Statutes, Regulations and Standards Manual

Statutes
(Federal, State Laws)

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Industry Standards
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U.S. Federal Laws

1	**National Organ Transplant Act (NOTA)** To address the nation's critical organ donation shortage and improve the organ matching and placement process, the U.S. Congress passed the National Organ Transplant Act (NOTA; P.L. 98-507) October 19,1984. The act established the Organ Procurement and Transplantation Network (OPTN) to maintain a national registry for organ matching. The act also called for the network to be operated by a private, non-profit organization under federal contract. **Organ Procurement Organizations: Part 273** Established requirements for OPO Boards and Advisory Boards, required OPOs to have hospital agreements with a substantial majority of the hospitals in its service area, provide professional education, arrange for acquisition and preservation of donated organs, provide quality standards for the acquisition of organs consistent with OPTN standards, arrange for testing to identify organs infected with human immunodeficiency virus (HIV), tissue typing of donated organs, equitably allocate organs, provide for organ transportation, have agreements with transplant centers in its service area, participate in the OPTN, have arrangements with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues, evaluate effectiveness organ acquisition, and assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors. **Organ Procurement and Transplantation Network, (OPTN) Part 274** Provided for the establishment of the Task Force on Organ Transplantation, created the OPTN to be run by contract by the Secretary of Department of Health and Human Services (DHHS), created the Scientific Registry of Transplant Recipients (SRTR), and an administrative unit within the DHHS to administer these activities. Section 301 of NOTA prohibits the exchange of organs for transplantation for valuable consideration. Established general provisions, including definitions of “transplant center” and “organ”. Provides for reimbursement of travel and subsistence expenses incurred toward living organ donation; public awareness; studies and demonstrations; studies relating to organ donation and the recovery, preservation, and transportation of organs and the Stephanie Tubbs Jones Gift of Life Medal.	42 U.S. Code § 273 - § 274i-3

	U.S. Federal Laws (continued)	
2	**Hospital Protocols for Organ Procurement and Standards for Organ Procurement Agencies** Requires hospitals to: have agreement with OPO, protocols for donation and to notify OPOs of all hospital deaths (routine notification); requires families to be notified of their opportunity to donate (federal "required request" law); establishes rules for hospital waivers; establishes requirements for OPO to receive payments from CMS; requires transplant centers to be member of OPTN.	42 USC § 1320b-8
3	**Health Insurance Portability and Accountability Act of 1996 (HIPAA)** Pub. L. No. 104-191, 110 Stat. 1936 (1996) 45 CFR 144 Purpose & Definitions 45 CFR 146 Requirements for Group Health Ins. 45 CFR 160 General Adm. Requirements 45 CFR 162 Transaction Standards and Security Regulations **45 CFR 164 Security and Privacy Regulations** *LifeShare staff: See files 14, 14A, 14B under: Federal Regulations and Guidance Material in this outline for specific regulations on the HIPAA and the Privacy Rule and how it pertains to OPOs.	42 U.S.C. 1302(a); 42 U.S.C. 1320d—1320d–8; sec. 264, Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320–2(note)); and secs. 13400—13424, Pub. L. 111–5, 123 Stat. 258–279.

Oklahoma Statutes

4	**Determination of Death** Legal definition of death; standard used in determining death; who may pronounce death. Provides for determination of death by irreversible cessation of circulatory and respiratory functions, or by irreversible cessation of all functions of the entire brain, including brain stem.	63 Okla. Stat. Chapter 61: § 3121 – § 3123
5	**Oklahoma Uniform Anatomical Gift Act** Legal Backbone of Donation - Organ/Tissue Donation and Anatomical Gifts: The UAGA contains all of the legal procedures for donation: Definitions, Who can make gift during life of donor; how gifts can be made; Invalidation or revocation of gift; Donor refusal to make gift;- Amendment or revocation of refusal; Person other than donor making, amending, or revoking gift; Effect of gift on future anatomical gifts; Unemancipated minor donors; Persons who may make anatomical gift; How to donate decedent's body; Persons to whom gift may be made; Gift unable to be transplanted; Reasonable search for family concerning donation; Procurement Organizations; Access to records; Who may transplant or remove part from decedent; Hospital agreements with procurement organizations; Purchase or sale of parts - penalties; permissible charges; intentional falsification; forgery concealment, defacement or obliteration of document of gift; Penalties- liability reliances on representations of class of individuals, validity and presumed validity of gift; Life Share Donor Registry; Conflict between determination or directive and medical suitability; Medical Examiner cooperation, jurisdiction, release of information, medico legal investigation, records, reimbursement/compensation.	63 Okla. Stat. Chapter 46: § 2200.1A – § 2200.27A
5A	**Uniform Anatomical Gift Act – NCUSSL Model Draft** National Conference of Commissioners on Uniform State Laws (NCUSSL) 2006 Uniform Anatomical Gift Act Recommendation to States. Updated definitions; who may donate; first person consent; ammending/revoking gift; who may receive gift; reasonable search; organ sales prohibited; restriction on medical examiner's ability to stop donation; immunity; donor registries; donation and advanced health-care directives; electronic signatures.	Revised Uniform Anatomical Gift Act; 2006. National Conference of Commissioners on Uniform State Law, July 7-14, 2006.
6	**Cheryl Selman Organ Donor Education and Awareness Act** Organ Donor Education and Awareness Program (OEDAP) Purpose - to promote and encourage organ donor education and awareness in Oklahoma. OAEDP revolving fund; tax form contribution; driver license applicant - voluntary contribution to OAEDP; OAEDP curriculum.	63 Okla. Stat. Chapter 46: § 2220.1 - § 2220.6
7	**Donor Notation on Driver License** Requires the Department of Public Safety to make space available on the front and back of the driver license and the identification card for an organ and tissue donor notation; sets forth requirements for individual desiring to remove donor designation from license or ID card.	63 Okla. Stat. Chapter 46: § 2211

	Oklahoma Statutes (continued)	
8	**Blood, Organs, Tissue, and Other Biologics** No implied warranty of the fitness, quality, suitability of purpose, safety, acceptability of human tissues or blood to the body of the patient, in the absence of negligence. Procurement of donated human sperm, tissue or organ prohibited from any person testing positive for the human immunodeficiency virus infection.	63 Okla. Stat. Chapter 45: § 2151
9	**Permit Required for Tissue Bank That Procures Bone, Skin, or Connective Tissue** Establishes requirements for tissue bank permit and nonrenewal or revocation of such permit, certification, medical director, compliance with FDA regulations, and priority in tissue distribution to Oklahoma patients.	63 Okla. Stat. Chapter 46: § 2209.1
10	**Eye Recovery Certification - Eye Bank - Accreditation, Permits, and Procedures** Establishes conditions under which technicians are permitted to recover eyes; limitation of liability. Requirements for accreditation, medical director, Oklahoma patient priority, permitting and annual reporting of bank from State Commissioner of Health.	63 Okla. Stat. Chapter 46: § 2210
11	**Medico legal Investigations** Establishment of office of the chief medical examiner; appointment and qualifications of examiner; responsibility of examiner - delegation of duties; office and laboratory; **types of deaths to be investigated*;*** production of records, documents, evidence or other material;; cooperation of state and county officials - notification of deaths; body removal liability; investigation by medical examiner; custody of the body; drug-related deaths; copies of reports; autopsy requirements; biological specimens; forensic services fee schedule; transporting of bodies; authority to accept gifts and creation of chief medical examiner revolving fund.	63 Okla. Stat. Chapter 37: § 931 - § 955 Section of interest to LifeShare staff: ***§63-938. Types of deaths to be investigated*** (see page 4)
12	**Dead Bodies** Establishment of state Anatomical Board; requirements for operations of donation of bodies for anatomical study; unclaimed body rules; recordkeeping burial or cremation after study of body completed; Burial or Cremation of Bodies After Scientific Study Completed; expense responsibility for unclaimed bodies; shipment of bodies; violation of act.	63 Okla. Stat. Chapter 6: § 91 – § 108

Federal Regulations and Guidance Material: Hospitals

13	**An Introduction:** **CMS Conditions of Participation for Hospitals: Organ, Tissue and Eye Procurement**	
13A	**CMS Conditions of Participation for Hospitals: Organ, Tissue, and Eye Procurement. Final Rule. *(Short version without comments)*** Routine Notification of all hospital deaths to OPO; notification in a timely manner; introduction of 'imminent death' and 'timely notification' requirements for referrals; OPO determines medical suitability; requirements for death record reviews; transplant hospitals must submit data to OPTN. NOTE: The actual regulation is on the last page, page 33875. NOTE: Questions and CMS's answers to those questions are on pages 33875-33875.	Federal Register / 42 CRF Part 482.45; Vol. 63, No. 119 / Monday, June 22, 1998 / pg. 33875. Rules and Regulations.
13B	**CMS Conditions of Participation for Hospitals: Organ, Tissue, and Eye Procurement. Final Rule. (Long version, including comments)** Routine Notification of all hospital deaths to OPO; notification in a timely manner; introduction of 'imminent death' and 'timely notification' requirements for referrals; OPO determines medical suitability; requirements for death record reviews; transplant hospitals must submit data to OPTN. NOTE: The actual regulation is on the last page, page 33875. NOTE: Questions and CMS's answers to those questions are on pages 33875-33875.	Federal Register / 42 CRF Part 482.45; Vol. 63, No. 119 / Monday, June 22, 1998 / pg. 33875. Rules and Regulations.
13C	**CMS Interpretive Guidelines: Conditions of Participation for Hospitals: Organ, Tissue, and Eye Procurement.** Interpretive Guidelines for CMS Site Surveyors to use in assessing an OPOs compliance with CFR §482.45	DHHS CMS Pub. 100-07 State Operations Provider Certification. Date: October 17, 2008
13D	**Questions & Answers on Hospital COPs with CMS (42 CFR § 482.45 and 63 Fed. Reg)** The questions and answers related to the Hospital COPs: Identification of Organ, Tissue Eye Donors. Last Modified on Thursday, September 16, 2004	Centers for Medicare & Medicaid Services, U.S. DHHS
13E	**Crosswalk Guide to the Organ Procurement and Transplant Network (OPTN) and the Centers for Medicare & Medicaid Services (CMS) Oversight of Organ Transplant Programs** CMS granted The Joint Commission deeming authority to evaluate whether hospitals (among other health care organizations) comply with the requirements set forth in federal regulations. By granting deeming authority, CMS has determined that The Joint Commission's accreditation requirements meet or exceed the federal requirements for hospitals, called Conditions of Participation (CoPs). The Joint Commission's deeming authority means a hospital found in compliance with Joint Commission standards can be "deemed" to be in compliance with federal hospital requirements. The 2014 Joint Commission and CMS Crosswalk can help your staff walk through each CoP and relate it to corresponding Joint Commission standards and elements of performance (EPs). These crosswalks can help staff identify how policies, procedures, and practices that your hospital has in place to support one or several Joint Commission standards show compliance with equivalent CMS regulations.	Memo #13-10-Transplant Posting Date 2013-02-01 Fiscal Year 2013 www.cms.gov

Federal Regulations and Guidance Material: Hospitals (continued)		
13F	**(CMS) Medicare Conditions of Participation for Organ Donation: An Early Assessment of the New Donation Rule: Office of Inspector General (OIG) Report.** At this point, somewhat of a historical document which shows, at the time, the status of OPOs and hospital relationships after the adoption of the CMS Hospital COPs on organ, tissue and eye donation. This is an early report, 2000, of the effects of CMS's final rule on the Hospital COPs. The language in here is interesting as some of it remains true today . It sounds a cautionary note about where OPOs are, were and may remain today and what the final final rule was intended to do. OPOs ***and*** hospitals are jointly accountable for organ donation. OPOs' adherence to the provisions of this final rule should not be sacrificed in the name of 'keeping a good relationship'. In fact, professional practice, which includes knowledge of these standards and adherence to these standards, is what creates a good relationship. *(The notes here are a comment of Teresa Shafer, RN, MSN, CPTC, 2003-2005 Co-Chair of the DHHS national Organ Donation Breakthrough Collaborative.)*	JUNE GIBBS BROWN Inspector General AUGUST 2000 OEI-01-99-00020
14	**HIPAA and Organ and Tissue Procurement – Summary** OPOs do not need to enter into "business associate agreements" with hospitals, unless they are acting as something other than OPOs. OPOs are neither covered entities, nor business partners, and are specifically permitted to perform their core functions, with stringent confidentiality, but outside the ambit of HIPAA.	
14A	**HIPPA - Health Insurance Portability and Accountability Act (Short Version, with relevant organ donation language excerpted)** Short Version of the specific area of the larger act that address organ tissue donation and HIPPA. Only included here is the relevant section: *§ 164.512 (h): Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.*	DHHS Office of the Secretary 45 CFR Parts 160 through 164 Rin: 0991-AB08
14B	**HIPPA - Health Insurance Portability and Accountability Act (The entire Act, which includes the brief section on organ donation.)** HIPAA is the acronym for the Health Insurance Portability and Accountability Act that was passed by Congress in 1996. HIPAA does the following: •Provides the ability to transfer and continue health insurance coverage for millions of American workers and their families when they change or lose their jobs; •Reduces health care fraud and abuse; •Mandates industry-wide standards for health care information on electronic billing and other processes; and •Requires the protection and confidential handling of protected health information The HIPAA Privacy Rule regulates the use and disclosure of Protected Health Information (PHI) held by "covered entities" (generally, health care clearinghouses, employer sponsored health plans, health insurers, and medical service providers that engage in certain transactions.) By regulation, DHHS extended the HIPAA privacy rule to independent contractors of covered entities who fit within the definition of "business associates". PHI is any information held by a covered entity which concerns health status, provision of health care, or payment for health care that can be linked to an individual. This is interpreted rather broadly and includes any part of an individual's medical record or payment history.	DHHS Office of the Secretary 45 CFR Parts 160 and 164 RIN: 0991–AB57 Federal Register / Vol. 75, No. 134 / Wednesday, July 14, 2010

Federal Regulations and Guidance Material: Hospitals (continued)		
15	**Veterans Hospitals and Disclosure of Patient Information to organ, tissue and eye procurement organizations.** Provides authority for VA to provide individually-identifiable VA medical records of veterans or dependents of veterans who are deceased or whose death is imminent to representatives of organ procurement organizations, eye banks, and tissue banks to determine whether the patients are suitable potential donors. This document modifies the interim final rule to clarify the definition of ''near death'' and to correct a grammatical error in the definition of ''procurement organization.'' This document also clarifies that eye bank and tissue bank registration with FDA must have an active status.	38 CFR Part 1 RIN 2900–AM65 §1.460; §1.485 §1.514(b) Disclosure of Information to Organ, Tissue and Eye Procurement Organizations AGENCY: Department of Veterans Affairs. 65258 Federal Register / Vol. 73, No. 213 / Monday, November 3, 2008 / Rules and Regulations.
15A	**VA Handbook: Organ Tissue & Eye Donation Process** This Veterans Health Administration (VHA) Handbook describes the procedures for processing referrals to local procurement organizations, which encompass solid organ, tissue, and eye donation.	VHA Handbook 1101.3; April 30, 2009
15B	**VHA Handbook: Organ Donation after Circulatory Death (DCD)** This Veterans Health Administration (VHA) Handbook establishes procedures to ensure that organ donation after circulatory death (DCD) is conducted in accordance with established ethical and clinical standards. AUTHORITY: 38 U.S.C. 7301(b). NOTE: Refer to VHA Handbook 1101.03 for additional requirements concerning organ, tissue, and eye donation.	VHA Handbook 1102.7; November 15, 2013

Federal Regulations & Guidance Material: OPOs & Transplant Centers		
16	**CMS Conditions of Coverage for Organ Procurement Organizations: Final Rule** Increase the re-certification cycle for OPOs from 2 to at least 4 years; establish outcome and process performance measures based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified OPOs; establish multiple outcome measures; establishes process for OPOs to appeal a de-certification; definitions.	42 CFR Parts §413, §441, et al. Centers for Medicare & Medicaid Services, U.S. DHHS 30982-31053 Wednesday, May 31, 2006
16A	**CMS Interpretive Guidelines for OPO Conditions of Coverage Survey Process** Interpretive Guidance for the Survey Process of the Organ Procurement Organization (OPO) Conditions for Coverage, published May 31, 2006, in the Federal Register – Interim Final Appendix Y – OPO Interpretive Guidelines	Center for Clinical Standards and Quality/Survey & Certification Group Ref: S&C: 14-16-OPO. Appendix Y
17	**CMS Transplant Center Conditions of Participation** Centers for Medicare & Medicaid Services Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants; Final Rule.	42 CFR Parts §405, §482, §488, and §498 Centers for Medicare & Medicaid Services, U.S. DHHS
17A	**CMS – Organ Transplant Program Interpretive Guidelines** The Organ Transplant Interpretive Guidelines represent the most recent surveyor guidance for conducting surveys of organ transplant programs and should replace all previously-released versions. Organ Transplant Interpretive Guidelines Update: Attached is an advance copy of the Organ Transplant Interpretive Guidelines. These Interpretive Guidelines will also be published in a new Appendix X of the State Operations Manual (SOM).	Center for Clinical Standards and Quality/Survey & Certification Ref: Ref: S&C-08-25 June 13, 2008
17B	**CMS Memo on CMS/OPTN Crosswalk Guide**	Center for Clinical Standards and Quality/Survey & Certification Ref: S&C: 13-10-Transplant Fe b 1, 2013

Federal Regulations & Guidance Material: OPOs & Transplant Centers (continued)		
17C	**Crosswalk Guide to the Organ Procurement and Transplant Network (OPTN) and the Centers for Medicare & Medicaid Services (CMS) Oversight of Organ Transplant Programs** Summary Development of Transplant Policy Crosswalk - CMS, the Health Resources and Services Administration (HRSA) and the OPTN Contractor, the United Network for Organ Sharing (UNOS), have collaboratively developed a document that compares OPTN policy and CMS requirements and identifies areas of overlap. The crosswalk summarizes how CMS and OPTN conduct their oversight activities and what surveyors review during their onsite visits. • Ongoing Efforts to Address Survey Process and Overlap - This Crosswalk is the first step in reviewing the two sets of oversight activities to identify potential policy changes and/or to improve the efficiencies in the survey process. • Background Information: The material in this memorandum is largely informational in nature, designed to assist surveyors in better understanding OPTN requirements and the manner in which CMS and OPTN requirements mesh. Cross reference of CMS Regulation (by TAG number) with OPTN requirements (bylaw or policy number)	www.optn.org
18	**OPTN Final Rule** Effective March 16, 2000, HHS implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN.	42 CFR Part §121—Organ Procurement and Transplantation Network
18A	**OPTN Final Rule with comments** Effective March 16, 2000, HHS implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN.	42 CFR Part §121—Organ Procurement and Transplantation Network
19	**OPTN Bylaws – (these are effectively regulations also; see OPO section)** Member rights and obligations; Criteria for Organ Procurement Organizations; Criteria for Transplant Centers; Criteria for Histocompatibility Laboratory Membership; transplant hospital requirements; Model Elements for Controlled DCD Recovery Protocols. Other bylaw requirements may be found on www.unos.org.	www.optn.org
20	**PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation** This document provides guidance to organ procurement organization (OPO) personnel; transplant center personnel, including physicians, nurses, administrators, and clinical coordinators; laboratory personnel responsible for testing and storing donor and recipient specimens; and individuals responsible for developing, implementing, and evaluating infection prevention and control programs for OPOs and transplant centers. This guideline supersedes the 1994 U.S. Public Health Service (PHS) Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs. http://www.publichealthreports.org/issueopen.cfm?articleID=2975	Centers for Disease Control, US Public Health Service; US DHHS

Federal Regulations & Guidance Material: OPOs & Transplant Centers (continued)		
20A	**Short Version of 2013 PHS Guidelines for Reducing HIV, HBV, and HCV Transmission through Organ Transplantation** PHS Guideline for Reducing HIV, HBV, and HCV Transmission through Organ Transplantation	
20B	**Comparison Document of 2013 PHS Guidelines to 1994 version:** "2013 Public Health Service (PHS) Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation" – the 2013 PHS guidelines replaced the 1994 PHS Guidelines on high risk donors. This document compares the 2013 to the 1994 Public Health Service (PHS) Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs 2013 Public Health Service (PHS) Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. The most significant changes are: • Expanding the guideline to include hepatitis B virus (HBV) and hepatitis C virus (HCV), in addition to human immunodeficiency virus (HIV); • Using factors known to be associated with an increased likelihood of recent HIV, HBV, or HCV infection to identify potential donors who may be at increased risk for transmitting infection; and • Limiting the focus to organs and blood vessel conduits recovered for organ transplantation because the Food and Drug Administration (FDA) implemented more comprehensive regulations for human cell and tissue products.	
20C	**Q&A's on the 2013 PHS Guidelines on Donor Risk** OPTN FAQs Regarding the 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation	
21	**PHS Centers for Disease Control: Clarification of Human Immunodeficiency Virus Screening Practices for Organ Donors** (Revision of the 1994 CDC recommendations on screening of organ donors for high risk behavior. Clarified that: (1) transplant centers (physicians) are responsible for informed consent from the recipient – not OPOs.) and (2) In the context of the current organ shortage, transplant teams are encouraged to accept and transplant organs from medically appropriate donors who test HIV-antibody negative but have behavioral risk criteria for HIV infection after the transplant teams have discussed the risks and benefits with potential recipients and/or their families.).	Centers for Disease Control, US Public Health Service; US DHHS; Code of Federal Register: 61 Fed. Reg. 58548 (November 1, 1996).

Federal Regulations – Tissue		
22	**An Introduction: Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments**	
22A	**HUMAN CELLS, TISSUES,AND CELLULAR AND TISSUE-BASED PRODUCTS. Final Rule (short version, the regulation)** Creates a unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's. Subpart A: General Provisions Subpart B: Procedures for Registration and Listing Subpart C: Donor Eligibility Subpart D: Current Good Tissue Practices Subpart E: Additional Requirements for Agencies Established in §1271.10 Subpart F: Inspection and Enforcement of Establishments in §1271.10	Food & Drug Administration; US Public Health Service; U.S. Department of Health and Human Services. 21 CFR Parts 16, §1270 and §1271 Federal Register: November 24, 2004 (Volume 69, Number 226) Page 68611-68688
22B	**Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (long version with comments)** The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to screen and test cell and tissue donors for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases. The agency is amending the current good manufacturing practice (CGMP) and quality system (QS) regulations that apply to HCT/Ps regulated as drugs, medical devices, and/or biological products to clarify the role of the new donor-eligibility regulations in relation to existing CGMP regulations. By preventing the transmission of communicable disease by the wide spectrum of HCT/Ps that are marketed now or may be marketed in the future, the agency's action will improve protection of the public health and increase public confidence in new technologies.	DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration 21 CFR Parts 210, 211, 820, and 1271 [Docket No. 1997N–0484S] [RIN 0910–AB27]
22C	**FDA GTP Guidance Documents: Donor Eligibility** Clarifies GTPs. Assists organizations making donor eligibility determinations, with complying with the requirements in Title 21 Code of Federal Regulations, part 1271, subpart C (21 CFR part 1271, subpart C) (Ref. 1). Sets out requirements for determining donor-eligibility, including donor screening and testing, for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps).	Food & Drug Administration; US Public Health Service; U.S. Department of Health and Human Services. Center for Biologics Evaluation and Research; August 2007

	Federal Regulations – Tissue (continued)	
22D	**FDA Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)** Small Entity Compliance Guide	U.S. DHHS Food and Drug Administration Center for Biologics Evaluation and Research August 2007
22E	**21 CRF §1271 – PowerPoint** 21 CFR Part 1271: Human Cells, Tissues and Cellular & Tissue-based Products [HCT/Ps] Summary PowerPoint of regulation.	

Industry Standards - Hospitals		
23	**The Joint Commission (JCR) Standards for Hospitals – Organ Donation** These standards and elements of performance are detailed under the following sections for hospital standards: ➢ Leadership Standards (LD) ➢ Ethics, Rights and Responsibility Standards (RI) ➢ Performance Improvement Standards (PI)	Standards, Elements of Performance (EP), and Rationale for LD, RI, PI [Critical Access Hospital, Hospital]
24	**Healthcare at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients** JCR Public Policy Initiative white paper – "This paper is a call to action for those who influence, develop or carry out policies that will lead the way to resolution of the issue. This is specifically in furtherance of the Joint Commission's stated mission to improve the safety and quality of health care provided to the public."	Health Care at the Crossroads: Strategies for Narrowing the Organ Donation Gap and Protecting Patients. JCAHO: 2004. 630-792-5631. www.jcaho.org
25	**The Joint Commission (TJC) - Transplant Safety Standards - Introduction** Introduction to TJC Transplant Safety Standards and TJC notice on: TS.01.01.01: The hospital, with the medical staff's participation, develops and implements written policies and procedures for donating and procuring organs and tissues.	
25A	**The Joint Commission (TJC) - Transplant Safety Standards** The standards in this chapter focus on the development and implementation of policies and procedures for safe organ and tissue donation, procurement, and transplantation.	TJC Standards Transplant Safety 01.01.01 - -3.03.01

Industry Standards – Organ Procurement Organizations		
26	**Association of Organ Procurement Organizations (AOPO)** Accreditation Standards and Interpretive Guidelines AOPO accreditation centers on the processes and systems that an organization utilizes to monitor and ensure that staff work within the established guidelines and regulations for how their jobs are to be performed. The standards are dynamic – they undergo regular review and revision and incorporate changes that occur in practice and in regulation. They encompass all aspects of OPO operations and practice. The standards are written by the Standards and Accreditation Committee, shared with the membership, and approved by the AOPO Executive Committee. For every standard written, there are Interpretive Guidelines that have been crafted to provide guidance to, and promote consistency of scoring for, the surveyors. Major areas covered by the standards include: • Administrative • Finance • Human Resources • Information Management • Business Continuity • Safety • Clinical • Hospital Development • Donor Family Services • Public Education • Ethics • Multicultural • Quality Improvement • Training	Association of Organ Procurement Organizations; Jan 1, 2015. www.aopo.org
Industry Standards – Tissue Recovery		
27	**American Association of Tissue Banks (AATB): Introduction and Reference to AATB Standards Manual** Standards are published in: AATB Standards for Tissue Banking, Copyright 2008, 13th Edition. Printing Date: February 2008. These standards can be accessed on LifeShare network site:	Standards for Tissue Banking. American Association of Tissue Banks. February, 2008. LCN: 84-7269. www.aatb.org

Professional Standards		
28	**Core Competencies for the Clinical Transplant Coordinator and the Procurement Transplant Coordinator – An Introduction.** The Core Competency guidelines provide a broad scope of diverse professional practices unique to each OPO and Transplant Center. The guidelines have been developed to provide a minimum competency for practitioners and set clear performance expectations for OPO and transplant practitioners. Core competencies established by NATCO for the following donation and transplantation coordinator professionals: • Procurement Transplant Coordinator • Requestor • Clinical Transplant Coordinator • Advanced Practice Transplant Professional • Clinical Transplant Nurse The documents below outline the core competencies for practitioners / coordinators in the field of clinical transplantation. These general practitioner / coordinator competencies are broad in scope to acknowledge the diverse professional practices unique to each OPO / transplant center. These competencies are meant to be applicable to both adult and pediatric age groups.	American Board of Transplant Coordinators; NATCO www.natco1.org
29	**Procurement Transplant Coordinator - Core Competencies**	NATCO 2009 www.natco1.org
29A	**Procurement Transplant Coordinator – Competency Evaluation Tool**	NATCO 2009 www.natco1.org
30	**Requestor - Core Competencies**	NATCO August 2006 www.natco1.org
31	**Clinical Transplant Coordinator - Core Competencies**	NATCO 2009 www.natco1.org
31A	**Clinical Transplant Coordinator – Competency Evaluation Tool**	NATCO 2009 www.natco1.org
32	**Advanced Practice Transplant Professional - Core Competencies**	NATCO 2010 www.natco1.org
33	**Clinical Transplant Nurse - Core Competencies**	NATCO 2010 www.natco1.org

OPO CONTRACTS WITH HOSPITALS		
34	**Organ Procurement Organizations (OPO) Agreements with Hospitals.** Hospital regulations at 42CFR 482.45 (a)(1) require that all hospitals have written agreements in place with their OPO to notify them of an imminent death or of a death which has occurred. OPO regulations at §486.322 (a) require that OPOs have a written agreement in place with 95 percent of all participating Medicare and Medicaid hospitals and Critical Access Hospitals that have both a ventilator and an operating room. Historically, OPOs have not initiated agreements with hospitals without a ventilator and an operating room as donor maintenance cannot be accomplished in that setting. • OPO Agreements with Hospitals That Do Not Have a Ventilator and Operating Room: While OPOs are not required to initiate agreements with hospitals that do not have a ventilator and an operating room, they are required at §486.303 (g) to enter into an agreement with any hospital that requests an agreement with them pursuant to the hospital regulations. However, for hospitals that do not have a ventilator and operating room, the agreement may be limited to notification of the OPO by the hospital of imminent death and/or death which has occurred in the facility.	Center for Clinical Standards and Quality/Survey & Certification Group. Memo #13-48-OPOPosting Date2013-07-26Fiscal Year2013
35	**LifeShare - 2012 Acute Care Hospital Agreement** Standard agreement between LifeShare and donor hospitals for duties and responsibilities of each. Addresses referral, management and recovery of donors, determination of medical suitability, recovery surgeons credentialing, & qualifications of LifeShare staff, among other things.	LifeShare Transplant Donor Services of Oklahoma
36	**LifeShare - 2012 Non-Acute Care Hospital Agreement** Standard agreement between LifeShare and donor hospitals for duties and responsibilities of each. Addresses referral, management and recovery of donors, determination of medical suitability, recovery surgeons credentialing, & qualifications of LifeShare staff, among other things.	LifeShare Transplant Donor Services of Oklahoma