ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS

Saving and improving lives through organ, eye, and tissue donation

STANDARDS & INTERPRETIVE GUIDELINES

MANUAL EFFECTIVE JANUARY 2020

***PLEASE NOTE: These standards are used for referrence only, they are no longer being updated or used for accreditation!**

AOPO STANDARDS AND INTERPRETIVE GUIDELINES
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ACCREDITATION STATUS

AOPO ESSENTIAL STANDARDS

Merriam Webster defines "essential" as "of the utmost importance; basic, indispensable, necessary."

AOPO Essential Standards

There are five Essential Standards that must be met for any 3-year reaccreditation. The specific standards upon which the Essential Standards are based are removed from scoring, in the regular part of the survey so there is not a double penalty. These are NOT new standards. They have been a part of the Standards for many years.

Full Accreditation requires the OPO to meet **ALL** the Essential Standards at 100% and a passing score (minimum 75%) for **ALL** sections of the existing standards.

Conditional Accreditation is automatic if one Essential Standard is missed (even if all other standards are met). This requires a corrective action plan to be submitted, approved and completed within three months per current accreditation procedures, and per the specific corrective action indicated with each Essential Standard.

Denial of Accreditation is automatic if two or more Essential Standards are missed (even if all other standards are met). This requires a corrective action plan and a new application and full survey. The OPO may reapply **no sooner than one year after notification** of denial. This is considered to be similar to a new accreditation, reviewing one year. The most recent year of policies, procedures and documents are reviewed during the survey.

AOPO
ESSENTIAL STANDARDS

1	**GOVERNING BOARDS** **Links to FS 2.5** The OPO budget is approved by the OPO board annually.	The survey team will review OPO records for evidence that the OPO budget was submitted to the OPO governing board of directors and approved by a vote consistent with the OPO Bylaws for each of the three years involving the accreditation cycle.
2	**QUALITY PLANS** **Links to QI 1.2** The OPO Quality Plan is reviewed by the OPO board annually.	The survey team will review OPO board (advisory OR governing) records for evidence of the OPO Quality Plan's review for each of the three years involving the accreditation cycle.
3	**AUTHORIZATION RECORDS** **Links to CL 3.2 & CL 3.4** 100% of OPO donor records **sampled** contain evidence of authorization for organs recovered	The survey team will review OPO donor records for evidence of OPO documentation of authorization for each of the three years involving the accreditation cycle. The survey team shall use the minimum sampling method used for routine donor record review.
4	**DEATH DECLARATION RECORDS** **Links to CL 2.2** 100% of OPO donor records **sampled** contain evidence of patient death declaration prior to beginning organ recovery surgery	The survey team will review OPO donor records for evidence of the donor hospital's documentation of patient death for each of the three years involving the accreditation cycle. The survey team shall use the minimum sampling method used for routine donor record review.
5	**INFECTIOUS DISEASE TESTING** **Links to CL 4D.1.1** 100% of OPO donor records **sampled** contain evidence of completed infectious disease testing	The survey team will review OPO donor records for evidence of OPO documentation of donor infectious disease for each of the three years involving the accreditation cycle. The survey team shall use the minimum sampling method used for routine donor record review.

ADMINISTRATIVE STANDARDS

Reference #	STANDARD	INTERPRETIVE GUIDELINES
AS 1 - Governing and Advisory Body		
AS 1	An organized governing and an advisory board must be established.	The surveying team should determine that the OPO has a governing board and a separate advisory board
AS 1.1	The OPO will adopt written bylaws, operating rules or administrative policies and procedures for the governing board and an advisory board.	Review the bylaws, operating rules or administrative policies and procedures. If separate bylaws, operating rules or administrative policies and procedures are not in place, the single bylaws should define the roles of each Board to include at a minimum their responsibility, oversight, and compensation. Assure there are procedures to address potential conflicts of interest. *Note the CMS Regulation (Standard 486.324; IG Z234) states "Members of the advisory board are prohibited from serving on any other OPO board."*
AS 1.2	The bylaws and operating rules (or administrative policies and procedures for a HOPO) specify at least the following:	Find the requirements for the standard in the bylaws or operating rules of the OPO.
AS 1.2.1	The role and purpose of the organization.	
AS 1.2.2	The duties and responsibilities of the governing board and of the advisory body.	The Governing Board must have full legal authority and responsibility for the management and provision of all OPO services and develop and oversee implementation of policies and procedures including: fiscal operation, the OPOs quality assessment and performance improvement program (QAPI) and services furnished under contract or arrangement, including agreements for these services. The Governing Board appoints an individual to be responsible for the day to day operation of the OPO. The Advisory Board has the authority to recommend policies for the following: procurement of organs, effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation, systematic efforts including professional education, to acquire all usable organs from potential donors, arrangements for the acquisition and perfusion of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards of the OPTN, appropriate tissue typing of organs, a system for the allocation of that is consistent with the rules and requirements of the OPTN, transportation of organs, coordination of activities with transplant hospitals, participation in the OPTN, arrangements to cooperate with tissue banks, annual evaluation of the effectiveness of the OPO and assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations from potential donors. The Advisory Board has no authority over any other activity of the OPO.

AS 1.2.3	The mechanism for selecting and removing members, including the length of terms.	Review the Bylaws to determine the mechanism for selecting and removing members, and that length of terms, attendance, frequency of meetings is defined. There should be no overlapping of representation between Boards. Assure that all mandated categories are represented on the Advisory Board. Mandated representation includes: hospital administrators, either intensive care or emergency room personnel, tissue banks, member of a voluntary health association, a member of the public, a physician or someone with a doctorate degree in histocompatibility, a neurosurgeon or other physician with knowledge or skills in the neurosciences, a transplant surgeon representing each transplant hospital and an organ donor family member.
AS 1.2.4	The composition and responsibilities of committees of the Governing and Advisory Boards.	Assess the committee structure, including the Finance or Audit Committee, and determine responsibilities.
AS 1.2.5	The mechanism for review and revision of the bylaws or operating rules.	Review bylaws to ensure the mechanism is defined.
AS 1.3	A record of current and ongoing proceedings of the governing and advisory board and functioning committees is maintained.	Review the meeting minutes of the Governing Board and of the Advisory Board and all Board committees. Both boards must meet at least annually unless otherwise specified by state law or the OPO bylaws.
AS 2 - Organization		
AS 2	The organ procurement organization will be administered effectively and efficiently.	An overall review of management practices will be necessary.
AS 2.1	There shall be a chief executive officer or equivalent responsible to a Board of Directors or appropriate hospital administrator for the day-to-day operation of the OPO. The Executive Leadership Team implements the policies established or recommended by the governing body (or advisory body or supervisory administrator for HOPO). The Executive Leadership Team ensures and documents that the organization is in compliance with applicable local, state and federal guidelines, laws and regulations. Position descriptions indicate the Executive Leadership Team is responsible for the development and implementation of personnel policies and the financial management of the organization. The Executive Leadership Team of a HOPO is responsible for adherence to the parent hospital personnel and financial management	Review the job description of the Executive Leadership Team or equivalent responsible to the Board of Directors or hospital administrator. Job description should outline the authority that is granted to this individual regarding the daily operation of the OPO; implementation of policies established by the OPO Governing or Advisory body; a mechanism to ensure compliance with documentation regarding the guidelines, laws and regulations set forth locally, statewide and federally. Review job description to determine responsibility for development and implementation of personnel policies and financial management of the organization. HOPOs need to provide personnel and financial management policies of hospital corporations.

AS 2.2	A physician or medical director shall be a part of the organizational structure, and the following criteria shall be met:	
AS 2.2.1	There is a formal job description that documents the relationship between the OPO and the physician/medical director.	
AS 2.2.2	A written policy exists that addresses potential conflicts of interest for the Medical Director.	
AS 2.2.3	The Medical Director is a physician licensed in at least one of the States or Territories within the OPO's DSA.	
AS 2.2.4	The Medical Director or designee is responsible for the oversight of the clinical management of potential donors, including providing assistance in managing a donor case.	
AS 2.3	There shall be Executive Leadership staff or arrangements to ensure compliance with sound business practices and procedures.	Assure that the administrative staff (clerical, data, business) are employed by the OPO to ensure compliance with sound business practices and procedures. Job descriptions should be reviewed. If there are associations with OPO management groups, the surveyor should review all contractual agreements.
AS 2.4	The OPO shall have an organizational structure that provides for proper operation of the OPO.	The surveyor should review the organizational chart and structure of the OPO/HOPO.
AS 3 - OPO Insurance		
AS 3.1	The independent OPO will maintain current insurance policies for professional liability and business practices (such as directors and officers and employment related practices). The HOPO will maintain current insurance policies or documentation of appropriate coverage by the parent company for professional liability and business practices.	Review evidence that the OPO has insurance policies for professional and business liability that takes into account such things as OPO size, service area and level of risk. Generally, a minimum level of $1 million is recommended.

AS 4 - Cooperation with Tissue and Eye Banks		
AS 4.1	The OPO shall have policies and practices in place for eye and tissue referrals, as required by Medicare Conditions of Participation. The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors: screening and referral of potential donors, obtaining authorization from families of potential tissue donors, retrieval, processing, perfusion, storage and distribution of tissues, and providing designated requester training.	The surveyor should review the documents to show the relationship the OPO has with tissue and eye banks. Specifically, these documents should include the mechanism in place to ensure that all usable tissues are obtained from potential donors. The OPO shall have policies and practices in place for eye and tissue referrals, as required by Medicare Conditions of Participation. The surveyors should review policy documents to ensure that a mechanism is defined for referring eye and tissue referral calls to the appropriate eye or tissue bank, including any written arrangements with an answering service, if necessary. The surveyor should also interview appropriate OPO employees (or answering service employees, if necessary), and examine referral call worksheets and practices to ensure that information is appropriately and timely transferred to an eye bank or tissue bank.
AS 5 - Corporate Compliance		
AS 5	The OPO will have a program or process which affirms its commitment to uphold the applicable laws by which it is governed.	
AS 5.1	The OPO must have a Code of Conduct for its employees and board members. This Code of Conduct is designed to prevent accidental and intentional non-compliance with applicable laws; to detect such non-compliance if it occurs, to discipline those involved in non-compliance behavior, to prevent future non-compliance, and to establish and implement a corrective action plan.	There should be evidence of a formal document, adopted by the OPO governing Board of Directors (or hospital administration, in the case of a hospital based OPO), which outlines standards specific to particular activities. The document should describe the conduct that is either required or prohibited in relation to that activity. Policies and procedures must be present that define how suspected incidents of non-compliance can be reported, and that reports can be made without fear of retribution. Statements should be present that define the range of discipline that may occur with non-compliance. Mechanisms, such as how investigations are conducted and what is done with the information in the investigation, should be in place to prevent future non-compliance. All of the parts of the standard must be present in order to meet the standard.
AS 5.2	The OPO shall define the monitoring and auditing systems as well as other evaluation techniques which fulfill the plan's requirements.	
AS 5.2.1	Reporting	There should be a system in place for the reporting of reasonably suspected incidents of non-compliance. Evidence of a mechanism for Board (if not HOPO), staff or agents to report non-compliance should be available, and staff should be familiar with the process for reporting.

AS 5.2.2	Tracking	There should be a tracking system defined for reports of non-compliance. A statement that the organization does not tolerate any form of retaliation against those who report non-compliance needs to be documented in personnel or corporate compliance policies. There should be baseline and periodic audits that determine areas of risk for non-compliance. We recommend that the OPO look at all recorded incidences.
AS 5.2.3	Auditing	An internal audit, or an externally contracted audit, to identify areas of risk within the organization for incidents of non-compliance within their corporate compliance program, Audit is to be conducted at least once during the three-year AOPO cycle. (An example of risk could be payment to residents to recover lymph nodes). This can be done in a variety of ways, depending on the size of the OPO (i.e., by department, overall organization, training effectiveness). The size of the audit and what is identified will vary between OPOs, but there should be common elements for all OPOs (i.e., federal, state and local laws/regulations, industry specific standard, billing policies/procedures/training, background checks, contract/agreement language, etc.).
AS 5.3	The OPO shall have a written protocol for investigation of suspected non-compliance with its plan. The plan must include procedures for the OPO to take prompt action in response to any violation once they are detected and steps to prevent future non-compliance.	The protocol should identify what steps the OPO will take to respond to reported noncompliance, including who will conduct the investigation and where the information will be reported. Since non-compliance incidents may range from general to criminal, many plans may include when to consult with legal counsel, and the appropriate oversight body/agency will be contacted as necessary. There should be language that calls for a corrective action plan for all reasonably suspected reports on non-compliance and that steps will be taken to prevent similar situations in the future. There should be evidence that the investigative process will be kept, to the extent possible, confidential.

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HUMAN RESOURCES STANDARDS

Reference #	STANDARD	INTERPRETIVE GUIDELINES
HR 1 - Personnel Policies and Procedures		
HR 1	The OPO shall have personnel policies and procedures in place that provide guidance to the OPO employees and satisfy legal requirements.	The surveyor should review personnel policies and procedures that are in place within the OPO. Specifically, these policies and procedures should be reviewed to ensure that the OPO has adequate personnel in place to support the mission and objective of the OPO. Additionally, the OPO should have a policy and procedure manual.
HR 1.1	Personnel policies and procedures should be in a collective format, i.e., personnel policies and procedures manual.	The surveyor should review personnel policies and procedures that are in place within the OPO. These may be incorporated into the Employee Handbook.
HR 1.2	Personnel policies and procedures will be documented, available and accessible to all personnel.	The surveyor shall determine how accessible the policies and procedures are to all employees.
HR 1.3	Personnel Policies and Procedures will provide for how changes and additions are communicated to all personnel.	Ascertain the process that addresses changes in policies and procedures and how they are communicated to OPO personnel. Survey staff as to how the process works.
HR 1.4	Personnel Policies shall contain the following information:	
HR 1.4.1	A statement and/or policy and procedure defining the compliance with local, state and federal regulations for employees. Examples may include (depending on the number of employees and other factors): Civil Rights Act, Fair Labor Standards Act, Americans with Disabilities Act, COBRA.	The policies and procedures should be verified to show compliance with local, state and federal regulations regarding EEOC, ADA, nondiscriminatory employment practices, minimum wage information, COBRA information and universal precautions. Recommend a review of required federal/state and local postings during the facilities tour. Interview the HR professional to determine the process for providing federally required information to staff during the on-boarding process, such as summary plan descriptions (SPDs), COBRA notices, etc.
HR 2 - Hiring and Termination		
HR 2.1	The hiring process shall be defined and may include definitions of probation/training periods.	Hiring and termination procedures must be defined. Specifically, processes which may include probationary or training periods.
HR 2.2	The termination process shall be defined.	Determine process through interview if no specific policy.
HR 2.3	Wage, Salary and Benefits Program to include:	Personnel Policies and/or Employee Handbook or other appropriate OPO policy must contain information regarding wages, salary and benefit programs.
HR 2.3.1	Definition of employees as exempt or non-exempt	Request organization provide policy/practice for determining Fair Labor Standards Act (FLSA) status for positions.
HR 2.3.2	Non-exempt wage and benefits program	
HR 2.3.3	Exempt salary and benefits program	

HR 2.3.4	Corporation's paid holidays and additional benefits, e.g., personal time, paid leave.	Corporation's paid holidays and additional benefits, (i.e., personal time, paid leave) should be documented.
HR 2.3.5	Definition and process for pay practices such as overtime and on-call time.	Review description of the process involved for overtime and on-call time.
HR 2.3.6	Definition of other forms of compensation, if appropriate, e.g., on-call pay and bonus programs.	Review definition of other forms of compensation, if appropriate, (i.e., on-call pay and bonus programs) and documentation of payment.
HR 3 - Job Expectations, Performance Review and Development		
HR 3	A formal job description is documented and available for each job category and shall include:	The surveyor should review job descriptions for each position within the OPO, paying attention to overall job summary, reporting structure and minimum job requirements. Additionally, the surveyor should assure that a job description is reviewed and documented with each employee prior to, or at the time of employment. The OPO should have an established Code of Conduct describing what professional behavior is. Review all job descriptions to ensure that every job position has a job description. Match job descriptions to organizational chart.
HR 3.1	Overall job summary	Synopsis of job should be included.
HR 3.2	Reporting structure	Reporting structure should be defined.
HR 3.3	Minimum (and essential, if applicable) job requirements, such as education, training, certification, experience and responsibilities.	Minimum (and essential, if applicable) job requirements, such as education, training, certification, experience and responsibilities will be defined.
HR 3.4	At the time of employment, the employee's job description will be reviewed and documented with the employee.	At the time of employment, the employee's job description will be reviewed and documented with the employee.
HR 3.5	A formal performance review process is documented and defined.	Review documentation for 10 employees which support the OPO's policy on how often performance reviews are conducted. This review must include positions that have direct impact on the donation process.

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FINANCE STANDARDS

Reference #	STANDARD	INTERPRETIVE GUIDELINES
FS 1 - Compensation		
FS 1	The OPO shall have a defined plan for determining employee compensation and, if applicable, contract physician fees or payments.	There must be a methodology within the personnel policies and procedures, employee handbook, and/or other appropriate OPO policy describing the procedure for salary changes. Surveyor should review the OPO's process for establishing salary levels for staff, management and physician administrators, and if applicable, fees or payments made to contract physicians. The review should assess the methodology for salary structure (salary survey, hiring philosophy related to placement within salary range). The surveyor should assure that the salary ranges are based upon a review of comparable data obtained by the OPO from independent source documentation.
FS 1.1	The OPO must provide evidence that salary ranges have been established for its staff level employees that reflect the position's requirements for level of experience and training and the scope of job responsibilities.	Determine that a compensation philosophy and methodology exist to recruit/retain and provide internal/external equity for staff compensation. Assess that salary grades and ranges have been established for staff level employees that reflect the requirements for level of experience, training and the scope of job responsibilities.
FS 1.2	The OPO must provide evidence that salary ranges have been established for the senior administrative staff based upon the individual's level of training and experience and the scope of the responsibilities of the position.	Determine that a compensation philosophy and methodology exist to recruit/retain and provide internal/external equity for senior administrative staff compensation. Assess that salary grades and ranges have been established for senior administrative staff that reflect the requirements for level of experience, training and the scope of job responsibilities.
FS 1.3	Full or part-time physician administrators' compensation.	Full and part-time physician administrators' compensation shall reflect training, experience and organizational responsibilities.
FS 2 - Financial Policies and Procedures		

FS 2	The OPO has policies and procedures in place that describe and document the processes in place to ensure the effective financial management and financial oversight of the organization. These documented processes also ensure the OPO complies with current and existing Federal laws and guidelines, as well as the appropriate utilization of financial resources. (HOPOs may be obligated to follow the fiscal and accounting procedures established by the hospital's governing directors and may, therefore, be exempt from specific procedures defined in this standard).	• The purpose of the review of this section is to ensure that the OPO has effective financial oversight in place and complies with existing laws and guidelines; ensuring that its fiscal and accounting procedures are consistent with this standard. • The surveyor should assure that the OPO has written financial policies and procedures in place in a manual or other organized format available for review. • HOPOs are required to follow accounting procedures established by their parent corporation. The parent corporation's accounting procedures should be reviewed.
FS 2.1	The OPO, or its parent organization, will be a nonprofit entity under section 501(c)(3) of the IRS Code of 1986.	Surveyor should verify: • Existence of "IRS 501(c)(3) Letter"- classifies the OPO or its parent organization as a nonprofit entity under IRS section 501(c)(3) • The letter is current (i.e., the determination remains the same) • Letters are in existence for all related entities including foundations
FS 2.2	The OPO will maintain certification from the Federal government to be reimbursed under CMS for the costs attributable to procurement of covered organs (42 CFR Part 485). A policy/procedure should be in place to ensure proper allocation of recovery costs for organs and/or tissues.	The surveyor should verify the following: • The OPO is currently CMS certified by reviewing current CMS OPO designation letter • Verify through the CMS Web Site (www.http://organdonor.gov) that the OPO is listed as a certified OPO. • Review policy and procedure documentation and processes in place to ensure: o Appropriate method of organ acquisition charge development o Appropriate methods of cost allocation to renal and non-renal cost centers o Proper board or finance committee approval and/or involvement. (Also, can review meeting minutes to verify statements in policies).
FS 2.3	The OPO must provide evidence that a Cost Report is completed at least annually in compliance with approved formats provided by the Medicare fiscal intermediary.	Review/verify the following: • The past three years cost reports have been filed. • Obtain the most recently settled cost report- o Verify this through the existence of intermediary documentation (usually a final adjustment report). o Examine the correspondence for any concerns noted by the intermediary, and determine if all questions were adequately answered or appropriately handled. o Review the adjustment report for any material adjustments or issues and follow up on how the OPO responded. • Review documentation on status of any re-opened cost reports or cost reports under appeal.
FS 2.4	The OPO shall have established procedures for obtaining payment for procurement services; and effective cash management should be in evidence to ensure the OPO's fiscal stability. The OPO must have a documented investment	A review of financial policy and procedure should be undertaken to verify: • OPO has policies and procedures in place for billing and obtaining timely payment for kidneys and non-renal organs provided to transplant centers. • An accounts receivable aging report should be available verifying outstanding A/R over 90 days are reasonable. Less than 10% (or less than 25% over 60 days) is a general

	policy that is reviewed annually by the investment committee, finance committee, or board of directors as applicable. The OPO must have a development plan for annual review of the OPO investment portfolio, reserve fund, or equivalent, if applicable.	guideline. Any issues should be investigated by reviewer. • The working capital ratio (current assets divided by current liabilities) should be determined for reasonableness. It is a measure of an organization's cash flow and ability to satisfy its short-term obligations. A guideline of 2 to 1 (current assets twice current liabilities) is generally appropriate. • Appropriate accruals for any Medicare receivables or payables should be reflected within the financial statements. • OPO has an investment policy in place and the investments held by the OPO comply with this policy. The investment policy is approved annually by the investment committee/finance committee or equivalent. This may be scored as "n/a" for hospital/university-based programs. • OPO has a documented plan for the annual review of the OPO investment portfolio, reserve fund, or equivalent. Evidence of OPO policies, meeting minutes, or other written materials shall serve as documentation of the review. This may be scored as an "n/a" for hospital/university-based programs.
FS 2.5 **Links to Essential Standard 1**	There shall be an annual budget approved by the governing or advisory body. The OPO must maintain a documented set of financial policies and procedures and must maintain a system for reporting of financial operating results to the governing body at least annually.	Review the financial policies prior to the site visit to ensure the following processes are addressed and are in place: • Budget development process, timelines, and finance committee and board approval process. Verify processes are followed through meeting minutes. • Interim financial reporting- o Processes are addressed and followed as documented in policy. Ask for and review most recently presented interim financial statements (verify through board/finance meeting minutes) o Determine frequency of reporting o Examine the timeliness of financial reports (generally most OPOs have their reports available within 4-6 weeks after the close of the accounting period.) o Review board/finance meeting minutes for acknowledgment and/or approval of financial results/spending plans • OPO follows GAAP and accrual accounting (review method of general ledger posting process) • Processing of accounts receivable o Issuance of invoices and billings o Handling of checks and bank deposits • Approval and processing of accounts payable o Expenditure approval o Check signing authority • Payroll procedures • Bank account reconciliation process • Fixed asset or property and equipment accounting and control
FS 2.6	Completed Form 990 has been provided to voting members of the OPO governing board, audit committee, or equivalent board level committee, for review and timely filing.	The surveyor should verify that the OPO has a board or board level committee or equivalent that annually reviews the Form 990 and the OPO's timely submission of the Form all three years of the (re)accreditation cycle. Evidence of OPO policies, and meeting minutes, or other forms of communication shall serve as documentation of review.

FS 2.7	The OPO must provide to its governing board of directors, or its equivalent, a comprehensive set of financial documents which include, but are not limited to, 1) Statement of Revenue and Expenses, 2) Balance Sheet, and 3) other financial reports as necessary, at least two times per year.	The surveyor should verify that the required financial documents are presented for review at least two times per year to the OPO governing board, or equivalent for review. Evidence of OPO policies, meeting minutes, or other forms of communication shall serve as documentation of review.

FS 3 - Financial Audit		
FS 3.1	Unless otherwise provided by law, there will be an annual financial audit conducted by an independent public accountant. In the case of HOPOs, the hospital must undergo an annual financial review related to OPO costs. Any issues identified by the financial audit or its resulting audit report will be effectively addressed by the OPO.	Surveyor should verify: • Completion of current annual independent audit performed by Certified Public Accountants. 1. Required Communications 2. Report of Independent Auditors (“Opinion Letter”) 3. Audited Financial Statements (including “Notes to Financial Statements”) 4. Report on Internal Control (“Management Letter”) • Required Communications: Statement of Auditing Standards No. 61 requires the auditor to ensure that the Board of Directors (or indirectly through the audit or finance committee) receives additional information regarding the scope and results of the audit that may assist the Board in overseeing management’s financial reporting and disclosure process. The surveyor should review the Required Communications Letter and determine if there are any: o Significant accounting policy changes o Significant audit differences or adjustments o Disagreements with management o Major issues discussed with management prior to retention o Consultation with other accountants o Serious difficulties encountered in performing the audit o Material errors, irregularities and illegal acts o Significant disclosures not made o Material weaknesses in internal controls o Independence issues Review the letter to determine if any of these areas presented by the auditors reflect negatively on management. If so, discuss with management and/or seek assistance and guidance from an appropriate financial resource. • Independent Auditor’s Report (“Opinion Letter”): o Is on the letterhead of the audit firm and should indicate that the auditors are Certified

		Public Accountants. o Includes the wording: “In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of <insert organization’s name> in conformity with U.S. generally accepted accounting principles”. If this wording includes the phrase “except for,” then seek assistance and guidance in interpreting the statement from an appropriate financial resource. Is signed and dated by the audit firm. • Management Letter: o A separate letter from the audit firm, usually addressed to the board of directors. o Includes observations regarding the auditor’s findings and recommendations for process and procedural improvements. It might indicate deficiencies, note concerns, make recommendations for compliance and/or change in practice, or give a “heads up” to the board on topics of operational or legal concern. o Examine the letter any noted deficiencies. Ask for management’s response to the letter and determine whether the recommendations were implemented, or the deficiencies corrected. If not, determine management’s reasoning. • Change in Auditors: o Determine if there has been a change in audit firms either two years previously or since the current audit report. o If there has been a change, inquire as to management’s reasoning. Ask specifically if a difference of opinion caused the change; and if so, what the difference of opinion was.
FS 4 - Documentation of Costs and the Establishment of Acquisition Charges		
FS 4	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/or tissue acquisition charges.	The surveyor should request a copy of the OPO’s most recent cost report for review of this section. HOPOs must adhere to the appropriate hospital authority’s policies, established accounting policies and procedures for this particular section. General guidance for AS 7.1 – AS 7.5: In review of the section, the surveyor should specifically be looking for expense allocations as provided in accordance with Medicare guidelines for and by the appropriate hospital authority. This should include a review of agreements with other agencies, companies, providers or vendors. The OPO’s records shall include documentation of allocations made to specific organ/tissue cost centers for direct expenses incurred by the organization for organ recovery. A review of a minimum of five donor hospital bills should be undertaken. Additionally, the accounting records must permit the expensing of indirect costs in compliance with Medicare rules and guidelines. The OPO’s policy as to the development of organ acquisition charges and the review of those charges shall be available. Review documentation that reflects at minimum annual review of OAC fees. In the case of HOPOs, the review of an OAC must be in accordance with a hospital governing policy. This policy must be reviewed.

FS 4.1	The OPO shall establish accounting policies and procedures to permit allocation of all its direct and indirect costs to the organ and/or tissue cost centers maintained by the organization. The policies and procedures shall be in compliance with the current approved Medicare cost report and all policies set forth by the current Medicare intermediary. HOPOs shall adhere to an appropriate hospital authority for established accounting policies and procedures.	The surveyor should examine policy and procedures manual and assure that practice and policy are consistent. Surveyor should review Worksheet A – Trial Balance of Expenses from the most currently filed cost report to verify that direct and indirect expenses are being broken down by organ for each line item. Surveyor should review Worksheet A-4 – Reclassifications and Worksheet A-5 – Adjustments to Expenses and review supplemental schedules that tie into worksheet A-4 and A-5.
FS 4.2	The OPO's accounting records shall be maintained to permit allocation of costs 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.	The surveyor should review the most recently closed cost report for any adjustments made by the intermediary. This would verify that changes have been implemented in subsequent cost reports or verify that the OPO is currently undergoing an appeals process for the recommended intermediary adjustments. Surveyor should also review the NPR and management letter, if any, from the intermediary for the most recently closed cost report year
FS 4.3	The accounting records of the organization shall include documentation of allocations made to organ and/or tissue cost centers, as applicable.	Records documenting the payment of a donor hospital bill shall identify the organs procured and shall document the allocation of the costs to each organ type. Review a minimum of five donor hospital bills and the accompanying donor charts to verify that expenses from the hospital bill are being allocated to that direct organ expense. Expenses directly related to a specific organ should be allocated only to that organ direct expense. For example, a cardiac catheterization would be expensed to heart direct expense, bilirubin would be expensed to liver direct expense, etc. Alternatively, an acceptable methodology is if the OPO divides total hospital bill by number of organs/tissues and makes the allocation.
FS 4.4	The accounting records of the organization shall document 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, to specific organ types, or to tissue recoveries.	Assure indirect costs are allocated to specific organs and tissues as Medicare requires. Surveyor should review Worksheet A-1 – Administrative and General Expenses.
FS 4.5	The acquisition charges are to be established in accordance with the governing body/policy (or advisory board/policy for HOPOs), and in compliance with prevailing Medicare program rules and regulations. The OPO shall maintain the ability to develop and utilize average procurement costs as a partial basis for establishment of its organ acquisition charges.	To assure OACs are established by Board policy, look for such things as: ° Financial policy and procedures with Board approval ° Board minutes ° Approval of the budget that includes the OAC ° Finance committee minutes with OAC discussion noted ° Randomly select and review two donor cases and tie out the revenue to those two donor cases

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BUSINESS CONTINUITY STANDARDS

Reference #	STANDARD	INTERPRETIVE GUIDELINES
BC 1 - Emergency Plan		
BC 1	Business Continuity: The OPO shall develop a written Emergency Plan.	
BC 1.1	The OPO conducts an analysis to identify potential emergencies that could disrupt its services, the likelihood of those events occurring, and the consequences of those events.	OPO may utilize an all hazards approach to developing the plan and conducting a risk analysis, as recommended by CMS. Review analysis to determine if potential emergencies have been identified and prioritized as to likelihood of occurrence and event consequences.
BC 1.2	The OPO uses the analysis to define activities designed to reduce the risk of and damage from the emergency.	Determine if activities designed to reduce risk have been identified and implemented.
BC 1.3	The OPO uses the analysis to create an Emergency Plan which defines the procedures to follow when emergencies occur, how the OPO will communicate with staff, hospitals, and partner agencies, the actions to restore operations, and the individuals with authority to activate the plan.	Review Emergency Plan for: procedures to follow during emergencies, communication plan, procedures to restore operations, individuals with authority are identified.
BC 1.4	The OPO evaluates the effectiveness of its emergency management planning activities.	The OPO conducts at a minimum an annual review of its risks, hazards and potential emergencies. The OPO conducts an annual review of its Emergency Plan. The OPO performs annual desktop or other activities to test its Emergency Plan effectiveness.

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SAFETY STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
SS 1 - Exposure Control Plan		
SS 1	The employer is to develop a written exposure control plan	
SS 1.1		Identify tasks and procedures where exposure may occur
SS 1.2		Identify the job classifications whose duties include those tasks
SS 1.3		Procedure for evaluating the circumstances surrounding exposure incidents
SS 1.4		Documented consideration and implementation of appropriate commercially available and effective internal controls.
SS 1.5		Documentation that direct patient care employees' input was sought in evaluation and implementation of internal controls and standards of practice (safety committee, surveys informal groups, audits, pilot testing etc.)
SS 1.6		Exposure control plan clearly identifiable and available to employees.
SS 1.7		Documentation that the plan is reviewed and updated annually (review includes documentation of incorporation of new standards, new or modified tasks, new job classifications, newly available medical devices for prevention)
SS 1.8		Schedule for implementing sections of the standard covering the methods of compliance, hepatitis B vaccination, post-exposure follow-up, communication of hazards to employees, and record keeping

SS 1.9	The OPO will maintain a list of hazardous chemicals kept within the facility. Each hazardous chemical will have a Material Safety Data Sheet (MSDS) on file in a separate file.	Each hazardous chemical will have a Material Safety Data Sheet (MSDS) on file in a separate file. Assess the presence of hazardous chemicals requiring an MSDS sheet. Determine the location of MSDS file if hazardous chemicals are maintained within the facility. Offer website such as www.msds.com to OPO to ensure immediate access to required MSDS information to hazardous chemicals used in their facility. OSHA standards require a listing of hazardous chemicals and the presence of MSDS sheets within the facility.
SS 2 - Universal Precautions		
SS 2	Universal Precautions must be observed. Employer and employees are to assume that all human blood and specified body fluids are infectious for HIV, HBV, and other bloodborne pathogens.	
SS 2.1		Policy written requiring use of PPE in all cases.
SS 2.2		Is policy followed? (review needle stick logs, injury logs when employee information has been redacted)
SS 3 - Personal & Protective Equipment		
SS 3	PPE must be used if occupational exposure remains after instituting work practice controls, or if those controls are not feasible.	
SS 3.1		PPE are provided free to OPO staff. PPE exist in appropriate sizes and are accessible to staff. Hypo-allergenic product must be available for those with latex allergies/sensitivities. PPE must be laundered/cleaned by employer.
SS 3.2		Ask employee to demonstrate appropriate use of PPE. Ask employees going to hospitals about PPE. Employer investigates and documents every instance where appropriate PPE was not used. (Review Occurrence Reports) Policy exists and outlines the following precautions for safely handling and using PPE: • Removing PPE before leaving the work area and after a garment becomes contaminated • Placing used PPE in appropriately designated areas or containers when being stored, washed, decontaminated, or discarded • Wearing appropriate gloves when it can be reasonably anticipated that the employee

		may have contact with blood or other potentially infectious materials • Replacing gloves when torn, punctured, contaminated or when their integrity is compromised • Prohibiting washing or decontamination of disposable gloves for reuse • Wearing appropriate face and eye protection such as mask with glasses with solid side shields or a chin-length face shield when splashes, sprays, spatters, or droplets of blood or other potentially infectious materials pose a hazard to the eye, nose, or mouth • Wearing of gowns, aprons, caps, and boots when occupational exposure is anticipated. • Scrubs and lab coats are not meant to be PPE.
SS 4 - Internal Controls		
SS 4	Internal controls and standards of practice Internal and work practice controls are the primary methods used to prevent occupational transmission of HBV and HIV. PPE are necessary when occupational exposure to bloodborne pathogens remains even after instituting these controls.	
SS 4.1		Documentation that sufficient internal controls and standards of practice are used.
SS 4.2		Review injury reports (if employee information has been redacted).
SS 4.3		Review evaluation questionnaires, pilot studies, published data used in establishing Environmental Controls and Work Practices.
SS 4.4		Documentation that regular inspection occurs –inspection of face shield for cracks, are present etc.
SS 5 - Hand Washing Facilities		
SS 5.1		Staff has ready access to soap and tepid water
SS 5.2		Policy requiring employees to wash hands after gloves are removed exists?
SS 5.3		Policy requiring employees to wash hands after contact with blood or other potentially infectious materials exists?
SS 6 - Safety		
SS 6.1	Contaminated Sharps	Policy exists and states that shearing, breaking, bending, recapping and removal is expressly prohibited, and that any exception must be documented in writing along with the justification and supporting evidence that no feasible alternative existed
SS 6.2	Reusable Sharps	Containers exist for contaminated scalpels, saws etc. and they meet the same requirements as containers for disposable sharps, except they need not be closeable since they will be reused. Documentation of evaluation of these containers exists.
SS 6.3	Food & Drink	Policy exists and states that no food or drink is allowed in the clinical work area, and appropriate signage exists. Hand washing procedures are followed.

SS 6.4	Spraying, Splashing	If applicable, power tools, electro-cautery devices etc. should be evaluated for potential to contaminate employees or work surfaces. Appropriate PPE and clean up required.
SS 6.5	Labeling: A fluorescent orange or orange-red warning label is to be attached to containers of regulated waste, refrigerators and freezers containing blood and other potentially infectious materials, and to other containers used to store, transport, or ship blood or potentially infectious materials	All specimens must be properly labeled in transit from or to OPO. Containers must be evaluated for leakage, punctures.

SS 7 - Housekeeping		
SS 7	The employer must develop and implement a cleaning schedule that includes appropriate methods of decontamination and tasks or procedures to be performed. The written schedule must be based on the location within the facility, the type of surfaces to be cleaned, the type of contamination present, the tasks or procedures to be performed, and their location within the facility.	
SS 7.1	Policy	Policy exists and ensures that the following housekeeping procedures are followed: • Cleaning and decontamination of all equipment and environmental and work surfaces that have been contaminated with blood or other potentially infectious materials. (Inspect cleaning schedules in Dirty Room and Laboratory) • Work surfaces are decontaminated with appropriate disinfectant • Inspect and decontaminate on a regular basis, reusable receptacles such as pails, bins, cans, etc. • Use of mechanical device to pick up contaminated broken glassware and not hands even if gloves are worn • Storage of reusable sharps that ensures safe handling • Placement of regulated waste in closable and labeled containers that are also leakproof • Ensure that sharps containers are easily accessible to staff and located as close as is feasible to the immediate area where sharps are being used; sharps containers are kept upright throughout use, replaced routinely, closed when moved, and not allowed to overfill • Prohibits manually opening, emptying, or cleaning reusable contaminated sharps disposal containers • Contaminated laundry is handled as little as possible; PPE used when handling contaminated laundry; contaminated laundry is bagged at its location of use and placed in leak-proof containers prior to transporting
SS 7.2	Demonstration	Ask available staff to: • Demonstrate proper procedure for cleaning up contaminated broken glass. • Demonstrate proper procedure for cleaning up spill. • Demonstrate proper, safe decontamination of equipment, glassware etc.

SS 8 - Regulated Waste		
SS 8.1		Check for appropriate use of red bags, labels, documentation for disposal
SS 8.2		Check for appropriate sharps containers, lids, overfilling, color-coding, labeling, height, accessibility to staff.
SS 8.3		Ask available staff to: • Demonstrate proper disposal of sharps and sharps containers (close lid securely, check for leakage, dispose of in medical waste containers) • Demonstrate knowledge of double-bagging technique (assume red-bag leaked into garbage container) • Demonstrate proper disposal of PPE
SS 9 - Hepatitis B Vaccines		
SS 9	The employer must make the hepatitis B vaccine and vaccination series available to all employees who have occupational exposure as well as provide a post-exposure evaluation and follow-up to all employees who experience an exposure incident.	
SS 9.1		The offer for immunization series must be made prior to first potential exposure. If accepted, the first shot of the series must be completed prior to first potential exposure. Documentation must be found for either: a) first dose; or b) declination and proof of immunity.
SS 9.2		Verify that the vaccination and follow-up fall within CDC guidelines
SS 9.3		Verify presence of signed declinations. Does declination document meet guidelines?
SS 9.4		Verify that a post-exposure incident plan is in place and that it assures immediate and confidential evaluation, prophylaxis and follow-up.
SS 9.5		Verify that Exposure Incident reports and P&P meet standard.
SS 9.6		Verify Needlestick Injury Log
SS 9.7		Verify OSHA Form 300A, “Summary of Work-Related Injuries and Illnesses,” is reporting annually through internal posting in the organization and externally through the OSHA approved electronic web-based Injury Tracking Application (ITA). (Reference: Final Rule 1904.41)

SS 10 - Recording Keeping		
SS 10.1	Employer must preserve and maintain for each employee an accurate record of occupational exposure according to OSHA's rule governing access to employee's exposure and medical records.	Under the bloodborne pathogens standard, medical records must include the following information: • Employee name and social security number • Employee's hepatitis B vaccination status including vaccination dates and any medical records related to the employee's ability to receive vaccinations • Results of examinations, medical testing, and post-exposure evaluation and follow-up procedures • Health care professional's written opinions • Copies of information provided to health care professionals
SS 10.2		Assure that all staff medical records are in a file separate from employee files.
SS 10.3		Assure that medical records are being kept confidential and are maintained for at least the duration of employment plus 30 years. When HR and Medical Records are supported by the same electronic system, it is acceptable if an electronic audit trail can be verified to document secure authorization to access records.
SS 10.4		Check that autoclave logs are properly filled out. Date, time, operator, temp. sensitive tape results, dates and results of calibrations, results of routine spore testing.
SS 11 - Archiving Serum Tissue Samples		
SS 11.1	The OPO shall assure that appropriate tissue samples (for example, if using sera or plasma, it should be pre-transfusion or other hemopoietic tissue) sera or plasma remaining from every recovered donor shall be archived for a period of at least 10 years after the date of recovery. This serum must be available for use for retrospective testing.	Check for policy defining the need to archive specimens and ask for documentation. Documentation may require a visit to lab or written reports from lab/agency that OPO has relationship with for archiving. There must be a unique identifier that correlates to OPO donor identification. The surveyor will identify dates of policy and date of standard and assure that since that date all specimen have been archived. If there is not sufficient quantity of sera or plasma to archive, this must be documented in the OPO's inventory of the archived specimens.
SS 12 - Refrigerator Storage		
SS 12.1	The OPO shall maintain a log of temperature records for supplies requiring temperature-controlled storage and show evidence of training of the appropriate personnel for this purpose.	Check for adequately maintained logs of refrigerator temperature monitoring. Assure that staff are trained on how to monitor and respond in the event that alarms or desired temperature limits are exceeded.

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CLINICAL STANDARDS		
REFERENCE #	**STANDARD**	**INTERPRETIVE GUIDELINES**
CL 1 - Response to Referrals		
CL 1	The Organ Procurement Organization shall have policies and procedures to respond to referrals of potential donors in a prompt, professional and standardized manner. This applies to all personnel, including donor coordination staff, surgical recovery team members.	
CL 1.1	The OPO response to referrals will be consistent with triggers established with the donor hospitals for referral. The OPO shall document prompt and efficient response to the referral. This will include establishing procedures to direct the Coordinator in handling the referral of a potential donor.	Assess for a written policy regarding donor referral response. Ask coordinator to verbally outline the OPO's policy and how it is implemented in practice. Surveyor will compare response time to clinical triggers used by OPO and donor hospital.
CL 1.2	Donor record has date and time of referral.	On donor record, assure the referral date and time are recorded.
CL 1.3	The OPO shall document availability of trained personnel at all times to receive all referrals of potential donors and adequately coordinate full organ donor cases.	Evaluate a published call schedule for each year being reviewed that denotes clinical staff on call. Schedule should provide adequate daily coverage for organ recovery.
CL 1.4	The OPO shall comply with OPTN requirements for referral documentation.	Presence of a systematic mechanism to assess donor referral information in compliance with OPTN requirements.
CL 2 - Verification of Death		
CL 2	The OPO shall assure that death has been legally determined and documented in the donor's medical record.	
CL 2.1	The OPO shall adhere to all local and/or state statutes.	Request documentation of state/federal laws related to organ donation; ask for evidence that information on these laws is included in coordinator training; quiz employees on above information.

CL 2.2 **Links to Essential Standard 4**	The OPO policy shall ensure that the determination and documentation of death is verified and recorded in the donor's hospital medical record.	Assess presence/content of policy regarding documentation of death; check for proper documentation of death in donor record. The pronouncement must be compliant with legal requirements and should be compliant with hospital policy. If the pronouncement meets legal requirements but does not meet hospital policy requirements, the OPO must have a process in place to notify OPO's administration and hospital administration of the variation from policy. In donor record, assure that date/time/cause/mechanism match DDR.
CL 3 - Authorization for Donation		
CL 3	OPO personnel shall ensure that authorization for donation is obtained in compliance with the OPO's policies regarding authorization.	Site surveyor should examine OPO policy and definition on authorization, and interview staff for compliance.
CL 3.1	The OPO shall comply with applicable state or local laws for facilitating first person authorization	The OPO recognizes/acts on first person authorization as permission for donation consistent with state laws in which the DSA operates. Verify that the OPO accessed donor registry for all donors. OPO policy must define its process and communication plan to handle opposition to first person authorization if it occurs. These cases should be well documented. Assess state law for applicability to research and/or DCD.
CL 3.2 **Links to Essential Standard 3**	Documentation of Authorization: The OPO shall ensure that authorization for organ and/or tissue donation is documented on an authorization form, disclosure form, registry form or legal document of gift that meets both hospital policies and the legal requirements of the jurisdiction in which authorization is being obtained. The OPO has a policy that specifies where the documentation is filed.	Review correlation between authorization process in comparison to local hospitals and/or state requirements. Look for evidence of • Disclosure form • Authorization form • State registry form Quiz coordinators as to proper distribution of original authorization or donor designation form and subsequent copies (hospital, OPO chart, ME, tissue banks, etc.). Look for a policy outlining the process for obtaining written authorization vs. utilization of a donor registry, if applicable. In donor record, assure applicable authorization documents are present (ex. authorization form, disclosure form or document of gift documentation).
CL 3.3	OPO shall have a defined effective request process and that process is standardized.	Through interview and policy assessment, surveyor will be able to identify the OPO's request process and assess how it is followed.

CL 3.3.1	The OPO shall assess the availability of staff, services, and volunteers and seek to ensure effective primary language communication and educational support to substantially sized and distinct linguistic, racial, and cultural communities, as determined by the OPO.	Interview staff and identify staffing or contracted or routinely available services to provide professional-level, primary language communications with potential donor families as needed to meet defined populations and actual language needs of approached potential donor families. TRAINING - Seek evidence of educational activities to assist staff in ensuring sensitivity to racial and cultural needs of defined populations and including training in means to overcome common racially based barriers to donation. What to look for and how to find it: • Interview - how do you handle donation conversations when there is a language or cultural barrier? • Training-look for elements of training/presentations on racial/ethnic/cultural needs to overcoming barriers to donation. Training checklist and competency evaluation • Availability of data on potential donor population related to racial and ethnic groups (defined population in the IG) • Availability of data on authorization rates. Performance improvement plans related to data below benchmarks. (effective primary language communication in the standard)
CL 3.4 **Links to Essential Standard 3**	Authorization form for organ donation lists specific organs for which authorization for removal is being given.	Review authorization form to determine that either: • Each specific organ and tissue is named and properly identified as to whether authorization has been given or denied to recover that specific organ or tissue; or • An opportunity is provided for the family to either: 1. Selectively grant or deny authorization to recover any specific organ or tissue; or 2. Indicate authorization for any needed organ or tissue; or 3. A combination of 1 and 2 above • Look for policy outlining what constitutes authorization for the OPO.
CL 3.5	The OPO shall have a policy and procedure for medical examiner/coroner contact.	Assess local guidelines for what is reportable to ME/coroner; check to see if there is a log. Review donor record to assure ME/Coroner contact was made as needed.
CL 4A - Evaluation & Management (Donor)		
CL 4A	Guidelines for Evaluation and Management of Potential Deceased Organ Donors Evaluation and management of donors shall meet the OPTN standards and requirements in effect at the time of the donor recovery.	Request written documentation on policy making. The OPO's organ donor evaluation and management policies and procedures must be reviewed at set intervals and exhibit written approval by the OPO Medical Director and/or the OPO Medical Advisory Committee (or its equivalent). Look for minutes of committee meetings, or written policy documents evidencing approval.
CL 4A.1	The OPO's organ donor evaluation and management policies and procedures must exhibit written approval by the OPO Medical Director or the OPO Medical Advisory Committee (or its equivalent).	

CL 4A.2	These procedures are to be undertaken with medical supervision and support as necessary.	
CL 4A.3	OPO personnel will have documented training regarding donor evaluation and management that includes training to obtain a medical and social history.	
CL 4A.4	Once the patient has been declared dead, or death is imminent, and authorization for donation has been obtained, the OPO should implement the guidelines for the evaluation and management of the potential organ donor.	
CL 4B - Donor Evaluation		
CL 4B	The evaluation of the donor shall include:	Request documentation on written policies regarding the acquisition of outlined information; All charts contain a medical and social history form that satisfies the USDHHS/CDC Guidelines; An inquiry designed to gain insight into the donor's medical behavioral and sexual history shall be conducted with the potential donor's next of kin, significant life partner and/or other appropriate individuals utilizing a standardized history questionnaire. *(PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation," (Public Health Reports: Vol. 128, pp 247-304, July-August 2013);* Review of a current chest x-ray for the purpose of ruling out metastatic pulmonary lesions. Provides additional requirement to ensure clinical safety of the potential transplant.
CL 4B.1	An inquiry designed to gain insight into the donor's medical, behavioral, and sexual history shall be conducted with the potential donor's next of kin, significant life partner and/or other appropriate individuals utilizing a standardized history questionnaire. (PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation," *(Public Health Reports: Vol. 128, pp 247-304, July-August 2013).*	In donor record, assure that the DRAI is complete. If the DRAI cannot be completed because a potential donor's next of kin, significant life partner and/or other appropriate individual is not available to provide a reliable medical history, then the donor must be identified as increased risk.
CL 4B.2	Documented physical examination	

CL 4B.3	Documentation of ABO group (and subgroup, if applicable), weight and height. Blood group subtyping of ABO-A donors (reference current UNOS/OPTN policy)	ABO testing and subtyping, if applicable, must in accordance with OPTN policy. Each OPO shall establish and implement a procedure for two individuals to verify the accuracy of the initial and second determination subtyping test results by utilizing both ABO subtyping source documents and document that this process has taken place.
CL 4B.4	Documentation of significant events in the clinical course. The current hospital history shall include:	
CL 4B.5	Description of injuries and treatments (e.g., surgeries)	
CL 4B.5.1	Completed hemodilution form	In donor record, look for a completed plasma/hemodilution documentation.
CL 4C - Donor Management Medications		
CL 4C.1	The OPO shall ensure that optimal respiratory, hemodynamic and electrolyte management of the donor is provided. The donor file shall include the donor's hemodynamic status.	The donor file shall include the donor's hemodynamic status includes: • All medications within 24 hours of cross clamp • Use of vasopressors, type, amount, duration, and response
CL 4D - Testing and Reporting		
CL 4D	The OPO shall ensure that proper antibiotic coverage, infectious disease testing, and tissue typing is conducted.	Request documentation on agreements with tissue typing laboratories: • Assess responsibilities of each party (OPO and tissue typing lab) as outlined by agreement • Assess approval status of HLA lab(s) by UNOS • Quiz coordinator staff on practices involved in the supply of tissue to lab.
CL 4D.1	The OPO shall evaluate the infectious disease status of the potential donor. Serological testing should be noted to be either pre or post transfusion. OPO Medical Director and/or the OPO Medical Advisory Committee (or its equivalent) establish policies in conformance with Federal and State law regarding notification of positive (confirmed) donor test results to hospital staff and family. Communication regarding test results shall be documented in the donor medical record.	Review state laws for the OPO regarding the reporting of serologic tests. Current standards do not provide a strongly worded requirement for notification of any positive infectious disease testing on the donor. This standard will cause the OPO to develop a specific policy and procedure for handling positive test results.
CL 4D.1.1 **Links to Essential Standard 5**	Serological testing according to current UNOS/OPTN policies and/or procedures	Must test and report per OPTN policies: Policy 2.9 (Required Deceased Donor Infectious Disease Testing; 2.9.3.)
CL 4D.1.2	Urine cultures	Cultures completed and reported as per OPTN guidelines.
CL 4D.1.3	Blood cultures	Cultures completed and reported as per OPTN guidelines.

CL 4D.2	For those organ systems for which the OPO assumes responsibility for tissue typing, the OPO must have arrangements for tissue typing and must ensure that tissue typing is performed, by an affiliated, OPTN approved histocompatibility laboratory and tissue typing material is provided to said laboratory for testing. (Ref. UNOS Bylaws, Attachment 2-4, Appendix B.)	
CL 4D.3	Documentation of communication in a timely fashion with the transplant center(s) of test results inclusive of but not limited to positive cultures, serological tests, and biopsy results. Unless otherwise directed by state or local regulations, the donor's next of kin or a physician who will counsel the next of kin shall be notified of any confirmed positive serological test results that may be medically relevant as determined by the OPO Medical Director. All other transplant and/or research organizations involved with the donor shall be notified of any positive confirmed test results in a timely manner.	Testing must be done and evidence of reporting of any positive test results as per OPTN requirements.
CL 4E - Evaluation of Organs		
CL 4E	The OPO shall ensure the evaluation of all medically suitable transplantable organ systems. Such evaluation shall include (if obtainable), but not be limited to:	Documentation of required organ evaluation testing must be maintained as part of donor record. If additional organ evaluation testing is performed that documentation must also be maintained as part of the donor record.
CL 4E.1	**All Donors:** • Chest x-ray • CBC • Electrolytes • Serum glucose • Urinalysis, within 24 hours of cross clamp	

CL 4E.2	**Kidney Evaluation:** Required: • Anatomical description, including number of blood vessels, ureters, and approximate length of each • HLA information as outlined in OPTN policy • Injuries to or abnormalities of blood vessels, ureters, or kidney • Kidney laterality If Performed: • Biopsy results • Kidney perfusion information	
CL 4E.3	**Liver Evaluation:** Required: Lab tests within 12 hours of the offer: • ALT/AST • Alkaline phosphatase • Total and direct bilirubin • INR or PT if INR not available • PTT If Performed: • Pre-procurement biopsy results • Pre-procurement CT imagining results • HLA information, as outlined by OPTN policy, if requested by the transplant center	
CL 4E.4	**Heart Evaluation:** Required: • ABG results and ventilator settings • Echocardiogram If Performed: • 12-lead electrocardiogram interpretation • HLA information, as outlined by OPTN policy, if requested by the transplant center • Central Venous Pressures • Swan Ganz measurements • Coronary angiography	

CL 4E.5	**Lung Evaluation:** Required: • ABG results and ventilator settings on 5cm/H2O/PEEP including PO2/FiO2 ratio and preferably 100% FiO2 within 2 hours prior to offer • Chest x-ray interpreted by a radiologist or qualified physician within 3 hours prior to the offer • Sputum gram stain, with description of sputum • Lung laterality If Requested or Performed: • Bronchoscopy results • HLA information, as outlined by OPTN policy, if requested by the transplant center	
CL 4E.6	**Pancreas Evaluation:** Required: • Family history of diabetes (including Type 1 and 2) • HLA information as outlined by OPTN policy • Insulin protocol • Serum amylase and lipase If Requested or Performed: • Hemoglobin A1C	
CL 5 - Allocation of Donated Organs		
CL 5	Organs shall be allocated according to the standards of the Organ Procurement and Transplantation Network (OPTN) and in keeping with approved local variances.	
CL 5.1	The OPO shall document that the OPTN computer was accessed for a donor/recipient match run on every donor organ procured by the OPO.	Assess that the match run in UNet was utilized for allocation of organs; this is done by accessing the printout in the OPO donor chart or asking the OPO staff to access UNet for verification. Assure that recipient information in donor record and DonorNet/TEIDI and Match Run are the same. Assure that recipient information in donor record DDR in TIEDI are the same. Assess UNOS donor registration forms are correctly completed and filed in a timely manner. Ask for UNET compliance report.

CL 6 - Operating Room Procedure		
CL 6	The OPO shall have standards to facilitate and coordinate the recovery of donated organs.	
CL 6.1	The OPO shall ensure that any surgeons working as consultants to the OPO for the recovery of donated organs (i.e., surgeons whose fees are paid by the OPO) meet qualifications and standards as set by the OPO Medical Director and/or its Medical Advisory Committee or its equivalent.	The OPO should have an established Code of Conduct describing what professional behavior is. An example is the AOPO Code of Conduct, developed by the Medical Directors' Council. Assess OPO's methodology for ensuring that all surgeons meet qualification criteria.
CL 6.2	The OPO must have protocols in place for quick verification of the credentialing and/or qualifications and training of recovery personnel prior to any recovery. Documentation of the verification must remain on file and confirm that verification was done before recovery.	Assess the OPO's methodology for maintaining the credentialing, and/or qualifications and training documentation. The OPO must conduct an annual review of licensure and must use AOPO's ACIN database or some other documentation method, for surgeons outside the OPO's service area.
CL 6.3	The OPO shall have a mechanism to review and document the surgical recovery of organs, addressing adherence to standards and technical performance of the surgeons providing consulting services to the OPO.	Assess mechanism by which Medical Director reviews standards and technical quality of recovery surgeons. Issues such as surgical errors and inappropriate conduct are addressed, documented and reported by the Medical Director of their designee to the OPO.
CL 6.4	The OPO is responsible for coordinating anesthesia support for the organ recovery process. The OPO shall document the provision of information/guidelines to anesthesia for the intra-operative procedure. The goal of this intra-operative support includes:	Do OPO personnel provide anesthesia with information on the following guidelines:
CL 6.4.1	Maintaining an adequate blood pressure, fluid volume, organ perfusion and function.	Acceptable parameters for BP, CVP, organ profusion and function per OPO policy.
CL 6.4.2	Oxygenation of the organs being recovered is documented.	Acceptable oxygenation parameters per OPO policy
CL 6.4.3	Intake and Output	Acceptable parameters for fluid replacement per OPO policy FROM CL 11.1: The OPO shall document volume intake - type (Crystalloid, colloid, blood and blood products) and amount - for a minimum of 8 hours prior to recovery and for the duration of the recovery period. FROM CL 11.3: The OPO shall document urine output for a minimum of 8 hours prior, if possible, to recovery and for the duration of the operative period. FROM CL 11.4: Any periods of oliguria, anuria, or the occurrence of diabetes insipidus (and its treatment) shall be documented.

CL 6.4.4	All medications given in OR: Administration of required and/or desirable medications inclusive of inotropic meds used at time of cross clamp to facilitate organ recovery and function.	Acceptable parameters for pharmacological Intervention per OPO policy, assure all medications given in the OR are documented in donor record as per OPTN policy.
CL 6.5	The OPO is responsible for packaging and labeling organs, tissue typing material and blood, according to OPTN standards and OSHA regulations.	Assess written policy for compliance with UNOS standard. Interview members of coordinator staff regarding packaging procedures. If the OPO utilizes Transnet, verify that written policies for utilization of the system and tracking and reporting of hardware/software issues exist, as well as a contingency plan when units and/or system are not available. If TransNet is not utilized for verification, must have SOP providing for verification of all labeling and packaging. Look for that documentation, such as a labeling/packaging checklist; verification form, etc.
CL 6.6	The OPO is responsible for distributing the following documentation to each transplant team at the time of recovery of an organ from an individual donor:	Assess written policy to determine compliance with information sharing/documentation requirements. Policy should require OPO to provide the following to each transplant team:
CL 6.6.1	Verification of donor ABO type/sub-type if applicable.	Per UNOS Policy, • Assess for a written policy that details this verification process and includes definitions for the unique identifier, acceptable resources and qualified health care professional. • The chart must include documentation of the OPO's verification of the donor ID; donor blood type and subtype (if used for allocation), and organ type (with laterality, if applicable) to be recovered on all deceased donors before incision. A qualified health care professional from the OPO and the recovering surgeon must complete this verification. • When the intended recipient is known, the OPO must verify the intended recipient's unique identifier, intended recipient's blood type, and that the donor and intended recipient are blood type compatible or intended incompatible. Two qualified health care professionals, one of whom must be an OPO staff member, must conduct this verification. • OPOs must use acceptable sources, as defined in the policies, to verify each data element.
CL 6.6.2	Copy of infectious disease testing results available at time of packaging from the donor's medical record.	
CL 6.7	The OPO assures that an operative procedure note is provided by the recovery surgeon for the donor's hospital medical record and OPO record.	Check for copy of operative procedure note. Assess written policy and procedure for compliance with this standard.

CL 6.8	The donor file shall document the events surrounding the surgical removal of all organs, including the following intraoperative information:	
CL 6.8.1	Blood products administered, type, amount	
CL 6.8.2	Type and amount of flush solutions and flush characteristics	
CL 6.8.3	Warm ischemia time	
CL 6.8.4	Type of storage solution	
CL 6.8.5	Type of recovery procedure; e.g., kidneys – *en bloc*, in situ flush	
CL 6.8.6	Aortic cross-clamp time and date	
CL 6.8.7	Description of typing material available	
CL 6.8.8	Anatomical description	
CL 6.8.8.1	Kidneys – (unless *en bloc*) include number of vessels and approximate length and diameter of each. Include biopsy results if done.	Biopsy performed and results attached to donor record. Biopsy results and anatomy match DDR.
CL 6.8.8.2	Extra-renals – include a description of any injuries or abnormalities, biopsies.	Biopsy performed and results attached to donor record.
CL 6.8.9	Organs retrieved and disposition	Final disposition must be coded per OPTN guidelines and match DDR.
CL 7 - Communication of Past Medical History, Risk Factors and Disease Transmission		
CL 7.1	The OPO documents that the potential recipient center(s) and tissue banks are informed in a timely basis of the donor's risk assessment, including increased risk factors as defined by the PHS, which are present in the donor or donor organ(s).	Look for documentation in the donor files and DonorNet that the donor's risk assessment has been timely communicated to all recipient centers. Look for policy statements requiring this action.
CL 7.2	Suspected donor derived diseases (infection or malignancies) must be reported to the OPTN as per the OPTN policy.	The surveyor looks for evidence of meeting this standard through a policy on sharing donor information, documentation that information was shared in a timely manner with all parties who have received an organ or a tissue from a donor in which a suspected disease transmission has occurred. The surveyor also asks to review a patient safety report or documentation of the reporting to transplant centers, tissue banks, and OPTN. Surveyor should ask to speak to the designated OPTN safety liaison. The OPO must have a designated OPTN safety liaison.

CL 8 - Donor File		
CL 8	The OPO shall compile the following information on each donor:	Look for a policy statement that meets the requirement. Determine if any state law adds further retention requirements. Ask to see or visit area where records are kept to ascertain that the minimum retention requirement is being met.
CL 8.1	The OPO shall compile the following information on each donor:	
CL8.1.1	Name	
CL 8.1.2	Age, sex, race, ABO and HLA if kidneys are recovered	
CL 8.1.3	Cause of death	Surveyor should confirm mechanism and circumstances of death are documented.
CL 8.1.4	Time and date of hospital referral	
CL 8.1.5	Time and date of pronouncement of death	
CL8.1.6	OPTN ID number	
CL 8.1.7	Time and date authorization obtained for organ donation.	Look for written documentation of intent to be a donor.
CL 8.2	The OPO shall document the following information for purposes of follow-up:	
CL 8.2.1	Name and address of the legal next-of-kin and relationship (or person with legal authority to give authorization)	
CL 8.2.2	Name of attending and consulting physicians	
CL 8.2.3	Name of medical examiner or coroner as applicable	
CL 9 - Documentation of Recipient Information		
CL 9	The donor file shall document recipient information prescribed by OPTN guidelines, in effect at the time of the donation.	The surveyor shall ask the OPO to demonstrate their process to confirm data entered in match run by such means as TIEDI or transplant center follow up reports.
CL 9.1	The following information shall be documented on each recipient:	
CL 9.1.1	Name	Must match the OPTN information on the DDR within TIEDI
CL 9.1.2	Recipient Center	Must match the OPTN information on the DDR within TIEDI

CL 10 - Machine Perfusion		
CL 10	OPO's that utilize machine reservation for recovered organs must define the appropriate use of this methodology, document its utilization, and establish appropriate policies and procedures for its use.	When the OPO uses machine perfusion for any organ, the OPO shall have a completed perfusion record within the donor record.
CL 10.1	The OPO has a written policy specifying the criteria by which organs should be placed on machine perfusion.	There may be a variety of practices used by OPOs for machine perfusion. The following definitions apply for assessing compliance with CL10: a) Internal Perfusion--The OPO manages all aspects of organ perfusion, supplies, equipment checks, staff training and monitoring. When this is OPO practice the OPO must comply with all elements in CL 10 for each organ type on which it uses machine perfusion. b) Contracted Services—The OPO has a formal contract with a service provider to machine preserve organs as per an OPO policy. The organ in this scenario remains in the custody of the OPO for placement and transportation. In this arrangement the assessment for compliance must include a written agreement that satisfies all components of CL 10, and an annual audit of the contracted provider that includes all elements in CL 10, plus an assessment that staff are trained. If the contracted provider is another accredited OPO, the host/local OPO needs to show a written agreement. The surveyor can verify with AOPO that the contracted OPO is currently accredited and compliant with CL10. c) Perfusion by Transplant Center—The organ is allocated to a Transplant Center who chooses to place organ on machine perfusion. The OPO is not responsible for assuring compliance to the elements in CL 10.
CL 10.2	OPO policy specifies where (donor hospital, transplant center, OPO) organs are placed on a perfusion machine pump or repackaged. If OPO SOP allows for the placement on organs on pumps or the repackaging of organs on the OPO premises the OPO must assure that the area and practice maintains sterility of the organ.	Check SOP and area where repackaging of organs, organ placement on machine perfusion, and where organs on machine perfusion are maintained, for being a controlled environment and that staff use proper aseptic technique. Assure that the area is a controlled environment that will assure the sterility of the organ in a designated area with controlled access. The use of appropriate PPE and sterile instrumentation should be utilized. Access cleaning logs for this area as another way to ascertain cleanliness, sterility. For OPOs that contract with outside agencies, surveyors need to see the area in person, or do a virtual tour, to assure the standard is met.
CL 10.3	OPO staff that monitor or administer to organs on machine perfusion have documentation of appropriate training for this activity.	Determine, through interview or document review, which employees provide machine perfusion. Examine personnel folders or training records of those employees for proper documentation of having completed training.

CL 10.4	Quality control checks are conducted on each perfusion machine in a time frame defined by the OPO, and which meet the manufacturer's requirements or instructions for its use.	Ask personnel for quality control checks performed on each perfusion machine utilized by the OPO. Ask for a copy of the manufacturer's instructions regarding minimum requirements for quality control checks, visual inspection, and documentation of cleaning after each use. Since the manufacturer's instructions may be minimal, look for compliance with at least those items named in the policy. Determine through OPO policy how malfunctions or problem solving occurs. Determine through interviews if the policy is followed. Determine what type of perfusion equipment is utilized, and if there are internal quality control checks; if there are not internal quality control checks, ask for evidence of how quality control is maintained.
CL 10.5	The OPO shall document in the donor file, and report to the receiving center, information regarding machine readings when pulsatile machine perfusion is used for any organ. Information documented and reported shall include at least the following:	Conduct chart review of those donors who meet the OPO policy definition requiring machine pulsatile perfusion. Review charts and score for inclusion of required information. If Donation after Cardiac Death is performed, pull specific charts to verify perfusion, if applicable. Confirm that perfusion record/parameters are on the AOPO form or attached to the donor record.
CL 10.5.1	Date and time when an organ is initially placed onto machine perfusion.	
CL 10.5.2	Initial perfusate flow and pressure and temperature	
CL 10.5.3	Subsequent date and time recordings of perfusion parameters at regular intervals, and at least each four hours.	
CL 10.5.4	Date and time when an organ is removed from machine perfusion.	
CL 10.5 5	Final perfusate flow and pressure and temperature when organ is removed from machine.	
CL 10.5.6	Name(s) of person(s) recording information in 4.1 through 4.5 above.	
CL 01.5.7	UNOS ID number on the perfusion record.	
CL 10.5.8	Type of perfusate used, and any additives or medications added to solution during perfusion.	
CL 10.5.9	Recorded lot number of cassettes with expiration date.	
CL 10.5.10	Recorded lot number of perfusate with expiration date.	

CL 10.6	The OPO shall have a policy to monitor organs while being perfused. The policy must state who is responsible, what is expected should there be an alarm or pump failure and how to document and communicate with receiving centers.	Look for policy and then documentation in perfusion records that all procedures as described in policy were followed and documented. If perfusion is done with an electronic alarm system, ask for demonstration and interview responsible staff as to what their response would be to an alarm. If the system used does not have an electronic alarm system must assure that kidneys are monitored at least hourly. If system has redundant hypothermic systems an alarm response may be delayed but time needs to be specified in policy. If system does not have redundant hypothermic capability the policy must provide for a response within an hour of failure.
CL 11 - OPO DCD Policy		
CL 11.1	OPO must have a DCD policy in order to facilitate organ donation after cardiac death (DCD).	Policy should include • Provision for OR or alternate recovery site extubation • Certification of death using standardized, objective, and auditable criteria that follow state law • Provision for patient care if the patient does not progress to asystole in acceptable time frame (e.g., families are told that donation may not be possible. If donation cannot occur, a plan is in place to return the patient to pre-determined unit or floor under the care of attending MD.) • Conflict of interest provision
CL 11.2	DCD policy should include statement about pronouncement of death.	Death cannot be pronounced, nor orders for sedation ordered, by a member of the procurement or transplant team. Policy should include observation of pulselessness, apnea and unresponsiveness for > 2 minutes but not more than 5 minutes CMS Resource Guidance: A. Interpretive Guidelines §486.344(f)(5) The OPO staff cannot make a death pronouncement. The person making the declaration must be a person authorized to do so by the donor hospital and applicable State laws… The OPO must have written protocols that discuss the wait time between declaration and the beginning of recovery (consistent with current expert recommendations). B. Interpretive Guidelines §486.344(f)(2) Once authorization [informed donation consent] is obtained, the OPO should work in collaboration with the donor hospital staff to prepare the family for withdrawal of support and honor the family's desire to be included as much as possible consistent with hospital policies and protocols. The OPO must have written protocols for its collaboration with the donor hospital staff regarding withdrawal of life support including clear directives as to the responsibilities of the donor hospital staff and the OPO staff in the period of time between extubation and declaration of death. The protocol should

		state that all recovery personnel (surgeons and other recovery practitioners) are prohibited from entering the operating room until declaration of death. OPO personnel may be in the operating room prior to the actual recovery pursuant to OPTN policy 2.3 which requires that they maintain complete information on any and all organs recovered. The OPO should have written policies consistent with current standards of practice regarding the length of time that must pass from declaration of death and the beginning of recovery.
CL 11.3	OPO must show evidence of a plan to facilitate DCD in their DSA.	Look at hospital agreements and verify there is a formal agreement of DCD plan. Plans should include: • Assessment of DCD potential • Introduction of DCD in selected hospitals • Education plans for OPO staff and hospital staff re: DCD.
CL 12 - DDR and Donor Record Match		
CL 12	DDR and Donor Record Match	Ensure that each field in the DDR matches the same field in the donor record.
CL 12.1	Date and time of withdrawal of support	
CL 12.2	Controlled yes of no	
CL 12.3	Date and time agonal phase begins (SBP<80 or O2 sat <80% for adult DCD donors)	
CL 12.4	Total urine output	
CL 12.5	Log including BP, HR. O2 sat, every 5 minutes until agonal phase then every 1 minute until asystole	
CL 12.6	Core cooling documented	If core cooling is used, the type of fluid, amount and temperature are recorded in donor record.

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DONOR FAMILY SERVICES STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
DO 1 - Donor Family Services		
DO 1	The OPO shall offer to all organ donor families a comprehensive, time sequenced program of information and follow-up or organ donation. Unless the family has asked to receive no further information following donation, or is lost to follow-up, the OPO shall offer post donation follow-up support to all donor families consisting of written materials and/or regularly scheduled activities such as: bereavement support services, groups or referrals to services, bereavement literature, donor family recognition ceremony, etc.	Follow-up services shall be offered to all donor families who have authorized donation or families of designated donors which may include the following: 1) Authorized Not Recovered (when the donor was determined to be ineligible and recovery did not occur) 2) Recovered Not Transplanted (Recovery occurred but determined ineligible for transplant/use). Look for evidence that donor families are offered follow-up bereavement information or contacts. The exact form and frequency of this follow-up information is at the discretion of each OPO. Some variability is expected. If the OPO does not maintain copies of each timed sequenced letter in the donor record, look for evidence of a system used that can substantiate this activity. These could include a template used, desk procedures outlining this requirement, or staff interviews which can substantiate this activity.
DO 1.1	Unless the family has asked to receive no further information following donation or is lost to follow-up, the OPO shall have a policy outlining a structured program of donor family follow-up, and which includes a specific number of contacts made by the OPO with the donor family within the first twelve months following donation.	Look for a written policy which fulfills the requirement. This policy should detail how to document if the family is unwilling to participate, has changed their mind about participating in follow-up, or if the family is lost to follow-up.
DO 1.2	Unless the family has asked to receive no further information following donation or is lost to follow-up, the OPO shall provide a written thank you letter to each donor family within the first six weeks following donation. The letter shall include information about what was recovered, and general demographic information about each of the recipients when available.	Within the sample of donor records reviewed, look for documentation in the OPO records of a copy of the letter sent, including to whom the letter was sent, and the date when it was sent. Ascertain that the six-week timeframe is met.

DO 1.3	The OPO shall have a policy regarding facilitation of correspondence and/or contact between donor families and recipients.	Look for a written policy which fulfills the requirement. This policy should detail how to facilitate and document any correspondence and/or contact between donor families and recipients. Within the sample of donor records reviewed, there may also be documentation of letters sent to and from the donor family and the recipients. These letters may be contained in the donor file itself or may be filed in a separate location.
DO 1.4	The OPO shall measure the effectiveness of the donor family care program and make revisions when appropriate.	Related to measuring the effectiveness of donor family care programs, look for documentation that an assessment of donor family follow-up care is conducted. This may be in the form of a donor family survey that is distributed on a regular basis to all or a representative sample of the OPO's donor families. Survey questions should address the families' experience with bereavement and follow-up care. Other means of acceptable assessment may include but are not limited to donor family advisory councils, periodic telephone contact or any means by which donor family feedback is provided. To measure the effectiveness of donor family care programs, look for evidence of initiatives or revisions to the OPO's donor family follow-up program which were undertaken as a result of donor family feedback.
DO 1.5	The OPO shall permit information exchange between donor family members and recipients, if mutual agreement is obtained.	Assess the OPO's policy regarding the exchange of information between donor family members and recipients. Determine method by which mutual agreement for the exchange of information is obtained.

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HOSPITAL DEVELOPMENT STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
HD 1 - Potential Donor Assessment		
HD 1	The OPO shall have documentation of its ability to assess donor potential in compliance with CMS rule regarding death record reviews (DRRs).	
HD 1.1	A written policy exists to define the OPO's death record review process. The OPO policy must address the following:	Look for evidence that the policy contains elements listed in HD 1.2 – 1.9.
HD 1.2	DRRs must be conducted in every Medicare and Medicaid participating hospital in its designated service area that has a Level 1 or Level 2 trauma center or hospitals with 150 or more beds, a ventilator and an intensive care unit. All other hospital DRR review processes are to be determined by the OPO, including defining organ donation potential for the DSA.	Look for evidence that the OPO complies with the CMS criteria through a random sampling of Level 1 or Level 2 trauma centers or hospitals with 150 or more beds, a ventilator and an intensive care unit, including frequency of DRR. Look for evidence that the OPO conducts reviews as outlined in the OPO policy in hospitals not meeting CMS criteria. The goal of the DRR process is to identify additional opportunities for organ donation. Look for evidence that the OPO possesses a broader definition than the national eligible definition for organ donation potential. This DRR process includes donation after circulatory death as well as brain death.
HD 1.3	Outlines what information is collected to provide continuity of reviews and effectively identifies missed referral opportunities.	Review the OPO tool for evidence that information is collected as stated in the OPO's policy.
HD 1.4	Which individual(s) is responsible for conducting DRR reviews?	Evidence that staff designated to conduct reviews is consistent with the OPO's policy.
HD 1.5	How recommendations are reported and followed up with the hospital.	Evidence of reporting to the hospital can include but is not limited to the following types of documentation: dashboards, emails, minutes from meetings, agendas and other correspondence.
HD 1.6	Submission to the OPO's QAPI Committee and governing board.	Look for evidence that DRR outcomes are reported to the OPO's QAPI committee and governing board in compliance with the OPO's policy.
HD 1.7	How corrective actions are tracked for compliance.	Look for evidence of how corrective actions are tracked for compliance through OPO dashboards, hospital dashboards, service plans or other documentation.
HD 1.8	How a periodic internal quality review is conducted by the OPO.	The surveyor will verify that an independent review (as defined by the OPO based on their staffing structure and resources) is completed annually by an individual not assigned to DRR responsibilities. The surveyor will review the internal audit schedule to verify the audits are following policy and being conducted.

HD 1.9	Evaluation of donor potential will include but is not limited to an assessment of referral, authorization, and conversion rates. The OPO may further describe trends in the donor pool and evaluate process metrics that impact conversion rates.	Evidence of process issues can be identified on OPO or hospital specific dashboards/scorecards or other documents.
HD 2 - Hospital Demographics		
HD 2	The OPO shall document and maintain information on acute care hospitals within its service area. Each profile includes the following information: The OPO may document this information within a single document or within a database, or in a combination of binders and database. Each profile includes the following information:	The OPO may document this information within a single document or within a database.
HD 2.1	Demographic (type of facility, i.e. teaching hospital, trauma, etc.)	
HD 2.2	Number of hospital beds, number of ICU beds	
HD 2.3	Deaths per year	
HD 2.4	Available services (ventilators, acute care, neuro staff, etc.)	
HD 2.5	Policies on brain death, organ donation after circulatory death (DCD), coroner and Medical Examiner.	For each hospital, there must be evidence of a policy on donation, and other donation-related policies as they occur and are updated (such as brain death, donation after circulatory death, and Medical Examiner/Coroner/JP considerations).
HD 2.6	Key contacts	
HD 2.7	Other information on donation such as donor resource councils and designated requesters, and hospital system affiliations, if applicable.	
HD 3 - Referral Tracking		
HD 3	The OPO shall maintain a referral tracking system to include the following information:	
HD 3.1	Hospital name	
HD 3.2	Unit name	
HD 3.3	Name of referring party	
HD 3.4	Date and time of referral	
HD 3.5	Outcome of the referral	
HD 3.6	Missed referrals corrective action	Review the OPO's system for corrective action in the event of a missed referral.

HD 4 - Hospital Development Plans		
HD 4	The OPO must have policy for hospital development plans with the goal of optimizing organ donation within the donation service area, with donation potential as discovered by DRR outlined in HD 1. Customized HD Plans are required for hospitals representing 80% of the OPO's donor potential. Templates may be used in hospitals representing the remaining 20%. Hospital plans will include, but not be limited to, the following information:	
HD 4.1	Analysis and application of hospital specific data to identify referrals and donor trends, addressing conversion rate (as established by the OPO and/or hospital), timely notification rate, effective requesting rate, and referral rate (addressing missed opportunities as discovered through DRRs).	Review policy for compliance with elements in HD 4.1 – 4.3. The surveyors shall review hospital plans meeting the criteria for individualized plan for all policy requirements according to the formula: the square root of number of acute hospitals in the DSA, plus 1. For Example: if the number of acute care hospitals is 140, then 13 hospital plans will be reviewed (11.8 + 1 = 13). The plans for review will be identified by the survey team.
HD 4.2	Plans and strategies addressing issues stated in, but not limited to, HD 4.1	Templates vs. Specific: goals can be the same. Surveyor to look for evidence that plans change from year to year. How quickly does the OPO react to what is going on and change what they do? Assess how the OPO works with hospitals to improve goals, conversion rates, effective request rates, authorization rates, referral rates, and OTPD rates.
HD 4.3	Evidence that educational planning is done in collaboration with hospitals.	Look for documentation that plans were developed collaboratively with key hospital personnel as appropriate. Evidence of this may include but not be limited to correspondence, meeting agendas, signatures, emails; surveyors may conduct phone interviews with key contacts at hospitals representing 80% of the OPO's donor potential. Key contacts to be provided by the OPO. Look at policy and team findings to see if they are following the plan.
HD 5 - Documentation of Hospital Development Activities		
HD 5.1	The OPO maintains documentation of HD activities. These activities may include but not be limited to meetings, rounding, education, and after-action reviews.	The OPO will direct the surveyor to its documentation of HD activity if requested. Surveyor needs to compare policy to practice (i.e., if policy says visit 2 times per year, did they do this?).

HD 6 - Statements of Affiliation		
HD 6	The OPO must have written agreements with 95% of the Medicare and Medicaid participating hospitals and critical access hospitals within its service area that have both a ventilator and an operating room. The agreement must include the following:	Assess for documentation of written statements of affiliation between the OPO and 95% of the hospitals within the DSA. It is important to note these requirements mirror CMS requirement for agreements and will be surveyed accordingly. CMS §486.322(a) Standard: Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at §482.45 or §485.643. The agreement must specify the meaning of the terms "timely referral" and "imminent death."
HD 6.1	Define the responsibility of the OPO such as: • Provision for timely and prompt response • Determining the suitability of the donor • Parameters for OPO interaction with hospital staff • Discretion and sensitivity in discussions with families • Training for new designated requesters and ongoing training • Ensure the proper composition and credentials of organ recovery teams • Notification to hospital of any policy changes that affect recovery, perfusion or transport • Ensure proper documentation is prepared for transplant program about recovered organs including blood type and other identifying information • Role of the OPO staff in organ/tissue management within the hospital • OPO roles and responsibilities in "after circulatory death" donation if applicable	

HD 6.2	Define the responsibility of the hospital: • Assignment of sufficient designated requester staff if applicable • Appropriate hospital staff participation in training provided by the OPO • Hospital staff roles for approaching, or not approaching, families regarding donation • Parameters and/or definition for timely notification of the OPO of an imminent death • Access for the OPO to hospital services (e.g., laboratory, radiological, operating room) • Access to hospital medical records • Hospital staff role and responsibility for management of organ viability • Hospital staff role and responsibility for donation after circulatory death, if applicable • Hospital expectations concerning credentialing information to be provided by the OPO for organ recovery team members upon request • Notification of the OPO of any change in the credentialing for any surgeon from the hospital routinely recovering organs for the OPO, if applicable.	

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PUBLIC AND MEDIA RELATIONS STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
PR 1 - Public and Media Relations		
PR 1	The OPO shall have an organized approach and/or cooperate with other agencies and organizations to enhance donor designation and awareness.	
PR 1.1	The OPO shall ensure that public education programs are implemented.	The surveyor shall look for public education policies and procedures that enhance donor designation and public awareness in the donation service area. If public education and/or public relations is contracted outside of the organization a signed agreement from both parties should be reviewed. The surveyor shall look for evidence that educational/awareness programs directed at the public are conducted and that OPO policy states information on donor designation is included in such programs. Evidence may include: copies of local television, radio or print stories or advertising, listings of school or college education programs conducted, listings of motor vehicle registration programs or contact, listings of civic group programs conducted and/or listings of any other programs directed to the public.
PR 1.2	The OPO shall have materials available that enable and assist donor designation and awareness education for demographics appropriate to the service area.	The surveyor shall look for evidence the OPO has reviewed current demographics of the donation service area and that printed literature or other materials are appropriate to reach the demographics in the service area. Examples of evidence include: copies of local or national census reports, brochures, posters, handouts, PowerPoints and video/audio recordings.
PR 1.3	The OPO shall be responsible for the dissemination of these materials.	The surveyor looks for evidence the OPO has a demonstrated practice regarding the dissemination of materials and/or educational messages regarding donor designation and awareness education. Examples of evidence may include: an OPO policy stating what materials are made available at every public education program conducted. Surveyor will ask for documentation that these have been distributed.
PR 1.4	The OPO shall have a system to recruit, educate and retain volunteers	The surveyor looks for evidence the OPO has a program in place to recruit, educate and retain volunteers. Examples of evidence may include: policies and procedures for the recruitment and education of volunteers, examples of volunteer duties and educational opportunities, and a listing of active volunteers and programs completed on behalf of or in conjunction with the OPO.
PR 1.5	The OPO shall have an SOP on the use of social media if it is used for public outreach or in their education program.	If the OPO uses social media for public outreach, the surveyor looks for evidence that the OPO has a policy/procedure regarding social media. The policy/procedure may include: specific responsibilities for maintenance and organizational standards regarding social media sites at a minimum. The OPO reviews metrics on social media sites being used.

PR 1.6	The OPO shall have a policy related to the release of donor, recipient and/or recovery organization information to the media.	Request a policy on dealing with the media. Determine whether or not there is a media release form to be signed by the family, donor hospital, transplant hospital, or OPO.

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ETHICS STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
ES 1 - Conflict of Interest		
ES 1	All OPOs shall have policies to properly manage conflicts of interest.	
ES 1.1	Any full, part, or per diem time OPO employee or board member having a financial interest in the OPO's transactions must disclose, on an annual basis, his/her financial interest(s) and abstain from voting in matters in which he or she (or an immediate family member) is directly or indirectly impacted	Determine whether OPO has adopted a consistent policy and practice regarding disclosure and management of potential conflicts of interest. Examples of evaluating OPO practice may include, but are not limited to: Any OPO employee or board member having a financial interest in the OPO's transactions must disclose his/her financial interests and abstain from voting or acting on matters in which he or she (or an immediate family member) is directly or indirectly impacted. Documentation that service contracts are awarded on the basis of fair bidding. Assess for policy regarding awarding of contracts or ask for examples of how decisions are made. Assess relationship of all board members to OPO, looking specifically for areas in which a board member may benefit financially from the relationship with the OPO. Assess written policy that addresses potential conflicts of interest for the OPO's Executive Director/CEO and COO. Interview the medical director or governing board member about how the OPO manages potential conflicts of interest.
ES 1.2	The OPO shall have a policy that addresses the direct supervision of relatives.	The OPO shall have a policy that addresses the direct supervision of relatives. Determine whether any of the OPO's management staff or Board of Directors are related. If employed relative exists, determine existing lines of supervisions. Also assess relative's qualifications for filling the position in question, and assure no special considerations are given.
ES 2 - Donor Referral Fees		
ES 2	There shall be no finder's fees, bounties or commissions paid for the referral of a potential donor.	

ES 2.1	An organ procurement organization shall not pay any monies or other form of direct benefits or inurement, to any donor hospital (including medical staff and employees), donor family member, funeral home or medical examiner/coroner for the referral of a potential donor. Fees for goods and services rendered that are not related to donor referral are acceptable.	The OPO's policy for reimbursement must not make any reference to referral fees. Assess a listing of accounts payable for one to two months to determine presence of payment to any individual, or entity, to ensure that the payment is for identifiable goods or services provided to the OPO for other than donor referral. If questionable entries are noted, request an explanation of services rendered.
ES 2.2	In the event specific hospital duty staff are designated to approach and obtain authorization from potential donor families, the OPO may make arrangements to pay a proportionate share of the designated individual salary.	There shall be no finder's fees, bounties or commissions paid for the referral of a potential donor, potential donor families, the OPO may make arrangements to pay a proportionate share of the designated individual salary. Assess current compensation methodology for organ recovery staff and other personnel for the specific function or job duty performed.
ES 3 - Confidentiality		
ES 3	The OPO shall maintain a policy regarding the confidentiality of donor and recipient information.	
ES 3.1	The OPO shall have a policy for the exchange of information with involved parties such as OPOs, transplant centers, the OPTN, AOPO, and CMS, regarding donors and recipients as required for data collection and follow-up.	The OPO shall maintain a policy regarding the confidentiality of donor and recipient information Assess ten donor charts at random to determine that recipient confidentiality is maintained in any correspondence to donor family, hospital, etc. The surveyor must assess the OPO infrastructure, including but not limited to, use of encryption for computer hardware, locked filing cabinets, limited access by visitors, etc.
ES 4 - Monetary Compensation of Donors		
ES 4	Except as authorized by statute, monetary compensation or goods or services of value shall not be offered to a donor, a deceased donor's next of kin, the donor's estate, or any other third party as an incentive to donation.	Except as authorized by statute, monetary compensation or goods or services of value shall not be offered to a donor, a deceased donor's next of kin, the donor's estate, or any other third party as an incentive to donation.
ES 4.1	An OPO shall not pay any monies or other form of direct compensation or goods of value to a donor, a deceased donor's next of kin, or any third party to influence the decision to donate.	When interviewing, be mindful of any processes that might be construed as providing direct compensation to donor next of kin or to any third party as an incentive to donation.
ES 4.2	Direct costs associated with an acceptable donation may be reimbursed to the party providing required service.	Verify with surveyor reviewing Financial Standards.
ES 4.3	Donors or their families should not be responsible for any expense directly related to the recovery of organs.	Review processes to ensure that the donor family is not billed for any expenses.

ES 5 - Interaction with Public Elected Officials		
ES 5.1	The OPO must have a policy to reflect its interactions with public elected officials to prevent any risk to the OPO's 501(c) (3) status.	The surveyor must determine if the OPO participates in any lobbying efforts and if there is any evidence of inappropriate contributions, or actions, by the OPO to publicly elected officials. The OPO policy and practice should also be evaluated to ensure that any political involvement by individual OPO employees does not involve any time or expense reimbursement to the employee by the OPO. • An OPO cannot participate in a campaign, directly or indirectly, on behalf of or in opposition to a candidate. Puts 501(c)3 status in jeopardy. • An OPO can participate in legislative advocacy and non-partisan activities • 990 , Schedule C • Political Campaign and Lobbying Activities • AOPO dues include lobbying and should be reported

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CONTINUOUS QUALITY IMPROVEMENT STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
QI 1 - Plan		
QI 1.1	Organizational Approach: The OPO must have a planned, systematic, and organization-wide approach to process design, performance measurement, assessment and improvement.	The surveying team shall determine that the Plan: • Is documented (policy or separate document) • Defines roles and responsibilities to accomplish the objective • Assesses quality • Focuses on goals to improve outcomes or reduce/prevent errors. • Defines the elements outlined in the *My OPO Plan** * Contained in the document, *Quality Council Model QI Plan Template.doc*. This document is also published on the AOPO Quality Council Portal.
QI 1.2 **Links to Essential Standard 2**	Planned: The Continuous Quality Improvement Plan is evaluated and documented by the leadership of the OPO **annually**.	The OPO's leadership ensures that the quality program reflects the OPO's stated mission and associated services through: • Meeting minutes • Board review • Leadership review • Plan approval and sign-off The surveyor should ensure that leadership's involvement in reviewing the OPO's Plan is documented. This documentation should contain: • A list of outcome measures • A list of improvement priorities • Detail of the quality program's assessments • The frequency of leadership's assessment
QI 1.3	Systematic	The Plan is based on specific quality indicators that are linked to the organization's goals. Consider observing these goals in the published organization goals, Quality Policy Statements, Improvement Projects, and the Quality Plan. The methodology for implementing the Plan is defined (Policy & Procedures, PDSA, Project Management)
QI 1.4	Organization-Wide	All OPO departments are explicitly referenced in the Quality Plan. All OPO departments are involved in the development of the Quality Plan.

QI 2 - Data & Collection Analysis		
QI 2.1	Systematic Data Collection: The OPO collects data for both improvement priorities and ongoing measurement. This data should focus on: • Operational volumes • Operational outcomes • Areas of risk or potential risk	The surveyor shall have access to the standard data reports utilized by the OPO. The source of the data is documented. Examples of sources are AOPO, SRTR, UNOS, and other internal sources. The data describing operational volumes may address measurements related to recovered and/or transplanted organs by organ type, frequency of surgical problems/errors encountered, conversion ratios pertaining to potential donors, etc. and/or other indicators that focus on the desired performance and/or problem prone areas for that OPO. Consider improvement project reports, data reports, and the Quality Plan to observe organizational choices on the type of data to be collected and the scope of data collection. There is a documented method for prioritizing the data.
QI 2.2	Data Time Frames: A period of time for collection of specific data is defined prior to review and analysis.	The frequency and detail of the analysis should be demonstrated and explained using the following components at a minimum: • Statistical methodology • Internal comparison • External comparison • Intensive assessment when there is undesirable variation.
QI 2.3	Review: The OPO makes internal comparisons of its performance of process and outcomes over time. The OPO compares performance data about its processes and outcomes to external sources.	Baseline performance is determined for each quality indicator. Statistical tools are used to review data. Some examples are run charts, histograms, pareto charts, scatter plots, and control charts. Any example of a statistical method being utilized should be verified with documentation of the methodology's type and the rationale for its use in each instance.
QI 2.4	Analysis: A systematic process is used to assess and analyze collected data. The assessment process uses appropriate statistical control techniques. The OPO initiates intensive assessment when statistical analysis detects undesirable variation in performance	There is a method used to analyze data. Special and common causes of variation and trends are identified in the OPO's data analysis. The surveyor assesses (review documentation, interview personnel) whether the OPO has the ability to: • Analyze its own data • Identify opportunities for improvement • Determine corrective action needed The organization learns from the analysis by developing an action plan based on the root causes identified.

QI 3 - Implementation		
QI 3.1	Appropriate Plans: The OPO supports quality program activities that are based on the Quality Plan, collected data, and the OPO's analysis.	Specific action plans are documented and used to accomplish the improvement. • Responsibilities are assigned for improvement activities/tasks. • Dates (start & finish) are set for these activities/tasks. • Activities/tasks are implemented. • Activities/tasks are reviewed. • Quality targets are set. • Quality targets are reviewed. • Quality targets are achieved.
QI 3.2	Leadership	The OPO's Leadership participates in the planning of the QI processes and the activities/tasks involved. The OPO's Leadership enables action plans to occur. • Provisions are made to have appropriate resources available.
QI 3.3	Commitment	Organization-wide commitment is shown through active improvement projects and indicators tracked in each department. • The practice within the OPO matches the established Quality Plan. • Planned QI activities/tasks and associated meeting commitments are kept. • Commitment tasks, dates and quality target are followed. • The OPO has active QI teams. • Interviews with employees demonstrate knowledge of the OPO's improvement plans and model used.
QI 4 - Evaluation/Continuous Improvement		
QI 4.1	Systematic: The OPO systematically improves its performance.	A review of the quality program's documentation and interviews of designated quality improvement staff shall demonstrate evidence of how the decisions to select improvement projects are conducted. • Improvement activities are decided by involving all staff, using management exclusively, or using the governing board. • The methodology is documented and supported by Leadership. • The surveyor shall find evidence of performance improvement activities that: • Tracks historic outcomes • Analyzes the opportunity for improvement of these outcomes • Implements changes by developing an action plan • Documentation that the changes are studied, tested, and monitored so feedback is obtained and education regarding the change for improvement is communicated throughout the OPO.

QI 4.2	Opportunities Analyzed: Improvement opportunities are prioritized and acted upon accordingly.	QI projects use the following methods: • GAP analysis, needs assessments, and audits are used to identify if outcomes are reaching desired goals. • Deviations from Standard Operating Procedures and non-conformities are reviewed to identify needed areas of improvement. • The method of prioritizing improvement opportunities is documented.
QI 4.3	Improvement Measured: Effects of improvement actions are measured and assessed.	Improvement action plans are reviewed and assessed for positive improvement.
QI 4.4	Improvement Implemented: Effective improvement actions are implemented.	The improvement is documented. OPO communicates work processes that have been improved in an effort to reapply lessons learned. The OPO has established or modified a policy or procedure based on the outcome of an improvement project. (e.g. PDSA)
QI 4.5	Ineffective Models Modified: When improvement plans are tested and found ineffective, they are modified.	Unsuccessful QI action plans have been evaluated, revised, or discontinued. • An example would be successive cycles of PDSA that indicate an ineffective test or theory that should be revised or discontinued.
QI 5 - CAPA System to Manage Non-Conformances		
QI 5.1	The OPO must establish written policies/procedures to address the process for identification, reporting, analysis and prevention of adverse events, complaints and non-conformance to policy or procedure that occur during the organ donation process.	The surveyor should look for a policy that describes the procedures for staff to report and investigate complaints, adverse reactions and non-conformance to deviations from policies and procedures. Request a sample of a blank occurrence report form and/or a demonstration of the system used to report and investigate an occurrence. A complaint should be considered any expression of dissatisfaction with services received from the OPO by a donor/recipient family, a clinician, funeral home, etc.
QI 5.2	Procedures must address occurrences by severity level and evidence of a formalized investigation, root cause, or other means of a structured correction and preventive actions taken.	Request examples of an investigation, a root cause analysis or similar methodology, of a non-conformance from established procedures and the corrective/preventative actions that resulted. Look for assessment of risk and/or assignment of severity level. Policy should describe the action for each level of severity.
QI 5.3	Procedures must address the reporting of non-conformances and adverse reactions to senior management, trending and analysis and reporting to applicable regulatory agencies as appropriate.	Look for evidence of reporting to OPO senior management and/or Board of occurrences, trending, analysis of risk and corrective actions.

QI 5.4	Procedures must address documentation of effectiveness assessment of corrective and/or preventive actions.	Examples may be focused audits, competency testing, or inspection/examination.
QI 6 - Internal Audit Procedures		
QI 6.1	The OPO must have a written policy that describes its internal audit process to monitor compliance with written procedures and activities relating to AOPO Standards, OPTN Policy and Procedure, and appropriate CMS Regulations.	The policy should describe who is responsible for conducting audits and their training for conducting audits. Auditors should, but are not required to, only audit areas over which they have no direct responsibility. While having an independent person may provide a better view of the process as they are a step removed and able to see details and the larger process, OPOs can define the frequency, responsibility and structure of internal oversight processes. E.g., a small organization with limited FTE flexibility might consider rotating these duties among staff so that the duty is not the responsibility of just one person.
QI 6.2	There must be evidence of regularly scheduled internal audits.	Surveyor should look for a published schedule of internal audits for each year of the survey cycle. The schedule should indicate the scope of each audit and show evidence that the audit was conducted and completed.
QI 6.3	Procedures must include the reporting of audit results to OPO management.	Surveyor should look for evidence that audit results, non-conformances, corrective actions, effectiveness checks and trending have been reported to management.
QI 6.4	Procedures must include effectiveness assessment of corrective actions to audit non-conformities.	Examples may include re-audits, inspection/examination or competency testing.
QI 7 - Documentation Methodology		
QI 7	The OPO shall utilize an internal standard format or form (OPO Donor Information Form) **to document all clinical donor records and other required donor information**. The OPO shall submit all required OPTN documents according to prescribed time frames and maintain adequate security for all medical records.	The OPO shall utilize a standard format to document all required donor information. This format may be paper or electronic and in either form shall meet all of the requirements set forth in the standard.
QI 7.1	The OPO will have a system or process defined by policy that defines the donor record. All source documents need to be attached	The OPO must identify in policy the methodology for the donor record. **This would include what source documents are, and that they are kept as part of donor record.** If the OPO utilizes both paper and scanned documents, the surveyor will review both for completeness and accuracy.
QI 7.2	All corrections or additions to the donor record must follow “Good Documentation Practices”.	During medical record review, check for entries in ink only and assure that whiteout or complete scratch outs are not present. Check to see that all corrections are dated and initialed. Check to ensure that no items are left blank. Examples for a written document could be a strike-through line, or “N/A.” In the electronic record, it could be a field that is grayed out, or in policy that blanks are intentional.

QI 7.3	The donor file that documents donor suitability, organ recovery, perfusion, quality assurance, and distribution shall be retained a minimum of 10 years and/or in compliance with state laws beyond the date of organ recovery. Records shall be maintained in an appropriate manner in such a way as to preserve their contents.	
QI 7.4	All donor records that are not electronic shall be completed using ink. All donor chart items must be completed whether electronic or as a written document. How blanks are handled must be explained in policy.	During medical record review, check for entries in ink only and assure that whiteout or complete scratch outs are not present. Check to see that all corrections are dated and initialed. Check to ensure that no items are left blank. Examples for a written document could be a strike-through line, or "N/A." In the electronic record, it could be a field that is grayed out, or in policy that blanks are intentional. **This would include what source documents are, and that they are kept as part of donor record.**
QI 7.5	All currently existing OPTN forms shall be completed by the OPO and submitted to the OPTN contractor within the prescribed time limits.	Surveyor may use the CMS performance letter for OPTN reporting or the summary sheet in UNET for data submission to confirm compliance.
QI 7.6	The OPO shall have a system to ensure the security of its medical records.	The OPO must have a policy on who can access the medical records, and how the records are secured after normal business hours. The policy should outline procedures for copying records and removing records from the OPO premises. The policy should also detail precautions for utilization of facsimile transmission. All donor records for which the official record is captured and maintained electronically must include an audit trail which captures every data change and data entry and includes the username and date/time of entry associated with each field. The audit trail must be viewable by the user and must be available in a printable format. The surveyor must view the audit trail. **If OPO has electronic medical records, record who hosts it and whether there is a methodology in place for data back-ups.**
QI 7.7	The OPO will have a system or process defined by policy that provides for the QA and closure of all donor records.	Look for policy that will define responsibility and timelines for closing donor records. Also, look for an established system to QA donor records and then assess that records have gone through the QA and closure processes as defined by policy. For electronic records, this must include the process and timeline to close or lock the record. There must be policy on how the record and by whose approved the record may be unlocked and/or printed or sent to any outside party. **All donor chart items must be in a "completed" status whether electronic or as a written document when the donor record is closed.**

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TRAINING AND EDUCATION STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
TR 1 - Onboarding		
TR 1	The OPO has a structured onboarding program to orient new hires to the organization.	
TR 1.1	The OPO must have a formal training program for all employees.	Documentation may include: new hire orientation schedule, job specific training plans, preceptor program.
TR 1.2	All employees must receive orientation to company and job specific policies and procedures.	Documentation may include: new hire orientation schedule, documentation of attendance if relevant, documentation of review of OPO policy and procedures.
TR 1.3	There must be documentation of training for all employees.	Documentation of attendance, employee training record.
TR 1.4	All employees, Governing Board members, and Advisory Board members must be trained on OPO-specific QAPI plans.	Documentation of attendance/course completion. Document for all 3 years; average of all 3 years is score. All employees, Governing Board members, and Advisory Board members must be trained on OPO-specific QAPI activities within 10 days of hire or prior to first board meeting
TR 1.5	Employees at risk (OSHA Category I and II) must be trained on Blood Borne pathogen exposure prior to being placed in an environment of potentially being exposed.	Documentation of completed training prior to exposure.
TR 1.6	Employees must be trained in OPO-specific software, and technology, and security practices	Documentation in good security practices, confidentiality of data, secure data transmission, and OPO-related software.
TR 2 - Job Specific Orientation		
TR 2	The OPO has a structured orientation program to train new hires to the core competencies and/or job responsibilities.	
TR 2.1	The OPO must have a formal process for determination of competency and/or readiness for responsibilities.	Documentation may include: job-specific checklists, progress notes, preceptor/trainer assessment, AAR/debriefing.
TR 2.2	The OPO must assess the training needs of each employee.	Assess through core competencies for job assignments and critical job skills. CMS 486.326c

TR 2.2.1	Any employee obtaining authorization must receive training in family discussions and required documentation.	Documentation may include: course completion, job-specific checklists, progress notes, preceptor-trainer assessment, AAR/debriefing.
TR 2.2.2	Any employee obtaining authorization must receive training in ensuring sensitivity to racial and cultural needs and means to overcome common racially based barriers to donation.	Documentation of attendance/course completion.
TR 2.2.3	Any employee performing DRAI discussions must receive training and determined competent.	Documentation of attendance/course completion and/or job-specific checklists.
TR 2.2.4	Any employee performing the physical assessment must receive training and determined competent.	Documentation of attendance/course completion and/or job-specific checklists.
TR 2.2.5	Any employee required to use mechanical devices must receive training to each device and determined competent for each device.	Documentation of attendance/course completion and/or job-specific checklists.
TR 2.2.6	Any employee required to use TransNet must receive training and determined competent.	Documentation of training and competency to use TransNet
TR 2.3	There must be documentation of training in the following areas for any employee performing hospital development activities • HD Process • Data Collection and Analysis • Planning and Implementation • Communication and Collaboration • Interviewing • Marketing	Training plan, job-specific checklist, and/or preceptor program.
TR 3 - Annual Training		
TR 3	The OPO provides the following required annual training:	
TR 3.1	There must be annual training for all designated requestors (OPO and other designated requestors) in authorization discussions and/or procedures.	Documentation may include: attendance/course completion, certificates, department meeting minutes
TR 3.2	There must be annual training for all employees, Governing Board members, and Advisory Board members in OPO-specific QAPI plans.	Documentation of attendance/course completion. The survey team will review OPO employee and OPO board (advisory and governing) records for evidence of QAPI training for each of the three years involving the accreditation cycle. The survey team shall use a minimum 10% sampling of employee and 100% of board member records to validate training. Must score minimum 90% to pass.

TR 3.3	There must be annual training for at risk employees (OSHA Category I and II) on Blood Borne Pathogens and Hazard Communications.	Documentation may include: attendance/course completion, certificates and/or assessments.
TR 3.4	There must be annual training for any employee performing DRAI discussions.	Documentation may include: attendance/course completion, certificates and/or assessments.
TR 4 - Continuing Education/Professional Development		
TR 4	The OPO provides opportunities for continuing education and professional development.	
TR 4.1	The OPO must have a structured process for the identification of individual training needs and procedure for providing relevant continuing education to meet the identified needs.	Documentation may include: exam results, skills day assessments, preceptor program, error rates, feedback from clinical directors.
TR 4.2	The OPO must have a structured process for training and/or communication of relevant updates and practice changes.	Documentation may include: course completion (SOP and policy updates), email communication, attendance at department meetings, skills day, clinical case reviews.
TR 4.3	Opportunities are available for all employees to participate in ongoing educational activities	Documentation may include: department meetings, webinars, certificates, internal or external program attendance/course completion, conference attendance.
TR 5 - Annual Corporate Compliance Training		
TR 5.1	100% of new OPO Governing Board Members and Advisory Board Members participate in corporate compliance training prior to first board meeting and 100% of existing Governing Board members and Advisory Board members will participate in corporate compliance training annually.	The survey team will review OPO board (advisory and governing) records for evidence of corporate compliance training for each of the three years involving the accreditation cycle. The survey team shall use a minimum 100% of board member records to validate training. Document for all 3 years; average of all 3 years is score.
TR 5.2	100% of new OPO employees participate in corporate compliance training within 10 days of hire and 100% existing employees participate in corporate compliance training annually.	The survey team will review OPO employee records for evidence of corporate compliance training for each of the three years involving the accreditation cycle. The survey team shall use a minimum 25% sampling of employee and records to validate training. Document for all 3 years; average of all 3 years is score. *CMS Reference: (Standard) §486.326(a)(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators. Interpretive Guidelines §486.326(a)(2) The OPO must have written policies and procedures for the identification, investigation and resolution of potential conflicts of interest (financial or personal) for the OPO director, medical director, senior management, and procurement coordinators. Confirm during review of employee files that potential conflict of interest is evaluated at the time of employment. Also, be alert in the employee files to any indication subsequent to employment of a potential conflict of interest (consistent with the OPO written policy). If noted, discuss the observation with the OPO Director to learn whether the situation was identified and what follow-up action was taken.*

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DATA AND INFORMATION MANAGEMENT STANDARDS

REFERENCE #	STANDARD	INTERPRETIVE GUIDELINES
IT 1 - Data and Information Management		
IT 1.1	The OPO will provide systems and data to support the functions of the OPO.	The OPO identifies and provides systems and data to support its' functions.
IT 1.2	The OPO's systems provide accurate accessible information in a useful format.	Determine that data and reporting provided by the system provide accurate and useful information to support OPO decision-making and to manage OPO processes. Determine that the OPO has processes to check the accuracy of the information entered into its' systems.
IT 1.3	The OPO's systems must be in a format that allows for transfer of information to other organizations, and which could be transported in their entirety to a successor OPO, if needed.	The OPO's systems must be in a format that allows for transfer of information to other organizations, and which could be transported in their entirety to a successor OPO, if needed.
IT 1.4	The OPO shall routinely backup its data.	Review the data backup policy for compliance. Ask the OPO to provide documentation of the process used to test that backups can successfully restore data. Look for evidence that the OPO has either restored lost data or tests its ability to restore data on a periodic basis but not less than annually.
IT 2 - Security		
IT 2	The OPO shall use reasonable efforts to ensure the security and confidentiality of its information systems and data.	
IT 2.1	**PASSWORD SECURITY**	Review the password policy: for example, strong passwords should be encouraged (such as minimum length 7 characters using 3 of the 4 following criteria: uppercase letters, lowercase letters, numbers and/or symbols). Passwords should be changed every 90-120 days with limited reuse of passwords).
IT 2.2	Virus & Spyware Protection	Virus Protection: Determine that all servers, computers, e-mails are scanned for viruses Are the and that virus definitions are up to date. Spyware: Determine that a procedure exists for handling spyware. SPAM: Determine that the OPO has a procedure for curtailing SPAM.
IT 2.3	Internet and Intranet Security	Internet Use: Determine that a policy exists regarding appropriate internet use. Determine that the OPO has a firewall installed and uses security tools on internal web servers (for example IIS, Apache, SSH).

IT 2.4	Physical Security	Servers and Telephone Switches: OPO policy defines who may have access to the server and switch rooms. Old Computers: Determine that old computers have been destroyed or reformatted to prevent release of confidential information.
IT 2.5	Mobile Computing Security	Determine that a policy exists regarding mobile computing which lists the requirements for physical protection, access controls, cryptographic techniques, back-ups, and virus protection.
IT 2.6	The OPO shall ensure the security and confidentiality of hospital EMR systems to which its employees have access.	Determine that OPO procedures exist for employees who receive access to hospital EMRs. Determine that the OPO has a written policy which addresses the confidentiality of information contained in hospital EMR systems (privacy, access, use, disclosure).
IT 2.7	Information Technology Security	Review New User Setup Procedures and User Termination Procedures Review policies for information access/security levels for network access and individual application access. User Audit: Determine that user access to network and key systems is reviewed on a regular basis. Determine that an external/internal security audit is performed at least every 24 months either by an outside vendor or by the OPO internally that demonstrates a defined minimum standard for testing the OPO level of security for systems defined in policy. Determine that corrective actions, or audit findings, were implemented or that a risk assessment was performed for uncorrected findings.
IT 3 - Infrastructure		
IT 3	Maintenance of Infrastructure: a plan and process to ensure that all mission critical software and hardware is supportable throughout the expected life of the product(s).	
IT 3.1	Mission-Critical Knowledge	Ask staff to explain the process if a key staff person left server access, passwords, vendor contacts. Determine that mission-critical information systems knowledge (such as passwords) resides with more than one individual.
IT 3.2	Hardware & Software Support	Determine that an inventory of network hardware, servers, and PCs, server support agreements/warranties and their scheduled upgrade or replacement dates exists. Determine that software is still supported by the vendor or a risk assessment exists for unsupported software.
IT 3.3	Infrastructure Documentation	Review documentation that details the network infrastructure, e.g., domains, server names, policies & procedures for key activities.

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