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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

REGULATORY IMPACT STATEMENT

Statutory Authority:

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

Legislative Objectives:

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

Needs and Benefits:

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

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

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

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

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

COSTS:

Costs to Regulated Parties:

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

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

Costs to Local and State Governments:

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

Costs to the Department of Health:

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

Paperwork:

This regulation imposes no additional paperwork.

Local Government Mandates:

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

Duplication:

These regulations do not duplicate any State or federal rules.

Alternatives:

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

Federal Standards:

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

Compliance Schedule:

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

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REGULATORY FLEXIBILITY ANALYSIS

Effect on Small Business and Local Government:

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

Compliance Requirements:

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

Professional Services:

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Small Business and Local Government Participation:

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

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

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

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

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

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

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

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

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

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

Compliance Costs:

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

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

Economic and Technological Feasibility:

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

Minimizing Adverse Impact:

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

Rural Area Participation:

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

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

STATEMENT IN LIEU OF JOB IMPACT STATEMENT

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

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (Department) received three comments regarding the revised proposed amendments to Sections 405.11 and 415.19 of Title 10 of the New York Codes, Rules and Regulations, as published in the State Register on June 28, 2023, and the identical proposed amendments as published in the State Register on November 15, 2023. These comments and the Department's responses are summarized below.

Comment: Two hospital associations objected to the provisions to require that all hospital and nursing home off-site stockpiles be warehoused within New York State to count toward the required stockpile amount. The associations noted that many facilities, particularly those located near border states, currently use out-of-state warehouses due to available space, lower cost, storage capabilities, and existing contracts with third-party logistics companies. The associations therefore encouraged that the regulations be revised to allow out-of-state warehousing of personal protective equipment (PPE).

Response: The regulatory provision requiring in-state storage of PPE to count toward the stockpile threshold is necessary to ensure New York can maintain control over PPE stockpiles in the event of a State disaster emergency, such as a future pandemic. Additionally, in-state storage is necessary to ensure State surveillance staff can inspect facilities for compliance with regulatory requirements. Therefore, the Department declines to make this change.

Comment: A hospital association asked that the Department consider methods for calculating the PPE stockpile other than the April 2020 study by the Johns Hopkins Bloomberg School of

Public Health Center for Health Security. The association further opined that the 60-day stockpile requirement is not reflective of current COVID-19 positivity rates.

Response: As an initial matter, the Department is not aware of any applicable, extensive academic research regarding PPE burn rates to use as an alternative to the Johns Hopkins methodology. As indicated in prior comments, the Department conducted extensive outreach to stakeholders following publication of the original proposed regulations, including outreach to nursing home and hospital associations, individual hospitals, labor unions, and medical societies, requesting recommendations for a third-party, independent methodology. Upon review of the responses received, the Department found that all alternative methodologies had flaws, including unclear assumptions or implementation challenges. Only one stakeholder suggested an academic study to determine PPE burn rates, but the underlying methodological assumptions, including the facility type and location, were inapplicable to New York State hospitals or nursing homes. Nevertheless, given the Department's recognition that new methodologies may be developed following promulgation of these regulations which are better suited than the underlying Johns Hopkins methodology, the revised regulations in sections 405.11(g)(8) and 415.19(f)(7) provide that the Commissioner of Health has authority to amend these regulations should an alternate methodology be developed. Should such an alternative methodology present itself, the association and other interested parties are invited to share any such methodology with the Department for consideration pursuant to sections 405.11(g)(8) and 415.19(f)(7).

With respect to the comment regarding the 60-day stockpile amount being too high, the Department notes that this requirement is consistent with the existing directive in Public Health Law (PHL) section 2803(12) to maintain a two-month PPE supply for nursing homes as part of a pandemic emergency plan, and requiring a 60-day PPE stockpile for both nursing homes and

hospitals will foster consistency in stockpile requirements. Further, the Department finds that 60 days is appropriate to ensure a sufficient supply in the event of a future supply chain issue. Notwithstanding that supply chain issues do not currently exist, the intention of the regulation is to ensure facilities are prepared in the event of a future emergency and PPE supply chain problems, using the State's experience combating the COVID-19 virus during surge periods. Therefore, the Department declines to amend the regulations in response to these comments.

Comment: A long-term care association opined that the regulations lead to wasted PPE because the current formula is based on the highest positivity rates during the COVID-19 State disaster emergency and such rates exceed current need.

Response: To maximize shelf life of stockpiled inventory and reduce waste, the revised regulations provide that facilities are "strongly encourage[d]" to rotate through their stockpile during regular usage and replace what has been used with more current PPE (see 10 NYCRR 405.11[g][6]; 415.19[f][5]). Given this existing language, no additional changes to the regulation will be made.

Comment: A long-term care association requested that the regulations be amended to allow facilities to count reusable PPE differently from single-use PPE.

Response: As has been noted previously, the Department finds that there is no reliable, accurate method to calculate single- versus multi-use PPE differently. Manufacturers have varying standards for reusability, there is no sound way for facilities to account for PPE that is being worn or washed when calculating the stockpile, and in the past facilities have inaccurately

reported their reusable PPE amounts when the Department employed a standard adjustor to account for reusability. Accordingly, no modifications have been made to the regulation.

Comment: A long-term care association opined that Medicaid rates must be adjusted to reimburse nursing homes for the cost of their PPE stockpiles.

Response: While the Department appreciates this suggestion, it is outside the scope of these regulations. Therefore, no changes have been made.

Comment: A long-term care association suggested that the Department initiate a collaborative effort to right-size the State's emergency PPE stockpile.

Response: The Department notes that State reserves are routinely used to address emergency response activities; throughout the COVID-19 State disaster emergency, PPE reserves were routinely accessed by State healthcare providers using the "NY Responds" system when necessary to supplement existing supply, whether due to supply chain issues or responding to an outbreak. In any event, this suggestion falls outside the scope of these regulations, and accordingly no changes have been made.

Comment: A long-term care association suggested that to ensure consistency and transparency, the regulation, or at a minimum Department guidance, should specify the method for calculating a nursing home's "average census" and the source of the data used in such determination.

Response: The Department has previously provided that average census will be determined for the calendar year 2022 based upon the facility-level HERDS COVID-19 survey submissions.

Nevertheless, the Department appreciates this suggestion and will consider adding clarifying guidance in a Dear Administrator Letter following adoption of these regulations.

Comment: A long-term care association opined that facilities should not be subject to regulatory citations when they need to use their PPE reserves and cannot immediately replenish their supply. The association therefore suggested that the Department amend section 415.19(f) to provide an exception to the requirement to "possess and maintain" the 60-day inventory in the event of an emergency or widespread supply chain interruptions.

Response: The stockpile is intended to be a reserve in the event an emergency arises and additional PPE is needed in the course of operations; as such, facilities must ensure that the 60-day stockpile is maintained even as facilities rotate through older PPE supplies. Accordingly, no changes have been made in response to these comments. However, the Department notes that it maintains its ability to exercise enforcement discretion when surveyors assess compliance with regulations, and such discretion may be exercised in the event of confirmed PPE supply chain issues that affect the geographic area in which the facility is located. However, facilities that experience difficulty acquiring necessary PPE, due to supply chain issues or otherwise, should immediately notify the Department for assistance resolving the issue.