Revise Requirements for Collection of Blood Components

Effective date: 9/9/20

Summary of Express Terms

Subpart 58-2 establishes regulatory requirements for all aspects of blood banking, including personnel qualifications, donor screening and care, record keeping, and certain technical specifications. In particular, section 58-2.14 addresses these aspects for blood banks conducting serial plasmapheresis, meaning the collection of "source plasma" that is intended to manufacture blood derivatives such as anti-SARS Cov-2 immunoglobulin. Section 58-2.15 addresses the requirements for blood banks collecting plasma and other blood components intended for transfusion. The requirements in 58-2.15 are similar to those in 58-2.14, but include technical requirements for collecting both cells and plasma.

Recent federal regulations at Title 21 of the Code of Federal Regulations ("CFR") Parts 630 and 640 comprehensively address the same subjects as 58-2.14 and 58-2.15. Accordingly, the proposed amendments to state regulation adopt relevant federal requirements by reference while retaining or adding certain New York State ("NYS") requirements to maintain consistency with other regulations and Public Health Law, and to provide clarifying details. This approach simplifies state requirements and harmonizes them with national standards, while maintaining a high level of safety. By more closely tracking federal regulations, the proposed amendments will make it easier for industry, hospitals, and other entities to contribute to the NYS supply of blood and blood components, such as COVID-19 convalescent plasma.

Pursuant to the authority vested in the Council on Human Blood and Transfusion Services and the Commissioner by Section 3121(5) of the Public Health Law, Sections 58-2.14 and 58-2.15 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended and new section 58-2.28 is added as follows, to be effective upon filing with the Secretary of State.

Section 58-2.14 is amended to read as follows:

§ 58-2.14 [Serial plasmapheresis] Collection of source plasma.

(a) [The standards that apply to whole blood collection and processing shall apply to serial plasmapheresis except as otherwise specified. Whenever the plasma is not intended for transfusion, or for the preparation of fractions for transfusion, the criteria for donor selection may be limited to those designed for the safety of the donor. In such instances, the plasma unit shall be prominently labeled, "NOT FOR TRANSFUSION", or similar language.] Notwithstanding any requirements in this Subpart to the contrary for blood collection by means other than plasmapheresis, blood banks collecting, processing, and/or distributing source plasma, as defined in Title 21 of the Code of Federal Regulations (CFR) Part 640 shall comply with applicable requirements in Title 21 CFR Parts 630 and 640 and any additional requirements in this section.

(b) *Direction.* The director of a [serial plasmapheresis program] blood bank collecting, processing, and/or distributing source plasma shall be a licensed physician who [must demonstrate satisfactory training in all aspects of hemapheresis, including a minimum of two year's experience] holds a Certificate of Qualification in Blood Banking Collection –

Comprehensive pursuant to Part 19 of this Title. The director may serve as the responsible physician as required by Title 21 CFR Part 630. If the director is not the responsible physician, the responsible physician shall be licensed in the state or jurisdiction where the blood bank is located and either hold a Certificate of Qualification in transfusion pursuant to Part 19 of this Title, or be board certified in clinical pathology or in clinical pathology/laboratory medicine. The director shall not delegate approval of new or revised standard operating procedure manuals or other procedural guides specific to the facility as required by section 58-2.8 of this Title.

(c) *Informed consent.* The consent of a prospective serial plasmapheresis donor shall be obtained in writing after a licensed physician, physician assistant, nurse practitioner or registered nurse, explains the hazards of the procedure to the donor in such a manner that he/she is offered an opportunity to refuse consent. The prospective donor shall be told of the risks of serial plasmapheresis, including the possibility of a hemolytic transfusion reaction if he/she is given someone else's red cells, risks of any medications or sedimenting agents to be used, and, if he/she is to be immunized or hyperimmunized, of the hazards involved. [For example, in the case of immunization] If the donor will be immunized with human blood components, the donor shall be [told specifically about] informed of the risk of [viral hepatitis, as well as about] transfusion-transmitted infections and the increased risk of receiving incompatible blood [if he/she ever needs a transfusion] in future transfusions. A prospective donor who is to be deliberately exposed to an antigen shall also be given a general description of the immunization program, including the nature of the material to be injected. All of this information shall also be

given to each prospective donor in written form, and the donor's consent shall be signed and witnessed [on a form approved by the department].

[(d) *Donor qualification*. A donor may not be accepted for serial plasmapheresis unless the criteria in section 58-2.2(b) and (c) of this Subpart, with the exception of sections 58-2.2(b)(5) and (7), and 58-2.2(c)(10) and (11), are met.]

([e]d) *Care of serial plasmapheresis donors*. [A qualified, licensed physician shall be available within fifteen minutes' travel time of the premises at which serial plasmapheresis is performed, immediately available for personal or telephone consultation in the treatment of a donor who manifests an adverse reaction, and responsible for all phases of plasmapheresis conducted.] A physician, [or a registered nurse designated by the medical director] physician assistant, nurse practitioner or registered nurse shall be available on the premises [at all times] whenever collections of source plasma are performed in order to supervise the care of plasma donors. A blood bank collecting source plasma must establish, maintain and follow standard operating policies and procedures for management of donor adverse reactions, including obtaining rapid emergency medical services, such as using 911, for donors when medically necessary. [The floor supervisor shall be a registered nurse, physician assistant, or person with at least two years' experience performing plasmapheresis procedures, and shall have completed a plasmapheresis training program that includes documented satisfactory performance of donor plasmapheresis procedures. Persons performing manual plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical

laboratory technologists, physician assistants, or persons with at least two years' experience performing manual plasmapheresis procedures. Persons performing automated plasmapheresis procedures shall be licensed practical nurses, registered nurses, clinical laboratory technologists, clinical laboratory technicians or physician assistants, or persons with at least six months' experience in collecting whole blood for transfusion.]

(e) *Personnel training.* All persons performing plasmapheresis procedures shall [have one year's experience performing plasmapheresis procedures or shall] have completed a training program in plasmapheresis procedure technique. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of [an] and initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each plasmapheresis operator must be able to:

(1) safely and effectively operate the cell separator systems in use at the facility;

(2) harvest plasma which meets quality standards;

(3) manage fluid volumes safely; and

(4) prevent, and when necessary, initially address adverse reactions[;].

[(5) develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and

(6) provide support to the donor while maintaining control of the operation of the instrument.

The director shall establish an agreement with an accredited hospital in the vicinity of the plasmapheresis center for the admission of donors who sustain adverse reactions and require hospital care.

(f) *Laboratory testing.* A serologic test for syphilis shall be performed within 24 hours on a specimen collected at the time of the first donation and at four-month intervals thereafter. A donor with a reactive serologic test for syphilis shall not be plasmapheresed again until the donor's serum is nonreactive in confirmatory testing, except that donors with reactive tests for syphilis may be plasmapheresed to obtain plasma to be used for manufacturing control serum for serologic tests for syphilis. Approved tests for HBsAg and antibodies to HCV, HIV-1 and HIV-2 shall be performed on the retained plasma or on a specimen obtained from the donor at the time of donation. If the plasma is intended for transfusion, all tests required in section 58-2.3(a) of this Subpart shall be performed.

(g) *Return of red blood cells to donor.* If it is not possible to return red blood cells to a plasmapheresis donor, or if whole blood is donated, the donor shall not be plasmapheresed again for eight weeks, unless the donor’s extracorporeal red blood cell volume during the procedure is not expected to exceed 100 milliliters.]

([h]f) *Manual plasmapheresis procedures.* [Containers and anticoagulants shall meet the standards for whole blood.] Before the blood container is separated from the donor for processing, it shall bear two separate and independent means of identification to enable both the donor and the phlebotomist to determine without doubt that the contents

originate from the donor. [Plasmapheresis shall be performed aseptically under conditions that avoid air embolism. During their separation, the red blood cells shall be maintained at a temperature not exceeding 37 degrees Celsius and under conditions known to assure the sterility and viability of these cells upon their return to the donor.] The identity of the donor and the container shall be confirmed by at least two [technical] staff members, trained in accordance with subdivision (e) of this section, prior to reinfusion of the red blood cells. Red blood cells shall be returned to the donor within two hours of the phlebotomy. [If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(i) *Automated plasmapheresis procedures.* Plasmapheresis shall be performed aseptically under conditions that avoid air embolism and maintain sterile technique. If plasmapheresis is to be performed using equipment dissimilar to blood bags used for the collection of blood so that the standards for containers and anticoagulants for whole blood do not apply, specific approval from the department is required.

(j) *Records.* All institutions performing plasmapheresis shall maintain records of all plasmaphereses performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on each donor, signed consent of the donor, his/her identification code, and the amount of plasma removed. When immunizations are performed, the antigen and the procedures employed shall be

identified and recorded, and the donor shall give specific consent for the immunization. These records shall be available for inspection for at least seven years after each plasmapheresis.]

Section 58-2.15 is amended to read as follows:

(a) [*Selection of donors.* The standards that apply to whole blood donation shall apply in the selection and care of the donor for apheresis, unless otherwise specified.] Notwithstanding any requirements in this Subpart to the contrary for blood collection by means other than apheresis, blood banks collecting blood components by apheresis must comply with applicable requirements in Title 21 CFR Parts 630 and 640 and any additional requirements in this section.

(b) *Direction.* The director of a blood bank collecting, processing, and/or distributing blood components for transfusion shall be a licensed physician who holds a Certificate of Qualification in Blood Banking Collection - Comprehensive pursuant to Part 19 of this Title. The director may be the responsible physician as required by Title 21 CFR Part 630. If the director is not the responsible physician, the responsible physician shall be licensed in the state or jurisdiction where the blood bank is located and either hold a Certificate of Qualification in transfusion pursuant to Part 19 of this Title or be board certified in clinical pathology or clinical pathology/laboratory medicine. The director shall not delegate approval of new or revised standard operating procedure manuals or other procedural guides specific to the facility as required by section 58-2.8 of this Title.

([b]c) *Informed consent.* The consent of a prospective donor shall be obtained in writing after a [qualified and specially trained individual] licensed physician, physician assistant, nurse practitioner or a registered nurse, explains the hazards of the procedure [in such a manner that] and the donor is offered an opportunity to refuse consent. The donor shall be informed of the risks of apheresis and the risks of any sedimenting agents or medications to be used.

([c]d) *Qualifications and care of the donor.*

(1) Only those persons may be accepted as blood donors for apheresis who are in good health as indicated by the qualifications of a whole blood donor specified in section 58-2.2 of this Subpart, with the following exceptions:

(i) Ingestion of aspirin-containing medications within [three] two days of donation shall preclude donation of platelets.

(ii) Cytapheresis of donors who do not meet the requirements of this subsection shall be performed only if the harvested cells are expected to be of particular value to an intended recipient, and only if the supervising physician has confirmed in writing the particular value of these cells and has certified that the donor's health permits cytapheresis.

(iii) Medications or sedimenting agents to facilitate cytapheresis shall not be used in donors whose medical history suggests that these may exacerbate previous or intercurrent disease. Guidelines for use of such agents shall be established by the medical director.

(2) [The medical director, who must demonstrate satisfactory training in all aspects of apheresis, including one year of experience, shall be responsible for all phases of apheresis conducted. Persons performing apheresis procedures shall be registered nurses, licensed practical nurses, clinical laboratory technologists, clinical laboratory technicians

or physician assistants, or persons with at least six months' experience collecting blood for transfusion.] All persons performing apheresis procedures [shall have at least one year's experience performing apheresis procedures or] shall have completed a training program in apheresis procedure [technique] techniques. The training program must include training in donor screening, venipuncture techniques, instrument operation, prevention of and initially addressing donor reactions, and proper documentation of all completed procedures. At the end of the training program, each apheresis operator must be able to:

(i) safely and effectively operate the cell separator systems in use at the facility;

(ii) harvest blood components which meet quality standards;

(iii) manage fluid volumes safely; and

(iv) prevent, and when necessary, initially address adverse reactions[;].

[(v) develop the ability to work independently, utilizing the floor supervisor as a resource when necessary; and

(vi) provide support to the donor while maintaining control of the operation of the instrument.

(3) The floor supervisor shall be a:

(i) registered nurse;

(ii) physician assistant;

(iii) person with at least two years' experience performing apheresis procedures; or

(iv) person with at least one year of experience supervising allogeneic blood collection.

(4) The floor supervisor shall have completed an apheresis training program that includes documented satisfactory performance of donor apheresis procedures.]

([5]3) A [person] physician, physician assistant, nurse practitioner or a registered nurse, who is specifically trained in recognizing and addressing reactions that may occur in association with the procedures being performed, shall be immediately available on the premises [at all times] during an apheresis procedure in order to supervise the care of donors. [A qualified licensed physician shall be immediately available, at all times during an apheresis procedure. A qualified licensed physician shall be immediately available, at least for telephone consultation, during all procedures.]

(4) The blood bank shall establish, maintain and follow standard operating procedures policies and procedures for management of donor adverse reactions, including obtaining rapid emergency medical services, that include using 911, for donors when medically necessary.

[(d) *Volume and frequency of apheresis.* Extracorporeal blood volume shall not exceed 15 percent of the donor's estimated blood volume. No more than 12.0 liters of plasma shall be removed per year from a donor weighing 175 pounds or less, and no more than 14.4 liters shall be removed per year from a donor weighing more than 175 pounds. The interval between procedures shall be at least 48 hours. The above volume and frequency requirements may be waived upon written authorization of the supervising physician, provided the donor meets all other eligibility requirements. Red blood cell loss shall not exceed 300 milliliters per eight weeks, unless the following requirements are met:

(1) for male donors, the donor's weight is at least 130 pounds;

(2) for female allogeneic donors, the donor's weight is at least 150 pounds;

(3) for female autogeneic donors, the donor's weight is at least 130 pounds;

(4) the allogeneic donor's hemoglobin content is 12.5 grams per deciliter or greater, or hematocrit is 38 percent or greater, and the donor meets the hemoglobin/hematocrit and weight requirements for use of the apheresis device, as approved by the F.D.A.;
(5) the autogeneic donor's hemoglobin content is 11.0 grams per deciliter or greater, or hematocrit is 33 percent or greater, and the donor meets the hemoglobin/hematocrit and weight requirements for use of the apheresis device, as approved by the F.D.A.;
(6) the volume of packed red blood cells removed does not exceed 550 milliliters; and
(7) the volume removed is replaced with at least 225 milliliters of normal saline.
Following a red cell apheresis procedure in which red blood cell loss exceeds 300 milliliters, the allogeneic donor shall not donate whole blood or undergo another apheresis procedure for a minimum of 16 weeks. For autogeneic donors, frequency and volume to be removed shall be determined by the medical director of the blood bank in conformance with recommendations of the manufacturer of the apheresis device.]

(e) *Volume and frequency of apheresis.* All collections shall follow criteria for the F.D.A. approved or cleared apheresis device used. In addition, the following requirements shall apply to:

(1) Plasmapheresis

(i) donors shall donate plasma no more frequently than twice in seven days, with at least two days between donations; and

(ii) donors shall be weighed at the time of each donation.

(2) Cytapheresis

(i) platelet, leukocyte, and granulocyte donors shall donate no more frequently than twice in seven days, with at least two days between donations. The total volume of plasma collected must not exceed the maximum for the instrument as cleared by F.D.A.;

(ii) double or triple platelet collections shall occur no more frequently than once in seven days;

(iii) donors may not donate more than 24 times in a twelve-month period;

(iv) cytapheresis shall not take place less than eight weeks after a whole blood donation, unless the apheresis instrument has an extracorporeal red cell volume less than 100 ml. When such an instrument is used, cytapheresis shall not take place less than two days after a whole blood donation; and

(v) if red cell loss during apheresis is greater than 200 ml, the next apheresis shall take place no sooner than eight weeks after the first.

(3) Plateletpheresis

(i) the blood bank shall collect a blood specimen from the donor before each plateletpheresis procedure to determine the donor's platelet count. This platelet count, if available, shall be used in the qualification of the donor. If this platelet count is not available, the donor's most recent platelet count may be used in the qualification of the donor, except in the case of triple platelet collections from first time donors. An acceptable platelet count is required for such donors prior to donation; and

(ii) the donor's platelet count must be greater than 150,000 per ul. Donors with fewer than 150,000 per ul must be deferred until the platelet count is acceptable.

(4) 2-unit red cell apheresis donors

(i) a 2-unit red cell apheresis donor shall not donate blood or blood components for at least 16 weeks after the apheresis; and

(ii) the blood bank shall not collect a red cell volume expected to result in a donor hematocrit of 30% or lower, or hemoglobin less than 10 g/dl after volume replacement.

[(e) *Return of red blood cells to donor.* If it is not possible to return red blood cells to a donor, or if whole blood is donated, the donor shall not undergo apheresis again for eight weeks, unless the donor's extracorporeal red blood cell volume during the procedure will not exceed 100 milliliters.

(f) *Procedures for collection of blood components by apheresis and their processing.* Such procedures shall follow a written protocol approved by the medical director. Containers and anticoagulants shall meet the standards for whole blood. Apheresis shall be performed aseptically under conditions that prevent air embolism, and assure sterility and viability of cells returned to the donor.

(g) *Required records.* All facilities performing apheresis shall maintain records of all such procedures performed, and the clinical and laboratory information pertinent thereto. These records shall include complete information on the donor, volume of blood removed, anticoagulants used, duration of the procedure, volume of components obtained, medications and sedimenting agents used, including manufacturer, lot number, expiration date and amount administered, and any adverse reactions and their

management. These records shall be available to the department for inspection for at least seven years after each procedure.]

Section 58-2.28 is added to read as follows:

§ 58-2.28 Incorporation by reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, Title 21, Parts 630 and 640, revised as of May 22, 2015 and April 1, 2016, respectively, published by the Office of the Federal Register, National Archives and Records Administration. The regulations incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

Regulatory Impact Statement

Statutory Authority:

Paragraph (1) of section 3121of the New York State Public Health Law ("PHL") establishes the Council on Human Blood and Transfusion Services (hereafter "Council"). Section 3121 of the PHL empowers the Council to enact, and from time to time, amend and repeal, rules and regulations regarding the collection, processing, fractionation, storage, distribution and supply of blood, blood components, and blood derivatives, subject to the approval of the Commissioner of Health ("Commissioner"). Section 576 of the PHL further authorizes the New York State Department of Health ("Department") to "prescribe standards for the proper operation of clinical laboratories and blood banks."

Legislative Objectives:

Through Section 3121 of PHL, the Legislature authorized the Department and the Council to protect the safety and supply of blood, blood components, and blood derivatives for transfusion. Subpart 58-2 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York (NYCRR) regulates the laboratories that perform blood typing as well as the blood banks that handle blood, blood components, and blood derivatives. In order to ensure a safe blood supply, Subpart 58-2, in its original adoption and all subsequent revisions, requires blood banks to be: directed by individuals with experience and training in blood banking; staffed by individuals trained in the activities of the blood bank; exclude donors who cannot safely donate blood; provide for donor safety; maintain specific records; and comply with certain

technical requirements.

Needs and Benefits:

Blood collection must have appropriate oversight to ensure both the safety and the availability of blood and its components. There is an urgent need for COVID convalescent plasma and biologics derived from plasma to treat severely ill COVID patients. Simplifying the regulatory landscape and harmonizing New York State requirements with national standards will enhance availability, while maintaining high blood safety standards.

A review of applicable federal requirements determined that 21 CFR Parts 630 and 640 address the same areas as sections 58-2.14 and 58-2.15 of Title 10 of the NYCRR, and are at least as stringent as current New York State requirements. Accordingly, the proposed amendments adopt the federal requirements by reference and add certain New York State requirements to ensure consistency with Part 58 of Title 10 of the NYCRR and the PHL, while providing clarity to regulated entities. The regulatory amendments will align New York State with the rest of the country, thereby simplifying the collection of these important materials.

Costs:

Costs to Regulated Parties

The proposed amendment will not impact costs to regulated parties.

Costs to the Agency, State and Local Governments

The proposed amendment will not impose additional costs to the Department, the program responsible for oversight of clinical laboratories, or to local governments. The program responsible for the oversight of blood banks and serial plasmapheresis facilities is a well-established program operated at the State level and the new language does not impact the costs of the oversight program.

Local Government Mandates:

The proposed regulations impose no new mandates on any county, city, town or village government; or school, fire or other special district.

Paperwork:

The proposed revisions to Subpart 58 do not require any additional forms or paperwork from applicants.

Duplication:

As mentioned above, the federal government has regulations at 21 CFR Parts 630 and 640, governing certain aspects of plasmapheresis sites. These amendments will align New York State regulations with federal requirements.

Alternatives:

The alternative to this amendment would be to maintain the current New York State requirements. However, these requirements are generally similar but not identical

to federal requirements without substantive additional benefit to donors or patients. These regulatory amendments will also provide greater regulatory clarity. Without amending the regulations, it will be more difficult for industry, hospitals, and other entities to contribute to the NYS supply of blood and blood components such as COVID-19 convalescent plasma.

Federal Standards:

As discussed above, the federal government has standards at 21 CFR Parts 630 and 640 and which govern aspects of apheresis and plasmapheresis, and, with several exceptions listed below, these amendments are designed to align New York State regulations with the federal standards. The exceptions include credentials and qualifications of personnel authorized to obtain donor consent and to supervise care of donors during the collection process. Exceptions also include details regarding the frequency and volume of blood or blood components that can be collected. These exceptions are necessary to clarify broad, general federal requirements and to formally incorporate details provided in F.D.A. guidance documents that would be unenforceable otherwise.

Compliance Schedule:

The Department expects that regulated parties should be able to comply with the proposed regulation as of its effective date.

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Statement in Lieu of Regulatory Flexibility Analysis

No regulatory flexibility analysis is required pursuant to section 202-b(3)(a) of the State Administrative Procedure Act. The amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

Statement in Lieu of Rural Area Flexibility Analysis

A Rural Area Flexibility Analysis for these amendments is not being submitted because the amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and employment opportunities is expected as a result of this proposed regulation.

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 Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, have had symptoms ranging from those that are mild (like a common cold) to severe pneumonia that requires medical care in a hospital and can be fatal. Older adults and those with certain pre-existing health conditions are at greater risk for severe illness.

There have been nearly 400,000 confirmed cases of COVID-19 and nearly 25,000 deaths reported in New York State. There is an urgent need for treatments. One potential treatment involves transfusing ill COVID-19 patients with plasma (the liquid part of blood) from a recovered COVID-19 patient. The recovered patient's plasma (known as "convalescent plasma") contains immune factors thought to help the recipient fight the SARS-CoV-2 infection. Initial clinical trials suggest that convalescent plasma may benefit some patients. However, larger trials are needed to determine how effective this treatment is and the circumstances under which it should be used. These trials require large amounts of convalescent plasma. If shown to be effective, even more plasma will be needed to treat patients.

Simplifying the regulatory landscape and harmonizing NYS requirements with national standards will enhance plasma availability, while maintaining high blood safety standards. In particular, there will be fewer hurdles for companies currently providing these services in other states to do so in New York State. Given the emergent nature of

the COVID-19 outbreak, these emergency regulations are necessary to help advance treatments for severely ill patients.