Hospital Personal Protective Equipment (PPE) Requirements

Effective date: 7/21/20

Pursuant to the authority vested in the Commissioner of Health by Section 2803 of the Public Health Law, and Executive Order 202, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by amending section 405.11, 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) (i) 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 guidance, for at least 60 days by August 31, 2020, and at least 90 days by September 30, 2020, at rate of usage equal the average daily rate that PPE was used between April 13, 2020 and April 27, 2020; provided, however, that upon request the Department may grant an extension of the deadline to October 30, 2020, at its sole and exclusive discretion for having at least a 90 day supply of PPE where the hospital demonstrates, to the Commissioner's satisfaction, that:

(A) the hospital's inability to meet this deadline is solely attributable to supply chain issues that are beyond the hospital's control and purchasing PPE at market rates would facilitate price gouging by PPE vendors; or

(B) the seven-day rolling average of new COVID-19 infections in New York State remains below one and a half percent (1.5%) of the total seven-day rolling average of COVID-19 tests performed over the same period; and there are ten or less states in the

United States that have a seven-day rolling average of new COVID-19 infections exceeding five thousand cases.

(ii) Failure to possess and maintain such a supply of PPE may result in the revocation or suspension of the hospital's license; provided, however, that no such revocation 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.

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.

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. According to Johns Hopkins' Coronavirus Resource Center, to date, there have been over 3.4 million cases and over 240 thousand deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has 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.

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. Subsequently, on March 13, 2020, President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

New York State first identified cases on March 1, 2020 and has since become the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. With over 412,000 confirmed cases and over 32,000 deaths, as of July 20, 2020, which accounts for approximately 22% of all deaths nationwide, New York State is currently the most impacted state in the nation.

Between 15% and 20% of all individuals infected with COVID-19 will require hospitalization. In order for hospital staff to safely provide care for these patients, 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. As a result of global PPE shortages, from the beginning of the COVID-19 outbreak New York

State has provided general hospitals and other medical facilities with PPE from the State's emergency stockpile.

Based on the foregoing, and pursuant to the Executive Order No. 202 issued on March 7, 2020, which permits the Commissioner to promulgate emergency regulations governing the operation of general hospitals, the Department has made the determination that this emergency regulation is necessary to ensure that all general hospitals maintain a 90-day supply of PPE, at a usage rate equal to the highest average rate of usage during the COVID-19 emergency, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.

COSTS:

Costs to Regulated Parties:

The purpose of this regulation is to require general hospitals to maintain adequate stockpiles of PPE. The initial cost to general hospitals as they establish stockpiles of PPE will vary depending on the number of staff working at each general hospital. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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, 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 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 have adequate stockpiles of PPE necessary to protect hospital staff from communicable diseases, compared to any alternate course of action.

Federal Standards:

Part 1910 of Title 29 of the Code of Federal Regulations requires general hospitals to provide adequate PPE to hospital staff. However, no federal standards apply to stockpiling of such equipment.

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 the next meeting of the Public Health and Health Planning Council following the termination of the COVID-19 emergency.

Contact Person: Katherine Ceroalo
New York State Department of Health
Bureau of Program Counsel, Regulatory Affairs Unit
Corning Tower Building, Room 2438
Empire State Plaza
Albany, New York 12237
(518) 473-7488
(518) 473-2019 (FAX)
REGSQNA@health.ny.gov

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. Currently there are five general hospitals in New York that employ less than 100 staff and qualify as small businesses.

Compliance Requirements:

These regulations require all general hospitals 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 to maintain adequate stockpiles of PPE. The initial cost to general hospitals as they establish stockpiles of PPE will vary depending on the number of staff working at each general hospital. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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:

As these regulations require general hospitals to maintain stockpiles of PPE, which they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

Small Business and Local Government Participation:

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

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	

There are 47 general hospitals located in rural areas.

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

These regulations require all general hospitals, 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 to maintain adequate stockpiles of PPE. The initial cost to general hospitals as they establish stockpiles of PPE will vary depending on the number of staff working at each general hospital. However, as general hospitals are already obligated to provide PPE to their staff by regulations established by the federal Occupational Health and Safety Administration, and as all stockpiled PPE is anticipated to be used as part of routine hospital operations, 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:

As these regulations simply require general hospitals to maintain stockpiles of PPE, that they are already obligated to provide to staff under existing federal regulations, any adverse impacts are expected to be minimal.

Rural Area Participation:

Due to the emergent nature of COVID-19, parties representing rural areas were not consulted.

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

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. According to Johns Hopkins' Coronavirus Resource Center, to date, there have been over 3.4 million cases and over 240 thousand deaths worldwide, with a disproportionate risk of severe illness for older adults and/or those who have serious underlying medical health conditions.

COVID-19 was found to be the cause of an outbreak of illness in Wuhan, Hubei Province, China in December 2019. Since then, the situation has 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.

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. Subsequently, on March 13, 2020, President Donald J. Trump declared a national emergency in response to COVID-19, pursuant to Section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act.

New York State first identified cases on March 1, 2020 and has since become the national epicenter of the outbreak. On March 7, 2020, with widespread transmission rapidly increasing within certain areas of the state, Governor Andrew M. Cuomo issued an Executive Order

declaring a state disaster emergency to aid in addressing the threat COVID-19 poses to the health and welfare of New York State residents and visitors. With over 412,000 confirmed cases and over 32,000 deaths, as of July 13, 2020, which accounts for approximately 22% of all deaths nationwide, New York State is currently the most impacted state in the nation.

Between 15% and 20% of all individuals infected with COVID-19 will require hospitalization. In order for hospital staff to safely provide care for these patients, 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. As a result of global PPE shortages, from the beginning of the COVID-19 outbreak New York State has provided general hospitals and other medical facilities with PPE from the State's emergency stockpile.

Based on the foregoing, and pursuant to the Executive Order No. 202 issued on March 7, 2020, which permits the Commissioner to promulgate emergency regulations governing the operation of general hospitals, the Department has made the determination that this emergency regulation is necessary to ensure that all general hospitals maintain a 90-day supply of PPE, at a usage rate equal to the highest average rate of usage during the COVID-19 emergency, such that sufficient PPE is available in the event of a continuation or resurgence of the COVID-19 outbreak.