



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, NY 12237

Antonia C. Novello, M.D., M.P.H., Dr.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

February 26, 2004

Dear Administrator:

Enclosed is a copy of the new regulations for Live Adult Liver Donation, which were adopted by the State Hospital Review and Planning Council on December 4, 2003 and became effective on February 25, 2004. This letter clarifies the Department's intent on some aspects of the regulations with respect to some issues raised during the public comment period for these regulations.

Several comments received raised concerns about the post-discharge requirement in subparagraph (v) of paragraph (12) of the new subdivision that provides "...hospitals should attempt to track the donor and his or her condition for the donor's lifetime...." The Department will work with hospitals to develop meaningful data-collection policies and procedures consistent with United Network for Organ Sharing (UNOS) and the Department of Health and Human Services (DHHS) initiatives. The Department expects all hospitals to cooperate with the New York Center for Liver Transplantation (NYCLT) and UNOS as the data tool to track donors is implemented, and to make every effort to track donors for their lifetime.

Concerns were also raised regarding the post-discharge requirement in subparagraph (i)(c) of paragraph (12) "...three dimensional liver scan with volume assessment at one year shall be performed on all donors of full right or full left lobes..." The commenters questioned the need to order such a test if there is no apparent clinical need. The Department of Health is open to revisiting the regulations in the future and modifying the requirements based on the empirical evidence that will result from the data collected in accordance with these regulations and other sources.

Comments received concerning the anesthesia requirements revealed the need for the Department to reinforce that the existing requirements for anesthesia services contained in NYCRR § 405.13 remain in effect for all anesthesia services provided in hospitals, including live liver donor programs. The existing regulation requires that anesthesia services be provided under the direction of a physician. The new regulations, as they pertain to anesthesia services in live donor cases, supplement the existing requirements, and clarify that an anesthesiologist must be present in the operating room for critical portions of the procedure. These provisions do not prohibit an anesthesiologist from being present and accepting full responsibility for the evaluation and all phases of the procedure and post-operative care rather than delegating such responsibilities to team members.

Concerns were also raised about the requirement in subparagraph (7) of the new subdivision, which requires that if a member of the anesthesia care team has specific education and training in pain management of liver donors, that person must be available for consultation with the transplant team regarding the pain control of the donor. This requirement only applies if the anesthesia team includes a professional with this specific background. If the anesthesia care team does not have a professional with this type of training and experience, the requirement does not apply.

Finally, concerns were raised about the provision in 10 NYCRR § 405.22 (1)(7)(vii) that requires any donor who has an emergent complication to be prioritized by the hospital to access the operating room. The Department's intent here is that these patients are given priority when in the need of immediate re-operation amongst patients in the same risk category. The Department does not expect live liver donors to have priority over patients in a higher risk category. Facilities are obligated to undertake any action necessary to adequately care for the donor, including making an operating room and staff available.

The Department remains committed to assuring that healthy individuals who risk their lives to donate are assured the best quality care. We will cooperate with the provider community as implementation of the regulations occurs.

Sincerely,

Wayne M. Osten
Director
Office of Health Systems Management

Enclosure

SUMMARY

The proposed regulations amend section 405.22 of Part 405 of 10 NYCRR to add a new subdivision (l) to set standards for live adult liver transplantation services.

The regulations require any hospital performing live adult liver transplantation to establish an Independent Donor Advocate Team (IDAT) whose main interest is to be centered on the well being of the potential liver donor. The regulations outline the team's composition, characteristics and responsibilities. The main responsibilities are to educate the potential donor on all aspects of live adult liver donation, evaluate the potential donor's medical and psychosocial suitability for donation, and support the potential donor through the entire decision-making and donation process. Upon completing its evaluation, the team is required to provide written recommendations to the donor surgeon regarding the potential donor's suitability for organ donation.

The IDAT is required to structure a process of "informed choice" designed to provide the potential donor with all the information necessary to make an informed decision and emphasize that the decision to donate is not a foregone conclusion. Specific information about the donation process and the medical, psychosocial and financial risks must be provided to the donor. The IDAT must also assess the potential donor's understanding of the procedure and risks, as well as the extent to which the potential donor may feel coerced to donate. A two-week period of reflection is required between the determination by the IDAT and donor surgeon that the potential donor is a suitable candidate for organ donation and the actual signing of the informed consent document. The entire disclosure and consent process must be documented in the donor's medical record.

The regulations establish medical and psychosocial criteria for both the donor and the recipient. Minimum standards and staffing requirements are also established for the members of the surgical teams and anesthesia teams. Requirements for the postoperative period include care levels

for the donor, minimum medical and nursing staffing requirements and radiology service requirements.

The post discharge provisions require a follow-up appointment with the donor surgeon and coordination of continuing post-operative care with the donor's primary care physicians. Minimum standards for post-discharge medical testing are established as well as a requirement for psychosocial follow-up as needed. The hospital is also required to attempt to follow donors for their lifetime to monitor the medical and psychosocial effects of donation and to report this data to the Department of Health.

Pursuant to the authority vested in the State Hospital Review and Planning Council and the Commissioner of Health by section 2803 of the Public Health Law, section 405.22 of Part 405 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York is hereby amended to be effective upon publication of a Notice of Adoption in the New York State Register:

A new subparagraph (iv) is added to paragraph (1) of subdivision (b) of Section 405.22 to read as follows:

(iv) Patient shall generally refer to both the donor patient and recipient patient except that 405.22(b)(2)(iv),(v) and (vi)(a) shall refer to a recipient only.

Section 405.22 subparagraph (vii) of paragraph (2) of subdivision (b) is amended as follows:

(vii) There shall be an organized system for follow-up of [transplant] patients after discharge which maintains records on the long-term survival of persons who have received a transplant or who have made a live adult liver donation.

A new paragraph (6) is added to subdivision (b) of Section 405.22 to read as follows:

(6) Hospitals performing live adult liver donation transplants shall comply with the standards established in subdivision (l) of this section.

A new subdivision (l) is added to Section 405.22 to read as follows:

(l) Live Adult Liver Transplantation Services.
Hospitals performing live adult liver transplants shall comply with the requirements of this subdivision.

(1) Independent Donor Advocate Team.

An independent donor advocate team shall be established for any live adult liver transplantation program. This team's interests shall be centered on the well being of the live donor.

(i) Composition of the team:

The independent donor advocate team shall consist of, at a minimum, an internal medicine physician, a transplant coordinator/nurse clinician, a Licensed Master Social Worker, and a psychiatrist assigned to evaluate the live donor. The team shall include the participation of an ethicist, as appropriate.

(ii) Team Responsibilities:

The team's main responsibility is to support the donor, beginning with the donor evaluation process and continuing through donation, the postoperative period, to discharge and postdischarge. The team shall assist the donor in making informed decisions and balance external/family pressures to donate. Team members should 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 team shall:

(a) structure the process of informed choice (specifically stating informed "choice" instead of preordained "consent") and emphasize that the decision to donate is not a foregone conclusion;

(b) safeguard the interests and well being of the donor;

(c) explain the evaluation process, what to expect, what it means to be a donor;

(d) evaluate whether any choice made by the donor is informed and not coerced by:

(1) evaluating whether there is monetary or property enrichment for the donor;

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

(3) providing adequate information to the recipient to ensure his or her understanding regarding the risks to the donor;

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

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

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

(7) if requested by the donor, assisting the donor in the preparation of a general statement of unsuitability for donation which shall not include falsified medical information.

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

(f) transmit its findings in writing to the surgical team. The transmittal shall include the reasons for the independent donor advocate team's recommendation and annex any documents and consultations considered by the team in its deliberations. The final determination of donor suitability rests with the attending surgeons of the surgical team;

(g) determine jointly with the attending surgeons of the surgical team who shall meet with the potential donor to advise him or her of the final determination of donor suitability. At least one of the attending surgeons of the surgical team shall participate in such meeting. The potential donor will be advised of the independent donor advocate team's recommendation. Regardless of whether they participate in such meeting, all members of the independent donor advocate team shall make

themselves available to the potential donor upon his or her request to discuss the independent donor advocate team's recommendation; and

(h) assure there is continuity of care during hospitalization and assure that there are appropriate referrals for postdischarge care including follow up from medicine, psychiatry or social work, as needed.

(iii) Team Characteristics:

(a) The independent donor advocate team shall not receive direct financial or personal gains from recommending continuation of the donor's participation.

(b) The status of the independent donor advocate team or its members at the transplant center may not be affected by any activities undertaken on behalf of the donor, including recommending for or against donation.

(c) The independent donor advocate team 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.

(d) Each member of the team shall have sufficient preparation in his or her role to recommend that a specific donor not be a candidate when appropriate.

(1) All team members shall have a comprehensive working knowledge of liver disease and transplantation.

(2) The Licensed Master Social Worker shall be skilled in individual and family counseling, shall understand the entire donation process, and be able to provide information on financial issues and community resources.

(e) Once team members are designated by the center to serve on the independent donor advocate team, they shall participate in at least three donor evaluation processes per year.

(iv) Education of the donor:

In order to ensure that the potential donor has the knowledge and capacity to exercise an informed choice, the team shall do the following:

(a) Thoroughly evaluate the intellectual and emotional capacity of the potential donor to exercise legally and ethically adequate informed choice as described in paragraph (2) of this subdivision.

(b) Devise a process appropriate for each individual potential donor to inform him or her orally and in writing about the risks and benefits of medical interventions.

(c) Evaluate whether there is a thorough understanding of the elements of the decision.

(d) Evaluate whether the potential donor's decision is voluntary.

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

(f) 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.

(2) Informed Choice.

A person who gives consent to be a live adult liver 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, have a vital emotional relationship with the recipient, and be likely to benefit in a way not involving the transfer of money or property. The following factors shall be present:

(i) Informed understanding:

(a) All information shall be presented to the potential donor in a language or manner understandable to him or her, consistent with his or her education level.

(b) The potential donor shall be able to demonstrate that he or she understands the essential elements of the donation process, especially the risks associated with the procedure.

(c) Adequate time shall be allowed for the potential donor to understand and assimilate the information provided, ask questions and have questions answered.

(d) The donor's family/loved ones shall be given the opportunity to discuss openly with the independent donor advocate and surgical teams their concerns in a safe and nonthreatening environment.

(e) The potential donor shall understand the need for and agree and commit to postoperative, long-term follow-up and testing by the transplant center.

(ii) Disclosure Requirements:

(a) The donation process shall be explained to the potential donor and shall include:

(1) donor evaluation procedure;

(2) surgical procedure;

(3) recuperative period;

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

(5) alternative donation and transplant procedures;

(6) potential psychological benefits and detriments to donor;

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

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

(9) donor's ability to opt out at any point in the process;

(10) information about how the transplant center will attempt to follow the health of the donor for life;

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

(c) There shall be a two-week period of reflection and reaffirmation of the decision to donate subsequent to the completion of the medical work-up and the surgical team's final approval to proceed before the potential donor signs the consent for the donation procedure.

(d) Consistent with the patients' rights provisions of paragraph 405.7 (a)(7) of this Part, non-English speaking candidates and hearing-impaired candidates shall be provided with a non-family interpreter who understands their language and culture.

(e) A member of the independent donor advocate team shall witness the potential donor signing the consent document for the procedure.

(iii) Risks.

Risks shall be fully explained to the potential donor. The explanation shall include:

(a) Physical

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

(2) potential for liver failure and the need for liver transplant, including increased risks associated with advanced age, such as reduced regeneration.

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

(4) scars;

(5) pain;

(6) fatigue;

(7) abdominal and/or bowel symptoms such as bloating and nausea.

(b) Psychosocial

(1) potential for problems with body image;

(2) possibility of recipient death;

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

(4) possibility of recurrent disease in recipient such as hepatitis C or hepatocellular carcinoma;

(5) possibility of adjustment disorder postsurgery;

(6) impact on donor's family;

(7) impact on recipient's family;

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

(c) Financial

(1) out-of-pocket expenses;

(2) childcare costs;

(3) possible loss of employment;

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

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

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

(iv) Documentation.

The entire disclosure and consent process shall be documented in the donor's medical record, which shall be maintained separate and distinct from the recipient's medical record.

(3) Primary Medical Evaluation.

A medical evaluation of the potential donor shall be made by a qualified attending physician member or members of the medical staff. The following are minimum criteria that the donor must meet:

(i) absence of systemic disease or probable future occurrence;

(ii) absence of current or past impairment to any vital organ;

(iii) absence of vulnerability to infection or blood loss or delayed wound healing; and

(iv) be 18 years of age or older.

(4) Psychiatric and Social Work Requirements.

(i) the donor should have a vital emotional relationship with the recipient and be likely to benefit in a way not involving the transfer of money or property.

(ii) a psychiatric and psychosocial evaluation of the potential donor shall be made by the psychiatrist and social worker members of the donor advocate team. The evaluation shall include, but not be limited to, consideration of the donor's current and past history of psychiatric illness, physical abuse, sexual abuse, alcohol abuse and substance abuse.

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

(5) Recipient Criteria.

The transplant center must establish written policies and procedures governing recipient eligibility for live adult liver donation. At a minimum, such policies and procedures shall:

(i) ensure the patient is listed on the cadaveric liver transplant waiting list developed in accordance with the national eligibility criteria for cadaveric donation;

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

(iii) establish conditions which require recipient exclusion; and

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

(6) Perioperative Care Requirements.

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

(a) 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 independent donor advocate team; all consultative reports; and the standards set forth in this subdivision.

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

(ii) Transplant centers shall have the ability to allow donors to bank a minimum of one unit of blood before surgery.

(iii) Surgeries may be scheduled only when sufficient staffing will be available for the post-operative period;

(iv) The transplant coordinator, or another team member, shall provide regular updates to the families/significant others of both the donor and recipient during the surgical procedures.

(v) Surgical Team Requirements:

(a) At least two liver transplant attending surgeons with experience as established in clause (e) of this paragraph shall participate in the surgery on the donor. These two surgeons shall be present for the critical parts of the surgery including the liver 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.

(b) A third liver transplant attending surgeon shall be present in the recipient operating room. This surgeon must have experience in cadaveric liver transplantation but does not necessarily need expertise in live donor resectional surgery.

(c) 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.

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

(e) Except as provided in clause (f) below, each of the two surgeons required to participate in the critical parts of the surgery shall have demonstrated experience in live donor hepatectomy (15 procedures) or demonstrated experience in major hepatobiliary resectional surgery (20 procedures) or surgical fellowship at an American Society of Transplant Surgeons (ASTS) approved liver transplant fellowship program (or an equivalent acceptable to the Department) with demonstrated experience (15 procedures) with live donor hepatectomy. This shall include written verification by the fellowship program director or by the director of the supervising transplant program of hands-on training at an institution performing live donor hepatectomy.

(f) For a new program with no experience in live donor adult liver transplantation, surgeons shall have demonstrated experience in major hepatobiliary resectional surgery (20 procedures). Surgeons shall also visit an established program and observe a minimum of five cases. Written verification shall be obtained from the director of the hosting program and retained in the surgeon's personnel file.

(vi) Anesthesia Requirements:

(a) There shall be two separate attending anesthesiologists; one each for the live 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;

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

(c) These teams shall each be directed by a separate attending anesthesiologist for the live donor and the recipient procedure. In addition to the attending anesthesiologist who shall be present

as specified in clause (a) above, at least one member of the anesthesia team who is an anesthesiologist, chief resident, fellow (postgraduate year 3, 4, or 5), and/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.

(7) Postoperative Care Requirements.

Donors shall receive postoperative care consistent with the following:

(i) Day 0-1: Live adult liver donors shall receive intensive care (ICU or PACU);

(ii) Day 2: If stable and cleared for transfer by the transplant team, 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. Liver donors should not at any time be cared for on any other unit unless 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) If there is an identified member of the anesthesia care team with specific education and training in pain management of liver donors, that person shall be available for consultation with the transplant team regarding the pain control of the donor;

(vi) 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

(vii) 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.

(8) Medical Minimum 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. and at all times on 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 should 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 as identified by the registered professional nurse shall be evaluated immediately by the medical staff. Notification to the appropriate senior medical staff member (fellow, chief resident, attending) shall be made within 30 minutes in accordance with written hospital policies and procedures.

(9) 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 on 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 provide the potential donor with pre-surgical information and shall offer the potential donor a tour of the unit before surgery.

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

(10) Radiology Service Requirements.

(i) Hospitals performing live adult liver transplantation shall have adequate radiological staff support including:

(a) a radiologist with demonstrated experience in evaluating preoperative imaging studies of a potential liver donor including computerized tomography (CT scan) or magnetic resonance imaging (MRI) with respect to liver volume estimates (right and left lobe) and detailed vascular and biliary anatomy;

(b) a radiologist with expertise in reviewing imaging studies in liver transplant recipients;
and

(c) radiologists with experience in interventional procedures (angiography) and ultrasound imaging studies in the live donor and liver transplant recipient (who should be available at all times including weekends and between the hours of 6 p.m. and 8 a.m.).

(ii) If there is an emergent complication requiring radiology services, these patients should be prioritized for access to radiology services by the hospital.

(11) 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:

(i) Representatives of the independent donor advocate team shall be available to the donor from pre-admission to postdischarge.

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

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

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

(a) activities;

(b) diet;

(c) medication for pain; and

(d) wound care.

(v) 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 live adult liver donation.

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

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

(12) Post-Discharge Requirements.

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

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

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

(c) serum liver chemistry tests at discharge or at six weeks (whichever is sooner) and six months and annually for the first five years; three dimensional liver scan with volume assessment at one year shall be performed on all donors of full right or full left lobes; and

(d) 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.

(ii) The hospital shall provide or arrange for follow-up social/psychological supports as needed, which may include measures such as:

(a) visits with a social worker with familiarity with organ transplantation issues;

(b) visits with a psychologist or psychiatrist with familiarity with organ transplantation issues;

(c) participation in a professionally run support group, similar to support groups for cadaveric donor families;

(d) participation in a center-sponsored computer donor listserv or bulletin board to share patient concerns; and

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

(iii) There shall be follow up on financial/insurance concerns, possibly by the transplant center's financial coordinator.

(iv) Hospitals shall periodically report to the commissioner, or his or her designee, such information as the commissioner 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 limited to, donor demographics, preoperative medical and psychosocial information; surgical information and complications; hospital staff training and experience; recipient outcome; and immediate and long-term postoperative care, complications, and impact on quality of life.

(v) Regardless of Department reporting requirements, hospitals shall attempt to track the donor and his or her condition for the donor's lifetime to determine if there are any long term health issues associated with the donation.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for the promulgation of this regulation is contained in section 2803(2) of the Public Health Law which authorizes the State Hospital Review and Planning Council to adopt and amend rules and regulations, subject to the approval of the Commissioner, to implement the purposes and provisions of Article 28 of the Public Health Law, and to establish minimum standards governing the operation of health care facilities.

Legislative Objective:

The legislative objective of Article 28 of the Public Health Law includes the protection of the health of the residents of the State by assuring the safe, efficient provision of the highest quality health services at a reasonable cost. This regulatory amendment furthers this objective by amending rules to establish standards for the safe and effective treatment of potential and actual live adult liver donors. The regulations will ensure that such donors are provided with sufficient and comprehensive information needed to consider the decision to donate, criteria upon which the decision should be based and safe and medically appropriate care throughout the donation, recovery and postrecovery.

Needs and Benefits:

Organ donation and transplantation have saved thousands of lives. However, the supply of usable organs from deceased donors has fallen well short of the demand; 15 people a day die while waiting for a suitable cadaveric organ to become available. Currently, there are more than 80,000 people on waiting lists for organs; more than 8,000 of these are New Yorkers.

In recent years, technology and medical advances have made it possible for live donors to donate a portion of their liver for transplant to individuals who would likely die without such donation. Live kidney donation has been a proven, safe, medical procedure since 1954. These procedures have saved many lives.

The availability and quality of an organ obtained from a live adult liver donor combined with the continuing shortage of recoverable organs from deceased donors has propelled an extensive effort to promote live adult liver donor organ transplantation. However, recent events, including a well-publicized death of a donor, have raised serious questions regarding the safety of the live adult liver donation procedure, particularly for the donor. Although the well being of the donor should be a primary consideration of any live donor organ transplantation, the donor's needs and rights have not always received sufficient attention. These proposed regulations will establish mandatory enforceable standards that will recognize the rights and obligations of both potential donors and recipients and ensure donors receive the highest quality of care.

Competing interests arise in live organ donation that are unique. These include the interests of the donor, the needs of the recipient and society for tissues or organs for transplantation, the interests of the next of kin of both the donor and recipient, and the interests of the transplant center. As a result of the concerns raised by these competing interests and the recent death of a donor, the Commissioner of Health requested the New York State Transplant Council establish a New York State Committee on Quality Improvement in Living Liver Donation to review the care and management of living liver donors in New York State. This Committee was established under

the auspices of the New York State Transplant Council, New York's 21-member advisory body appointed by the Governor and the State Legislature to advise the Commissioner of Health on issues related to organ and tissue donation and transplantation.

Members of the Committee included several nationally recognized transplant physicians with expertise in live adult liver transplantation, an organ procurement organization representative, a liver transplant recipient, a liver donor, a representative of the New York State Nurses Association, a social worker, a psychiatrist with live donor transplant experience, an ethicist and representatives from each of the five liver transplant programs in New York State. Two federal government representatives served in an *ex officio* capacity since this issue is being examined by other states and the federal government.

The Committee met in June, August, October, and November 2002 to review existing requirements and develop new guidelines and protocols in accordance with State and federal laws concerning donor and recipient selection, informed consent, preoperative evaluation, and intraoperative and postoperative care of live adult liver donors.

The Committee developed recommendations, which the New York State Transplant Council unanimously endorsed at its meeting on December 19, 2002. At that time, the Commissioner indicated that the key components of the recommendations would be adopted as regulations to ensure that hospitals performing such transplants complied with these new mandatory standards.

Some innovative features of the guidelines are being incorporated in the proposed regulations. Among them is a requirement that hospitals performing such surgery must establish Independent Donor Advocate Teams to ensure that potential donors have all the information necessary to exercise "informed choice," and that such potential donors are screened to determine

whether there are medical or non-medical reasons to rule out the potential donor. The team's main responsibilities are to support the potential donor. Its role begins with the donor evaluation process and continues through donation, the postoperative period to discharge and post discharge. Team members will complement the surgical team, ensuring that the needs of the donor are fulfilled in a prompt manner and in accordance with best medical practice.

Another feature is the establishment of minimum standards for the availability of surgeons and anesthesia staff during and following surgery and minimum staffing ratios for medical and nursing staff during the recovery period. The Committee on Quality Improvement in Living Liver donations unanimously agreed that these staffing requirements are necessary to ensure the health and safety of the donor to the fullest extent possible. Transplant centers will also be required to collect and report information to the Department regarding the medical and psychosocial status of donors during the donation process and long-term. This data will be made available to the Department of Health to assist in determining the impact of this procedure on donors. Due to the current lack of information on the long-term effects of live liver donation, the Committee regarded collection of this data as essential. This data will assist clinicians, as well as potential donors, in determining the long-term risks of undertaking live liver donation and identifying potential areas for improvement in the donation process. Overall, the recommendations are expected to serve as a model for the nation.

Costs:

Cost for the Implementation and Continuing Compliance with this Regulation to Regulated

Entities:

Currently there are five hospitals (Westchester Medical Center, New York Presbyterian Hospital, Mt. Sinai Medical Center, New York University Hospital and Strong Memorial Hospital)

statewide that are performing liver transplantation and all five facilities had representatives on the Committee on Quality Improvement in Living Liver Donation who voted in favor of the standards contained in this proposal. The Department of Health is not aware of any additional hospitals considering adding this service.

Hospitals that have chosen to perform liver transplantation surgery using live donors and choose to continue such surgery under the new regulations would only face increased costs for compliance if they were not already in substantial compliance with the new requirements. The Department canvassed the five affected hospitals to ascertain the current level of compliance and/or potential additional costs. Although the Department was unable to obtain complete information, those responding indicated they are currently meeting most, if not all, of the standards recommended by the Committee on Quality Improvement in Living Liver Donation; the same standards as those enunciated in the proposed regulations. Two facilities indicated they were augmenting existing staff to comply with the post operative care staffing requirements. However, since costs will vary depending on the extent of current compliance and salaries of any needed additional staff at each of the facilities, and at least one facility has reported current full compliance, actual cost per hospital or per discharge cannot be calculated. Additionally, since the recent death of a donor was attributed to inadequate post operative care and the Committee, including the representatives of the five affected facilities, voted unanimously in favor of these standards, it is highly unlikely these facilities would not comply with the proposed requirements independent of any regulation. To fail to do so would subject such facilities to extensive potential liability costs far exceeding any potential costs of compliance.

Any additional costs associated with developing the Independent Donor Advocate Teams, surgical coverage or data collection and submission are expected to be minimal as the functions can

be provided by existing surgical and support staff, and those facilities responding to the Department's inquiry have reported current compliance with these requirements.

Costs to State and Local Government:

This action will not result in additional costs to State or local government.

Costs to the Department of Health:

There will be no additional costs to the Department of Health. Monitoring for compliance will be incorporated into the existing surveillance programs.

Local Government Mandates:

This regulation does not impose any new programs, services, duties or responsibilities upon any county, city, town, village, school district, fire district or other special district.

Paperwork:

Hospitals, through their new Independent Donor Advocate Teams, will have to provide potential donors with additional written material to assist them in understanding the organ donation and consent process, including potential medical, psychological and financial implications.

Hospitals will also be required to document the entire disclosure and consent process and maintain such documentation in the donor's medical record. In some areas, hospital written policies and procedures may require updating. The requirements for a written discharge plan contain elements that exceed discharge plans for some other hospital patients. There is a requirement for a written summary of the donor's condition to be provided to the donor or his or her representative upon discharge. Also, there is a requirement that hospitals attempt to collect and submit medical and

psychosocial data on donors during the donation process and long-term to determine if there are any long-term health issues associated with the donation. Although facilities may choose to use paper during the compilation of this information, the department expects that most of the data will be recorded and submitted electronically.

Duplication:

This regulation does not duplicate any other state or federal law or regulations.

Alternatives:

The Department considered eschewing regulatory change while relying on the newly released guidelines to establish a standard of care for live adult liver donors. The Department rejected that option because it recognized serious flaws in the current treatment of live adult liver donors and determined that legally enforceable standards were necessary to address such flaws. The Department also sought to impress upon hospitals the gravity with which the Department views the need for uniformly high standards of care and safety for donors.

The Department considered adopting the current guideline document "in toto" via an incorporation by reference. The Department rejected this option primarily because there are certain elements of the guidelines which, while appropriate in an advisory document, do not fit well as an enforceable requirement.

The Department also considered including the committee's recommendation that the Independent Donor Advocate Team have "veto

power” over any proposed donation. However, the Department received several comments from members of the State Hospital Planning and Review Council and other interested parties expressing concern over a “third party” interfering with the normal physician-patient decision-making process. As a result, the Department has replaced this provision with an express requirement that the donor surgeon consider the reports and recommendation issued by the Independent Donor Advocate Team, and if a physician decides to proceed with a donation notwithstanding an adverse recommendation of the Independent Donor Advocate Team, document the reasons for doing so in the donor’s medical chart. This change was discussed with several interested members of the committee, the Transplant Council and the State Council who all agreed that this substitution retains the intent of the committee of ensuring that the Independent Donor Advocate Team’s recommendation is given the weight required to protect the interests of the donor, while adequately addressing the concerns raised by the original “veto” provision.

Several other recommendations contained in the committee’s report concerning specific donor or recipient exclusion criteria were modified to reflect the potential changes in standards as this procedure is refined and to recognize that special circumstances may warrant proceeding with a donation

despite the existence of some conditions which would be considered “exclusionary criteria” in most circumstances. Instead, hospitals are required to develop exclusion criteria and conduct case-by-case psychiatric and social evaluations that thoroughly consider the exclusionary criteria as well as any other psychosocial concerns.

Federal Requirements:

This regulatory amendment does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

The proposed rule will become effective upon filing of a Notice of Adoption with the Secretary of State. The five hospitals performing liver transplant participated in the development of, and are thoroughly familiar with the guidelines. These facilities are also aware of the Department’s plans to proceed with the development of regulations using the standards set forth in the guidelines, and therefore, are expected to be able to comply with the regulations immediately upon adoption.

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**REGULATORY FLEXIBILITY ANALYSIS
FOR
SMALL BUSINESSES AND LOCAL GOVERNMENTS**

Pursuant to section 202-b of the State Administrative Act, a regulatory flexibility analysis for small businesses and local government is not required. None of the five hospitals currently performing liver transplants (New York Presbyterian Hospital, Mt. Sinai Medical Center, New York University Hospital, Strong Memorial Hospital and Westchester Medical Center) are small business or are operated by local governments. Nor are any hospitals classified as small businesses or operated by local governments likely to seek approval for liver transplantation programs in the foreseeable future. The proposed rule will not impose an adverse economic impact on the hospitals which are small businesses or are operated by local governments in New York State and will not impose any additional recordkeeping, reporting and other compliance requirements on small businesses or local governments.

RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to section 202-bb of the State Administrative Procedure Act, a rural area flexibility analysis is not required. This regulatory action affects five major hospitals that do not function in rural areas. In view of the nature of live liver transplantation, it is unlikely that any rural hospitals will seek to provide this service in the foreseeable future.

The proposed rule will not impose an adverse economic impact on hospitals located in rural areas in New York State and will not impose any additional recordkeeping, reporting, or other compliance requirements on them.

JOB IMPACT STATEMENT

A Job Impact Statement is not included because it is apparent from the nature and purpose of these amendments that they will not have a substantial adverse impact on jobs and employment opportunities. If there is any impact at all, it will relate to the minimum staffing requirements and result in additional, not fewer, staff.