments by these proposed regulatory amendments, most requirements would only be in effect for the duration of a declared state disaster emergency, with the hope of limiting costs to the extent possible. Ongoing costs requiring hospitals to maintain a minimum PPE supply and ensure work from home capabilities should have been addressed throughout the ongoing COVID-19 pandemic, thereby limiting costs of continued implementation. Ongoing costs related to hospital development of disaster emergency response plan will complement and build upon existing planning documents that hospitals are already required to have, which also limits costs.

Economic and Technological Feasibility:

There are no economic or technological impediments to the proposed regulatory amendments.

Minimizing Adverse Impact:

Although the proposed regulatory amendments impose some additional requirements on regulated parties, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would impose ongoing requirements would only apply to hospitals, and as noted above, will largely be a continuation of the efforts already being employed by these entities.

Small Business and Local Government Participation:

The Surge and Flex Health Care Coordination System was activated during the COVID-19 State disaster emergency which was first declared on March 7, 2020, and it has been used throughout the COVID-19 pandemic. The public has been permitted to comment at the public meetings during which the Public Health and Health Planning Council has approved this regulation on an emergency basis. A Notice of Proposed Rule Making was published in the State Register on February 16, 2022, with a public comment period that ended on April 18, 2022, and the Department will publish an Assessment of Public Comment before a Final Rule is adopted.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

Although this rule applies uniformly throughout the state, including rural areas, for the purposes of this Rural Area Flexibility Analysis (RAFA), "rural area" means areas of the state defined by Exec. Law § 481(7) (SAPA § 102(10)). Per Exec. Law § 481(7), rural areas are defined as "counties within the state having less than two hundred thousand population, and the municipalities, individuals, institutions, communities, and programs and such other entities or resources found therein. In counties of two hundred thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein." The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County	St. Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates 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 2010.

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

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

A significant portion of these regulatory amendments are designed to provide regulatory relief during a declared state disaster emergency. Where the regulatory amendments would impose requirements, most of them would only be applicable when there is a declared state disaster emergency. An example of a requirement that may be implemented during a declared state disaster emergency is reporting of data and inventory as requested by the Commissioner (i.e. medical supplies and equipment, hospital bed capacity, bed utilization, patient demographics, etc.). There are certain ongoing requirements proposed by this regulatory amendments, regardless of whether there is a declared state disaster emergency, in which hospitals would be required to: (1) maintain minimum levels of PPE; (2) ensure work from home capabilities; and (3) develop disaster emergency response plans. This regulation provides that the Commissioner's directives shall be incremental and geographically tailored and targeted at the Statewide, regional, or community level, as dictated by infection rate data.

It is not expected that any professional services will be required to comply with the proposed regulatory amendments.

Costs:

As a large part of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to public and private entities in rural areas.

To the extent additional requirements are imposed on public and private entities in rural areas by these proposed regulatory amendments, such requirements would only be in effect for the duration of a declared state disaster emergency.

Lastly, per SAPA § 202-bb(3)(c), it is not anticipated that there will be any significant variation in cost for different types of public and private entities in rural areas.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

Although the proposed regulatory amendments impose additional requirements on regulated parties, including those in rural areas, most of these requirements are only triggered during a declared state disaster emergency. Proposed amendments that would require disaster emergency preparedness planning on the part of regulated parties will complement and build upon existing state and federal planning requirements.

Rural Area Participation:

The Surge and Flex Health Care Coordination System was activated during the COVID-19 State disaster emergency which was first declared on March 7, 2020, and it has been used throughout the COVID-19 pandemic. The public has been permitted to comment at the public meetings during which the Public Health and Health Planning Council has approved this regulation on an emergency basis. A Notice of Proposed Rule Making was published in the State Register on February 16, 2022, with a public comment period that ended on April 18, 2022, and the Department will publish an Assessment of Public Comment before a Final Rule is adopted.

Job Impact Statement

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

Assessment of Public Comment

The agency received no public comment.

EMERGENCY RULE MAKING

Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements

I.D. No. HLT-23-22-00001-E
Filing No. 953
Filing Date: 2022-11-18
Effective Date: 2022-11-18

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Amendment of sections 405.11 and 415.19 of Title 10 NYCRR.

Statutory authority: Public Health Law, section 2803

Finding of necessity for emergency rule: Preservation of public health.

Specific reasons underlying the finding of necessity: These regulations are needed on an emergency basis to ensure hospital and nursing home staff, as well as the patients and residents for whom they provide care, are adequately protected during the 2019 Coronavirus (COVID-19) or another communicable disease outbreak. These regulations are specifically meant to address the lessons learned in New York State from 2020 to 2021 during the COVID-19 pandemic with respect to PPE. Notwithstanding the end of the State disaster emergencies relating to COVID-19, infections in nursing homes across the state persist and hospitals remain at the front lines of response. Further, a possible resurgence of COVID-19 or another communicable disease outbreak necessitates that hospitals and nursing homes continue to have an adequate supply of PPE to protect these vulnerable populations and the staff who provide care.

New York State first identified COVID-19 cases on March 1, 2020 and thereafter became the national epicenter of the outbreak. However, as a result of global PPE shortages, many hospitals and nursing homes in New York State had difficulty obtaining adequate PPE necessary to care for their patients and residents. 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.

These regulations are needed on an emergency basis to ensure that hospitals and nursing homes Statewide do not again find themselves in need of PPE from the State's stockpile should another communicable disease outbreak occur, COVID-19 or otherwise. It is critically important that PPE, including masks, gloves, respirators, face shields and gowns, is readily available and used when needed, as hospital and nursing home staff must don all required PPE to safely provide care for patients and residents with communicable diseases, while ensuring that they themselves do not become infected with a communicable disease.

Based on the foregoing, the Department has made the determination that this emergency 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 resurgence of COVID-19 or another communicable disease outbreak.

Of note, a Notice of Proposed Rule Making was published in the State Register on June 8, 2022, with a public comment period that ended on August 8, 2022. The Department intends these emergency regulations to be in effect only until such time as the Assessment of Public Comment and Final Rule can be published in the State Register, which would make the Proposed Rule permanent.

Subject: Hospital and Nursing Home Personal Protective Equipment (PPE) Requirements.

Purpose: To ensure that all general hospitals and nursing homes maintain a 60-day supply of PPE during the COVID-19 emergency.

Text of emergency rule: 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) 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.

(4) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers and inventory should be rotated through regular usage and replace what has been used in order to ensure a consistent readiness level, and 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.

(5) 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.

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 number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 24;

(ii) for gowns, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 3;

(iii) for surgical masks, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, multiplied by 1.5; and

(iv) for N95 respirator masks, the applicable positivity rate, multiplied by the number of certified nursing home beds as indicated on the nursing home's operating certificate, 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.

(3) In order to maximize the shelf life of stockpiled inventory, providers should follow the appropriate storage conditions as outlined by manufacturers and inventory should be rotated through regular usage and replace what has been used in order to ensure a consistent readiness level, and 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.

(4) 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.

This notice is intended to serve only as a notice of emergency adoption. This agency intends to adopt the provisions of this emergency rule as a permanent rule, having previously submitted to the Department of State a notice of proposed rule making, I.D. No. HLT-23-22-00001-P, Issue of June 8, 2022. The emergency rule will expire January 16, 2023.

Text of rule and any required statements and analyses may be obtained from: Katherine Ceroalo, DOH, Bureau of Program Counsel, Reg. Affairs Unit, Room 2438, ESP Tower Building, Albany, NY 12237, (518) 473-7488, email: regsqna@health.ny.gov

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 emergency 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 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. 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 addition 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 filing with the Department of State. These regulations are expected to be proposed for permanent adoption at a future meeting of the Public Health and Health Planning Council.

Regulatory Flexibility Analysis

Effect of rule:

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 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. 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:

Small business and local governments were not directly consulted given the urgent need to ensure hospital patients and nursing home residents are adequately protected in the event of a resurgence of COVID-19 or another communicable disease outbreak. However, the Department plans to issue an advisory to hospital CEOs and nursing home administrators alerting them to the anticipated proposed rulemaking on these regulations and opportunity to submit public comments.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

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

thousand or greater population 'rural areas' means towns with population densities of one hundred fifty persons or less per square mile, and the villages, individuals, institutions, communities, programs and such other entities or resources as are found therein."

The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010:

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

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

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

Parties representing rural areas were not directly consulted given the urgent need to ensure hospital patients and nursing home residents are adequately protected in the event of a resurgence of COVID-19 or another communicable disease outbreak. However, the Department plans to issue an advisory to hospital CEOs and nursing home administrators alerting them to the anticipated proposed rulemaking and opportunity to submit public comments.

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.

Assessment of Public Comment

The agency received no public comment.

NOTICE OF ADOPTION

Nursing Home Minimum Direct Resident Care Spending

I.D. No. HLT-46-21-00005-A
Filing No. 950
Filing Date: 2022-11-17
Effective Date: 2022-12-07

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 415.34 to Title 10 NYCRR.

Statutory authority: Public Health Law, section 2828

Subject: Nursing Home Minimum Direct Resident Care Spending.

Purpose: Every RHCF shall spend a minimum of 70% of revenue on direct resident care and 40% of revenue on resident-facing staffing.

Text of final rule: Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Section 2828 of the Public Health Law, Part 415 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended by adding a new Section 415.34, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

415.34. Minimum Direct Resident Care Spending.

(a) Purpose. This Section sets forth the requirements of the minimum direct resident care spending law set forth in Section 2828 of the Public Health Law and applies to all residential health care facilities licensed pursuant to this Part, except as provided in subdivision (c) of this Section.

(b) Definitions. The definitions of this Section shall have the same meaning as those terms set forth in subdivision (2) of Section 2828 of the Public Health Law. Additionally, the following terms shall have the following meanings:

(1) "Contracted out" shall mean services provided by registered professional nurses, licensed practical nurses, or certified nurse aides who provide services in a residential health care facility through contractual or other employment agreement, whether such agreement is entered into by the individual practitioner or by an employment agency on behalf of the individual practitioner. Such agreement may be oral or in writing.

(2) "Direct resident care" shall mean the following cost centers in the residential health care facility cost report:

(i) Nonrevenue Support Services - Plant Operation & Maintenance, Laundry and Linen, Housekeeping, Patient Food Service, Nursing Administration, Activities Program, Nonphysician Education, Medical Education, Medical Director's Office, Housing, Social Service, Transportation;

(ii) Ancillary Services - Laboratory Services, Electrocardiology, Electroencephalogy, Radiology, Inhalation Therapy, Podiatry, Dental, Psychiatric, Physical Therapy, Occupational Therapy, Speech/Hearing Therapy, Pharmacy, Central Services Supply, Medical Staff Services provided by licensed or certified professionals including and without limitation Registered Nurses, Licensed Practical Nurses, and Certified Nursing Assistant; and

(iii) Program Services - Residential Health Care Facility, Pediatric, Traumatic Brain Injury (TBI), Autoimmune Deficiency Syndrome (AIDS), Long Term Ventilator, Respite, Behavioral Intervention, Neurodegenerative, Adult Care Facility, Intermediate Care Facilities, Independent Living, Outpatient Clinics, Adult Day Health Care, Home Health Care, Meals on Wheels, Barber & Beauty Shop, and Other similar program services that directly address the physical conditions of residents. Direct resident care does not include, at a minimum and without limitation, administrative costs (other than nurse administration), capital costs, debt service, taxes (other than sales taxes or payroll taxes), capital depreciation, rent and leases, and fiscal services.