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ORGAN, TISSUE, AND EYE DONATION

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines policy and establishes guidelines for Department of Veterans Affairs (VA) medical centers to enter into agreements (Agreements) with their local Organ Procurement Organizations (OPO), tissue and/or eye banks for organ, tissue, and/or eye donation. This policy also sets out standard language for VA medical centers to use when entering into the Agreements.

2. BACKGROUND

a. Section 9318 of the Omnibus Budget Reconciliation Act (OBRA) of 1986 amended the Social Security Act to include several provisions relating to organ transplantation. Title 42, United States Code (U.S.C.), Section 1138(a) of the Social Security Act requires hospitals to establish written protocols for the identification and referral of potential organ donors to a certified OPO.

b. Effective August 21, 1998, the Health Care Financing Administration (HCFA) has implemented a revised regulation requiring Medicare-participating hospitals to meet certain additional requirements in order to continue participating in the Medicare program. VA is not required to comply with these regulations, as VA medical centers are not Medicare-participating hospitals. In order to enhance and maintain VA transplant programs, however, VA will voluntarily comply with the HCFA regulation to the extent possible under the law.

c. The revised regulation states that the hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO and will contact the OPO, or a third-party designated by the OPO, in a timely manner about individuals who die or whose death is imminent.

(2) Incorporate an agreement with at least one tissue bank and one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement.

(3) Ensure that the hospital will work with the OPO to inform families of patients about the option to donate organs, tissues and/or eyes. The individual designated by the hospital to approach the family must be either an organ procurement representative from the OPO or the hospital's designated requestor.

(4) Encourage discretion and sensitivity when dealing with families and potential donors, and will work cooperatively with OPOs and tissue and eye banks to educate staff on donation issues.

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(5) Ensure that the hospital works cooperatively with the OPO and tissue and eye banks in educating staff on donation issues, reviewing death records and maintain potential donors while necessary testing and placement takes place.

d. The HCFA regulation requires the release of patient information to OPOs and tissue and eye banks. VA, however, must comply with strict statutory limits regarding the release of patient information and medical records. Therefore, VA can comply with the regulation only to the extent that such compliance will not violate existing statutory law.

e. Three statutes control VA's release of patient information.

(1) **The Privacy Act, 5 U.S.C., Section 522a.** This limits VA's ability to provide information in a living patient's medical record to an OPO without the patient's prior written consent.

(2) **Title 38 U.S.C. , Section 5701a.** This limits VA's ability to provide to an OPO the name of a patient, the patient's dependents and their home addresses regardless of whether they are living or deceased.

(3) **Title 38 U.S.C., Section 7332.** This limits VA's disclosure of information identifying the patient, whether living or deceased, as being treated by VA for sickle cell anemia, Human Immunodeficiency Virus (HIV) infection, alcohol abuse or drug abuse to an OPO.

f. The Joint Commission on Accreditation of Healthcare Organization (JCAHO) has adopted this HCFA regulation as the standard for all hospitals. For VA medical centers to be in compliance with JCAHO, within the legal constraints under which VA must operate when disclosing patient information, they must meet JCAHO Standard RI.2 ; i.e., The hospital implements policies and procedures, developed with the medical staff's participation, for the procuring and donation of organs and other tissues. *NOTE: Under the Intent of the Standard, notification by Federally administered health care agencies is carried out according to procedures approved by the respective agency.*

g. Definitions

(1) **Agreement.** The term "agreement" is defined as an agreement between a medical center and an OPO, or a medical center and a tissue bank or an eye bank. The agreement must detail the responsibilities and obligations of the parties with regard to identifying potential donors and facilitating the donation process.

(2) **Designated Requestor.** A designated requestor is a hospital-based health care professional who has completed a course offered or approved by the OPO, designed in conjunction with the tissue and eye bank community, that provides training in the methodology for approaching potential donor families and requesting, organ, tissue and eye donation.

(3) **OPO Coordinator.** An OPO coordinator is an OPO staff member who is an organ procurement specialist. The coordinator responds on-site at the medical center, or by telephone, to assist in donor suitability determination and medical management, to facilitate the consent

process, to coordinate the surgical procurement of organs, and to assume immediate responsibility following procurement for the preservation and distribution of the organs to transplant centers according to guidelines established by United Network for Organ Sharing (UNOS).

(4) **Potential Donor.** A potential donor is an individual who suffers from a condition with terminal prognosis, or who is at a point where cardiac and respiratory death, or brain death has occurred or is imminent, and who, in the opinion of the attending physician, and in consultation with the OPO coordinator, meets the local OPO organ, tissue, or eye donor criteria.

3. POLICY

a. It is VHA policy that each medical center will enter into Agreements to identify potential organ, tissue, and/or eye donors and to notify family members of each potential donor of their option to donate or to decline donation of organs, tissue, or eyes. *NOTE: Discretion and sensitivity will be exercised along with respect to individual circumstances, views and beliefs of patients and families of potential donors.*

(1) An agreement between a medical center and an OPO must describe the medical center's process for notifying the OPO, or a third-party designated by the OPO, of individuals whose death is imminent, or who have died in the medical center. The OPO must be notified only after VA personnel have determined that patient information can be released to the OPO pursuant to the statutes listed in preceding subparagraph 2e. If the necessary releases are signed, the patient, family, or legal representative will be approached with the donation request, in accordance with VA policy described in this Directive. The agreement must indicate whether or not the OPO is responsible for determining medical suitability for eye tissue and eye donation.

(2) An agreement between a medical center and a tissue and/or eye bank must describe the medical center's procedures to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes. The eye bank or tissue bank must be notified of a potential donor only after VA personnel have determined that patient information can be released pursuant to that statutes listed in preceding subparagraph 2e. If the necessary releases have been signed, the patient, family, or legal representative will be approached with the donation request, in accordance with VA policy described in this Directive.

b. A written policy on processing referrals will be in place at all medical centers.

4. ACTION

a. All VA medical centers shall enter into Agreements for the referral of potential organ donors who have died or whose death is imminent. *NOTE: In some areas, the OPO determines 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 medical center.*

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(1) The Agreements must ensure that copies of the VA medical records and patient information are released by the VA medical center only in accordance with applicable Federal laws.

(2) The Agreements must have an exclusion provision which stipulates that prior to release of information to the OPO, tissue and/or eye bank, a preliminary review of the medical record be performed by the designated requestor to ascertain whether there is a prior written consent by the patient, or in some cases by the patient's family, or legal representative.

(3) The agreement must indicate that the OPO must be insured for professional liability services and activities performed under the agreement, and that this coverage extends to its directors, officers, employees, physicians, independent contractors, agents or representatives performing services under the agreement. Further, the agreement must indemnify and hold harmless VA from any and all liability for loss, for claims for damages or injury against VA that are caused by, or the result of, negligent and/or willful acts or omissions of the OPO, including employees, independent contractors, agents or representatives of the OPO. This indemnification must include all costs and expenses, including reasonable attorney fees.

b. Prior to notifying the OPO of a veteran's death or imminent death or releasing any information to the OPO, the medical center's designated requestor must review the veteran's records to determine what information, if any, can be released to the OPO. The designated requestor is responsible for ensuring that all necessary consent forms are signed.

(1) **Section 7332 information.** If a record contains Section 7332 information, VA cannot release any information identifying the patient as being treated by VA for sickle cell anemia, HIV infection, alcohol abuse or drug abuse, without the prior written consent of the patient.

(a) Section 7332 information can be released to the OPO if the veteran has signed the appropriate consent form. *NOTE: Other standard consent forms must also be obtained.*

(b) If a deceased veteran did not sign a consent form to release Section 7332 information, or if a veteran whose death is imminent is no longer able to provide such consent, VA cannot release any Section 7332 information to the OPO. The death records of such a veteran would not be available to the OPO for reviewing. In these instances, the OPO will not be notified of the death or imminent death of the veteran, but the reason for non-notification must be documented in the medical record (see Att. A). It is suggested that a copy of the documentation also be maintained in a central location for ease of retrieval and review by an accrediting agency.

(2) **Privacy Act Information (5 U.S.C., Section 552a) and Section 5701 information.** The Privacy Act is applied as follows for:

(a) Living Patients

1. With prior written consent by the patient, VA may release information and/or allow the OPO access to the patient's medical records.

2. Without prior written consent of the patient, VA cannot release information that is protected by the Privacy Act until VA implements a “routine use” authorizing such release to the OPO. Without the consent, the OPO will not be notified of the death or imminent death of the veteran, but the reason for non-notification must be documented in a notification log or some similar method of record-keeping. Such records are best maintained in a central location for ease of retrieval and review by an accrediting agency. If VA implements a “routine use” for releasing information to the OPO, certain information protected under 5 U.S.C., Section 552a, can be released to the OPO without the patient’s prior written consent. However, the facility may not release information protected by Section 7332 pursuant to such “routine use.” **NOTE:** *When the “routine use” for this written consent is implemented, this policy will be revised and reissued.*

3. Without the veteran’s prior written consent, 38 U.S.C., Section 5701 prohibits the release of the names and addresses of the living veterans and their dependents.

4. A court-appointed legal guardian or the parent of a minor may execute the prior written consent authorizing release of information on a patient to the OPO.

(b) Deceased Patients

1. The restrictions of the Privacy Act (Section 552a) do not apply to the records of a deceased veteran.

2. Under 38 U.S.C., Section 5701, the patient’s next of kin may execute the prior written consent authorizing the release of Section 5701(a) information to the OPO.

c. The VA medical center will have in place a written protocol which:

(1) Addresses organ donation as a part of the advance directives discussion with the patient and written consent for release of information.

(2) Identifies the affiliated OPO, tissue and/or eye banks.

(3) Describes the procedure used for notifying the OPO in a timely manner of a patient who has died, or whose death is imminent, as well as the procedure for maintaining records of potential donors whose names have been sent to the OPO, tissue and/or eye banks. There must be documentation of those instances where notification to the OPO is not made. **NOTE:** *This is best maintained in a central location for ease of retrieval and review by an accrediting agency.*

(4) Describes the procedure, developed in collaboration with the designated OPO, for notifying the family of each potential donor of the option to donate, or decline to donate, organ, tissue or eyes. The decision to donate or not donate must be documented in the patient’s medical record or in a central location designated by the hospital.

(5) Addresses the medical center staff’s discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential donors.

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(6) Sets out the guidelines used for working cooperatively with the OPO, tissue and/or eye banks in reviewing death records to improve identification of potential donors, and to maintain potential donors while the necessary testing and placement of potential donated organs, tissues and eyes takes place. These guidelines must take into account the statutory limits on disclosing patient information as set forth in subparagraphs 4.b.(1) and 4.b.(2).

(7) Addresses staff education on donation issues as a cooperative venture with the OPO, tissue and eye banks.

(8) Addresses staff education required to perform medical chart reviews.

(9) Defines clear roles and responsibilities for the medical center staff and the OPO coordinator.

(10) Additional elements of the protocol may include:

(a) Communicating often and honestly with the family about patient's prognosis.

(b) Making sure the family understands the concept of brain death.

(c) Decoupling the request for donation from the explanation of brain death.

(d) Using a quiet, private setting for discussion of donation option.

d. The protocol is to be implemented on or before the occurrence of all deaths in the medical center within a timeframe to permit viable donation.

e. The following factors influence the consent rate when the family is advised of its right to consent to donate or to decline donation.

(1) The family must be given time to understand and accept their relative's death before the donation request is made.

(2) The designated requestor, in conjunction with the OPO coordinator, should make the request. **NOTE:** *The donation option can first be mentioned to the family by the designated requestor, but the formal request should involve the OPO coordinator.*

(3) The request to donate should be made to the family in a quiet, private setting.

f. All 50 states have passed some version of the Uniform Anatomical Gift Act. Similarly, all have established locally-accepted criteria (usually the Uniform Determination of Death Act) for determining the time of a patient's death. The written protocols at each facility must include a reference and/or a copy of these state standards.

g. Medical Examiner cases do not preclude donation. The medical center will refer a case to the Medical Examiner in the usual way and will follow the same procedure in reporting these

deaths to the OPO, as donation may be an option. The OPO will contact the Medical Examiner regarding the release of suitable organs, tissues or eyes for donation.

h. The medical center will work cooperatively with the OPO, the tissue bank and/or the eye bank in maintaining potential donors while necessary testing and placement of potential donated organ and tissues takes place. Whenever possible, referrals should be made when death is imminent to ensure that brain-dead or near brain-dead patients are maintained until a referral is made and are not referred to the OPO after mechanical support has been discontinued and the organs are no longer viable. Regardless of whether a medical center has full ventilator capability, ventilator capability only for patients who are to be transferred to a larger facility, or no ventilator capability, the OPO must be notified if the patient privacy and confidentiality criteria are met.

i. **Responsibilities**

(1) The Governing Board of the medical center must have a written protocol that meets the intent of JCAHO Standard RI.2 to identify potential organ donors and implement the policies and procedures set forth in this Directive.

(2) The Chief of Staff is responsible for

(a) Implementing, enforcing and monitoring the protocol.

(b) Identifying an individual(s) to be responsible for notifying the OPO of a death or imminent death of a patient.

(c) The notification and release of information must only take place after review of the patient's chart by the designated requestor to ascertain whether all necessary releases have been obtained. *NOTE: The OPO will send a coordinator to carry out the requirements of the Agreement.*

(d) Identifying a nurse, physician or other health care professional to be the medical center's designated requestor.

(3) It is the Medical Staff's responsibility to be aware of the rights of the patient and patient's family to make, or decline to make, organ, tissue and/or eye donations. JCAHO Standard RI.1.2.4 requires the hospital to address advance directives. Under this Standard, if a patient elects to donate organs at the end of life, the hospital must have a process to honor that directive. *NOTE: This process should comply with the version of the Uniform Anatomical Gift Act in effect in that state.*

(4) The designated requestor at each medical center will be responsible for:

(a) Educating the nurses, physicians, and residents to identify donors.

(b) Performing a preliminary medical chart review to determine if the VA patient, parent of a minor patient or the patient's legal guardian under the applicable confidentiality statutes, has

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executed a consent for release of information. If there is no prior written consent in the file, obtain one, if possible. If it is not possible to obtain a prior written consent, determine whether any information can be released to the OPO, e.g., for a deceased patient, is there Section 7332-protected information in the patient's medical record.

(c) Notification of the OPO, or third-party designated by the OPO, tissue and/or eye bank of a patient's death or that a death is imminent. The designated requestor, or a designee, shall make and document the call on VA Form 10-0382, Routine Donor Referral Form, (see Att. A).

(d) Closely managing and coordinating the consent process with the OPO coordinator.

(e) Assisting organ procurement coordinators in donor management.

(5) The medical center must provide for an operating room with appropriate staff and equipment for performing recovery of major vital organs, tissue and eyes. For tissue and eye recovery the morgue may be used in lieu of the operating room. In medical centers without facilities for organ, tissue or eye recovery, the OPO will make arrangements for transfer of the donor to a community-based facility.

(6) The medical center and the OPO shall establish a schedule of fees for the medical center's facilities, staff and equipment used in the maintenance of the donor and the recovery of organs, tissue or eyes. All costs related to the maintenance of the donor and recovery of organs, tissue or eyes will be paid by the OPO.

(7) A VA medical center in which any type of solid organ transplant is performed must be a member of the Organ Procurement and Transplantation Network (OPTN). The VA medical center must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs to the extent allowed by statutes pertaining to the release of information. The VA medical center must provide such data directly to the Department of Health and Human Services when requested by the Secretary, Department of Health and Human Services.

5. REFERENCES

- a. Omnibus Budget Reconciliation Act of 1986, Public Law Number 99-509, 100 Stat 1874.
- b. The Social Security Act, 42 U.S.C., Section 601, et seq.
- c. Title 42 Code of Federal Regulations, Section 482.45(a)(1).
- d. Title 5 U.S.C., Section 552a.
- e. Title 38 U.S.C., Section 5701(a) and Section 7332.
- f. Joint Commission 1999 Comprehensive Accreditation Manual for Hospitals, Standard RI.2, Standard RI.1.2.4.

6. FOLLOWUP RESPONSIBILITY: The Chief Patient Care Services Officer (11) is responsible for the contents of this Directive.

7. RECISSION: None. This VHA Directive expires February 28, 2005.

S/ Frances Murphy, M.D. for
Thomas L. Garthwaite, M.D.
Deputy Under Secretary for Health

Attachment

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ATTACHMENT A



10-0382.pdf