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 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 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

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 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 four comments regarding the proposed amendments to Sections 405.11 and 415.19 of Title 10 of the New York Codes, Rules and Regulations. The comments and the Department's responses are summarized below.

A hospital located in New York State submitted the following comments:

Comment: The hospital opined that the 60-day stockpile requirements for hospitals is unreasonable, particularly given the lack of current PPE supply chain issues; a 30- to 45-day stockpile based on a facility's average six-month rolling PPE use would be more reasonable.

Response: As these regulations apply to nursing homes, the 60-day stockpile requirement is consistent with the existing directive in Public Health Law (PHL) section 2803(12) to maintain a two-month PPE supply. Further, requiring a 60-day PPE stockpile for both nursing homes and hospitals will foster consistency in stockpile requirements. Finally, 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 problem, 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: The hospital suggested that the Department impose requirements for PPE manufacturers so health care organizations would not need to warehouse large quantities of PPE.

Response: While the Department appreciates this suggestion, the Department does not regulate manufacturers of PPE. Accordingly, no changes have been made to the regulation.

The Department received three comments from healthcare trade associations, as follows: (1) an association representing nursing homes (hereinafter, "nursing home association"), (2) an association representing hospitals and health systems in New York State (hereinafter, "hospital association"), and (3) an association representing hospitals, health systems, nursing homes, and other healthcare providers in New York State (hereinafter, "healthcare association") (hereinafter, collectively, "the associations").

Comment: The hospital association expressed support for the regulation's reduction of the required PPE stockpile from 90 days to 60 days.

Response: The Department appreciates this support.

Comment: The associations commented that the regulations lead to wasted PPE because the current formula is based on the highest positivity rates during the COVID-19 State of Emergency and such rates exceed current need, particularly in nursing homes. The healthcare association further recommended that the Department review existing State PPE practices, including best practices from the State Department of Homeland Security (DHS) regarding rotating through stock, and consider using DHS's regional caches to supplement facilities' PPE stockpiles.

Response: Two changes have been made to the revised regulations in response to this comment. First, to maximize shelf life of stockpiled inventory and reduce waste, the Department has added language to the revised proposed regulations to "strongly encourage" nursing homes and

hospitals 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]).

Second, with respect to the specific suggestion to review DHS's and other best practices for PPE storage, the Department is committed to reviewing all pertinent information available to inform its decision-making and regulatory actions, including emergency preparedness standards. However, because practice standards are frequently reviewed and revised, the Department generally does not incorporate specific best practices into the text of regulations, which are subject to lengthy public review and publication requirements under the State Administrative Procedure Act; instead, the Department will actively review best practices and, if necessary, share administrative guidance, which can be issued more promptly than regulations. The Department will consider distributing a Dear Administrator Letter (DAL) to covered facilities if DHS or other federal or State entities publish best practices for PPE storage that are applicable to regulated healthcare facilities, including hospitals and nursing homes. Further, the Department notes that State reserves are routinely used to address emergency response activities; throughout the COVID-19 Public Health 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.

Nevertheless, to address more general concerns regarding warehousing of PPE on-site, the Department has revised the regulations to provide that off-site storage of PPE is permissible within the conditions outlined in sections 405.11(g)(3)(ii) and 415.19(f)(3)(ii).

Comment: The associations requested that in proposed 10 NYCRR 415.19(f)(2) "staffed beds" be used as a multiplier instead of the nursing home's "certified beds," as is done for hospitals in proposed 10 NYCRR 405.11(g)(2).

Response: The Department has revised the regulations to change the term "certified beds" in section 415.19(f) to "the nursing home's average census as determined annually by the Department." The revised regulations further provide that the Department shall determine the nursing home's average census annually, by January 1 of each year, and shall communicate such determination to each facility (10 NYCRR 415.19[f][4]). There is no standard definition of "staffed beds" for nursing homes in either Public Health Law Article 28 or 10 NYCRR Part 415, nor does the Department currently utilize the concept of "staffed beds" in other areas of nursing home reporting or oversight. As such, the Department finds that "average census as determined annually by the Department" is a more fitting term than "staffed beds."

Additionally, the hospital stockpile regulations at section 405.11(g) have similarly been revised to require the Department to periodically recalculate the number of hospital staffed beds and allow the Commissioner of Health to use a bed multiplier other than staffed beds if necessary.

Comment: The nursing home association suggested that as an alternative to these regulations, the Department rely on the "Personal Protective Equipment Burn Rate Calculator" published by the U.S. Centers for Disease Control and Prevention (CDC). Similarly, the hospital association asked the Department to explain why a 2020 academic study remains relevant for determining PPE usage rates versus more recently-published tools.

Response: The Department has made changes to the regulations in response to this comment. First, the Department notes that the methodology set forth in the proposed regulations is more comprehensive and sound than the CDC's PPE Burn Rate Calculator and remains reliable notwithstanding that it was published in 2020, insofar as the regulation's methodology is based on modeling performed by the Center for Health Security at Johns Hopkins University Bloomberg School of Public Health, available at https://www.centerforhealthsecurity.org/resources/COVID-19/PPE/PPE-assumptions. The Johns Hopkins modeling, in turn, is based on a thorough academic study that assessed incidence, duration of hospitalization, and clinical outcomes of acute COVID-19 inpatient admissions in a cohort of over 9 million individuals enrolled in healthcare delivery plans from Kaiser Permanente in California and Washington state. The full study is available at https://www.medrxiv.org/content/10.1101/2020.04.12.20062943v1. The CDC PPE Burn Rate Calculator, in comparison, is not based on academic research and does not take into account the multitude of factors assessed in the aforementioned study.

Moreover, 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. Indeed, the Department conducted extensive outreach to stakeholders following publication of the 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 responses received, the Department found that the 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, the Department recognizes that new methodologies may be developed following promulgation of these regulations which are better suited than the underlying Johns Hopkins methodology. Therefore, 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 that is appropriate for New York and would adequately ensure the safety of hospital staff and patients is developed.

Comment: The associations requested that the regulations be amended to allow facilities to count reusable PPE differently from single-use PPE.

Response: 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 this regulation as a result of these comments.

Comment: The nursing home association requested that the Department clarify that facilities will not be penalized if supplies fall below the requisite 60-day stockpile amount due to widespread PPE shortages. Similarly, the healthcare association requested that the Department

amend the regulations to specify that facilities can use their existing stockpile without incurring penalties in the event of supply chain shortages and to reduce waste.

Response: The Department 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. Regarding waste, as indicated above, the proposed regulations strongly encourage nursing homes and hospitals to rotate through their stockpile during regular usage and replace what has been used with more current PPE to maximize shelf life of stockpiled inventory and reduce waste. As such, waste is expected to be minimal. The Department further reminds covered entities that 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. No changes have been made in response to these comments.

Comment: The healthcare association requested that the Department clarify what is meant by the following reference to CDC guidance in Sections 405.11(g)(1) and 415.19(f)(1): "The [nursing home and 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…"

Response: The CDC guidance referenced in Sections 405.11(g)(1) and 415.19(f)(1) refers to CDC guidelines regarding what PPE should be worn by healthcare personnel depending on

which patients they are providing care to and the infection status at the facility. No changes have been made to the text of the regulation in response to this inquiry.

Comment: The hospital association requested that the Department reconsider the peak usage dates used to calculate the PPE formula for nursing homes, per 10 NYCRR 415.19(f)(2)(v). Instead of specifying dates in the regulatory text, the hospital association suggests that the Department issue a DAL that details the applicable dates to calculate the "applicable positivity rate" to allow the regulations to be more dynamic and evolve based on current circumstances.

Response: The Department respectfully disagrees that it would be more appropriate to indicate applicable dates through a DAL rather than defining the term "applicable positivity rate" directly within the regulation. Fully defining the term "applicable positivity rate" within the regulation, including the relevant dates, provides long-term clarity to nursing homes to ensure they can contract to purchase sufficient PPE to meet the threshold amount and are replenishing used PPE appropriately. Fluctuating the dates through multiple DALs is likely to lead to confusion for facilities and inaccurate PPE stockpile reporting to the Department. Further, the peak positivity dates referenced within the regulation will ensure maximum preparedness for facilities in the event of another pandemic to best protect staff and residents. The Department notes that, in the past 90 days to date, between 26 to 52 percent of nursing homes have active COVID-19 cases, and therefore PPE must be utilized to prevent widespread infection. Accordingly, the Department declines to make the requested changes.

Comment: The nursing home association commented that the "applicable positivity rate" multiplier did not meaningfully apply to those facilities previously designated by the Department

as COVID-positive only nursing homes during the COVID-19 State of Emergency, insofar as the "applicable positivity rate" multiplier would necessarily be high due to the special population these facilities served during such State of Emergency and may not be reflective of the facility's infection rates during any future pandemic.

Response: The Department has taken this comment into consideration and revised the regulations to allow nursing homes previously designated by the Department as COVID-positive only facilities to utilize 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" as the "applicable positivity rate" multiplier.