STATE OF NEW YORK: DEPARTMENT OF HEALTH -----X

IN THE MATTER

OF

ORDER FOR SUMMARY ACTION

THE PREVENTION AND CONTROL OF EBOLA VIRUS DISEASE

-----X

WHEREAS, Ebola Virus Disease (EVD) is a rare and potentially deadly disease caused by infection with one of four Ebola virus strains known to cause disease in humans; and

WHEREAS, the current EVD event in West Africa has resulted in nearly 9,000 cases and more than 4,000 deaths in Sierra Leone, Guinea and Liberia and is the largest EVD outbreak in history; and

WHEREAS, EVD in the current event has a high case fatality rate with 58% of known cases resulting in death; and

WHEREAS, the World Health Organization has declared the current EVD outbreak in West Africa to be an international health emergency; and

WHEREAS, the Centers for Disease Control and Prevention (CDC) has issued a travel notice urging all United States (US) residents to avoid nonessential travel to Liberia, Guinea, and Sierra Leone because of the unprecedented outbreaks in those countries; and

WHEREAS, the CDC, in a Morbidity and Mortality Weekly Report (MMWR), dated September 26, 2014, reported that an analysis of Ebola cases in Liberia and Sierra Leone performed to predict the number of future Ebola cases indicates that, if conditions continue without scale-up of interventions, cases will continue to double approximately every 20 days, and the number of cases in West Africa will rapidly reach extraordinary levels; and

WHEREAS, on September 30, 2014, the CDC confirmed the first travel-associated case of EVD to be diagnosed in the US. The patient passed away on October 8, 2014; and

WHEREAS, on October 12, 2014, the CDC confirmed that a healthcare worker who provided care for the index patient has tested positive for EVD, and on October 15, 2014 confirmed that a second healthcare worker who provided care for the index patient also tested positive for EVD. These cases of EVD among healthcare workers demonstrate the importance of all facilities maintaining infection control protocols and equipment that assure the safety of all personnel by maintaining a high rate of compliance among all healthcare workers on the proper use of personal protective equipment; and

WHEREAS, CDC estimates that 150 travelers return daily to the US from the countries of Sierra Leone, Guinea and Liberia, and 94% of them arrive at one of five international airports, including John F. Kennedy International Airport. Enhanced airport screening could help identify individuals with fever or other symptoms, and exposures placing them at increased risk for EVD; and

WHEREAS, the epidemic in West Africa could continue for an additional nine months or longer depending on the success of control measures and contact tracing such that there is a continued risk of patients presenting at healthcare facilities in the US with suspected EVD; and

WHEREAS, healthcare providers caring for EVD patients and the family and friends in close contact with EVD patients are at the highest risk of getting sick because they may come in contact with the blood or body fluids of sick patients. The virus also can be spread through contact with objects (like clothes, bedding, needles, syringes/sharps or medical equipment) that have been contaminated with the virus. Exposure to EVD can occur in healthcare settings where hospital staff are not wearing appropriate personal protective equipment; and

WHEREAS, the CDC has developed and issued infection prevention and control recommendations for hospitalized patients with known or suspected EVD in US hospitals, which are designed and intended to minimize the risks from treating patients diagnosed with or suspected of having EVD, and limit and control EVD transmission; and

WHEREAS, based upon the foregoing, the Acting Commissioner of Health of the State of New York is of the opinion that all covered entities, as defined on the annexed Attachment A, must immediately implement and comply with the requirements identified in the attached document, and that the failure to do so constitutes a danger to the health, safety and welfare of the people of the State of New York; and

WHEREAS, the Acting Commissioner of Health of the State of New York believes that requiring the covered entities to immediately implement and comply with the requirements annexed hereto as Attachment A cannot be achieved through alternative means, including the adoption by the Public Health and Health Planning Council of emergency regulations, without delay, which would be prejudicial to health, safety and welfare of the people of the State of New York; and

WHEREAS, it therefore appears to be prejudicial to the interest of the people to delay action for fifteen (15) days until an opportunity for a hearing can be provided in accordance with the provisions of Public Health Law Section 12-a.

NOW, THEREFORE, THE ACTING COMMISSIONER OF HEALTH HEREBY ORDERS THAT:

Pursuant to Public Health Law Section 16, any covered entity to which this Order has been issued (also referred to as "Respondent"), shall immediately implement and comply with the requirements annexed hereto as Attachment A.

FURTHER, I DO HEREBY give notice that any entity that receives notice of and is subject to this Order may request a hearing, to be held within fifteen (15) days, at an office of the New York State Department of Health to be determined, to present any proof that failure to implement and comply with the requirements annexed hereto as Attachment A does not constitute a danger to the health of the people of the State of New York. If any such entity desires such a hearing, a request for a hearing must be made in writing to James E. Dering, General Counsel, New York State Department of Health, Corning Tower, Room 2438, Governor Nelson A. Rockefeller Empire State Plaza, Albany, New York 12237, within ten (10) days of their receipts of this Order.

DATED:

Albany, New York

October 16, 2014

NEW YORK STATE DEPARTMENT OF HEALTH

BY:

Acting Commissioner of Health

REQUIREMENTS FOR EVD PREPAREDNESS

<u>Purpose</u>

This Attachment to the Order of the Acting Commissioner of Health describes requirements regarding management and treatment of Persons Under Investigation, Confirmed Cases, and bodies of persons who have expired from Ebola Virus Disease (EVD). It contains several sections, and multiple sections may apply to your entity. Accordingly, you must review this document in its entirety and identify all requirements that apply. If you have any questions regarding these requirements, please submit your questions by email to Ebola-Preparedness@health.ny.gov.

Definitions

As used in this document, the following definitions apply.

- "Confirmed Case", consistent with current guidance from the Centers for Disease Control and Prevention (CDC), means a case with laboratory-confirmed diagnostic evidence of Ebola virus infection.
- 2. "Covered Entity" means:
 - a. All general hospitals regulated pursuant to Article 28 of the Public Health Law (PHL);
 - b. All diagnostic and treatment centers and off-campus emergency departments regulated pursuant to Article 28 of the PHL;
 - c. Ambulance and advanced life support first response services, licensed pursuant to Article 30 of the PHL; and
 - d. Funeral Directors and Funeral Establishments, licensed and registered pursuant to Article 34 of the PHL.
- 3. "Covered Personnel" means all employees, contractors, students, and all other personnel who may:
 - a. come into contact with a Patient, or a laboratory specimen from a Patient; or
 - b. be involved in the cleaning or disinfection of equipment or Patient care areas, including vehicles used to transport Patients.

This includes, but is not limited to, contract nurses, attending physicians and residents.

- 4. "Patient" means a Person Under Investigation; a Confirmed Case; or the body of a person who has expired from EVD.
- **5.** "Person Under Investigation" or "PUI", means a person who has both consistent symptoms and risk factors as set forth in the <u>Specifications required under the Commissioner's Order</u> (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order).

Timetable for Compliance

Any covered entity to which this Order has been served shall immediately begin implementation and compliance with these requirements, with full implementation and compliance to be achieved no later

than ten (10) days after receipt of the Order; provided, however, that if there are changes to the information at: Specifications required under the Commissioner's Order (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order), that will be stated on the web site and Covered Entities will be provided additional time per the web site update to achieve full implementation and compliance with such changes.

All general hospitals, diagnostic and treatment centers, off-campus emergency departments, and ambulance services

The Covered Entities referenced above must:

- Identify to the NYSDOH at least two lead points of contact for EVD preparedness and response
 activities, one of whom must be available 24 hours per day, seven days per week. The lead points of
 contact must be assigned to the role of 24/7 Ebola Lead in the Health Commerce System (HCS)
 Communication Directory by your organization's HCS Coordinator. Instructions are available at:
 https://apps.health.ny.gov/pub/ctrldocs/alrtview/postings/HCS Role Assignment.pdf.
- 2. Provide all Covered Personnel with personal protective equipment (PPE) that, at a minimum, meets the applicable specifications at Specifications required under the Commissioner's Order (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner order).
- 3. Conduct in-person training for all Covered Personnel, on donning and removing PPE, including physically practicing donning and removing PPE in the setting that will be used for Patients. A designated trainer with infection control expertise selected by the Covered Entity must be present at the training to assess whether Covered Personnel have initially achieved satisfactory competence. The training used must, at a minimum, meet the applicable specifications at Specifications required under the Commissioner's Order
 (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order). The Covered Entity must reassess Covered Personnel every month after initially achieving satisfactory competence, and must retrain any Covered Personnel who do not demonstrate satisfactory competence are allowed to provide care to Patients. The Covered Entity must maintain a log that identifies all Covered Personnel who have received training, the dates they obtained satisfactory competence, and dates and results of monthly reassessments.
- 4. Maintain a log of all personnel coming into contact with a Patient, or a Patient's area or equipment, regardless of the level of PPE worn at the time of contact. Covered Entities shall measure the temperature twice daily of all personnel who come in contact with a Patient, a Patient's area or equipment, or obtain the temperatures from off-duty personnel. The log must describe each person's measured temperatures and any symptoms. "Contact" for the purposes of this provision is defined as coming in physical contact, entering a patient room, coming within three feet of a Patient, or performing laboratory testing on a specimen from a Patient.
- 5. Implement a written protocol to safely contain, store and dispose of regulated medical waste in all settings where Patients will be cared for that is in compliance with the applicable specifications at

<u>Specifications required under the Commissioner's Order</u> (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner order).

6. Implement a written protocol to safely clean and disinfect any room, vehicle or equipment with which Patients have come into contact, in accordance with applicable specifications at Specifications required under the Commissioner's Order
(http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order).

All general hospitals, diagnostic and treatment centers, and off campus emergency departments

The Covered Entities referenced above must:

- 1. Implement a written patient registration protocol for the immediate identification, isolation, and medical evaluation of <u>any person</u> presenting for care with: (1) a travel history within the last 21 days to Liberia, Guinea, or Sierra Leone, or any other country that CDC designates as having a widespread EVD outbreak; and (2) any symptoms of EVD including fever, headache, muscle pain, vomiting, diarrhea, abdominal pain, or unexplained hemorrhage. The protocol must require reception staff to obtain a travel history and symptoms from all patients upon initial reception. The protocol also must include a plan for the Covered Personnel on all shifts who would be involved in the medical evaluation or other care of a PUI placed in isolation for the medical evaluation of EVD.
- 2. Conduct training on the patient registration protocol for personnel on all shifts who are involved in patient registration, triage or who work in outpatient settings or emergency departments.
- 3. Post signs prominently at all entrances, at reception, and at triage locations, in at least English, French, Spanish, Chinese, Russian, Italian, Korean and Haitian Creole asking <u>all persons</u> presenting for care to provide their international travel history.
- 4. Designate a room for isolation that is in, or in proximity to, the area in which Patients would reasonably be expected to present for care, for patients in need of medical evaluation of EVD. The room must have a door, and it must have access to a private bathroom or have a portable commode. Space must be identified in or adjacent to the room, to be used by staff to don and remove PPE. Such space must have access to hand-washing facilities. If the space is adjacent to the room to be used for isolation, traffic in the area must be restricted to avoid exposure of other persons. Access to the room to be used for isolation and adjacent rooms must be restricted to avoid exposure of other persons.
- 5. Maintain a list of <u>all persons</u> who came into contact with a Patient before they were placed in isolation, including direct physical contact or coming within three feet of a Patient. The list shall be provided to the local health department where the hospital is located. The Covered Entity shall monitor the temperature and symptoms of any of its personnel on this list.
- 6. Immediately notify the local health department or the New York City Department of Health and Mental Hygiene (NYCDOHMH), as applicable, when a PUI is placed in isolation for the medical evaluation of EVD.

7. Conduct drills with personnel on all shifts on the patient registration protocol initially within 5 days of receipt of the Order and then every month, following the initial drill. A written description of the drill, including the items reviewed, number of staff included in the drill, gaps identified, conclusions, and next steps, must be maintained and made available to the New York State Department of Health upon request.

All general hospitals

All general hospitals must:

1. Develop a written treatment protocol for the initial inpatient care of Patients that identifies a designated negative pressure room to house the Patient. The location shall have either an anteroom with doors that close, or an area outside the room where Covered Personnel can remove PPE that is not taken off in the Patient's room. The anteroom or PPE removal area shall provide access to hand-washing facilities. There also should be additional rooms available for staff to don PPE, and to shower after removing all PPE. The entire area must be secured to prevent access by unauthorized staff and the public, with either locking doors or the continuous presence of hospital security personnel.

2. Develop either:

- a. A written transport protocol for the safe transportation of any Patient to another facility, if it becomes necessary. The transport protocol must identify an ambulance service as well as the receiving facility. The transport protocol must include provisions requiring prompt notification that the protocol has been initiated to the receiving facility, local health department, NYSDOH, and the ambulance service. Notification to the receiving facility and the ambulance service will allow them to direct staff to use PPE and prepare vehicles and receiving areas; or
- b. A written plan for the ongoing care of Confirmed Cases. If ongoing care will be provided at the hospital, the plan must address each of the following items. Hospitals agreeing to be designated to provide care to patients with EVD may submit an initial plan to the Department for review.
 - i. Identify a designated negative pressure room to house the Confirmed Cases. The location shall have either an anteroom with doors that close, or an area outside the room where Covered Personnel can remove any final PPE that is not taken off in the Confirmed Cases' room. The anteroom or PPE removal area shall also provide access to hand-washing facilities. There also should be additional rooms available for staff to don PPE, and to shower after removing all PPE. The entire area must be secured to prevent access by unauthorized staff and the public, with either locking doors or the continuous presence of hospital security personnel.
 - ii. Develop a roster of personnel on all shifts for the care of Confirmed Cases for three weeks. The roster must include a staff member on every shift who is responsible for observing all Covered Personnel to assure adherence to infection control protocol and proper use of PPE.

- iii. Maintain provisions for the full range of patient care including critical care and subspecialty services.
- iv. Maintain readily available N-95 respirators or powered air purifying respirators to be used by personnel who will care for Confirmed Cases for situations when copious amounts of bodily fluids are present, or for aerosol generating procedures such as intubation, and take other additional precautions including but not limited to double gloving, and use of disposable shoe covers and leg coverings. Training for this additional level of PPE shall be included in the plan for training on PPE in the General Requirements section of this Order.
- Maintain a readily available inventory of biohazard containers for the safe transportation of specimens to the NYSDOH or NYCDOHMH laboratory for testing for EVD. Such containers must meet applicable specifications at <u>Specifications required under the Commissioner's Order</u> (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order).
- 4. Develop a written biohazard risk assessment and protocol for the receipt, processing, and testing of any laboratory samples from Patients. Safety precautions, including readily available PPE, must meet applicable specifications for the safe handling of specimens at <u>Specifications required under the Commissioner's Order</u> (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order).
- 5. Ensure that staff are available on every shift, who are trained and certified in the packaging and shipping of infectious substances, for the purpose of submitting specimens for EVD testing. Training must cover classifying infectious substances, proper packaging of infectious substances, and labeling packages to meet regulatory requirements.

All diagnostic and treatment centers and off-campus emergency departments

All diagnostic and treatment centers and off-campus emergency departments must:

 Develop a written transport protocol for the safe transportation of any Patient with suspected or confirmed EVD to another facility. The transport protocol must identify an ambulance service as well as the receiving facility. The transport protocol must include provisions requiring prompt notification that the protocol has been initiated to the receiving facility, local health department, NYSDOH, and the ambulance service. Notification to the receiving facility and the ambulance service will allow them to direct staff to use PPE and prepare vehicles and receiving areas.

Funeral Directors and Funeral Establishments

All funeral directors and funeral establishments must:

1. Maintain compliance with the applicable specifications for Safe Handling of Human Remains of Ebola Patients in US Hospitals and Mortuaries at Specifications required under the Commissioner's Order (http://www.health.ny.gov/diseases/communicable/ebola/#commissioner_order).