Surge and Flex Health Coordination System

Effective: August 6, 2020

SUMMARY OF EXPRESS TERMS

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. 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 90-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.

As of July 2020, there are 213 hospitals - public, private, and independent - across New York State, each operating as essentially a private entity in a highly competitive environment. Prior to the COVID-19 pandemic, these individual institutions and hospital networks rarely worked together or coordinated as a unified healthcare system. But a pandemic on the scale of the COVID-19 crisis demonstrated that our health care facilities could not meet the demand of the moment unless a new and innovative system was put into place requiring unprecedented coordination, cooperation, and agility.

No one situation best encapsulates this lack of coordination than what transpired at Elmhurst Hospital, a facility in the New York City-operated Health & Hospitals (H&H) system, during the third week of March. Elmhurst Hospital was overwhelmed with patients at a time when there were just 4,000 total COVID-19 hospitalizations statewide, nearly 900 available beds across the eleven hospitals in the H&H system, and more than 3,500 open beds across all public and private hospitals in New York City. In other words, the problem the Elmhurst situation exposed was not one of hospital capacity, but one of patient load management across all hospitals and hospital systems.

As the Elmhurst situation demonstrated, 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. There was an immediate realization that if peak projections actually materialized in New York, 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.

This approach was operationalized in late March when Governor Andrew M. Cuomo directed the New York State Department of Health (NYSDOH) to create a new and innovative "Surge and Flex" system, designed to create for the first time one singular coordinated statewide public healthcare system to prevent the virus from overwhelming any one hospital in the state. The approach was literally a life-saver—it helped New York at our peak of hospitalizations in April to facilitate the transfer of thousands of patients. The purpose of this NYSDOH regulation is to institutionalize the Surge and Flex operation to both allow the state to quickly activate Surge

and Flex in the event of a resurgence of coronavirus, while also giving hospitals the time and guidance to adequately prepare for a potential future activation of Surge and Flex.

The Surge and Flex system operation launched in March 2020 included four key elements which this regulation will institutionalize, as detailed below.

First, the state quickly built unprecedented hospital capacity.

Health experts modeled that New York State could potentially near as many as 140,000 COVID-only hospital beds when there were only 53,000 hospital beds total in the entire state. As a result, New York State had to quickly build unprecedented bed capacity including requiring all hospitals to delay non-life-threatening elective procedures and increase their number of beds by at least 50 percent (by turning single rooms into doubles and freeing meeting rooms and other areas for patient care among other measures) and preferably 100 percent. In addition, the State worked with local and federal government partners to deploy and stand up temporary hospitals and create contingency plans with large-scale venue operators, hotels, and college dormitory operators, to ensure we were prepared for a worst-case scenario - a projected need for as many as 140,000 COVID patients hospitalized at one time. In total, this approach enabled New York State in a matter of weeks to expand hospital capacity from 53,000 total beds to more than 90,000.

Second, more beds require more staff.

Staffing was a major issue. In many cases, health care staff were becoming sick with COVID and unable to work. This put tremendous strain on the system. To address staffing shortages, New York State established a web portal to recruit and connect health care professionals from across the nation willing to serve, an effort that enlisted the support of nearly 100,000 health care workers. New York State connected these healthcare heroes with housing as

needed and provided support to hospital human resource offices to expedite the onboarding process. Further, New York State facilitated transfers of healthcare staff from upstate hospitals that had few COVID-19 patients to hospitals in New York City in need of staffing support. In the case of another wave of COVID-19 or another infectious disease it is critical that extra staffing capacity be available to meet the emergency.

Third, more beds require more supplies and equipment.

Access to life-saving supplies and materials was a scramble for every state in the nation because our country is reliant on an international supply chain. There was a dire need for ventilators and there was a literal hunger games scenario among states and nations to purchase enough to meet the demand under the crisis. But purchasing alone wasn't enough. There simply weren't enough supplies. To address any potential supply and equipment shortages, New York State used data and a daily reporting system to build a statewide inventory of personal protective equipment (PPE), ventilators, medications and other critical items. Using a reporting system, New York State could take limited resources and distribute them to the hospitals and other institutions that needed it the most. For example, a hospital in New York City may have had only a few ventilators while other facilities nearby had more than a 100. The Surge and Flex system allowed for the overburdened hospital to get unused ventilators from a nearby facility. New York State distributed more than 13,000,000 pieces of PPE and other equipment, including thousands of ventilators. To ensure no hospital lacked for supplies and equipment while others had excess, the state built an operational system that could quickly transport supplies and equipment from a hospital with excess to a hospital in need.

Fourth, the state had to coordinate all aspects of the Surge and Flex operation.

For this operational undertaking, the State convened a Hospital Capacity Coordination Committee (HCCC), an around the clock command center with representatives from each of the state's hospital systems to serve as the central hub for operations related to patient transfers, supply and equipment deployment, and staffing support. Guided by online data dashboards that tracked hospital capacity, equipment use, and supply stockpiles by institution in real time, and provided a 24/7 hotline accessible to every hospital in the state, the HCCC had a dedicated desk and assigned leader for every aspect of the operation: patient management, supply & equipment deployment, staffing deployment, and for each supporting function including transportation, legal, and intergovernmental relations.

Taken together, the "Surge and Flex" strategy enabled New York during our apex in late March and through the month of April to save lives and avoid the type of catastrophic failure of the healthcare system that Italy and other nations experienced. This regulation provides the Department of Health with the necessary tools to enact each of these four critical parts of NYS Surge and Flex operation during a second wave of COVID-19, or a future public health emergency. Further, this regulation is designed to help each hospital and healthcare system 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 health care delivery 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 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, health care facilities shall increase by at least 50% and up to 100% 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 all non-essential elective procedures or allow such procedures only pursuant to such conditions as the Commissioner may determine. The Department shall 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 90-days pursuant to Sections 360.2 and 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, but at minimum every 24 hours.

(ii) Requiring that the patient census be reported to the Department, in a form and with such frequency as the Commissioner may determine, but at minimum every 24 hours.

(iii)For any infectious and communicable disease, ensuring that testing results are reported immediately if positive, and four times per day if such testing results are

negative via the electronic clinical laboratory reporting system, or any other form and frequency 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 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 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, and up to a 100% increase within 30 days. 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.

(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 90-day supply of PPE within 30 days, based on a usage rate determined by the Commissioner, 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.

(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 and 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, every six months 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 90-day supply of PPE appropriate for use in a disaster emergency including a pandemic, based on a usage rate and determined by the Commissioner, and 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 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 every 24 hours, 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 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 his 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 Commissioner 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 his 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 his 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 Chapter, 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 his 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 his 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 his 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 his 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.

Executive Order No. 202, as extended, authorizes the Commissioner to directly issue emergency regulations pursuant to PHL sections 225 and 2803. 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.

Each of these areas has been impacted by COVID-19. 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 he is 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 any statute, local law, ordinance, orders, rules, or regulations, or parts thereof, of any agency . . . if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the state disaster emergency." To that end, on March 7, 2020 and in response to the COVID-19 pandemic, Governor Andrew M. Cuomo issued Executive Order No. 202, declaring a state disaster emergency, thereby enabling additional State action that aided in addressing the threat COVID-19 presents to the health and welfare of New York State residents and visitors.

Since March 7, 2020, fifty-five (55) Executive Orders have been issued to address the COVID-19 pandemic, with many of them containing temporary suspensions and modifications of regulations within Titles 10 and 18 of the NYCRR. Further, nine (9) of these Executive Orders were issued, either in whole or in part, to extend previously suspended or modified regulations in Titles 10 and 18 of the NYCRR.

Although the Governor retains authority to issue Executive Orders to temporarily suspend or modify regulations and issue directives pursuant to the Executive Law, these proposed regulatory amendments would provide an expedient and coherent plan to implement quickly the relevant temporary suspensions, modifications, and directives. 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 90-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 a significant portion of these regulatory amendments would give the State Commissioner of Health authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties.

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, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.

Costs to Local Governments:

As a significant portion of these regulatory amendments would give the Commissioner authority to temporarily suspend or modify certain regulations within Titles 10 and 18 of the NYCRR during a state disaster emergency, these regulatory amendments are not expected to result in any significant costs to regulated parties, including facilities operated by local governments.

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, thereby limiting costs. The ongoing cost to hospitals of requiring a minimum PPE supply have already been realized through Executive Orders.

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.

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:

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 a significant portion 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 small businesses and local governments.

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, thereby limiting costs. 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.

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 commenter 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.

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 is 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.

Given the possibility of a second wave of COVID-19 in New York State, the Department has determined that these regulations should be issued on an emergency basis.