





**Standard 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.

**Elements of Performance for TS.01.01.01**

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| 1. | <p><b>D</b> The hospital has a written agreement with an organ procurement organization (OPO) and follows its rules and regulations. (See also PI.02.01.01, EP 7)</p>  | A |
| 2. | <p><b>D</b> The hospital's written policies and procedures identify the organ procurement organization (OPO) with which it is affiliated.</p>  | A |
| 3. | <p><b>D</b> The hospital has a written agreement with at least one tissue bank and at least one eye bank to cooperate in retrieving, processing, preserving, storing, and distributing tissues and eyes.<br/>                     Note 1: This process should not interfere with organ procurement.<br/>                     Note 2: It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its organ procurement organization (OPO) to provide tissue procurement services, nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement, and is free to have an agreement with the tissue bank or eye bank of its choice.</p>  | A |
| 4. | <p><b>D</b> The hospital works with the organ procurement organization (OPO) and tissue and eye banks to do the following:</p> <ul style="list-style-type: none"> <li>- Review death records in order to improve identification of potential donors.</li> <li>- Maintain potential donors while the necessary testing and placement of potential donated organs, tissues, and eyes takes place in order to maximize the viability of donor organs for transplant.</li> <li>- Educate staff about issues surrounding donation.</li> <li>- Develop a written donation policy that addresses opportunities for asystolic recovery that is mutually agreed upon by the hospital, its medical staff, and the designated OPO. When the hospital and its medical staff agree not to provide for asystolic recovery and cannot achieve agreement with the designated OPO, the hospital documents its efforts to reach an agreement with its OPO, and the donation policy addresses the hospital's justification for not providing for asystolic recovery.</li> </ul> | A |
| 5. | <p>Staff education includes training in the use of discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential organ, tissue, or eye donors.</p>  | A |
| 6. | <p><b>D</b> The hospital develops, in collaboration with the designated organ procurement organization, written procedures for notifying the family of each potential donor about the option to donate or decline to donate organs, tissues, or eyes.</p>  | A |
| 7. | <p>The individual designated by the hospital to notify the family regarding the option to donate or decline to donate organs, tissues, or eyes is an organ procurement representative, an organizational representative of a tissue or eye bank, or a designated requestor.<br/>                     Note: A designated requestor is an individual who has completed a course offered or approved by the organ procurement organization. This course is designed in conjunction with the tissue and eye bank community to provide a methodology for approaching potential donor families and requesting organ and tissue donation.</p>   | A |

**KEY:** A indicates scoring category A; C indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

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| 8.  | <p><b>D</b> The individual designated by the hospital documents that the patient or family accepts or declines the opportunity for the patient to become an organ, tissue, or eye donor.</p>   | A |
| 9.  | <p>The hospital notifies the organ procurement organization (OPO) of patients who have died and of mechanically ventilated patients whose death is imminent, according to the following:</p> <ul style="list-style-type: none"> <li>- Clinical triggers defined jointly with its medical staff and the designated OPO</li> <li>- Within the time frames (ideally, within one hour of death for patients who have expired) jointly agreed on by the hospital and the designated OPO</li> <li>- For mechanically ventilated patients, prior to the withdrawal of life-sustaining therapies including medical or pharmacological support</li> </ul> | A |
| 10. | <p>In Department of Defense hospitals, Veterans Affairs medical centers, and other federally administered health care agencies, notification to the organ procurement organization of patients who have died or whose death is imminent is done according to procedures approved by the respective agency.</p>   | A |
| 11. | <p>The organ procurement organization determines medical suitability of organs for organ donation and, in the absence of alternative arrangements by the hospital, it determines the medical suitability of tissue and eyes for donation.</p>  | A |
| 12. | <p><b>D</b> The hospital maintains records of potential organ, tissue, or eye donors whose names have been sent to the organ procurement organization and tissue and eye banks.</p>  | A |

**Standard TS.02.01.01**

The hospital complies with organ transplantation responsibilities.

**Elements of Performance for TS.02.01.01**

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| 1. | <p>The hospital performing organ transplants belongs to and abides by the rules of the Organ Procurement and Transplantation Network (OPTN) established under section 372 of the Public Health Service (PHS) Act.</p> <p>Footnote: The term "rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.</p> | A |
| 2. | <p>If requested, the hospital provides all data related to organ transplant to the Organ Procurement and Transplantation Network (OPTN), the Scientific Registry, or the hospital's designated organ procurement organization (OPO).</p>   | A |

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**Standard TS.03.01.01**





The hospital uses standardized procedures for managing tissues.

**Elements of Performance for TS.03.01.01**

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| 1.     | The hospital assigns responsibility to one or more individuals for overseeing the acquisition, receipt, storage, and issuance of tissues throughout the hospital.<br>Note: Responsibility for this oversight involves coordinating efforts to provide standardized practices throughout the hospital. A hospital may have a centralized process (one department responsible for the ordering, receipt, storage, and issuance of tissue throughout the hospital) or a decentralized process (multiple departments responsible for the ordering, receipt, storage, and issuance of tissue throughout the hospital).   | A   |
| 2.     | (D) The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of tissues. (See also TS.03.02.01, EP 5)  | A   |
| 3.     | The hospital confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.<br>Note: This element of performance does not apply to autologous tissue- or cellular-based products considered tissue for the purposes of these standards but classified as medical devices by the FDA.<br>Footnote: For U.S. Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA's online database: <a href="http://www.fda.gov/cber/tissue/tissregdata.htm">http://www.fda.gov/cber/tissue/tissregdata.htm</a> .     | A   |
| 4.     | The hospital coordinates its acquisition, receipt, storage, and issuance of tissues throughout the hospital.  | A   |
| 5.     | The hospital follows the tissue suppliers' or manufacturers' written directions for transporting, handling, storing, and using tissue.  | 3 A |
| (M) 6. | (D) The hospital documents the receipt of all tissues. (See also TS.03.02.01, EPs 3 and 6)  | C   |
| (M) 7. | (D) The hospital verifies at the time of receipt that package integrity is met and transport temperature range was controlled and acceptable for tissues requiring a controlled environment. This verification is documented. (See also TS.03.02.01, EP 6)<br>Note 1: If the distributor uses validated shipping containers, then the receiver may document that the shipping container was received undamaged and within the stated time frame.<br>Note 2: Tissues requiring no greater control than "ambient temperature" (generally defined as the temperature of the immediate environment) for transport and storage would not need to have the temperature verified on receipt. | C   |
| (M) 8. | (D) The hospital maintains daily records to demonstrate that tissues requiring a controlled environment are stored at the required temperatures. (See also TS.03.02.01, EP 5)<br>Note 1: Types of tissue storage include room temperature, refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen storage.<br>Note 2: Tissues requiring no greater control than "ambient temperature" (defined as the temperature of the immediate environment) for storage would not require temperature monitoring.   | C   |

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| 9.  | <p>The hospital continuously monitors the temperature of refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues.</p> <p>Note 1: Continuous temperature recording is not required but may be available with some continuous temperature monitoring systems.</p> <p>Note 2: For tissue stored at room temperature, continuous temperature monitoring is not required.</p>   | A   |
| 10. | <p>Refrigerators, freezers, nitrogen tanks, and other storage equipment used to store tissues at a controlled temperature have functional alarms and an emergency back-up plan.</p> <p>Note: For tissue stored at room temperature, alarm systems are not required.</p>   |  A |
| 11. | <p>The hospital complies with state and/or federal regulations when it acts as a tissue supplier.</p> <p>Note: The U.S. Food and Drug Administration (FDA) considers the routine policy or practice of shipping tissue to another facility as distribution which requires FDA registration. Returning unused tissue back to the tissue supplier is not considered distribution and does not require FDA registration.</p> <p>Footnote: Please refer to the following Web site: <a href="http://www.fda.gov/cber/tissue/tisreg.htm">http://www.fda.gov/cber/tissue/tisreg.htm</a>.</p> | A   |

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