SOLID ORGAN, TISSUE AND EYE DONATION

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive states policy for processing referrals of solid organ, tissue and eye donors to local procurement organizations.

2. SUMMARY OF MAJOR CHANGES: This directive includes the following updates:
   a. Updated title to specify that policy encompasses solid organ donation.
   b. Added definition for Deceased Donor (see paragraph 3.c.).
   c. Clarified responsibilities for Department of Veterans Affairs (VA) medical facility Director (see paragraph 5.f.).


4. RESPONSIBLE OFFICE: The National Surgery Office (11SURG) is responsible for the contents of this VHA directive. Questions may be referred to the VA National Surgery Office at 202-461-7130.


6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of August 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:

/s/ Kameron Leigh Matthews, MD, JD, FAAFP
Assistant Under Secretary for Health for Clinical Services

NOTE: All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on August 30, 2021.
SOLID ORGAN, TISSUE AND EYE DONATION

1. PURPOSE

This Veterans Health Administration (VHA) directive defines policy for Department of Veterans Affairs (VA) medical facilities to enter into agreements with local procurement organizations for solid organ, tissue and eye donation. This directive also establishes standard language for use in entering into such agreements. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. BACKGROUND

a. 42 U.S.C. § 1320b-8 requires hospitals participating in Medicare to establish written protocols for the identification and referral of potential donors to a certified procurement organization. The statute also requires these hospitals to participate in the Organ Procurement and Transplantation Network (OPTN). VA voluntarily complies with these provisions and other regulations of the Centers for Medicare and Medicaid Services regarding organ donation and transplantation.

b. VA has authority under the Privacy Act of 1974 (5 U.S.C. § 552a) and Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 C.F.R. § 164.512) to allow disclosure of all pertinent health care information to procurement organizations for the purpose of determining individual suitability for solid organ, tissue and eye donation after circulatory death (DCD), as provided in 38 U.S.C. §§ 5701(k)(1)(A) and 7332(b)(2)(E).

c. VA medical facilities must comply with external accrediting agencies and regulatory requirements to develop policies and procedures, with the medical staff’s participation, for the donation and procurement of organs, tissue or eyes.

d. The Uniform Anatomical Gift Act (UAGA) was drafted in 1968 by the National Conference of Commissioners on Uniform State Laws Commission. The UAGA was completed in order to increase organ and blood supplies and donation and to protect patients in the United States. It replaced numerous state laws concerning transplantation and laws lacking a uniform procedure of organ donation and an inadequate process of becoming a donor. All 50 States, the District of Columbia, Puerto Rico and the U.S. Virgin Islands have adopted the UAGA, and many have adopted subsequent amendments, the most recent dating from 2009. This directive contains many references to applicable State law, and most of these are likely to be addressed by the UAGA. Users are advised to consult with Regional Counsel for more information on the applicability of UAGA and other State laws to organ procurement and donation matters. **NOTE:** For the most recent text of the UAGA, see [https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=6705441e-40b7-fbd4-edd5-5748c63fbd79&forceDialog=0](https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=6705441e-40b7-fbd4-edd5-5748c63fbd79&forceDialog=0). This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.
3. DEFINITIONS

a. **Agreement.** An agreement is a contract between a VA medical facility and a procurement organization that details the responsibilities and obligations of each party with regard to identifying potential donors and facilitating the donation after death process. **NOTE:** For further information regarding agreements, see paragraph 6.

b. **Death.** For purposes of this directive, death is defined by applicable State law. The state of death, or deceased, can be established by either neurological criteria (brain death) or circulatory criteria (circulatory death).

   (1) **Brain Death.** Brain death is the irreversible cessation or loss of all functions of the brain, including the brainstem. Irreversible means that function will not resume spontaneously or artificially.

   (2) **Circulatory Death.** Circulatory death is the irreversible cessation of circulatory and respiratory functions. Irreversible means that function will not resume spontaneously or artificially. The criteria applied by providers for determination of circulatory death are established by State law, and must include a documented absence of circulation, apnea, and lack of responsiveness to verbal and tactile stimuli.

c. **Deceased Donor.** For purposes of this policy, a deceased donor is an individual from whom at least one organ or tissue source is recovered for transplantation after declaration of death. **NOTE:** 42 C.F.R. part 486 defines deceased donor as a deceased individual from whom at least one organ is procured and transplanted, or pancreas is recovered for research or islet cell transplantation.

d. **Donation after Circulatory Death.** Donation after circulatory death (DCD), also referred to as controlled DCD, is the voluntary decision of a patient (or an individual authorized by State law to make a donation decision on the patient’s behalf) to donate the patient’s organs, tissue or eyes following the death of the patient after voluntary removal of life-sustaining treatments. A DCD donor may also be called a non-heart beating, asystolic or donation after cardiac death donor. Until declaration of death, the patient is considered a potential donor.

e. **Electronic Health Record.** Electronic health record (EHR) is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. **NOTE:** The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.

f. **Procurement Organization Coordinator.** A procurement organization coordinator is a procurement organization staff member who coordinates with the VA medical facility designated Requestor or Liaison to carry out donation processes and procedures.
g. **Potential Donor.** For purposes of this policy, a potential donor is an individual who consented to organ, tissue or eye donation documented before their death in a manner that satisfies applicable State laws in the potential donor’s State of residence. A patient who refuses donation or expresses a preference against donation does not qualify as a potential donor. Such refusal or preference by the patient must be documented in the EHR.

h. **Procurement Organization.** A procurement organization is an organ procurement organization (OPO), an eye bank or a tissue bank.

1. An OPO is an organization responsible for procurement of deceased donor organs for organ transplantation. OPOs must meet the applicable requirements of 42 U.S.C. § 273(b)(1) and be certified by the Department of Health and Human Services (HHS).

2. Eye banks and tissue banks are organizations responsible for procurement of deceased donor corneas and tissues respectively for transplantation and regulated by HHS under 42 U.S.C. § 482.45 and 21 C.F.R. part 1271. Eye banks and tissue banks are often separate from OPOs, however, some OPOs may also provide eye and tissue procurement services.

4. **POLICY**

   It is VHA policy that all VA medical facilities enter into agreements with their local procurement organizations to identify potential solid organ, tissue and eye donors in a manner consistent with applicable State law. It is also VHA policy that donation and procurement must be adequately documented and must proceed in accordance with the highest medical and ethical standards.

5. **RESPONSIBILITIES**

   a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

   b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the National Surgery Office with implementation and oversight of this directive.

   c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

      1. Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

      2. Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.
(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **National Director of Surgery.** The National Director of Surgery is responsible for monitoring agreements between VA medical facilities and procurement organizations.

e. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that agreements between procurement organizations and VA medical facilities within the VISN comply with the requirements set forth in this directive.

f. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

- (1) Ensuring that appropriate VA medical facility staff comply with the requirements of this directive.

- (2) Establishing individual agreements with an OPO, a tissue bank and an eye bank, or establishing a single agreement with an OPO which provides all three procurement services including solid organ, tissue and eye.

- (3) Verifying annually with the Food and Drug Administration (FDA), in accordance with 38 C.F.R. § 1.514b, that:

  (a) Each eye bank and tissue bank with which the VA medical facility has an agreement has complied with the FDA registration requirement 21 C.F.R. part 1271.

  (b) The registration status is active and is not subject to any regulatory action to cease, suspend or otherwise limit operations before permitting an eye bank or tissue bank to receive protected health information.

- (4) Verifying that the VA medical facility has provided all required information to procurement organizations as specified in their agreement.

- (5) Ensuring that all disclosures of protected health information to procurement organizations are tracked to meet the accounting of disclosure requirements of VHA Directive 1605.01, Privacy and Release of Information, dated August 31, 2016.

- (6) Ensuring that the appropriate VA medical facility health care team and designated Requestor or Liaison work with the procurement organization to specify “maintenance of the deceased donor” parameters, relative costs and reimbursement arrangements in the agreement with the procurement organization. (See paragraph 6.)

- (7) Ensuring that the appropriate VA medical facility health care team and designated Requestor or Liaison are trained on and comply with the standard procedures for communicating with family members of DCD donors and the protocol for processing DCD donors. (See Appendices A and B.)

- (8) Ensuring that educational materials regarding organ donation and deceased donor registration are developed in collaboration with the local procurement
organization and available for educating patients and families. **NOTE:** Educational materials and indication of patient donation preferences may be incorporated into the usual clerical functions at enrollment, inpatient admission or stay, new patient orientation or outpatient encounters.

(9) Ensuring that a written communication procedure is in place for:

(a) Notifying the potential donor’s family of the patient’s decision (recognized by State law) to donate, as requested.

(b) Or, in the absence of a donor document or patient decision to donate made in accordance with applicable State law, notifying the individual authorized by State law to make a DCD decision on the patient’s behalf of their option to donate, or decline to donate, organs, tissue or eyes (see Appendix A). **NOTE:** The VA medical facility health care team and designated Requestor or Liaison should collaborate with the procurement organization to establish this procedure.

(10) Ensuring that written procedures for donating and procuring organs, tissue and eyes are in place that:

(a) Meet standards established by the procurement organization as required by accrediting entities.

(b) Comply with Section 3.1 of Department of Defense (DoD) Instruction 6465.03, Anatomic Gifts and Tissue Donation, dated June 8, 2016, or subsequent guidance provided by DoD for active duty Service members receiving treatment in a VA medical facility. **NOTE:** A copy of DoD Instruction 6465.03 can be located at: https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/646503p.pdf.

(11) Ensuring that a written procedure on processing DCD referrals is in place that includes guidelines for working with the procurement organizations to improve the deceased donor pool and maintain potential donors. See Appendix B.

(12) Ensuring that procurement of organs, tissue or eyes takes place only after the donor is declared dead by a qualified clinician not affiliated with any of the procurement organization or transplant teams. **NOTE:** The criteria applied by health care providers to determine death are established by State law.

(a) In accordance with applicable State law, death may be declared on the basis of cardiopulmonary criteria (circulatory death) or neurologic criteria (brain death).

(b) Cases referred to a medical examiner do not preclude donation after circulatory death or brain death. A case must be referred to the medical examiner following the same procedure in reporting these deaths to the procurement organization, as donation may be an option. The procurement organization contacts the medical examiner regarding the release of suitable organs, tissue or eyes for donation.
(13) Ensuring that an operating room (OR) with trained OR staff and equipment are available for performing recovery of major vital organs, tissue and eyes. For tissue and eye recovery, the morgue or bedside may be used in lieu of the OR. For those VA medical facilities without an OR, the procurement organization may make arrangements for transfer of the deceased donor to an appropriate medical facility.

(14) Ensuring that VA Transplant Centers in which any type of solid organ transplant procedures are performed onsite:

(a) Maintain membership in the OPTN.

(b) Provide organ transplant-related data to the OPTN, the Scientific Registry for Transplant Recipients, OPOs and HHS as requested.

(15) Providing appropriate management of procurement organization coordinators by ensuring that:

(a) The procurement organization is in compliance with requirements in law, regulations, VA and VHA policies to ensure the procurement organization coordinators, and procurement organization staff who perform procurement procedures, undergo appropriate level of background screening.

(b) If the procurement organization coordinators are accessing VA EHR, that they undergo the appropriate level of background screening required by VA. NOTE: All of personnel security must follow VHA Directive 0710, VHA Personnel Security and Suitability Program, dated October 11, 2018; VA Directive 6500, VA Cybersecurity Program, dated January 24, 2019; and VA Handbook 6500, Risk Management Framework for VA Information Systems-Tier 3: VA Information Security Program, dated March 10, 2015.

g. VA Medical Facility Chief of Staff or Associate Director of Patient Care Services/Nurse Executive. The VA medical facility Chief of Staff or Associate Director of Patient Care Services (ADPCS)/Nurse Executive, depending on the VA medical facility, is responsible for:

(1) Implementing, enforcing and monitoring protocols and procedures for solid organ, tissue and eye donation.

(2) Identifying staff, based on locally defined criteria, to be trained as VA medical facility designated Requestors or Liaisons.

(3) Ensuring there is trained VA medical facility designated Requestor or Liaison coverage for all shifts.

(4) Ensuring that the VA medical facility staff are aware of the right of the patient to consent or decline to consent to solid organ, tissue and eye donations in a manner consistent with State law. Additionally, in the absence of the patient’s decision and for
active duty Service members receiving treatment in VA medical facilities, ensuring the proper identification of the appropriate person responsible under State law to authorize donation of the patient’s organs, tissue or eyes under DoD Instruction 6465.03. **NOTE:** Consult with Regional Counsel as needed about the proper identification of such person under applicable State law.

h. **VA Medical Facility Designated Requestor or Liaison.** The VA medical facility designated Requestor or Liaison is responsible for:

(1) Notifying the procurement organization, or third party designated by that organization, of a patient’s death or that a death is imminent. The Requester or Liaison must make and document the call in a location easily accessible for review. (See Appendix B.) **NOTE:** A third party can be a call center independently contracted with the procurement organization that acts on behalf of that organization to receive notifications from medical facilities and facilitate communications related to the DCD process.

(2) Collaborating with procurement organization coordinators to facilitate the DCD authorization process.

(3) Ensuring that procurement organization coordinators have the information required by the procurement organization to make deceased donor suitability determinations.

(4) Ensuring relevant EHR are available for viewing by procurement organization coordinators.

(5) Notifying the family of the patient’s decision (recognized by State law) to donate their organs, tissue or eyes or, in the absence of such a decision, notifying the individual responsible for authorizing donations under State law of their right to donate, or decline to donate, the patient’s organs, tissue or eyes. **NOTE:** The VA medical facility designated Requestor or Liaison must complete a course offered and approved by the procurement organization that provides training in the methodology for approaching potential donor families.

i. **VA Medical Facility Attending Clinician.** The VA medical facility attending clinician is responsible for:

(1) Notifying the VA medical facility Director, the Chief of Staff, the ADPCS/Nurse Executive or the anesthesia staff (including the anesthesiologist or Certified Registered Nurse Anesthetist) in accordance with locally defined processes whether solid organ, tissue or eye donation is contemplated after death.

(2) Ensuring adherence to the standard procedures related to communication with family members of DCD donors and protocol for processing DCD donors (see Appendices A and B).
6. AGREEMENTS

a. Each VA medical facility must enter into agreements with specific procurement organizations for solid organ, tissue and eye donation. A list of OPOs is located at: https://www.organdonor.gov/awareness/organizations/local-opo.html. **NOTE:** In some areas, the OPO determines the medical suitability for tissue and eye donations, in effect acting as the gatekeeper for the tissue and eye banks. If an OPO is performing this duty, it must be noted in the agreement with the VA medical facility. In the absence of a tissue bank or an eye bank in some areas, the VA medical facility may enter into agreements with the OPO servicing those areas to provide tissue or eye procurement services.

b. Each agreement must:

1. Indicate that the procurement organization is insured for professional liability for services and activities performed under the agreement, and that the same or similar coverage exists for its directors, officers, employees, physicians, independent contractors, agents and representatives performing services under the agreement. The nature and amount of such insurance must be stated in the agreement.

2. State that the procurement organization will indemnify and hold VA harmless from any and all liability for loss, claims, damages, injury or death, including all costs, expenses, and reasonable attorney fees caused by or resulting from the acts or omissions of the procurement organization, its directors, officers, employees, physicians, independent contractors, agents or representatives for services and activities performed under the agreement.

3. Indicate the procurement organization’s compliance with law, regulations, VA and VHA policies to ensure that the procurement organization coordinators and procurement organization staff who perform procurement procedures undergo the appropriate level of background screening.

4. If the procurement organization coordinators are accessing VA EHR, ensure that they undergo the appropriate level of background screening required by VA. **NOTE:** All of personnel security should follow: VHA Directive 0710, VHA Personnel Security and Suitability Program, dated October 11, 2018; VA Directive 6500, VA Cybersecurity Program, dated January 24, 2019; and VA Handbook 6500, Risk Management Framework for VA Information Systems-Tier 3: VA Information Security Program, dated March 10, 2015.

5. Include requirements and specific process for the facility to notify the procurement organization, or third party designated by the OPO, tissue bank or eye bank, of a patient’s death or that a death is imminent. **NOTE:** A third party can be a call center independently contracted with the procurement organization that acts on behalf of that organization to receive notifications from medical facilities and facilitate communications related to the DCD process.
7. TRAINING

There are no formal Talent Management System training requirements associated with this directive. Each VA medical facility designated Requestor or Liaison must complete a course offered and approved by the procurement organization, as outlined in paragraph 5.h.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

9. REFERENCES


d. 21 C.F.R. part 1271.

e. 38 C.F.R. § .514b.

f. 42 C.F.R. part 486.

g. 45 C.F.R. § 164.512.


COMMUNICATING WITH FAMILY MEMBERS OF POTENTIAL DONATION AFTER CIRCULATORY DEATH DONORS

a. VA medical facility procedures must ensure that the family is notified of the patient’s decision, as recognized by State law, to donate their organs, tissue or eyes. In the absence of such a decision, these procedures must ensure that the individual who is responsible to authorize donations under State law is notified of the individual’s right to donate or decline to donate the patient’s organs, tissue or eyes. Such notification is to be made only by the procurement organization coordinator or a trained Department of Veterans Affairs (VA) medical facility-designated Requestor or Liaison.

b. The following are certain elements that facilitate communication with the donor’s family and, if applicable, with the individual responsible for making the donation decision under State law:

(1) Prior to approaching the family, the VA medical facility-designated Requestor or Liaison must review the patient’s electronic health record (EHR) to determine whether the patient’s decision has been documented to donate their organs, tissue or eyes in a manner consistent with applicable State law. If so (and the decision was not subsequently revoked prior to brain death or circulatory death), then the procurement organization coordinator must notify the patient’s family of the patient’s decision and that their decision will be honored. If the record shows that the patient refused donation, then the family must not be approached about donation. If the patient did not make a decision to donate that is recognized under applicable State law but had or had not expressed a preference in favor of donation, the procurement organization coordinator must share this information and the opportunity to donate solid organ, tissue or eyes with the family and, more specifically, with the individual authorized under State law to make the donation decision. **NOTE: In addition to the procurement organization coordinator, notification to the patient’s family or to the individual responsible for making the donation decision under State law may also come from a trained VA medical facility-designated Requestor or Liaison.**

(2) The family must be given time to understand and accept their relative’s imminent death before the donation discussion. The medical staff must continue to communicate honestly with the family regarding the patient’s prognosis. The family must be provided sufficient information to have a good understanding of the concepts of brain death and circulatory death.

(3) With the exception of patients subject to the terms of Department of Defense (DoD) Instruction 6465.03, when obtaining and determining authorization for donation after circulatory death, VA medical facility staff must follow applicable State law in all cases. Any disputes that arise must be referred to Regional Counsel and decided under applicable State law.
(4) Any discussion with the family regarding donation must be held in a quiet, private setting.
PROTOCOL FOR PROCESSING DONATION AFTER CIRCULATORY DEATH REFERRALS

The protocol for processing donation after circulatory death (DCD) referrals must include guidelines for working with the procurement organizations to improve the deceased donor pool and maintain potential donors. This protocol must:

a. Outline Department of Veterans Affairs (VA) medical facility processes and procedures for ensuring that patients are given the opportunity to indicate their preferences regarding solid organ, tissue and eye donation.

b. Ensure the patient’s decision complies with applicable State law or, in the absence of such a decision, ensure the patient’s preferences are documented and honored in a manner consistent with applicable State law.

c. Identify the affiliated procurement organization.

d. Outline processes and procedures for ensuring procurement organization coordinators undergo background screening as required by paragraph 6.

e. Describe the procedure used for notifying the procurement organization in a timely manner of a patient who has died or whose death is imminent, typically within one hour of the patient meeting the clinical triggers for death or imminent death. Instances where the procurement organization is not notified must be documented. **NOTE: OPOs should be notified of all hospital deaths. Documentation of death notification is best maintained in a location easily accessible for review.**

f. Ensure a procedure for maintaining the records of potential donors.

g. Address the requirement for VA medical facility staff discretion and sensitivity to the circumstances, beliefs and desires of potential donors and their families.

h. Establish guidelines for working cooperatively with the procurement organization in reviewing death records to improve identification of potential donors and to maintain potential donors while the necessary testing takes place.

i. Specify that prior to approaching the family of a medically suitable candidate for donation, the VA medical facility-designated Requestor or Liaison must review the patient’s electronic health record (EHR) for any documentation stating that the patient has made a decision or indicated a preference either in favor of or against DCD.

j. Specify that the family must not be approached for DCD if the patient has either made a decision or indicated a preference against DCD that is documented in the EHR.
k. Educate staff on medical chart reviews and DCD issues in cooperation with the procurement organization. Staff education must clarify the roles and responsibilities for both the VA medical facility and the procurement organization.

l. Address the timeframe for procurement practices to ensure viable DCD.

m. Include a reference or a copy of the applicable State laws governing (cadaveric) donation of organs, tissue and eyes. **NOTE:** Several states have done so by enacting or revising the Uniform Anatomical Gift Act of 1968.

n. Include a copy of the applicable State law(s) and criteria that define the time of a patient’s death. Regional Counsel must be contacted to obtain the appropriate legal reference materials. **NOTE:** Many States have done so by adopting the Uniform Determination of Death Act of 1980.