

### **Standards for OPOs (In addition to Section 59A-1.005)**

(20) Each OPO shall comply with 42 CFR Part 485, 1994, and make the records relating to the federal standards available upon request to surveyors for the AHCA.

(21) Financial policies and procedures. Each OPO shall comply with existing federal laws and guidelines in its fiscal and accounting procedures.

(a) The OPO shall have accounting and other fiscal procedures necessary to ensure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant centers.

1. There shall be an annual budget approved by the board of directors or advisory board.

2. Unless otherwise provided by law, there shall be an annual audit conducted by an independent public accountant. In the case of HOPOs, the hospital must undergo an annual financial audit.

3. There shall be adequately trained staff or qualified contractors to ensure the establishment and maintenance of internal controls and general accounting functions. The general accounting functions shall include management of accounts receivable, management of accounts payable and other disbursements, and the handling of cash. An OPO shall maintain the ability to generate periodic statements of the status of the agency's assets, liabilities and fund balance, and statements of its periodic revenues and expenses. HOPOs shall be exempt from this requirement to the extent that these functions are performed by hospital staff.

(b) The OPO shall have policies and procedures established for the documentation of all direct and indirect costs. These costs shall be used as the basis for the establishment of organ and tissue procurement charges.

(c) An OPO shall establish accounting policies and procedures to permit allocation of all its direct and indirect costs to the organ and tissue cost centers maintained by the agency. HOPOs shall adhere to an appropriate hospital authority for established accounting policies and procedures.

(d) The accounting records of the OPO shall include documentation of allocations made to organ and tissue cost centers, as applicable, for each direct expense incurred by the OPO. Allocations shall be made insofar as they are related to the procurement of the particular organ. For example, records documenting the payment of a donor hospital bill shall identify the procured organs of the particular case and shall document the equal allocation of the costs to each organ type. The same procedure shall apply to other direct expenses related to the procurement, such as tissue typing or transportation. When these expenses are for the purpose of procurement of a particular organ(s), the cost shall be allocated only to that organ(s).

(e) The accounting records of the OPO shall permit the expensing of indirect costs, (e.g., office rent, utilities, administrative salaries and salary related costs) so that they may be allocated in compliance with Medicare rules and guidelines.

1. The OPO's costs shall be charged as expenses and allocated in accordance with the appropriate guidance provided by the Medicare program or by the appropriate hospital authority for HOPOs and by established agreements with other agencies, companies, providers or vendors.

2. The costs paid by the OPO for services used in the procurement of organs (for example, surgeon's fees, donor evaluation fees, laboratory, transportation, etc.) shall be based on reasonable and customary fees within the service area as determined by the OPO. The OPO may refer to limitations on the reimbursement of such costs as specified by the Medicare program.

(f) The OPO shall maintain the ability to develop and utilize average procurement costs as a basis for establishment of its organ and tissue acquisition charges. The acquisition charges are to be established in accordance with the OPO's board of directors or advisory board and with reference to prevailing Medicare program rules and regulations. These charges shall be reviewed at least semi-annually and appropriate adjustments made unless otherwise proscribed.

(22) Verification of death. The OPO shall ensure that death has been determined in accordance with traditional cardiopulmonary criteria or Section 382.009, F.S., and documented in the organ donor's medical record.

(23) Autopsy. A gross external and internal examination of any area of the donor altered by the excision shall be performed and dictated or otherwise recorded by the excising surgeon(s) at the time of the surgical removal of

organs from the cadaveric donor. A written report of these findings shall be immediately prepared and delivered to the person(s) responsible for the autopsy of the donor. The report shall contain an itemization of all normal conditions noted as well as all abnormal pathological findings found during the gross internal examination of the donor. Whenever a full medical autopsy of the donor will not subsequently be performed by a medical examiner, the OPO shall attempt to obtain a full medical autopsy by other means. Upon request, the OPO shall make a copy of the autopsy report available to all recipient transplant programs that were in receipt of the donor's organs, tissues and eyes and will affix a copy of the report to the donor record.

(24) Guidelines for the evaluation and management of a potential cadaveric organ donor. Evaluation and management of donors is mandatory for organs which may be allocated to and received by the Organ Procurement and Transplantation Network (OPTN)-approved transplant programs to ensure that all organ donors meet the minimum standards and the requirements established by the OPTN. The OPTN guidelines are part of UNOS requirements incorporated herein by reference, effective March 22, 1996.

(a) The OPO's organ donor evaluation and management procedures shall be approved by the OPO's medical director. These procedures are to be undertaken with medical supervision and support.

(b) Once the patient has been declared dead or death is imminent and consent for donation has been obtained from the next of kin and from the medical examiner, if the death meets the requirements for referral to the medical examiner as specified in Chapter 406, F.S., the OPO shall implement the guidelines for the evaluation and management of the potential organ donor.

(c) The evaluation of the donor shall include:

1. An attempt to acquire a social history which may be obtained from individuals not limited to the person giving consent;

2. A physical examination of the donor;

3. Documentation of the donor's ABO group, donor's weight and height;

4. A review of the donor's current inpatient medical record; and

5. Documentation of significant events in the donor's clinical course.

(d) In the brain dead donor, the OPO shall ensure that adequate respiratory, hemodynamic and electrolyte management of the donor is provided.

(e) The OPO shall ensure that the donor receives appropriate antibiotic coverage, if a need is indicated.

(f) The OPO shall evaluate the infectious disease status of the potential donor. All serological testing shall be noted to be either pre- or post-transfusion. Such evaluation shall include:

1. Hepatitis testing according to OPTN policies and procedures;

2. FDA-licensed HTLV test;

3. Appropriate FDA-licensed HIV-1 and HIV-2 screens;

4. Serologic test for syphilis (STS);

5. Blood and urine cultures;

6. Cultures of preservation solutions;

7. Cytomegalovirus (CMV); and

8. Complete blood count (CBC).

(25) Allocation of donated organs.

(a) Each OPO shall have a policy to ensure that donated organs are allocated according to the standards of the OPTN and in keeping with OPTN-approved local variances. Organs that are allocated outside of the sequence of patients, as determined by the OPTN, shall have documentation explaining the reason for the variance.

(b) The OPO shall document that the OPTN computer was accessed and reason for selection of a donor/recipient match and the placement allocation of the donor organ.

(c) Organs shall be allocated by the OPO utilizing the sequence of patients as determined by OPTN computer or by an approved OPTN variance.

(d) Any variation from the OPTN donor/recipient match routine shall be documented and made a permanent part of the donor record.

(e) Documentation of actual allocation of each organ procured shall be filed in accordance with OPTN

guidelines as specified in subsection 59A-1.005(24), F.A.C.

(26) Procurement procedures. The OPO shall have policies and procedures to facilitate and coordinate the procurement of donated organs by trained and qualified personnel.

(a) A certified HHS OPO shall ensure that any surgeons (i.e., surgeons whose fees are paid by the OPO) working as consultants to the OPO for the surgical recovery of donated organs meet qualifications and standards as set by the OPO's medical director.

(b) The medical director of the OPO shall be responsible for the surgical standards and technical quality of services provided by their consulting surgeons.

(c) In the brain dead donor, the OPO is responsible for coordinating anesthesia support for the organ procurement process. The OPO shall provide protocols to the anesthesia support service for the intra-operative procedure. The goal of this intra-operative support includes:

1. Maintaining an adequate blood pressure, fluid volume, organ perfusion and function;
2. Adequate oxygenation and oxygen transport to the organs being procured;
3. Replacement of excessive volume loss; and
4. Administration of required and desirable medications to facilitate organ procurement and function.

(d) If the anesthesia records are not included in the donor's chart, records reflecting documentation of anesthesia protocol used by the OPO shall be available for inspection.

(e) In all organ donors, the OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to OPTN policy 5.0, incorporated herein by reference.

(f) In all organ donors, the OPO is responsible for distributing the following documentation to each transplant center receiving an organ from an individual donor:

1. Verification of donor ABO type;
2. Copy of death determination from the donor's medical record;
3. Copy of consent for organ procurement from the donor's medical record; and
4. Copy of the following OPO donor information:

a. The OPO shall be responsible for documentation of demographic information relative to the donor so that pertinent information is available for centers considering organs for transplant. The OPO shall document information that will enable follow-up with the next of kin and donor hospital personnel.

b. The OPO shall have a standardized method of recording the following information on each donor:

- (I) Name;
- (II) Age, sex, race;
- (III) Cause of death;
- (IV) Time and date of hospital admission;
- (V) Time and date of pronouncement of death;
- (VI) United Network for Organ Sharing (UNOS) identification number; and
- (VII) OPO identification number.

c. The OPO shall document the following information for purposes of follow-up:

- (I) Name and address of the legal next of kin;
- (II) Record of the organs donated;
- (III) Name of attending and consulting doctor;
- (IV) Medical examiner or coroner, as applicable;
- (V) Copy of signed consent form; and
- (VI) Copy of declaration of death note.

d. Documentation of donor history. The OPO shall obtain a medical and social history of each potential donor in an attempt to determine whether the potential donor is in a "high-risk" group as described in paragraph 59A-1.005(11)(a), F.A.C. That history shall be communicated in writing to the physician responsible for the care of the recipient.

e. The documented past medical history shall, when available, include significant episodes of the following:

- (I) Any previous hospitalization;

- (II) Any prior surgery;
- (III) History of a chronic illness, e.g., diabetes, hypertension, cardiovascular disease, etc.;
- (IV) History of communicable disease, e.g., hepatitis; and
- (V) History of disease specific to transplantable organs and treatment of same.

f. The current hospital history is the most vital and shall include:

- (I) Description of injuries and treatments (e.g., surgeries);
- (II) Account of significant febrile episodes – duration, treatment, and response;
- (III) Account of cardiac and pulmonary arrests – type, duration, and all treatment required to restore function

(particularly closed chest massage); and

- (IV) Record of blood transfusions – type and amount.

g. Documentation of donor hemodynamics. It is essential that the OPO document a detailed picture of the donor's hemodynamic status from admission through organ procurement in a standardized, easy to interpret manner.

h. Documentation of blood pressures shall include:

- (I) Average pressure;
- (II) Any hypotensive periods – noting lowest pressure and duration;
- (III) Use of vasopressors – type, amount, duration, and response;
- (IV) Any periods of prolonged hypertension – highest pressure, duration, and treatment instituted;
- (V) Any abnormal heart rhythm and treatment; and
- (VI) Swan Ganz and central venous pressure readings and which shall be correlated with blood pressure, when available.

i. Transfused donor.

(I) All potential donors are to be tested for HIV-1 and HIV-2 antibodies, pursuant to Rule 64D-2.005, F.A.C., and for HTLV antibodies for which FDA-licensed test systems are available. If the donor's pre-transfusion test is antibody negative and subsequent transfusions are pre-tested, retesting for HIV-1 and HIV-2 antibodies and HTLV antibodies is not necessary. If no pre-transfusion blood sample is available, the donor institution must provide, along with the screening test results, a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organs. Organs from donors with repeatedly reactive screening tests for HIV-1 and HIV-2 antibodies and HTLV antibodies are not suitable for transplantation unless subsequent confirmation testing unequivocally indicates that the original test result was unconfirmed. If additional tests related to HIV-1 and HIV-2 antibodies and HTLV antibodies are performed, the results of all tests must be communicated immediately to the recipient's institution. Exception to cases in which the testing cannot be completed prior to transplant are as follows:

(II) Exceptions to the guidelines set forth above shall be made in cases involving non-renal organs, when, in the medical judgment of the staff of the donor and recipient institutions, an extreme medical emergency warrants the transplantation of an organ, the results of which are not immediately available for HIV-1 and HIV-2 antibodies and HTLV antibodies. The transplant surgeon is obligated to notify the recipient or next of kin in such cases.

(27) Documentation of organ-specific laboratory results. The OPO shall provide the transplanting physician with certain test results for the evaluation of organ function. These results shall be documented in a standardized manner.

(a) The OPO shall document the following available lab results for ALL donors:

1. CBC;
2. Electrolytes;
3. ABO typing;
4. Blood and urine cultures;
5. Serological testing in accordance with OPTN guidelines;
6. Appropriate FDA-licensed HIV-1 and HIV-2 screens, FDA-licensed HTLV test. If blood products have been given, a pre-transfused sample shall be obtained. If unavailable, explanation shall be documented in the donor's medical record;
7. Cultures, including blood, urinary, and perfusion fluid, when appropriate, which allow for interpretation of

laboratory results. Each OPO must define procedures for the type, source and indication for obtaining these cultures;

8. CMV antibody.

(b) KIDNEY evaluation:

1. Urinalysis;
2. Creatinine; and
3. Blood urea nitrogen (BUN)

(c) LIVER evaluation:

1. Liver enzymes;
2. Total bilirubin;
3. Direct bilirubin; and
4. Prothrombin time/partial thromboplastin time (PT/PTT).

(d) HEART evaluation:

1. 12 lead EKG;
2. Cardiology consult;
3. Chest X-ray;
4. Blood gases;
5. Echocardiogram or cardiac cath (optional); and
6. Creatine phosphokinase including MB fraction.

(e) PANCREAS evaluation:

1. Serum amylase;
2. Serum lipase; and
3. Glucose.

(f) LUNG evaluation:

1. Blood gases;
2. Chest X-ray; and
3. Sputum gram stain and culture.

(g) The OPO shall utilize an internal standard format or form (i.e., UNOS Cadaver Donor Registration/Referral Form) to document all of the above-mentioned information according to UNOS requirements in subsection 59A-1.005(24), F.A.C.

(28) In brain dead donors, the OPO shall document detailed information on volume intake and urine output in order to assess and maintain donor stability.

(a) The OPO shall document volume intake type (crystalloid vs. colloid) and amount for a minimum of 8 hours prior to organ procurement and for the duration of the operative procedure. The use of any blood or blood products shall be noted.

(b) The OPO shall document urine output for a minimum of 8 hours prior, if possible, to organ retrieval and for the duration of the operative procedure. Any periods of oliguria, anuria, or the occurrence of diabetes insipidus and its treatment shall be documented.

(29) Documentation of retrieval procedure.

(a) The OPO is responsible for proper documentation of the events surrounding the surgical removal of all organs for transplantation.

(b) On ALL donors, the OPO shall document the following intra-operative information:

1. Blood pressures, urine output, and fluids administered;
2. Medications administered;
3. Blood products administered;
4. Type and amount of perfusion solution and flush characteristics;
5. Type of storage solution;
6. Type of procurement procedure (i.e., enbloc, in-situ perfusion);
7. Aortic cross-clamp time and date;
8. Description of typing material available;

9. Warm ischemia time;

10. Anatomical description:

a. Kidneys – include number of vessels and approximate length and diameter of each;

b. Extra renal – include description and any injuries or abnormalities; and

11. Organs procured and not disposed. If the organs are not used for transplantation or research, a written note regarding discard shall be documented in the OPO's donor records.

(30) Documentation of recipient information.

(a) The OPO shall document specific information on the recipients of procured organs.

(b) The following information shall be documented on each recipient:

1. Name;

2. A UNOS recipient identification number;

3. Recipient center; and

4. Age, sex, and race.

(31) Completion of OPTN required forms. Each OPO shall routinely submit documentation describing donor activity to the OPTN, as required by 42 CFR Part 485, 1994. The OPO shall comply with OPTN reporting requirements.