Organ Transplant Provisions

Effective date: 9/10/14

SUMMARY OF EXPRESS TERMS

This proposal amends Section 405.13, repeals Subdivisions (c) and (k) of Section 405.22 and adds Sections 405.30 and 405.31 to Part 405 (Hospitals – Minimum Standards) of Title 10 of the Official Code of Rules and Regulations of the State of New York (10 NYCRR), particularly as they relate to organ transplant and donor services. Hospitals as referred to in Part 405 are general hospitals.

Section 405.13 of Part 405 pertains to anesthesia services. This amendment specifies that hospitals providing living liver donor transplants must also comply with the provisions contained in the newly added Section 405.31, subdivision (p) paragraph (2). Section 405.31 sets forth the living donor transplantation services provisions. Subdivision (p) of Section 405.31 outlines the living adult donor to adult recipient liver transplantation services provisions and paragraph (2) proposes the anesthesia requirements within Section 405.31. Current regulations address only living liver transplantation. These regulations address all living donation, including kidney donation.

Section 405.22 currently contains the critical care and special care services provisions. This amendment repeals the organ transplant center and live liver

transplantation services provisions contained within Section 405.22 in subdivisions (c) and (k) respectively.

Two new sections are created in this proposal. Section 405.30 sets forth the organ and vascularized composite allograft transplant services/programs provisions. Section 405.31, as stated above, sets forth the living donor transplantation services provisions.

The organ and vascularized composite allograft transplant services/programs provisions in Section 405.30 define the terms " living donor," "organ," "organ procurement organization (OPO)," "organ trafficking," "patient," "qualified mental health professional," "qualified social worker," "recipient," "transplant center," "transplant commercialism," "transplant program," "transplant services," "transplant tourism," "travel for transplant," and "vascularized composite allograft." This section specifies general requirements for hospitals that provide transplant services, and also outlines organization and staffing and quality assessment and performance improvement (QAPI) requirements.

Section 405.31 outlines the living donor transplantation services requirements. It specifies that hospitals performing living donor transplants shall comply with the requirements of this section, section 405.30 (see above) and with subdivision (a) of Section 405.22 of this Part. Section 405.22 subdivision (a) contains the general provisions of the critical care and special care services requirements. Section 405.31 also

defines a donor advocate as a person or team responsible for ensuring that the rights and interests of the living donor and the prospective living donor are protected. It sets forth donor advocate responsibilities, donor advocate requirements, education of the donor requirements, informed consent provisions, disclosure requirements, risks, primary medical evaluation and psychosocial provisions, recipient criteria, donor management, imaging service, discharge planning and post-discharge requirements. This section contains the living adult donor to adult recipient liver transplantation services provisions and outlines the surgical team, anesthesia, postoperative care, and minimum medical and nursing staffing requirements.

Pursuant to the authority vested in the Public Health and Health Planning Council and subject to the approval by the Commissioner of Health pursuant to Sections 2800 and 2803 of the Public Health Law, Section 405.13 is amended, Subdivisions (c) and (k) of Section 405.22 are repealed, and new Sections 405.30 and 405.31 are added to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The introductory paragraph of section 405.13 of Part 405 is amended to read as follows:

405.13 Anesthesia services.

If anesthesia services are provided within a hospital, the hospital shall develop, implement and keep current effective written policies and procedures regarding staff privileges consistent with provisions set forth in section 405.4 of this Part, the administration of anesthetics, the maintenance of safety controls and the integration of such services with other related services of the hospital to protect the health and safety of the patients in accordance with generally accepted standards of medical practice and patient care. Such policies and procedures shall be reviewed and updated as necessary, but at a minimum biennially. Hospitals providing living liver donor transplants shall also comply with the provisions contained in Section 405.31 (p) (2).

405.22 Critical care and special care services.

Subdivisions (c) and (k) of Section 405.22 of Part 405 are repealed. Section 405.22 of Part 405 is amended to add a new subdivision (c) to read as follows:

(c) Reserved.

A new Section 405.30 of Part 405 is added to read as follows:

405.30 Organ and Vascularized Composite Allograft Transplant Services/Programs.

(a) *Definitions.* For purposes of this section the following shall have the following meanings:

(1) *Department* shall meant the New York State Department of Health.

(2) *Living donor* is an individual who donates an organ or a vascularized composite allograft while alive.

(3) *Organ* means a human kidney, heart, liver, lung, pancreas, uterus, stomach, intestine, and/or any other tissue requiring revascularization or immunosuppression in the recipient.

(4) *Organ procurement organization* (OPO) means a facility or institution engaged in procuring organs and/or vascularized composite allografts for transplantation, or therapy purposes but does not include:

(i) facilities or institutions which permit procurement activities to be conducted on their premises by employees or agents of an approved organ procurement organization; or

(ii) facilities or consortia of facilities which conduct transplantation activities in accordance with article 28 of the public health law when the organ is procured through an approved organ procurement organization, or from a living donor.

(5) *Organ trafficking* is the recruitment, transport, transfer, harboring or receipt of living or deceased persons or their organs by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of organs for transplantation.

(6) *Patient* means either the living donor or the recipient:

(i) Adult means a patient 18 years of age or older at the time of the transplant;

(ii) Pediatric patient means a patient who has not reached his or her eighteenth birthday at the time of the transplant.

(7) *Qualified mental health professional* shall mean a psychiatrist, psychologist, or qualified social worker assigned to evaluate the potential recipient and/ or living donor.

(8) *Qualified social worker* shall mean a person who is licensed and registered by the State Education Department to practice as a licensed master social worker (LMSW) or licensed clinical social worker (LCSW), within the scope of practice defined in Article 154 of the Education Law.

(9) *Recipient* is an individual who receives transplanted organs, or a vascularized composite allograft.

(10) *Transplant center* means a unit within a hospital that performs transplants, including but not limited to activities such as qualifying patients for transplant, registering patients on the national wait list, performing transplant surgery and providing care before and after transplant. A transplant center may include one or more transplant programs.

(11) *Transplant commercialism* is a policy or practice in which an organ is treated as a commodity, including being bought, sold, or used for material gain.

(12) *Transplant program* means the persons or entity that provides organ specific transplant services within a transplant center.

(13) *Transplant services* means the provision of organ, living donor and or vascularized composite allograft transplants and other medical and surgical specialty services required for the care of transplant recipients and living donors.

(14) *Transplant tourism* is travel for transplant that involves organ trafficking and/or transplant commercialism.

(15) *Travel for transplant* is the movement of organs, vascularized composite allografts, donors, recipients, or transplant professionals who travel across national borders for transplant purposes.

(16) *Vascularized composite allograft* means a contiguous segment of mixed allogeneic tissues whose relationships have been altered only at the segment boundaries and whose transplantation requires revascularization and/or immunosuppression in the recipient. Vascularized composite allografts include, but are not limited to, hand, face, and other such contiguous segments.

(b) *General requirements.* Hospitals shall not admit patients for, or otherwise provide, transplantation services unless the hospital is specifically approved by the

Department to provide transplant services. Transplant services for pediatric patients shall only be provided in a hospital approved by the Department to provide transplant services. Hospitals that provide pediatric transplant services must comply with subdivision (a) of Section 405.22 of this Part and must develop and adhere to written policies and procedures specific to pediatric patients.

In addition, the following standards apply to all transplant centers and programs:

(1) Transplant services, or any new Institutional Review Board (IRB) approved medical/surgical treatments which involve transplant medical/surgical care including but not limited to transplant immunology, shall be performed only in hospitals approved by the Department to perform such transplant services.

(2) The hospital shall be a member in good standing of the Organ and Procurement and Transplantation Network (OPTN) approved by the Secretary of the U.S. Department of Health and Human Services (HHS) and shall abide by its rules and requirements.

(3) When fully operational, to ensure quality of care, the hospital shall perform at least 10 liver transplants per year if it is to continue as an approved liver transplant program; or at least 10 human heart transplants per year if it is to continue as an approved heart transplant program; or at least 10 kidney transplants a year if it is to continue as an approved kidney transplant program; or at least 10 lung transplants per year if it is to

continue as an approved lung transplant program. The Department will monitor outcomes for graft and patient survival.

(4) The hospital shall participate in a patient registry program with an organ procurement organization designated by the Secretary of the U. S. Department of Health and Human Services. Before arranging for the placement of the patient on the waiting list, each facility shall inform a patient awaiting transplantation of the prohibition against being placed on multiple facility waiting lists within New York State before arranging for the placement of the patient on the waiting list.

(5) Every hospital performing transplant services shall maintain written criteria for the selection of patients for such services which shall be consistent with professional standards of practice, applied consistently, and made available to the public.

(6) The hospital shall maintain a record of:

(i) all patients who are referred for transplantation and the date of their referral;

(ii) the results of the evaluation of all candidates for transplantation which documents the reasons a candidate is determined to be either suitable or unsuitable for transplantation;

(iii) the psychosocial evaluation;

(iv) the date a suitable candidate is selected for transplantation;

(v) the reasons for, and date of, any declination of a matching organ or vascularized composite allograft offered to a potential recipient;

(vi) the date the transplantation surgery occurred;

(vii) documentation of donor and recipient blood type;

(viii) the donor's United Network for Organ Sharing (UNOS) identification number; and

(ix) the organs or vascularized composite allografts utilized;

(7) The hospital will ensure that appropriate informed consent is obtained from both the recipient and if applicable, the living donor. The process for obtaining such consent shall include the provision of information, at a minimum of the following:

(i) the evaluation process used to determine suitability for transplant;

(ii) the surgical procedure including the post-operative period;

(iii) the availability of alternative treatments;

(iv) organ donor risk factors that could affect the success of the graft or the health of the patient, including, but not limited to, the donor's history, condition or age of the organs or vascularized composite allografts used, and the recipient's potential risk of contracting the human immunodeficiency virus (HIV) and other infectious diseases if the disease cannot be detected in an infected donor;

(v) if applicable, providing adequate information to the recipient to ensure his or her understanding regarding the risks to the living donor;

(vi) potential medical and psychosocial risks;

(vii) the national and transplant center outcomes for recipients;

(viii) the patient's right to refuse transplantation, or the donor's right to refuse to be a donor; and

(ix) the effect that provision of transplant services provided in a facility not approved as a Medicare-approved transplant center could have on the recipient's ability to have his or her immunosuppressive drugs paid for under Medicare Part B.

(8) For procedures involving a living donor, the hospital must obtain a written attestation from the living donor attesting that the donor has not received anything of value in exchange for the donation, aside from reimbursement for expenses associated with the donation to the extent allowed by New York State and federal law. The recipient must also attest in writing that he or she has not offered and is not aware of any offers of valuable consideration to the donor for their donation, except as allowed by New York State or federal law.

(9) The hospital must utilize an organized system for follow-up of patients after discharge, including maintenance of records on the long-term survival of persons who have received a transplant or who have made a living donation. Transplant centers must follow the health of each donor for at least two years post-donation.

(10) The hospital shall ensure that written procedures are maintained and implemented for the receipt, identification, and verification of all organs and vascularized composite allografts for transplantation.

(11) The hospital shall develop, maintain and implement written infection control policies and procedures specific to the transplant services, as an integral part of the hospital's infection control program.

(12) The hospital shall ensure that the infection control program utilizes sufficient professional and laboratory resources to address transplant-related transmissible infections, including discovery, identification and management of complications from organisms associated with transplants whether commonly or uncommonly encountered.

(13) Each transplant center shall develop and implement a policy for a formalized process of communication with OPOs, the center's clinical staff, the Department and as appropriate, local/city departments of health with regard to suspected and confirmed donor disease transmission. This policy shall include:

(i) identification of a patient safety contact, with coverage so that there is a person available on a 24 hour, 7 days a week, 365 days a year basis, to be the primary contact for possible disease transmission events;

(ii) a procedure to promptly contact the OPO that recovered the organ whenever a suspected disease transmission has occurred;

(iii) prompt communication and documentation when made aware of the suspected transmission;

(iv) identification of an infectious disease resource available to assist in the evaluation of a potential disease transmission; and

(v) the documentation of and notification to the transplant program director or his or her designee of the potential disease transmission, and the implementation of mechanisms to ensure that the information is acted upon in a timely manner.

(14) Every transplant center shall develop and implement a policy on travel for transplant including, transplant tourism, transplant commercialism and organ trafficking. Such policy may include:

(i) notice to all potential donors and recipients of the legal prohibitions against the sale of organs or vascularized composite allografts;

(ii) information about the medical risks of receiving an organ or vascularized composite allografts in a foreign country, in particular, the risk of infectious disease transmission to and from the recipient, the possible difficulties in obtaining recipient records related to the surgical procedure and post-operative treatment, and in cases of living donation the records regarding the donor's social/ medical history.

(iii) notice that participation in transplant commercialism and or organ trafficking may violate the laws of the countries involved as well as international treaties or conventions;

(15) Transplant centers that provide liver transplant services must join and be a member in good standing of a recognized consortium organization providing quality assurance, peer review, data sharing, and best practices collaboration activities for liver transplant services. If such a consortium(s) exists for other transplant services, such as heart or kidney, transplant centers must join the appropriate organization relevant to the transplants it performs and be a member in good standing.

(16) Review. Facilities shall allow the Department, or its designee, to conduct site visits to and/or survey data and patient record reviews from existing and prospective new transplant centers.

(17) Closure.

(i) Failure to meet one or more statutory or regulatory requirements or inactivity in a program for a period of 12 months may result in actions up to and including withdrawal of approval as a transplant center.

(ii) Voluntary closure. The hospital must provide a closure plan and written notification of potential closure to the Department at least 60 days prior to planned discontinuance of transplant services. Such closure plan must address and provide a means of implementation with regard to, at minimum, the following: the means by which the program's patients (including those being evaluated for transplant, wait-listed patients,

transplant recipients and living donors currently being treated by the program) will be provided with written notice of the planned closure and the means by which such persons may transfer to another transplant program; the means by which the Organ Procurement and Transplant Network, operated under contract with the U.S. Department of Health and Human Services by the United Network for Organ Sharing, the federal Centers for Medicare and Medicaid Services and the hospital's transplant program's referral networks will be notified of the planned closure; and the means by which the program's patients (including those being evaluated for transplant, wait-listed patients, transplant recipients and living donors currently being treated by the program) will be assisted in transferring to another transplant program. No transplant service shall discontinue operation without prior written approval from the Department.

(18) Notification of significant changes. A hospital must notify the Department in writing within 7 days of any significant changes in its transplantation services including, but not limited to: (a) any temporary or permanent suspension of services, (b) departure of or change in the physician program director, (c) unavailability of the transplant surgeon or physician of more than 15 days, if a program is without a physician credentialed to perform one or more of the procedures or services of the transplant service as a result of such unavailability, or (d) inability to meet workload requirements.

(19) Data collection and reporting. Data and governmental and accrediting body reports shall be maintained for a period at least as long as that required for the retention

of patient medical records under this Part, and made available to the Department upon request.

(c) *Organization and staffing.*

(1) The director of the transplant center, in addition to the requirements in paragraph (1) of subdivision (a) of section 405.22 of this Part, shall be a qualified specialist with previous experience and demonstrated competence in the transplant service. The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities including, but not limited to overseeing the transplant center's quality assurance and performance improvement (QAPI) program.

(2) Each transplant center shall have on-site a qualified transplant physician and another person who is a qualified transplant surgeon who may also fulfill the requirement as director of the service.

(3) The hospital shall provide a clinical transplant coordinator and sufficient staff to coordinate the activities of the transplant center, including patient follow-up after discharge. The clinical transplant coordinator shall be a physician, registered professional nurse, registered physician assistant, or nurse practitioner, licensed and currently registered or certified to practice in New York State.

(4) The hospital shall ensure that all staff members providing transplant services are prepared for their responsibilities through ongoing education, experience, demonstrated competence and completion of in-service education programs as needed.

(5) From admission to discharge, including post discharge follow-up, patient care evaluation, planning and management shall be performed by a multidisciplinary care team involved with the care of the patient; (which includes, at a minimum physicians, surgeons, nurses, qualified social workers, clinical transplant coordinators, nutritional services as needed and pharmacy as needed). The patient and, as appropriate, the patient's family shall be involved and have input into the patient's care plan.

(6) The transplant center shall make available nutritional assessments and diet counseling services to all transplant recipients and donors.

(7) The transplant center shall make psychiatric and social services available, directly or via referrals, to patients to assist with psychosocial problems of the patients, as related to the donation. Such professionals shall be skilled in individual and family counseling, shall understand the entire donation and transplantation process, and be able to provide information on financial issues and community resources.

(d) *Quality assessment and performance improvement (QAPI) programs.*

(1) The transplant center must develop, implement and maintain a written, comprehensive, data driven QAPI program to monitor and evaluate performance of all transplantation services, including services provided under contract or arrangement;

(2) The transplant center's QAPI program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to: patient and donor selection criteria, accuracy of the waiting list in accordance with the Organ Procurement Transplantation Network (OPTN) waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ and vascularized composite allograft recovery, consent practices, patient education, patient satisfaction, and patient rights;

(3) The transplant center must take actions that result in ongoing performance improvements and track performance to ensure that improvements are sustained;

(4) A transplant center must establish and implement written policies to identify, analyze, report, address and document adverse events that occur during any phase of an organ or vascularized composite allograft transplantation case, and utilize such efforts to prevent future adverse events.

(e) *Organ and vascularized composite allograft acceptance criteria.*

(1) In consultation with an organ procurement organization, the hospital shall develop and uniformly apply organ and vascularized composite allograft acceptance criteria and establish written policies and procedures to ensure the medical suitability of organs and vascularized composite allografts to be transplanted. Hospitals shall also develop and uniformly apply acceptance criteria for living donors. Such acceptance criteria shall be consistent with professional standards of practice, and shall ensure that the living donor is at least eighteen (18) years of age at the time of the initial living donor evaluation. Specific medical conditions of the donor shall be determined by the transplant surgeon through the donor's medical history, appropriate clinical laboratory testing and other confirmation methods and must be documented in the recipient's medical record. A parent may consent to a living donation to the parent's own child, regardless of the parent's age.

(2) Written organ and vascularized composite allograft acceptance criteria shall be:

(i) specific for each type of organ or vascularized composite allograft;

(ii) shall describe those medical conditions and circumstances which would make the potential donor ineligible; and

(iii) shall describe those medical conditions for which medical discretion may be exercised.

(3) The potential recipient will be fully informed of the risks and benefits of the particular solid organ or vascularized composite allograft.

A new Section 405.31 of Part 405 is added to read as follows:

Section 405.31 Living donor transplantation services.

Hospitals performing living donor transplants shall comply with the requirements of this section, section 405.30 and with subdivision (a) of Section 405.22 of this Part. In addition, the following standards apply to all living donor transplant services:

(a) Definition.

(1) *Donor advocate* is a person or a team responsible for ensuring that the rights and interests of the living donor and the prospective living donor are protected.

(b) Donor advocate responsibilities. A donor advocate shall be established for any living donor transplantation program. The transplant program shall, as appropriate, consult with an ethicist, and a psychiatrist or other qualified mental health professional, as defined in Section 405.30 (a)(6) of this Part. The donor advocate's primary responsibility is to support the donor, beginning with the donor evaluation process and continuing through donation, the postoperative period, and discharge, and to ensure that there are appropriate referrals for post discharge care. The advocate shall assist the donor in making informed decisions and balancing external/family pressures to donate. The advocate must evaluate the donor and make a recommendation concerning donor suitability and ensure that the needs of the donor are fulfilled promptly and in accordance with best medical practice. The advocate shall:

(1) Advocate for the interests and well-being of the donor;

(2) Explain the evaluation process, what to expect, what it means to be a donor;

(3) Verify that such living donor is at least 18 years of age at the time of such donor's initial evaluation related to the transplant procedure or is a parent donating to his or her child;

(4) Ensure all decisions made by the donor are informed and not coerced by:

(i) evaluating whether there is monetary or property enrichment for the donor, and ensuring the donor signs an attestation as specified in Paragraph (4) of this subdivision ;

(ii) evaluating whether there is overt coercion to donate by family or others;

(iii) assessing the donor's intellectual and emotional capability of participating in a balanced discussion of potential risks and benefits;

(iv) providing information to the donor about the medical, psychosocial, and financial implications of the living donation for the potential donor and about the recipient's options for deceased donation transplant, including risks and outcomes;

(v) ensuring the donor understands that he or she may decline to donate at any time prior to his or her surgery; and

(vi) if requested by the donor, assisting the donor in the preparation of a general, medically accurate statement of unsuitability for donation.

(5) consult with the surgical team regarding donor suitability before issuing a formal recommendation;

(6) transmit donor advocate findings in writing to the surgical team. The transmittal shall include the reasons for the donor advocate's recommendation. The final determination of donor suitability rests with the attending surgeons of the surgical team;

(7) The potential donor will be advised of the donor advocate's recommendation. At least one attending surgeon and the donor advocate shall make themselves available to the potential donor upon his or her request to discuss the donor advocate's recommendation; and

(8) assure there is continuity of care during hospitalization and assure that there are appropriate referrals for post-discharge care.

(c) *Donor Advocate requirements.*

(1) Such donor advocate or, in the case of multiple members of a donor advocate team at least one member of such team, must not participate in the care of transplant recipients. The advocate's interests shall be centered on the well-being of the living donor.

(2) The donor advocate shall not receive any direct or indirect benefit from recommending continuation of the donor's participation.

(3) The status of the donor advocate at the transplant center may not be affected by recommending for or against donation.

(4) The donor advocate shall be medically sophisticated in transplantation and aware of relevant statistics such as center volume and outcome data, and be able to explain such information to the potential donor.

(5) The donor advocate shall have sufficient preparation in his or her role to recommend that a specific donor is or is not a candidate for living donation.

(6) The donor advocate shall have a comprehensive working knowledge of living donor transplantation.

(d) Education of the donor.

In order to ensure that the potential donor has the knowledge and capacity to exercise informed consent, the advocate shall do the following:

(1) consider the intellectual and emotional capacity of the potential donor to exercise legally and ethically adequate informed consent as described in subdivision (e) of this section;

(2) inform him or her orally and in writing about the risks and benefits of medical interventions;

(3) evaluate whether there is a thorough understanding of the elements of the decision;

(4) evaluate whether the potential donor's decision is voluntary;

(5) inform the potential donor that the donor advocate may recommend against donation and that the advocate's recommendation will be given significant consideration in the surgical team's decision. The reasons for the advocate's decision shall be explained to the donor; and

(6) advise the potential donor of the opportunity to discuss donation with others who have donated in the past and assist in making arrangements to do so, if requested by the donor.

(e) *Informed Consent.* A person who gives consent to be a living donor shall be competent, willing to donate, free from coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, fully informed of the risks, benefits and any alternative treatments available to the recipient, at least eighteen (18) years of age at the time of the donor's initial evaluation related to the transplant procedure unless the person is a parent seeking to donate to their own child, and be likely

to benefit in a way not involving the transfer of money or property in connection with the donation, other than reimbursement of donation-related expenses as allowed by law. The informed consent process must include:

(1) informed understanding:

(i) presentation of all information to the potential donor in a language or manner understandable to him or her, consistent with his or her education level;

(ii) The potential donor shall be given the opportunity and adequate time to assimilate the information provided, ask questions and have questions answered;

(iii) The donor shall identify the family and loved ones who shall be given the opportunity to discuss openly with the donor advocate and the surgical team their concerns in a safe and non-threatening environment; and

(iv) The potential donor shall be informed with regard to the need for postoperative, long-term follow-up and testing by the transplant center. The donor shall also be provided with information regarding the need and importance for long term follow-up and annual primary care.

(f) *Disclosure Requirements.*

(1) The donation process shall be explained to the potential donor. This explanation shall address, at a minimum:

(i) donor evaluation procedure;

(ii) surgical procedure;

(iii) recuperative period;

(iv) short and long term follow-up care;

(v) alternative donation and transplant procedures;

(vi) potential psychological benefits and detriments to the donor;

(vii) transplant center and surgeon specific statistics of donor and recipient outcomes;

(viii) confidentiality of the donor's information and decision;

(ix) donor's ability to opt out at any point in the process up to the time of surgery; and

(x) information about how the transplant center will follow the health of the donor for at least 2 years post donation.

(2) The transplant team and the donor advocate shall disclose their institutional affiliations to the potential donor.

(g) *Risks.* Risks shall be fully explained to the potential donor. The explanation shall include:

(1) physical;

(i) potential for surgical complications including risk of donor death;

(ii) potential for organ failure and the need for transplantation,

(iii) potential for other medical complications including long-term complications;

(iv) scars;

(v) pain;

(vi) fatigue;

(vii) abdominal and/or bowel symptoms such as bloating and nausea;

(2) psychosocial

(i) potential for problems with body image;

(ii) possibility of recipient death;

(iii) possibility of recipient rejection and need for retransplantation;

(iv) possibility of recurrent disease in the recipient;

(v) possibility of adjustment disorder post-surgery;

(vi) possible impact on donor's family;

(vii) possible impact on recipient's family; and

(viii) potential impact of donation on the donor's lifestyle.

(3) Financial.

(i) out of pocket expenses;

(ii) possible loss of employment;

(iii) potential impact on ability to obtain future employment;

(iv) potential for disability benefits and need for assistance completing relevant paperwork; and

(v) possible impact on ability to obtain health and life insurance.

(h) *Documentation.* The entire disclosure and consent process, including the attestation required by paragraph (8) of subdivision (b) of section 405.30 of this title shall be documented in the donor's medical record, which shall be maintained separate and distinct from the recipient's medical record.

(i) *Primary Medical Evaluation.* A medical evaluation of the potential donor shall be made by an appropriate medical physician. Appropriate laboratory and imaging studies shall be done. Additionally, the following shall also be assessed:

(1) compatibility of the potential donor to the recipient;

(2) general health of, and surgical risk for, the potential donor;

(3) co-morbidities and significant medical conditions that impact the potential donor's suitability;

(4) the potential donor's vulnerability to infection, blood loss, or delayed wound healing; and the potential donor's personal and family medical history.

(j) *Psychosocial.*

(1) A psychosocial evaluation of the potential donor shall be made by the qualified mental health professional, as defined in Section 405.30 (a) (6) of this Title. The evaluation shall include, but not be limited to: consideration of the donor's current and past history of: any psychiatric illness, physical abuse, sexual abuse, alcohol abuse, and substance abuse.

(2) Social services shall be provided in accordance with Section 405.28 of this Part as well as any additional requirements established in this Part.

(k) *Recipient Criteria.* The transplant center must establish written policies and procedures governing recipient eligibility for living donation. At a minimum, such policies and procedures shall:

(1) ensure the patient meets the center's written eligibility criteria as specified in paragraph (5) of subdivision (b), and subdivision (e), of Section 405.30 of this Part;

(2) ensure the recipient has received information regarding specific risks and benefits, alternative treatments and expected outcome of the transplantation;

(3) establish conditions which require recipient exclusion; and

(4) ensure that the benefits to both the donor and the recipient outweigh the risks before any living transplant is performed.

(l) *Donor Management.*

(1) The donor surgeon shall have the primary responsibility for the donor's care and welfare throughout his or her hospital stay.

(i) The donor surgeon is responsible for making the final determination regarding a donor's suitability after reviewing and considering the donor's medical, psychological, and social history; the donor's current medical, psychological and social status; the recommendation of the donor advocate, all consultative reports; and the standards set forth in this subdivision.

(ii) If the donor surgeon decides to proceed with a donation after receiving an adverse recommendation from the donor advocate, the surgeon shall document the reasons for doing so in the patient's medical record.

(m) *Imaging Service Requirements.*

Hospitals performing living donor transplantation shall have adequate imaging services and staff support appropriate to evaluate recipients and living donors. Radiologists with experience in interventional procedures (angiography) and ultrasound imaging studies in the living donor and recipient, must be available at all times including weekends and holidays. If there is an emergent complication requiring imaging services, these patients should be prioritized for access to such imaging services by the hospital.

(n) *Discharge Planning Requirements.*

The hospital shall comply with the discharge planning requirements contained in Section 405.9 of this Part as well as the following:

(1) The donor advocate shall be available to the donor from pre-admission to post-discharge.

(2) A detailed, written discharge plan shall be developed, given to the donor and provided to all health care professionals involved in the donor's care, including the donor's primary care physician.

(3) This plan shall be reviewed with the donor by a health care professional such as a registered professional nurse, qualified social worker or transplant coordinator.

(4) The plan shall include, at a minimum, instructions on:

(i) activities;

(ii) diet;

(iii) medication for pain; and

(iv) wound care.

(5) The patient shall be provided with a 24-hour contact number that he/she can call with questions. The responder shall be available when needed and knowledgeable about living donation.

(6) Information shall include the name, address and telephone number of the surgeon and instructions for the follow-up visit.

(7) Instructions for family members or caregivers shall be provided.

(o) *Post-Discharge Requirements.*

(1) Medical follow-up shall meet generally accepted standards for someone who has undergone a major transplant procedure. This follow-up shall include:

(i) postoperative visits with the donor's surgeon(s);

(ii) follow-up coordinated with the donor's primary care physician to assess wound healing and to monitor for signs/symptoms of infection;

(iii) laboratory studies as appropriate; and

(iv) a written summary of the donor's condition, which shall be provided to the donor and his or her primary care physician upon the donor's discharge from the hospital.

(2) The hospital shall provide or arrange for follow-up social/psychological supports directly related to the donation as needed, which may include measures such as:

(i) visits with a social worker familiar with organ transplantation issues;

(ii) visits with a psychologist or psychiatrist familiar with organ transplantation issues;

(iii) participation in a professionally run support group ;

(iv) participation in a center sponsored computer donor listserve or bulletin board to share patient concerns; and

(v) invitation to a donor recognition event, such as an annual recognition ceremony or presentation of a donor medal.

(3) Donors shall be informed of the option to discuss financial/insurance concerns with the transplant center's financial coordinator.

(4) Hospitals shall report to the department such information as the department shall require to assist the department in assessing the quality of care provided; determining routine or unusual complications or outcomes, and identifying potential improvements to donor education, screening, consent, preoperative, surgical and postoperative care and follow-up. Such information shall include, but not be limited to:

(i) donor demographics;

(ii) preoperative medical and psychosocial information;

(iii) surgical information and complications;

(iv) hospital staff training and experience,

(v) recipient outcome; and

(vi) immediate and long-term postoperative care, complications, and impact on quality of life.

(5) Hospitals shall track the donor and his or her condition for at least 2 years post donation in accordance with the provisions set forth in Section 405.30 (b) (9) of this Part.

(p) *Living Adult Donor to Adult Recipient Liver Transplantation Services.*

(1) Surgical Team Requirements:

(i) At least two liver transplant attending surgeons with experience as established in subparagraph (v) of this paragraph shall participate in the surgery of the donor. These two surgeons shall be present for the critical parts of the surgery including the live parenchymal transection. They both shall be available and scrubbed if needed for complications, however, only one surgeon need be present for the remainder of the donor operation.

(ii) A third liver transplant attending surgeon shall be present in the recipient operating room. This surgeon must have experience in deceased liver transplantation.

(iii) All three surgeons shall be board certified or board admissible in general surgery or have foreign certification determined to be equivalent by the New York State Department of Health.

(iv) All three surgeons shall have demonstrated experience in liver transplant surgery.

(v) One of the two surgeons must demonstrate experience as the primary surgeon or first assistant in 20 major hepatic surgeries (to include living donor hepatectomies or major hepatic resections), 7 of which must have been live donor hepatectomies within the prior 5 year period. The other of the two surgeons must be either a liver transplant surgeon or hepatobiliary surgeon practicing at a transplant hospital and must have performed at least 20 major liver resections within the prior 5 year period. Both of the surgeons must be available during the donor hepatic resection.

(2) Anesthesia Requirements:

(i) There shall be two separate attending anesthesiologists; one each for the living adult liver transplantation donor and recipient operations. These anesthesiologists shall be present for the critical anesthetic and surgical portions of the procedures and immediately available at all other times. As one case is completed, either anesthesiologist may take responsibility for the ongoing case. The anesthesiologists shall have experience in liver transplant anesthesia and/or major hepatic resection surgery and/or cardiac surgery anesthesia;

(ii) There shall be two separate anesthesia teams in two operating rooms (one for the donor, one for the recipient); and

(iii) These teams shall each be directed by a separate attending anesthesiologist for the living donor and the recipient procedure. In addition to the attending anesthesiologist who shall be present as specified in subparagraph (i) of this paragraph, at least one member of the anesthesia team who is an anesthesiologist, chief resident, fellow (postgraduate year 3, 4, or 5), or qualified certified registered nurse anesthetist shall be present and responsible, under the direction of the attending anesthesiologist, for the evaluation and care of the patient through all phases of the procedure pertaining to the administration of, and recovery from, anesthesia. All team members shall have ongoing education and training in liver and/or cardiac surgery and have had anesthesia responsibility for major liver resections.

(3) Postoperative Care Requirements. Donors shall receive postoperative care consistent with the following:

(i) Day 0-1: Living adult liver donors shall receive intensive care (ICU or PACU) for at least 24 hours, at a minimum;

(ii) Day 2: If stable and cleared for transfer by the transplant team after the first 24 hour period, donors shall be cared for in a hospital unit that is dedicated to the care of transplant recipients or a hospital unit in which patients who undergo major

hepatobiliary resectional surgery are cared for. Living liver donors may be cared for on another unit if a specific medical condition of the donor warrants such a transfer and the transfer is documented in the donor's medical record;

(iii) The donor shall be evaluated at least daily by one of the qualified liver transplant attending physicians with documentation in the medical record;

(iv) The transplant team shall be responsible for the pain management of the donor. In institutions where a pain management team is available, the transplant team may delegate its responsibility to this team. However, there shall be a written protocol in place for assessment and management of donor pain;

(v) The patient care staff shall be familiar with the common complications associated with the donor and recipient operations and have appropriate monitoring in place to detect these problems should they arise; and

(vi) If there is an emergent complication requiring reoperation, these patients shall be prioritized by the hospital for access to the operating room by the institution.

(4) Minimum Medical Staffing Requirements.

(i) There shall be 24-hour, seven day-a-week continuous coverage of the transplant service by general surgery residents at the postgraduate year 2 level or higher,

transplant fellows, nurse practitioners or physician assistants. Between the hours of 6 p.m. and 8 a.m. on weekdays and at all times on the weekends and holidays, the covering residents, fellows, nurse practitioners, or physician assistants should be dedicated to the transplant service and not covering other surgical or nonsurgical patients. An attending transplant surgeon shall be available immediately as a resource for the residents, fellows, nurse practitioners or physician assistants at all times.

(ii) Any patient with abnormal vital signs or unusual symptoms shall be evaluated immediately. Notification to the appropriate senior medical staff member (fellow, chief resident, attending) shall be made in accordance with written hospital policy and procedures and in no case no more than 30 minutes after abnormal vital signs or unusual symptoms were first observed.

(5) Nursing Minimum Staffing Requirements.

(i) Nursing staff shall have ongoing education and training in live donor liver transplantation nursing care (donor and recipient). This shall include education in the pain management issues particular to the donor. The registered professional nursing ratio shall be at least one registered professional nurse for every two patients (1:2) in the ICU/PACU level setting, increased as appropriate for the acuity level of the patients.

(ii) After the donor is transferred from the ICU/PACU, the registered professional nursing ratio shall be at least 1:4 on all shifts, increased as appropriate for the acuity level of the patients

(iii) The same registered professional nurse shall not take care of both the donor and the recipient.

(iv) The nursing service shall verify that the potential donor received appropriate pre-surgical information.

(v) The names and contact numbers of the transplant team shall be posted on all units receiving transplant donors.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of these regulations is contained in Public Health Law (PHL) Sections 2800, 2803 (2) and 4351. PHL Article 28 (Hospitals), Section 2800 specifies that "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 2803(2) authorizes the Public Health and Health Planning Council (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 health care facilities.

PHL Section 4351 sets forth duties of hospital administrators, organ procurement organizations and eye bank and tissue banks with respect to requests for consent to an anatomical gift.

Legislative Objectives:

The legislative objective of PHL Article 28 includes the protection of the health of the residents of the State by assuring the efficient provision and proper utilization of health services, of the highest quality at a reasonable cost. The legislative objective of PHL Article 43-A is to set forth the duties of hospital administrators, organ procurement organizations, eye banks and tissue banks regarding requests for consent to an anatomical gift.

Needs and Benefits:

Nationally approximately 116,000 individuals are waiting for organ(s) and approximately 10,000 of them are New Yorkers. While regulations concerning organ transplant were last revised in 2004 regarding live adult liver donors, other transplant provisions have not been revised, nor comprehensively examined in over 20 years. During that time period transplant has changed, most notably in the growth of living organ donor transplant as well as the potential for other organ transplants such as face, hands and arms. However, current regulations do not recognize these emerging areas and thus these services could be provided in a non-transplant center hospital. Neither the Department, nor the transplant community, thinks this is safe or appropriate for patients.

In addition, federal Centers for Medicare and Medicaid Services (CMS) regulations issued in June of 2007, contradict some current state requirements.

The transplant community has expressed support for revising the regulations. The Department of Health has utilized the New York State Transplant Council (TC) in the comprehensive review of this proposal, along with the New York Center for Liver Transplant (NYCLT), who requested that the current regulations concerning the care of living liver donors be reexamined. New York State has worked closely with the transplant community to develop guidance on a variety of areas which have served as national and international models of transplant care. Most notable are the guidance documents on the care of living liver donors: New York State Committee on Quality Improvement in Living Liver Donation – A Report to: New York State Transplant Council and New York State Department of Health - December 2002 and living kidney donors New York State Transplant Council – New York State Committee on Quality Improvement in Living Kidney Donation – December 2007 .

The Department of Health has determined that the transplant provisions currently contained in the Critical Care and Special Care Services provisions set forth in Section 405.22 should be deleted. In its place two new sections are proposed. Section 405.30 would contain Solid Organ and Vascularized Composite Transplant/Services provisions. Section 405.31 would contain the Living Donor Transplantation Services provisions. This latter section incorporates the existing living liver donor requirements and adds general requirements for all living donors consistent with existing federal CMS and

United Network for Organ Sharing (UNOS) rules. Currently kidney and liver are the most common organs transplanted in NYS. These regulations are written to be flexible as transplant changes and other organs (e.g. living lungs) become more commonly transplanted. This rewrite also retains some of the added protections that were included in 2004 for living liver donors in recognition that liver donation carries more potential risk than kidney donation.

Costs for the Implementation of and Continuing Compliance with these Regulations to the Regulated Entity:

According to the transplant administrators on the New York State Transplant Council's Regulation Workgroup, there will be a minimal cost to the affected parties related to the additional requirement that hospitals obtain an attestation from a potential living donor that such donor has not received anything of value in exchange for the donation, aside from reimbursement for expenses associated with the donation to the extent allowed by New York State and US federal law. The recipient must also attest in writing that he or she has not offered and is not aware of any offers of valuable consideration to the donor for their donation, except as allowed by New York State or US federal law. Any additional costs related to these regulations are offset by the elimination of the requirement that transplant centers track living donor outcomes for life. These regulations mirror and complement existing federal requirements so additional costs are not expected.

Cost to State and Local Government:

State transplant centers (State University of New York (SUNY) Downstate, SUNY Syracuse, SUNY Stony Brook) must abide by these provisions the same as any transplant center in New York State. There are no county transplant centers in New York State. There are no additional costs to state and local governments over and above the cost impacts as the private centers for the implementation and continued administration of this rule.

Cost to the Department of Health:

As stated above, there are no additional costs to state and local government over and above the cost impacts of the private centers to implement this regulation. Existing Health Department staff will be utilized to conduct surveillance of the regulated parties and monitor compliance with these provisions.

Local Government Mandates:

There are no additional programs, services, duties or responsibilities imposed by this rule upon any county, city, town, village, school district, fire district or any other special district.

Paperwork:

This measure will require a written attestation not already required from a potential living donor attesting that the donor has not received anything of value in exchange for the donation, aside from reimbursement for expenses associated with the

donation to the extent allowed by New York State and US federal law. The recipient must also attest in writing that he or she has not offered and is not aware of any offers of valuable consideration to the donor for their donation, except as allowed by New York State or US federal law.

Duplication:

This regulation will not conflict with any state or federal rules. It clarifies federal requirements set forth in 42 CFR Part 482 for general hospitals providing transplant services and mirrors federal volume standards and living donor advocate requirements. This streamlines the process for transplant facilities.

Alternative Approaches:

There are no viable alternative approaches. The Department of Health could have left the regulation as is, but it is outdated and must be updated to reflect current practice to conform to federal standards, and to ensure that transplant centers achieve minimum volume requirements.

Federal Requirements:

The federal requirements for transplant services are set forth in 42 CFR Part 482. These provisions update the New York State standards to be in compliance with the federal standards and to also reflect current practice.

Compliance Schedule:

This proposal will go into effect upon a Notice of Adoption in the New York *State Register*.

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REGULATORY FLEXIBILITY ANALYSIS
FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any general hospital designated as a transplant center pursuant to 10 NYCRR Section 709.7 will be required to comply with these provisions. There are no small businesses (defined as 100 employees or less), independently owned and operated, affected by this rule. Currently in New York State there are 15 hospitals that perform organ transplants.

Compliance Requirements:

In order to comply with these requirements, hospitals will need to develop an attestation form to meet the living donor travel tourism requirements.

Professional Services:

No additional professional services will be required pursuant to these provisions.

Compliance Costs:

These regulations mirror and complement existing federal requirements so additional costs are not expected due to these regulations.

Economic and Technological Feasibility:

This proposal is economically and technically feasible.

Minimizing Adverse Impact:

These provisions mirror and clarify the federal Centers for Medicare and Medicaid (CMS) requirements as set forth in 42 CFR Part 482. As a result, hospitals will not have to follow two different standards, especially in the area of volume requirements and long-term follow-up of living donors.

Small Business and Local Government Participation:

Outreach to the affected parties has been conducted. This proposal has been discussed and reviewed by the New York State Transplant Council, the New York Center for Liver Transplant (NYCLT), the Healthcare Association of New York State (HANYS) and the Greater New York Hospital Association (GNYHA), all of which represent various transplant centers. They were also given notice of this proposal by its inclusion on the agenda of the Codes and Regulations Committee of the Public Health and Health Planning Council (PHHPC). This agenda and the proposal will be posted on the Department's website. The public, including any affected party, is invited to comment during the Codes Regulations and Legislation Committee meeting.

Cure Period:

Chapter 524 of the Laws of 2011 requires agencies to include a "cure period" or other opportunity for ameliorative action to prevent the imposition of penalties on the party or parties subject to enforcement when developing a regulation or explain in the Regulatory Flexibility Analysis why one was not included. This regulation creates no new penalty or sanction. Hence, a cure period is not necessary.

RURAL AREA FLEXIBILITY ANALYSIS

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb (4) (a) of the State Administrative Procedure Act (SAPA). It is apparent, from the nature of the proposed amendment that it will not impose any adverse impact on rural areas as no transplant centers are located in rural areas, and it does not impose any new reporting, recordkeeping or other compliance requirements on public or private entities in rural areas.

JOB IMPACT STATEMENT

Nature of Impact:

This rule is not expected to have a significant impact on jobs. Any increase in jobs has occurred pursuant to the 2007 federal regulations The intent of this proposal is to strengthen the Department's oversight to monitor a hospital's ability to appropriately care for transplant patients. It is also intended to firm up expectations of appropriately credentialed staff. This proposal is necessary to update the current provisions to reflect current practice. All transplant centers already have appropriate staff to meet these requirements.

Categories and Numbers Affected:

There are 15 transplant centers that perform various types of transplant.

Regions of Adverse Impact:

This rule is not expected to cause any regions in the State to have an adverse job impact.

Minimizing Adverse Impact:

These provisions mirror and clarify the federal Centers for Medicare and Medicaid (CMS) requirements as set forth in 42 CFR Part 482. As a result, hospitals will not have to follow two different standards, especially in the area of volume requirements and long-term follow-up of living donors.

ASSESSMENT OF PUBLIC COMMENT

During the public comment period, three letters in support of the proposed regulation were received; one letter was from the Chair of the NYS Transplant Council and two other letters were entities (one a hospital and the other an organ procurement organization) that are planning to initiate the practice of vascularized composite tissue allograft (VCA) (aka face and hands) transplantation in the near future.