STATE OF NEW YORK
SPECIAL PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

AGENDA

November 17, 2022

Immediately following the Special Committee on Codes, Regulations and Legislation Meeting (Codes scheduled to begin at 10:15 a.m.)

- ***90 Church Street, Conference Rooms 4 A/B, NYC***
- ***Empire State Plaza, Concourse Level, Meeting Room 6, Albany***

I. INTRODUCTION OF OBSERVERS

Jeffrey Kraut, Chair

II. REGULATION

Report of the Committee on Codes, Regulations and Legislation

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

For Emergency Adoption

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

For Adoption

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

For Emergency Adoption

20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR; Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination System)

For Adoption

20-24 Addition of Sections 1.2, 700.5 and Part 360 to Title 10 NYCRR; Amendment of Sections 400.1, 405.24 & 1001.6 of Title 10 NYCRR and Sections 487.3, 488.3 and 490.3 of Title 18 NYCRR (Surge and Flex Health Coordination System)

21-13 Addition of Section 415.34 to Title 10 NYCRR (Nursing Home Minimum Direct Resident Care Spending)

21-20 Amendment to Sections 415.2 and 415.13 of Title 10 NYCRR (Minimum Staffing Requirements for Nursing Homes)

III. NEXT MEETINGS

December 8, 2022 (Albany and NYC)

IV. ADJOURNMENT

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 filing with the Secretary of State, 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) 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.

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.

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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 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

Type 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.

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.

EMERGENCY JUSTIFICATION

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.

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) 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.

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 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 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 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

Type 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.

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

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.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon filing with the Secretary of State, to read as follows:

A new Part 360 is added to Title 10, to read as follows:

Part 360 Surge and Flex Health Coordination System Activation During a State Disaster Emergency Declaration

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

Hospitals across New York State, prior to the COVID-19 pandemic, rarely worked together or coordinated as a unified system. But a pandemic on the scale of the COVID-19 crisis demonstrated that hospitals could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility. The New York State Department of Health takes note of the successful implementation of the Surge and Flex System by New York State's hospitals and offers these regulations as an additional way to strengthen the pandemic response. Surge and Flex Health Coordination System Activation has helped hospitals respond to the COVID-19 state disaster emergency, and New

York's hospitals have made commendable efforts to coordinate their response to the pandemic, to direct patients to the hospitals with the capacity to treat them, and to increase capacity as needed, during each wave of the pandemic.

The COVID-19 crisis demanded a new coordinated approach to ensure no one hospital was overwhelmed by COVID-19 patients or needed more ventilators, while a hospital nearby had capacity for more patients and excess equipment. It was imperative for government to coordinate and organize all hospitals under the umbrella of one unified system, and efficiently use all the resources available in the state to attempt to meet the significant demands of the crisis.

The "Surge and Flex" system is designed to create a single, coordinated statewide system to prevent a disaster from overwhelming any one hospital in the state. The purpose of this NYSDOH regulation is to institutionalize Surge and Flex operation, giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex. This regulation provides the Department of Health with the necessary tools to enact Surge and Flex operation during another wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital prepare for this contingency in order to ensure a straightforward transition from standard operating procedures to "Surge and Flex."

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's hospital systems and mitigating the threat to the health of the people of New York. Further, this Part establishes certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

To the extent that any provision of this Part conflicts with any other regulation of the Department, this Part shall take precedence. All authorities granted to the Commissioner shall be subject to any conditions and limitations that the Commissioner may deem appropriate. The Commissioner may delegate activation of the authorities provided by this Part to appropriate executive staff within the Department. In the event that there are inconsistent statutes, which would preclude effectiveness of such regulation, such regulation shall be effective upon the suspension of such inconsistent statute by the Governor pursuant to authority in Article 2-B of the Executive Law, and such regulation shall immediately be effective.

Section 360.2. Surge and Flex Health Care Coordination System Requirements.

(a) In the event of a declared State disaster emergency, the Commissioner shall have all necessary authority and procedures to activate the Surge and Flex Health Care Coordination System (hereinafter "Surge and Flex System"), including the following:

(1) Increase Bed Capacity. At the Commissioner's direction, which shall be incremental and geographically targeted, health care facilities shall increase by up to 50% the number of acute care beds and/or change the service categories of beds certified or otherwise approved in any entity regulated by the Department. At the Commissioner's direction, health care facilities shall postpone up to 100% of non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall establish procedures to approve temporary changes at regulated health care facilities to physical plants, to facilitate the increased capacity and shall expedite review of construction applications related to temporary locations, provided that schematics are filed with the Department and patient safety is maintained.

(2) Enhanced Staffing Capacity. Health care facilities shall establish plans to meet enhanced staffing levels sufficient to ensure that the increased bed capacity has adequate staffing. The Commissioner may further expand or modify criteria for staffing. Health care facilities shall have access to a State-run portal for staffing needs identifying both volunteers and available staff; whether licensed or registered in New York State, or authorized or licensed to practice in any other state or Canada.

(3) Availability of Supplies and PPE. Health care facilities shall maintain and actively manage a supply of personal protective equipment (PPE) appropriate for use during a declared health emergency that could last at least 60-days pursuant to Section 405.11(g) of this Title. The Commissioner shall have all necessary authority to re-distribute the resources of a regulated entity if there is a determination that such resources are limited and in order to preserve the health and safety of New Yorkers, including:

(i) Requiring that any medical or other equipment that is held in inventory by any entity in the State, or otherwise located in the State, be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and as determined by the Commissioner if such testing results are negative, via the electronic clinical laboratory reporting system or as the Commissioner may determine.

(iv) Suspending or restricting visitation, in accordance with the need to conserve PPE, and subject to such conditions or limitations as the Commissioner may determine.

(4) Statewide Coordination.

(i) Discharging, transfer, and receiving of patients. Health care facilities regulated by the Department shall, if directed to do so by the Commissioner, rapidly discharge, transfer, or receive patients, while protecting the health and safety of such patients and residents, and consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA). The Department shall coordinate with health care facilities to balance individual facility patient load, and may promulgate further directives to specify the method and manner of transfer or discharge.

(ii) Designating Health Care Facilities as Trauma Centers. The Department is authorized to designate an entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; or modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility or other determination about patient care as appropriate, including restricting admission or treatment to patients with a particular diagnosis.

(iii) Maintaining a Statewide Health Care Data Management System. Health care facilities or health systems shall report as directed by the Department any information necessary to implement the Surge and Flex System (e.g. available hospital beds, equipment available and in use) and the Department shall use that health facility or health system data in order to monitor, coordinate, and manage during the emergency.

Section 360.3. Hospital emergency Surge and Flex Response Plans.

(a) Every general hospital (hereinafter, “hospital”) shall adopt a detailed emergency Surge and Flex Response Plan (hereinafter, “plan”) that, at a minimum, includes the following elements:

(1) Bed surge plan. The plan shall explain how the hospital will increase the number of current staffed acute care operational beds to a number set by the Commissioner, which shall be up to a 50% increase of such beds within seven days from the date of the declaration of the state disaster emergency. For the purposes of this Part, an “acute care operational bed” means a bed that is staffed and equipped with appropriate infrastructure such that it can be used to deliver health care services to a patient. The Commissioner may further define the type of acute care operational beds for a given state disaster emergency, which may include isolation beds, intensive care (ICU) beds, pediatric and/or acute care beds. The plan shall contain scenarios for increases of current staffed acute care operational beds in phased increments, detailing the associated considerations for PPE, staffing, and other supplies and equipment, including whether the hospital can meet those requirements using internal resources and capabilities, as well as intra-system load balancing and postponement of some or all non-essential elective procedures. These plans shall inform the Commissioner’s directives, which shall be incremental and geographically tailored at the Statewide, regional, or community level, as dictated by infection rate data.

(2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 60-day supply of PPE, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain agreements executed by the hospital. Such plan shall further include, as appropriate,

how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions. A PPE surge plan may provide for hospital utilization of some, but not all, of the stockpile reserves during a State disaster emergency, provided that within 30 days of the end of the State disaster emergency, the stockpile reserve is fully restored.

(3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.

(4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.

(5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

(b) The Chief Executive Officer (CEO) of the hospital, or system if authorized by the Commissioner to report on a system-wide basis, shall certify to the review and approval of the plan, including an attestation that it can be implemented and achieved in the event of a declared disaster emergency. The CEO shall be responsible for ensuring that the plan is reviewed and updated, as necessary, periodically as specified by the Commissioner and shall re-certify that it is able to be implemented and achieved upon each review.

(c) The Department may require the hospital to submit its disaster emergency response plan and history of semi-annual certifications for review, and may require the hospital to make such amendments to the plan as the Commissioner deems appropriate, to ensure that the plan will achieve the requirements established in subdivision (a) of this section, including increases in bed capacity.

(d) In the event of a declared state disaster emergency, any or all hospitals shall execute their plans immediately upon the direction of the Commissioner.

(e) Additional preparedness requirements.

(1) PPE. Every hospital shall, at all times, continue to maintain the required 60-day supply of PPE appropriate for use in a disaster emergency including a pandemic, pursuant to section 405.11(g) of this Title.

(2) Information technology. Every hospital shall ensure that non-essential staff who are capable of working remotely in the event of an emergency are equipped and trained to do so, and that infrastructure is in place to allow for the repurposing of existing workspaces as needed when activating the Surge and Flex System.

(f) Reporting requirements during the activation of the Surge and Flex System.

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals or health systems shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2. Such data may include, but shall not be limited to:

(i) Bed availability, both in total and by designated service.

(ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.

(iii) Patient demographics.

(iv) Other health statistics, including deaths.

(v) PPE and other supplies, in stock and ordered.

(vi) PPE and other supply usage rates.

(2) Such reports shall be submitted periodically as determined by the Commissioner, except and unless otherwise directed by the Department.

Section 360.4 Clinical laboratory testing

(a) In the event of a declared state disaster emergency, the Commissioner shall have all necessary authority to:

(1) Authorize clinical laboratories to operate temporary collecting stations to collect specimens from individuals.

(b) In addition, and to the extent consistent with any Executive Order issued by the Governor, the Commissioner shall have all necessary authority to:

(1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test

specimens from New York State, provided that such laboratories must meet any federal requirements.

(2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.

(3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.

(4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.

(5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.

(6) Permit licensed pharmacists to order and administer clinical tests.

(c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.

(d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

Subdivision (g) of section 405.24 of 10 NYCRR is amended to read as follows:

Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster. This shall be in addition to the Surge and Flex Plan that is required pursuant to Part 360 of the Title.

Section 400.1 of 10 NYCRR is amended to read as follows:

(a) This Subchapter shall be known and may be cited as "Medical Facilities--Minimum Standards," and shall apply to medical facilities defined as hospitals within article 28 of the Public Health Law. The standards within a particular article shall constitute the minimum standards for the identified medical facility in addition to those standards that may apply to such facilities as set forth in Articles 1 and 3 of this Subchapter as applicable.

(b) During the period of a state disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of

regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 700.5 of 10 NYCRR is added to read as follow:

700.5 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or

modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (8) is added to subdivision (e) of section 1001.6 of 10 NYCRR, to read as follows:

(8) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 1.2 of 10 NYCRR is added to read as follows.

1.2 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Title, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (4) subdivision (g) of section 487.3 of 18 NYCRR is added to read as follows:

(4) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the

Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (6) subdivision (f) of section 488.3 of 18 NYCRR is added to read as follows:

(6) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (5) subdivision (g) of section 490.3 of 18 NYCRR is added to read as follows:

(5) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

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.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Type and Number 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.

Compliance 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.

EMERGENCY JUSTIFICATION

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.

SUMMARY OF EXPRESS TERMS

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.

Pursuant to the authority vested in the Public Health and Health Planning Council and the Commissioner of Health by Sections 225, 2800, and 2803 of the Public Health Law; and in the Commissioner of Health by Sections 576 and 4662 of the Public Health Law and Section 461 of the Social Services Law, Title 10 (Health) and Title 18 (Social Services) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

A new Part 360 is added to Title 10, to read as follows:

Part 360 Surge and Flex Health Coordination System Activation During a State Disaster Emergency Declaration

Part 360. Surge and Flex System

Section 360.1. Administrative Purpose, Application and Scope

(a) Administrative purpose.

Hospitals across New York State, prior to the COVID-19 pandemic, rarely worked together or coordinated as a unified system. But a pandemic on the scale of the COVID-19 crisis demonstrated that hospitals could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility. The New York State Department of Health takes note of the successful implementation of the Surge and Flex System by New York State's hospitals and offers these regulations as an additional way to strengthen the pandemic response. Surge and Flex Health Coordination System

Activation has helped hospitals respond to the COVID-19 state disaster emergency, and New York's hospitals have made commendable efforts to coordinate their response to the pandemic, to direct patients to the hospitals with the capacity to treat them, and to increase capacity as needed, during each wave of the pandemic.

The COVID-19 crisis demanded a new coordinated approach to ensure no one hospital was overwhelmed by COVID-19 patients or needed more ventilators, while a hospital nearby had capacity for more patients and excess equipment. It was imperative for government to coordinate and organize all hospitals under the umbrella of one unified system, and efficiently use all the resources available in the state to attempt to meet the significant demands of the crisis.

The "Surge and Flex" system is designed to create a single, coordinated statewide system to prevent a disaster from overwhelming any one hospital in the state. The purpose of this NYSDOH regulation is to institutionalize Surge and Flex operation, giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex. This regulation provides the Department of Health with the necessary tools to enact Surge and Flex operation during another wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital prepare for this contingency in order to ensure a straightforward transition from standard operating procedures to "Surge and Flex."

(b) Application and Scope. In the event of a State disaster emergency declared pursuant to section 28 of the Executive Law, the Commissioner may exercise the authorities granted in this Part, thereby maximizing the efficiency and effectiveness of the State's hospital systems and mitigating the threat to the health of the people of New York. Further, this Part establishes

certain ongoing emergency planning requirements, called the Surge and Flex Health Care Coordination System, for facilities and agencies regulated by the Department.

To the extent that any provision of this Part conflicts with any other regulation of the Department, this Part shall take precedence. All authorities granted to the Commissioner shall be subject to any conditions and limitations that the Commissioner may deem appropriate. The Commissioner may delegate activation of the authorities provided by this Part to appropriate executive staff within the Department. In the event that there are inconsistent statutes, which would preclude effectiveness of such regulation, such regulation shall be effective upon the suspension of such inconsistent statute by the Governor pursuant to authority in Article 2-B of the Executive Law, and such regulation shall immediately be effective.

Section 360.2. Surge and Flex Health Care Coordination System Requirements.

(a) In the event of a declared State disaster emergency, the Commissioner shall have all necessary authority and procedures to activate the Surge and Flex Health Care Coordination System (hereinafter "Surge and Flex System"), including the following:

(1) Increase Bed Capacity. At the Commissioner's direction, which shall be incremental and geographically targeted, health care facilities shall increase by up to 50% the number of acute care beds and/or change the service categories of beds certified or otherwise approved in any entity regulated by the Department. At the Commissioner's direction, health care facilities shall postpone up to 100% of non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall establish procedures to approve temporary changes at regulated health care facilities to physical plants, to facilitate the increased capacity and shall expedite review of construction applications related to

temporary locations, provided that schematics are filed with the Department and patient safety is maintained.

(2) Enhanced Staffing Capacity. Health care facilities shall establish plans to meet enhanced staffing levels sufficient to ensure that the increased bed capacity has adequate staffing. The Commissioner may further expand or modify criteria for staffing. Health care facilities shall have access to a State-run portal for staffing needs identifying both volunteers and available staff; whether licensed or registered in New York State, or authorized or licensed to practice in any other state or Canada.

(3) Availability of Supplies and PPE. Health care facilities shall maintain and actively manage a supply of personal protective equipment (PPE) appropriate for use during a declared health emergency that could last at least 60-days pursuant to Section 405.11(g) of this Title. The Commissioner shall have all necessary authority to re-distribute the resources of a regulated entity if there is a determination that such resources are limited and in order to preserve the health and safety of New Yorkers, including:

(i) Requiring that any medical or other equipment that is held in inventory by any entity in the State, or otherwise located in the State, be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine.

(iii) For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and as determined by the Commissioner if such testing results are negative, via the electronic clinical laboratory reporting system or as the Commissioner may determine.

(iv) Suspending or restricting visitation, in accordance with the need to conserve PPE, and subject to such conditions or limitations as the Commissioner may determine.

(4) Statewide Coordination.

(i) Discharging, transfer, and receiving of patients. Health care facilities regulated by the Department shall, if directed to do so by the Commissioner, rapidly discharge, transfer, or receive patients, while protecting the health and safety of such patients and residents, and consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA). The Department shall coordinate with health care facilities to balance individual facility patient load, and may promulgate further directives to specify the method and manner of transfer or discharge.

(ii) Designating Health Care Facilities as Trauma Centers. The Department is authorized to designate an entity as a trauma center; extend or modify the period for which an entity may be designated as a trauma center; or modify the review team for assessment of a trauma center; or change the level of acuity designation or health services of a facility or other determination about patient care as appropriate, including restricting admission or treatment to patients with a particular diagnosis.

(iii) Maintaining a Statewide Health Care Data Management System. Health care facilities or health systems shall report as directed by the Department any information necessary to implement the Surge and Flex System (e.g. available hospital beds, equipment available and in use) and the Department shall use that health facility or health system data in order to monitor, coordinate, and manage during the emergency.

Section 360.3. Hospital emergency Surge and Flex Response Plans.

(a) Every general hospital (hereinafter, “hospital”) shall adopt a detailed emergency Surge and Flex Response Plan (hereinafter, “plan”) that, at a minimum, includes the following elements:

(1) Bed surge plan. The plan shall explain how the hospital will increase the number of current staffed acute care operational beds to a number set by the Commissioner, which shall be up to a 50% increase of such beds within seven days from the date of the declaration of the state disaster emergency. For the purposes of this Part, an “acute care operational bed” means a bed that is staffed and equipped with appropriate infrastructure such that it can be used to deliver health care services to a patient. The Commissioner may further define the type of acute care operational beds for a given state disaster emergency, which may include isolation beds, intensive care (ICU) beds, pediatric and/or acute care beds. The plan shall contain scenarios for increases of current staffed acute care operational beds in phased increments, detailing the associated considerations for PPE, staffing, and other supplies and equipment, including whether the hospital can meet those requirements using internal resources and capabilities, as well as intra-system load balancing and postponement of some or all non-essential elective procedures. These plans shall inform the Commissioner’s directives, which shall be incremental and geographically tailored at the Statewide, regional, or community level, as dictated by infection rate data.

(2) PPE surge plan. The plan shall explain how the hospital will increase its supply of personal protective equipment (PPE) appropriate for use in a pandemic to achieve continuous maintenance of its required 60-day supply of PPE, pursuant to section 405.11(g) of this Title. The plan shall list the contracted entities or other supply chain

agreements executed by the hospital. Such plan shall further include, as appropriate, how the hospital will repurpose existing equipment, replenish the inventory from other areas of the health system, and establish cooperative agreements to obtain PPE to accommodate supply chain interruptions. A PPE surge plan may provide for hospital utilization of some, but not all, of the stockpile reserves during a State disaster emergency, provided that within 30 days of the end of the State disaster emergency, the stockpile reserve is fully restored.

(3) Mass casualty plan. The plan shall explain how the hospital will receive and treat mass casualty victims, in the event of a secondary disaster arising from the interruption of normal services resulting from an epidemic, earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences, while addressing the continued need for surge capacity for the underlying state disaster emergency declaration.

(4) Staffing plan. The plan shall explain how the hospital will: identify and train backups for employees who may be unable to report to work during a pandemic; institute employee overtime protocols; and increase staffing by inter- and intra-system loan, cross-training, and volunteer programs, which would be operational on seven days' notice.

(5) Capital plan. The plan shall explain how the hospital shall ensure continuous operation of facilities and access to utilities, materials, electronic devices, machinery and equipment, vehicles, and communication systems. The plan shall ensure that the hospital routinely performs all required maintenance and peak load testing of its

infrastructure systems, including: electrical, heating, ventilation and air conditioning (HVAC), and oxygen supply.

(b) The Chief Executive Officer (CEO) of the hospital, or system if authorized by the Commissioner to report on a system-wide basis, shall certify to the review and approval of the plan, including an attestation that it can be implemented and achieved in the event of a declared disaster emergency. The CEO shall be responsible for ensuring that the plan is reviewed and updated, as necessary, periodically as specified by the Commissioner and shall re-certify that it is able to be implemented and achieved upon each review.

(c) The Department may require the hospital to submit its disaster emergency response plan and history of semi-annual certifications for review, and may require the hospital to make such amendments to the plan as the Commissioner deems appropriate, to ensure that the plan will achieve the requirements established in subdivision (a) of this section, including increases in bed capacity.

(d) In the event of a declared state disaster emergency, any or all hospitals shall execute their plans immediately upon the direction of the Commissioner.

(e) Additional preparedness requirements.

(1) PPE. Every hospital shall, at all times, continue to maintain the required 60-day supply of PPE appropriate for use in a disaster emergency including a pandemic, pursuant to section 405.11(g) of this Title.

(2) Information technology. Every hospital shall ensure that non-essential staff who are capable of working remotely in the event of an emergency are equipped and trained to do so, and that infrastructure is in place to allow for the repurposing of existing workspaces as needed when activating the Surge and Flex System.

(f) Reporting requirements during the activation of the Surge and Flex System.

(1) In the event of a declared state disaster emergency, upon the Commissioner's direction, hospitals or health systems shall report to the Department all data requested by the Commissioner, in a manner determined by the Commissioner under Section 306.2. Such data may include, but shall not be limited to:

(i) Bed availability, both in total and by designated service.

(ii) Bed capacity, meaning acute care operational beds as defined in paragraph (a)(1) of this Section.

(iii) Patient demographics.

(iv) Other health statistics, including deaths.

(v) PPE and other supplies, in stock and ordered.

(vi) PPE and other supply usage rates.

(2) Such reports shall be submitted periodically as determined by the Commissioner, except and unless otherwise directed by the Department.

Section 360.4 Clinical laboratory testing

(a) In the event of a declared state disaster emergency, the Commissioner shall have all necessary authority to:

(1) Authorize clinical laboratories to operate temporary collecting stations to collect specimens from individuals.

(b) In addition, and to the extent consistent with any Executive Order issued by the Governor, the Commissioner shall have all necessary authority to:

(1) Waive permit requirements for clinical laboratories and establish minimum qualifications to allow non-permitted clinical laboratories to accept and test specimens from New York State, provided that such laboratories must meet any federal requirements.

(2) Establish minimum qualifications of individuals that may perform clinical laboratory tests, provided that such persons meet federal requirements.

(3) Allow clinical laboratories to accept specimens without an order, subject to a plan approved by Commissioner to ensure the result of any tests are reported to the patient or the patient's personal representative and there will be appropriate follow up with the patient based on the results.

(4) Authorize licensed pharmacists to order clinical laboratory tests, consistent with federal law, including certificate of waiver requirements.

(5) Permit licensed pharmacists to be designated as qualified healthcare professionals for the purpose of directing a limited service laboratory, pursuant to Section 579 of the Public Health Law.

(6) Permit licensed pharmacists to order and administer clinical tests.

(c) Prioritization of clinical laboratory tests. In the event the declared state disaster emergency requires utilization of clinical laboratory testing at a rate that exceeds available capacity, no laboratory shall perform such test unless the test has been ordered consistent with the testing prioritization published by the Commissioner.

(d) Reporting of results of any communicable disease during a Surge and Flex period shall be made immediately via the Electronic Clinical Laboratory Reporting system, if positive, and on a schedule as determined by the Commissioner if negative.

Subdivision (g) of section 405.24 of 10 NYCRR is amended to read as follows:

Emergency and disaster preparedness. The hospital shall have a written plan, rehearsed and updated at least twice a year, with procedures to be followed for the proper care of patients and personnel, including but not limited to the reception and treatment of mass casualty victims, in the event of an internal or external emergency or disaster arising from the interruption of normal services resulting from earthquake, flood, bomb threat, chemical spills, strike, interruption of utility services, nuclear accidents and similar occurrences. Personnel responsible for the hospital's accommodation to extraordinary events shall be trained in all aspects of preparedness for any interruption of services and for any disaster. This shall be in addition to the Surge and Flex Plan that is required pursuant to Part 360 of the Title.

Section 400.1 of 10 NYCRR is amended to read as follows:

(a) This Subchapter shall be known and may be cited as "Medical Facilities--Minimum Standards," and shall apply to medical facilities defined as hospitals within article 28 of the Public Health Law. The standards within a particular article shall constitute the minimum standards for the identified medical facility in addition to those standards that may apply to such facilities as set forth in Articles 1 and 3 of this Subchapter as applicable.

(b) During the period of a state disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay

action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 700.5 of 10 NYCRR is added to read as follow:

700.5 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Subchapter, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority

under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (8) is added to subdivision (e) of section 1001.6 of 10 NYCRR, to read as follows:

(8) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new section 1.2 of 10 NYCRR is added to read as follows.

1.2 Commissioner authority to suspend and modify regulations

During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Title, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (4) subdivision (g) of section 487.3 of 18 NYCRR is added to read as follows:

(4) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the state disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the

Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies state statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (6) subdivision (f) of section 488.3 of 18 NYCRR is added to read as follows:

(6) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by state statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a State disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

A new paragraph (5) subdivision (g) of section 490.3 of 18 NYCRR is added to read as follows:

(5) During the period of a State disaster emergency declared pursuant to section 28 of the Executive Law, the State Commissioner of Health or their designee may suspend or modify any provision, of parts thereof, of this Part, that is not otherwise required by State statute or federal law, if compliance with such provisions, or parts thereof, would prevent, hinder, or delay action necessary to cope with the State disaster emergency, or if necessary to assist or aid in coping with such disaster. Such suspension or modifications may include any modifications of regulation, exceptions, limitations or other conditions as the Commissioner or their designee deems appropriate and necessary to respond to the disaster emergency. Provided, further, that should the Governor declare a state disaster emergency pursuant to section 28 of the Executive Law, which suspends or otherwise modifies State statutes pursuant to the Governor's authority under section 29-a of the Executive Law, the Commissioner or their designee may suspend or modify any provision of any regulation that is consistent with the statutory authority as modified or suspended, for the period of such suspension or modification.

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 publication of a Notice of Adoption in the New York State Register.

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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:

Due to the emergency nature of COVID-19, small businesses and local governments were not consulted.

RURAL AREA FLEXIBILITY ANALYSIS

Type and Number 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.

Compliance 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:

Due to the emergency nature of COVID-19, parties representing rural areas were not consulted in the initial draft. However, parties representing rural may submit comments during the notice and comment period for the proposed regulations.

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.

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.

(3) “Resident-facing staffing” shall mean all staffing expenses in the ancillary and program services categories on Exhibit H of the residential health care facility cost reports.

(4) “Revenue” shall mean the total operating revenue from or on behalf of residents of the residential health care facility, government payers, or third-party payers, to pay for a resident's occupancy of the residential health care facility, resident care, and the operation of the residential

health care facility as reported in the residential health care facility cost reports submitted to the Department; provided, however, that revenue shall exclude:

(i) the average increase in the capital portion of the Medicaid reimbursement rate from the prior three years;

(ii) funding received as reimbursement for the assessment under Public Health Law section 2807-d(2)(b)(vi), as reconciled pursuant to Public Health Law section 2807-d(10)(c);

(iii) the capital per diem portion of the reimbursement rate for nursing homes; provided, however, that such exclusion shall not apply:

(*a*) for nursing homes that have an overall one-, two-, or three-star rating assigned pursuant to the inspection rating system of the U.S. Centers for Medicare and Medicaid Services (CMS rating); or

(*b*) to any amount of the capital per diem portion of the reimbursement rate that is attributable to a capital expenditure made to a corporation, other entity, or individual, with a common or familial ownership to the operator or the facility as reported under Public Health Law section 2803-x(1); and

(iv) any grant funds from the federal government for reimbursement of COVID-19 pandemic-related expenses, including, but not limited to, funds received from the federal emergency management agency or health resources and services administration.

(c) Applicability.

(1) For the purposes of this Section, residential health care facilities shall not include:

(i) facilities that are authorized by the Department to primarily care for medically fragile children or young adults, people with HIV/AIDS, persons requiring behavioral

intervention, or persons requiring neurodegenerative services. For the purposes of this subparagraph, a facility shall be considered to primarily care for such specialized populations if at least 51 percent of certified beds are designated for persons with such specialty health care needs; or

(ii) continuing care retirement communities licensed pursuant to Article 46 or 46-A of the Public Health Law.

(iii) A facility may apply to the Commissioner for a waiver of applicability of this Section on the basis of providing specialty care services if such facility primarily provides care to a specialized population other than one listed in subparagraph (i) of this paragraph. Such application shall detail what specialty services the facility provides, the percentage of the resident population needing such specialty services, and whether any other residential health care facilities licensed by the Department provide such specialty services. The Commissioner shall have discretion to approve or reject applications submitted pursuant to this subparagraph, and shall provide the facility with the basis for the Commissioner's determination within a reasonable timeframe upon receipt of a complete application. Factors the Commissioner will assess in determining whether to grant or deny a waiver application based on provision of services to a specialty population include, but are not limited to, the following:

(a) the number of other residential health care facilities licensed by the Department that provide the services identified by the facility as specialized services;

(b) whether a majority of current facility residents have special health care needs as identified by the facility; and

(c) the unique training or licensing required of facility staff to provide services to the identified specialized population.

(iv) In the event a facility no longer provides care for a specialty population, as identified under subparagraphs (i) and (iii) of this paragraph, the facility shall comply with this Section by January first of the first year following the date on which the facility ceased operating as a specialty residential health care facility, as determined by the Commissioner.

(2) Additional Waivers. A facility may apply to the Commissioner for a waiver of applicability of this Section on the basis of unexpected or exceptional circumstances that prevented compliance. Such application shall detail the specific unexpected or exceptional circumstance experienced by the facility; when the facility first learned of such circumstances; why the facility could not have anticipated such circumstances arising; actions the facility took to address such circumstances; expenses incurred as a result of addressing such circumstances; when the facility expects such circumstances to be resolved; and what preventive steps the facility is taking to ensure that such circumstances do not unexpectedly arise in the future. The Commissioner shall have discretion to approve or reject applications submitted pursuant to this paragraph, and shall provide the facility with the basis for the Commissioner's determination within a reasonable timeframe upon receipt of a complete application. Factors the Commissioner will assess in determining whether to grant or deny a waiver application based on unexpected or exceptional circumstances include, but are not limited to, the following:

(i) whether the facility should have anticipated such events occurring;

(ii) whether any other residential health care facilities licensed by the Department experienced similar circumstances but have not applied for a waiver under this paragraph;

(iii) whether the facility has implemented sufficient policies and procedures to ensure such events do not recur.

(d) Minimum Spending Requirements. By January 1, 2022, residential health care facilities shall comply with the following minimum expenditures:

(1) 70 percent of revenue shall be spent on direct resident care; and

(2) 40 percent of revenue shall be spent on resident-facing staffing.

(i) All amounts spent on resident-facing staffing shall be included as a part of amounts spent on direct resident care; and

(ii) 15 percent of costs associated with resident-facing staffing that are contracted out by a facility for services provided by registered professional nurses, licensed practical nurses, or certified nurse aides shall be deducted from the calculation of the amount spent on resident-facing staffing and direct resident care.

(3) For the purposes of assessing whether a facility has met the minimum spending requirements, a facility may apply to the Commissioner to have certain revenues and expenses excluded from the calculation of the facility's total revenue and total expenditures, where the facility has satisfactorily demonstrated to the Commissioner that such revenues and expenses were incurred due to the following circumstances:

(i) a natural disaster, where a federal, State, or local declaration of emergency has been issued; or

(ii) the facility has received extraordinary, non-recurring revenue which, in the discretion of the Commissioner, does not accurately reflect operating revenue for the purposes of this rule, including but not limited to revenue received through insurance or legal settlements.

(e) Recoupment.

(1) A residential health care facility shall be subject to recoupment for excessive total operating revenue if:

(i) the facility's total operating revenue exceeds total operating and non-operating expenses by more than five percent of total operating revenue; or

(ii) the facility fails to spend the minimum amount necessary to comply with the minimum spending standards for resident-facing staffing or direct resident care, as set forth in subdivision (d) of this Section, as calculated on an annual basis, or for 2022, on a pro-rata basis for April 1, 2022 through December 31, 2022.

(2) Remission of excess revenue.

(i) The Department shall issue a notice of noncompliance to a facility subject to recoupment for excessive total operating revenue, which indicates the amount to be remitted based on the amount of excess revenue or the difference between the minimum spending requirement and the actual amount of spending on resident-facing staffing or direct care staffing, as applicable, as well as acceptable forms of payment.

(ii) Upon receipt of a notice of noncompliance pursuant to subparagraph (i), the facility shall remit the total amount indicated in the notice of noncompliance by November first in the year following the year in which the expenses are incurred.

(3) Penalties. Failure to remit the total required fee by the due date may result in adverse action by the Department, including but not limited to: bringing suit in a court of competent jurisdiction, taking deductions or offsets from payments made pursuant to the Medicaid program, and imposition of penalties pursuant to Section 12 of the Public Health Law.

(4) Recouped funds shall be deposited by the Department into the Nursing Home Quality Pool, pursuant to Section 2808(2-c)(d) of the Public Health Law.

(f) Residential Health Care Facility Cost Reports.

(1) The Department shall, no less frequently than annually, audit the residential health care facilities' cost reports for compliance in accordance with this Section.

(2) If a facility did not report data in the 2019 residential health care facility cost report, they must promptly provide the Department with data on the facility's direct resident care and resident facing staffing expenses in accordance with this Section and Section 2828 of the Public Health Law. This data must be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. If the data is not submitted within a reasonable timeframe, as determined by the Department, the Department shall use the previous available cost report data applicable to such facility.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under section 2828 of the Public Health Law (PHL), which directs the Department of Health (Department) to promulgate regulations governing the disposition of revenue in excess of expenses permitted under PHL § 2828 for residential health care facilities. Specifically, PHL § 2828 directs that, as of January 1, 2022, every residential health care facility shall spend a minimum of 70 percent of revenue on direct resident care and 40 percent of revenue on resident-facing staffing, wherein amounts spent on resident-facing staffing are included in the amount spent on direct resident care.

Laws of 2022, Chapter 57, Part M, § 1, amended the definition of "revenue" in PHL § 2828.

In general, PHL § 2828 provides that remission of excess revenue is calculated on an annual basis. Laws of 2022, Chapter 57, Part M, § 4, provides that in 2022, the remission of excess revenue shall be on a pro-rata basis for only that portion of the year during which the failure of a residential health care facility to spend a minimum of seventy percent of revenue on direct resident care, and forty percent of revenue on resident-facing staffing, may be held to be a violation of the Public Health Law, i.e., April 1, 2022, through December 31, 2022, the portion of 2022 after Executive Order 4.4 expired. See 9 NYCRR §9.4.4, which was in effect from January 1, 2022, through March 31, 2022.

Legislative Objectives:

The legislative objective of PHL § 2828 is to ensure that residential health care facilities spend a majority of their revenue on direct resident care (70 percent), with 40 percent of such

expenses focused on paying for resident-facing staffing. The goal of these minimum spending requirements is to help ensure a high quality of resident care.

Needs and Benefits:

These regulations are necessary to implement the statutory directive of PHL § 2828. Specifically, pursuant to the statute, the regulations (1) set forth how facilities that fail to meet the statutory minimum spending requirements must pay the State, (2) provide exceptions from the minimum spending requirements for residential health care facilities that serve certain specialized populations, (3) set forth factors the Department will use to determine whether to waive the spending requirements for facilities unable to comply due to "unexpected or exceptional circumstances that prevented compliance," and (4) provide factors the Department will use to determine whether to exclude extraordinary revenues and capital expenses from the calculations to determine whether a facility has met its minimum spending requirements.

Requiring nursing homes to spend an appropriate amount of revenue on the direct care of residents and resident-facing staffing will reduce errors, complications, and adverse resident care incidents. It will also improve the safety and quality of life for all long-term care residents in New York State.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall

expenditures to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Costs to Local and State Governments:

This regulation will not impact local or State governments unless they operate a residential health care facility, in which case the costs will be the same as for privately-operated facilities. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State.

Costs to the Department of Health:

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

Paperwork:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit revenue and expense information through an annual cost report submitted to the Department, such costs reports are current required pursuant to PHL §§

2805-e and 2808-b. If a facility has not submitted a cost report for 2019, the regulation requires the expense and revenue data to instead be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. Although this data form would be a new requirement, because it is merely a temporary measure to substitute for a missing 2019 cost report, the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities subject to this new paperwork requirement.

Local Government Mandates:

Residential health care facilities operated by local governments will be affected and will be subject to the same requirements as any other residential health care facility licensed under PHL Article 28.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

These regulations are mandated pursuant to PHL § 2828. Accordingly, the alternative of not issuing these regulations was rejected.

Federal Standards:

No federal standards apply.

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

This regulation will not impact local governments or small businesses unless they operate a residential health care facility. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State. Additionally, to date, 79 residential health care facilities in New York qualify as small businesses given that they have 100 or fewer employees.

Compliance Requirements:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. In accordance with this statute, residential health care facilities will be required to meet these aforementioned minimum spending requirements, unless they meet certain exceptions as detailed in both PHL § 2828 and these regulations, including facilities that provide care to Commissioner-designated specialty populations and facilities that are unable to comply with the minimum spending requirements due to natural disaster or other "unexpected or exceptional circumstances that prevented compliance."

Facilities that fail to meet the minimum spending requirements of PHL § 2828 and these regulations will be required to remit a penalty payment in the amount of the facility's excessive total operating revenue, based on the amount of excess revenue or the difference between the minimum spending requirement and the actual amount of spending on resident-facing staffing or direct care staffing, as applicable.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL § 2828 and necessary to ensure that direct resident care is prioritized by setting forth minimum spending requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Small Business and Local Government Participation:

Health care provider organizations, individual institutions, local health departments and the public are invited to comment during the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). Interested parties and members of the general public will be notified and provided in advance of the PHHPC meeting the time and place of the meeting, the text of the regulation for their review and a chance to submit oral and written comments. All written comments will be sent to PHHPC members 72 hours in advance of the meeting.

Further, the Department will engage in active discussions and dialogue with all interested parties, including industry associations directly impacted by this regulation, to inform them of their need to comply, to answer questions and listen to comments they may have on this regulation. Specifically, the Department will issue a *Dear Administrator Letter (DAL)* to each effected nursing home, either operated by a local government, or privately, which will outline the date such regulation will go into effect, the specific requirements outlined in the regulation and the penalties for non-compliance. Further, the Department will formally solicit questions from each effected party and will prepare a *Frequently Asked Questions*, (*FAQ*) which will be updated regularly and publicly posted on the Department's website for review and feedback.

Cure Period:

This regulation does not include a cure period given that compliance is required by January 1, 2022 per PHL § 2828.

RURAL AREA FLEXIBILITY ANALYSIS

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

The following counties 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	

Licensed residential health care facilities are located in these identified rural areas.

Reporting, recordkeeping, and other compliance requirements; and professional services:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit revenue and expense information through an annual cost report submitted to the Department, such costs reports are currently required pursuant to PHL §§ 2805-e and 2808-b. If a facility has not submitted a cost report for 2019, the regulation requires the expense and revenue data to instead be submitted with a written certification by the operator, officer, or public official responsible for the operation of the facility, in a form and format determined acceptable by the Department, attesting that all data reported by the facility is complete and accurate. Although this data form would be a new requirement, because it is merely a temporary measure to substitute for a missing 2019 cost report, the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities subject to this new paperwork requirement.

Compliance Costs:

This regulation seeks to implement PHL § 2828, which requires residential health care facilities to spend a certain percentage of revenue (70 percent) on direct resident care, with 40 percent of such revenue focused on resident-facing staffing. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum spending requirements, but rather may appropriately manage expenditures to balance overall expenditures

to meet the minimum spending thresholds. While the Department anticipates that costs will be borne by residential health facilities, and that those costs may create financial challenges for some organizations, compliance with these minimum spending requirements is mandated by statute (PHL § 2828), and as such these regulatory amendments are necessary. Moreover, any recouped funds from residential health care facilities that fail to comply with PHL § 2828 will be deposited into the Nursing Home Quality Pool to benefit high-quality residential health care facilities, thereby helping to offset any costs for high-performing facilities while also encouraging the provision of quality resident care.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL § 2828 and necessary to ensure that direct resident care is prioritized by setting forth minimum spending requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Rural Area Participation:

The Department will notify all residential health care facilities, including those located in rural areas, of the existence of these regulations and the opportunity to submit public comments or questions to the Department.

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

Pursuant to the authority vested in the Public Health and Health Planning Council and Commissioner of Health by sections 2803 and 2895-b of the Public Health Law, Sections 415.2 and 415.13 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (h) of Section 415.2 is amended to read as follows:

(h) Nurse aide (see section [415.13(c)(1)] 415.13(d)(1) of this Part).

Section 415.13, and the title thereof, are amended to read as follows:

Section 415.13 Nursing Services and Minimum Nursing Staff Requirements.

(a) Staffing standards. The facility shall have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care. The facility shall further assure that staffing levels enable each resident to receive[s] treatments, medications, diets and other health services in accordance with individual care plans. At a minimum, the facility shall ensure its daily nursing staff levels comply with paragraph (2) of subdivision (b) of this Section; provided, however, that compliance with paragraph (2) of subdivision (b) of this Section shall not serve as a defense where the facility has failed to provide sufficient nursing care to residents in accordance with their resident assessment and individual plans of care, or the facility failed to ensure residents received ordered treatments, medications, diets or other health services consistent with the residents' individual plans of care and in accordance with federal and State law and regulations.

[(a)] (b) Sufficient staff.

(1) The facility shall provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) registered professional nurses or licensed practical nurses;

(ii) certified nurse aides, meaning any person included in the nursing home nurse aide registry pursuant to Section 2803-j of the Public Health Law; and

(iii) other nursing personnel.

(2) Minimum Nursing Staff Requirements. At a minimum, the facility shall employ certified nurse aides, registered professional nurses, licensed practical nurses, or nurse aides sufficient to maintain the following daily staffing hours per resident:

(i) From January first, two thousand twenty-two through December thirty-first, two thousand twenty-two, the facility shall maintain daily average staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide, registered professional nurse, licensed practical nurse, or nurse aide. Out of such 3.5 hours, no less than 2.2 hours of care per resident per day shall be provided by a certified nurse aide or a nurse aide, and no less than 1.1 hours of care per resident per day shall be provided by a registered professional nurse or licensed practical nurse.

(ii) Beginning January first, two thousand twenty-three and thereafter, every nursing home shall maintain daily average staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide, registered professional nurse, or licensed practical nurse. Out of such 3.5 hours, no less than 2.2 hours of care per resident per day shall be provided by a certified nurse aide, and no less than 1.1 hours of care per resident per day shall be provided by a registered professional nurse or licensed practical nurse.

[(2)] (3) The facility shall designate a registered professional nurse or licensed practical nurse to serve as a charge nurse on each tour of duty who is responsible for the supervision of total nursing activities in the facility. Alternatively, as necessitated by resident care needs, the facility may designate one charge nurse for each tour of duty on each resident care unit or on proximate nursing care units in the facility provided that each nursing care unit in the facility is under the supervision of a charge nurse.

[(b)] (c) Registered professional nurse.

(1) The facility shall use the services of a registered professional nurse for at least 8 consecutive hours a day, 7 days a week, or more often as necessary to comply with the minimum staffing requirements set forth in paragraph (2) of subdivision (b) of this Section.

* * *

[(c)] (d) Nurse aide.

(1) For the purpose of this section and section 415.26(d) of this Part, nurse aide shall mean any person [who provides direct personal resident care and services including, but not limited to, safety, comfort, personal hygiene or resident protection services, for compensation, under the supervision of a registered professional nurse or licensed practical nurse in the facility] who is included in the nurse aide hour component of the federal Centers for Medicare and Medicaid Services payroll based journal for long-term care facilities but has not yet been certified as a certified nurse aide, including individuals who are in the first four months of employment and who are receiving training in a Department-approved nurse aide training and competency evaluation program and are providing nursing or nursing-related services for which they have been trained and are under the supervision of a licensed or registered nurse, or individuals, other than a licensed professional, who have been approved by the Department to

administer medications to residents. For the purposes of this section and section 415.26(d) of this Part, a nurse aide does not include volunteers or [except for] those individuals who furnish services to residents only as feeding assistants as defined in Section [415.13(d)] 415.13(e) of this Part. Certification of such nurse aide shall be in accordance with the provisions of section 415.26(d) of this Part.

* * *

[(d)] (e) Feeding Assistant.

* * *

(f) Non-Compliance with Staffing Standards.

(1) Compliance with the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section shall be determined on a quarterly basis, as determined by the Department, by comparing the daily average of the number of hours provided per resident, per day, using the most recent data available from the federal Centers for Medicare and Medicaid Services payroll based journal and the facility's average daily census on a daily basis.

(i) The Department shall initially determine whether a facility is compliant or non-compliant with the minimum nursing staff requirements by conducting the following three assessments:

(a) Assessing whether the total daily staffing hours provided per resident by nurse aides (only from January first, two thousand twenty-two through December thirty-first, two thousand twenty-two), certified nurse aides, licensed practical nurses, or registered nurses fell below 3.5 hours of care per resident on average over the course of the quarter; and

(b) Assessing whether at least 2.2 hours of care per resident per day was provided by a certified nurse aide or a nurse aide (only from January first, two thousand twenty-two through December thirty-first, two thousand twenty-two) on average over the course of the quarter; and

(c) Assessing whether at least 1.1 hours of care per resident per day was provided by a registered professional nurse or licensed practical nurse on average over the course of the quarter.

(ii) A facility that, on average over the course of the quarter, fell below the hourly requirements set forth in clauses (a) through (c) of subparagraph (i) will be considered non-compliant for the purposes of this Section. Any facility that the Department finds non-compliant shall have progressive penalties assessed based upon the number of days per quarter in which the daily staffing hours provided per resident fell below the minimum hourly requirements set forth in paragraph (2) of subdivision (b) of this Section.

(iii) For the purposes of determining compliance, an individual shall not be counted while performing administrative services, as defined in the Centers for Medicare and Medicaid Services payroll based journal for long-term care facilities. Further, individuals who are attending training, either onsite or offsite, and are not available to perform their primary job duties shall not be counted for purposes of determining compliance with the minimum daily staffing hours.

(2) Penalties.

(i) The Department shall impose a penalty of up to two thousand (2,000) dollars per day for each day in a quarter that a facility fails to comply with the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section, unless mitigating or aggravating factors exist.

(ii) Mitigating Factors. The Department may reduce penalties in a quarter that a facility is non-compliant, if the Department determines, in its sole discretion, that any of the following mitigating circumstances existed during the period of non-compliance:

(a) Extraordinary circumstances faced the facility. For the purposes of this clause, extraordinary circumstances shall mean that the facility experienced a natural disaster; a national emergency affecting the facility has been officially declared; a State or municipal emergency affecting the facility has been declared pursuant to Article 2-B of the Executive Law; or the facility experienced a catastrophic event that caused physical damage to the facility or impaired the ability of facility personnel to access the facility. Provided, however, that the facility must first demonstrate, to the satisfaction of the Department, that such extraordinary circumstances could not have been prevented or mitigated through effective implementation of the facility's pandemic emergency plan, prepared pursuant to Section 2803(12) of the Public Health Law, and that the facility complied with the disaster and emergency preparedness requirements set forth in Section 415.26(f) of this Part; or

(b) An acute labor supply shortage of nurse aides, certified nurse aides, licensed practical nurses, or registered nurses exists in the Metropolitan and Nonmetropolitan Area in which the facility is located, as such areas are defined by the federal Bureau of Labor Statistics.

(*1*) For the purposes of determining whether a facility was located in an area experiencing an acute labor supply shortage during the period of non-compliance, the Commissioner shall issue a determination on a quarterly basis as to whether an acute labor supply shortage of nurse aides, certified nurse aides, licensed practical nurses, or registered nurses exists in any Metropolitan or Nonmetropolitan Area of New York State. Such determination shall be made in consultation with the New York State Department of Labor and shall take into account job availability metrics developed by the New York State Department of Labor, which may include but is not limited to the list of job openings in New York State.

(*2*) The fact that the facility is located in an area experiencing an acute labor supply shortage pursuant to this clause shall not serve as a mitigating factor unless the facility has demonstrated, to the satisfaction of the Department, reasonable attempts to procure sufficient staffing during the period of non-compliance, notwithstanding the acute labor supply shortage. Reasonable attempts may include, but not be limited to, incentivizing new personnel through increased wage and benefit offers and searching for personnel outside of the Metropolitan and Nonmetropolitan Area in which the facility is located;

(*3*) The fact that the facility is located in an area experiencing an acute labor supply shortage pursuant to this clause shall not serve as a mitigating factor unless the facility has demonstrated, to the satisfaction of the Department, that it has taken steps over the course of the quarter to ensure resident health and safety notwithstanding any labor supply shortage, including but not limited to discontinuing admissions or transferring residents to another appropriate facility; or

(c) A verifiable union dispute exists between the facility and nurse aides, certified nurse aides, licensed practical nurses, or registered nurses employed or contracted by such facility, resulting in a labor shortage at the facility.

(g) Eligibility for Funding to Comply with Minimum Nursing Staff Requirements.

The Department shall determine which nursing homes are anticipated to be in compliance with Section 2828 of the Public Health Law based on the most current, available Residential Health Care Facility cost report data, or such other source of cost information as the Department shall identify. Pursuant to methodology set forth in the current Medicaid State Plan Amendment, the Department shall determine whether such nursing homes must expend additional funds to comply with this Section, beyond any costs necessary to comply with Section 2828 of the Public Health Law. Any such nursing home that the Department finds will be required to expend

additional funds to comply with this Section shall be eligible to receive from the Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements set forth in paragraph (2) of subdivision (b) of this Section.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The statutory authority is provided under sections 2803 and 2895-b of the Public Health Law, which provides that the Commissioner of Health enact regulations establishing standard nursing home staffing levels.

Legislative Objectives:

The legislative objective of PHL section 2895-b is to ensure safe and appropriate levels of nurse staffing in nursing homes in order to improve the care for residents of nursing homes.

Needs and Benefits:

These regulations are necessary to implement the statutory directive of PHL section 2895-b. Specifically, pursuant to the statute, the regulations: (1) set forth minimum nurse staffing standards; (2) provide for the imposition of penalties for failure to meet minimum staffing standards; (3) provide for mitigating factors for failure to meet the minimum staffing requirements; and (4) set forth a process for the Department to determine facilities that are in need of assistance to meet the staffing requirements.

Research has demonstrated that as nurse turnover increases in nursing homes, the quality of resident care declines. Therefore, having adequate nurse staffing levels provides residents with the highest quality of care. Requiring these facilities to meet this minimum level of staffing will help ensure patient safety and improve the quality of care received by the residents of the nursing home.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

This regulation seeks to implement standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

C**osts to State and Local Governments:**

This regulation will not impact local or State governments unless they operate a residential health care facility, in which case the costs will be the same as for privately-operated facilities. Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and 6 residential health care facilities operated by the State.

Costs to the Department of Health:

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

Local Government Mandates:

Residential health care facilities operated by local governments will be affected and will be subject to the same requirements as any other residential health care facility licensed under PHL Article 28.

Paperwork:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this data does not create a new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

These regulations are mandated pursuant to PHL section 2895-b. Accordingly, the alternative of not issuing these regulations was rejected. The Department considered different alternatives for the imposition of civil penalties and determined that penalties need to be high enough to prevent facilities from simply paying the penalty as a cost of doing business rather than complying with the law.

Federal Standards:

No federal standards apply.

Compliance Schedule:

The regulations incorporate the compliance dates contained in the Public Health Law section 2895-b, which requires a certain level of staffing by January 1, 2022, and a certain level by January 1, 2023.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

This regulation implements PHL Section 2895-b, which provides the Commissioner of Health authority to establish minimum staffing standards for nursing homes and impose civil penalties for nursing homes that fail to adhere to the minimum standards. These minimum standards, which take effect January 1, 2022, require every nursing home to maintain daily staffing hours equal to 3.5 hours of care per resident per day by a certified nurse aide (CNA), licensed practical nurse, or registered nurse with at least 2.2 hours of care per resident per day being provided by a CNA and at least 1.1 hours of care per resident per day provided by a licensed nurse. The nursing home must post information regarding nurse staffing at the facility. Penalties may not be assessed against nursing homes until April 1, 2022, and the Commissioner may take into consideration several mitigating factors when issuing penalties including declared disaster emergencies, the frequency of non-compliance, and regional labor supply shortages.

Currently, there are 21 residential health care facilities operated by local governments (counties and municipalities) and there are 115 providers that reported 100 or fewer employees according to recently filed cost data reports.

Compliance Requirements:

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this

data does not create any new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Professional Services:

No professional services are required by this regulation.

Compliance Costs:

This regulation seeks to implementing standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL section 2895-b and necessary to ensure that direct resident care is prioritized by setting forth minimum staffing requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Additionally, regulations provide that the Department shall determine whether nursing homes must expend additional funds to comply, and nursing homes that the Department finds will be required to expend additional funds to comply may be eligible to receive from the Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements.

Further, regulations establishing the civil penalties include mitigating factors to account for: (1) extraordinary circumstances facing the facility such as officially declared emergencies or natural disasters; (2) the frequency of the violations of the facility; and (3) the existence of a nurse labor shortage in the area of the nursing home.

Small Business and Local Government Participation:

The Department will notify such entities of the existence of these regulations and the opportunity to submit comments or questions to the Department. The Department will engage in active discussions and dialogue with all interested parties, including industry associations directly impacted by this regulation, to inform them of their need to comply, to answer questions and listen to comments they may have on this regulation.

The Department has already taken several steps to notify the nursing home industry on the effects of this regulation and has provided the opportunity for public comment. On October 7, 2021, at the Public Health and Health Planning Council (PHHPC), the Department presented this regulation for information and discussion purposes. At that meeting the regulation was reviewed and discussed by PHHPC members. In addition, the public, including the effected parties to this regulation, were afforded and opportunity to ask questions and provide comments.

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

Further, the regulation will be filed in the State Register, providing another opportunity for public comments and review. Once completed, the regulation will again go to PHHPC where there will be another opportunity for public comment.

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

The governing statute directs the Commissioner of Health to establish civil penalties for those facilities that fail to comply with the minimum staffing requirements. However, there are several mitigating factors set forth in the regulation to potentially reduce the fine amount; additionally, the regulation provides for a progressive system of penalties depending on the number of days per quarter the facility was out of compliance with the minimum staffing requirements.

Rural Area Flexibility Analysis

Types and Estimated Numbers of Rural Areas:

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

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	

Licensed residential health care facilities are located in these identified rural areas.

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

This regulation generally imposes no additional paperwork requirements. Although facilities will be required to submit staffing and care information through the facility's average daily census on a daily basis, such reporting is already required. Therefore, the submission of this data does not form any new requirement, and the Department does not anticipate that this requirement will be unduly burdensome for the residential health care facilities.

Costs:

This regulation seeks to implementing standard minimum nursing home staffing levels. Residential health care facilities are not necessarily required to expend additional resources to meet these minimum staffing requirements, but rather may appropriately manage expenditures to balance overall expenditures to meet the minimum staffing thresholds. In any event, if costs are borne by residential health care facilities, compliance with these minimum staffing requirements is mandated by Public Health Law section 2895-b, and as such these regulatory amendments are necessary.

Minimizing Adverse Impact:

This regulation is mandated pursuant to PHL section 2895-b and necessary to ensure that direct resident care is prioritized by setting forth minimum staffing requirements for such care. Therefore, any adverse impacts are outweighed by the regulation's health and safety benefits to residents as well as the legal mandate for promulgation.

Additionally, regulations provide that the Department shall determine whether nursing homes must expend additional funds to comply, and nursing home that the Department finds will be required to expend additional funds to comply may be eligible to receive from the Department additional funds, subject to availability from the New York State Division of the Budget, to hire nursing staff necessary to achieve the minimum nursing staff requirements.

Further, regulations establishing the civil penalties include mitigating factors to account for: (1) extraordinary circumstances facing the facility such as officially declared emergencies or natural disasters; (2) the frequency of the violations of the facility; and (3) the existence of a nurse labor shortage in the area of the nursing home

Rural Area Participation:

The Department will notify all residential health care facilities, including those located in rural areas, of the existence of these regulations and the opportunity to submit public comments or questions to the Department. The Department will engage in active discussions and dialogue with all interested parties, including industry associations directly impacted by this regulation, to inform them of their need to comply, to answer questions and listen to comments they may have on this regulation.

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. To the contrary, given the minimum requirements for nursing staff, including nurse aides, certified nurse aides, licensed practical nurses, and registered nurses, the Department anticipates that these regulations will have a positive impact on nursing jobs throughout the State, to the extent these regulations will help incentivize hiring in these professions.