

hailed by a U.S. Coast Guard vessel by siren, radio, flashing light, or other means, the person or vessel shall proceed as directed. If permission is granted, all persons or vessels must comply with the instructions of the Captain of the Port, Baltimore, Maryland, and proceed at the minimum speed necessary to maintain a safe course while within the zone.

(d) Enforcement. The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State and local agencies.

(e) Enforcement period. This section will be enforced from 2 p.m. through 7 p.m. on September 14, 2007.

Dated: August 9, 2007.

Austin J. Gould,

Commander, U.S. Coast Guard, Acting Captain of the Port, Baltimore, Maryland.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AM65

Disclosure of Information to Organ Procurement Organizations

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) regulations to implement section 204 of the Veterans Benefits, Health Care, and Information Technology Act of 2006. This regulatory change will provide 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 (OPOs) as defined in section 371(b) of the Public Health Service Act (PHS Act), eye banks, and tissue banks to determine whether the patients are suitable potential donors.

DATES: *Effective Date:* This interim final rule is effective August 23, 2007.

Comments must be received by VA on or before October 22, 2007.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to the Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to RIN 2900-

AM65—"Disclosure of Information to Organ Procurement Organizations." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273-9515 for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Stephania Putt, Veterans Health Administration Privacy Officer, Office of Information (19F2), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington DC 20420, (202) 320-1839.

SUPPLEMENTARY INFORMATION: Organ procurement organizations, eye banks, and tissue banks in the United States operate under specific statutory and regulatory authority. The statutory authority is contained in specific provisions of the Social Security Act (Act) and the PHS Act.

As noted in the preface to the 1988 edition of the United States Code, because title 42, United States Code (USC), has not been enacted into positive law, the provisions in title 42, U.S.C., are prima facie evidence of the laws rather than legal evidence of the laws. Consequently, the Secretary of Health and Human Services (HHS) generally uses and refers to the provisions of the Act and the PHS Act rather than the provisions as codified in title 42, U.S.C., when implementing the provisions of those laws in regulations. *e.g.*, 21 CFR 1271.1, 1271.10. Congress enacted title 38, U.S.C., into positive law, (Pub. L. 85-857 (1958) and reorganized and renumbered in Pub. L. 102-40 and 102-83 (1991)); as a result, the provisions of title 38 as published are legal evidence of the laws contained therein. People who deal with the VA are accustomed to using the section numbering in title 38, U.S.C., as published.

Because VA cites the code sections contained in title 38 and HHS cites the sections of the public laws underlying title 42, the VA will use the HHS citation form for laws under its responsibility, and title 38 section numbers in the regulations. However, for the convenience of the persons who will interact with the VA in the course of the VA's implementation of these regulations, the VA includes the title 42, U.S.C., cross-reference for the provisions of the Act and PHS Act when first cited in the preamble and the rule.

Section 1138(a) of the Act (42 U.S.C. 1320b-8(a)), requires all hospitals or critical access hospitals to establish written protocols for the identification of potential organ donors, and for referrals of potential donors to qualified OPOs that meet the criteria of section 1138(b)(1)(A) of the Act. Section 1138(b) provides that a qualified OPO: (1) Is described in section 371(b) of the PHS Act (42 U.S.C. 273(b)) that is operating under a grant made under section 371(a) of the PHS Act, or (2) has been certified or recertified by the Secretary of Health and Human Services (HHS Secretary) within the previous two years, or four years if the Secretary determines that the organization's past practices merits such treatment as meeting the HHS Secretary's standards to be a qualified OPO. The HHS Secretary shall designate only one OPO for each service area as provided in section 371(b)(1)(E) of the PHS Act. The implementing regulations are at 42 CFR 486.301-348.

Ocular tissue and other tissues are regulated by HHS under section 361 of the PHS Act (42 U.S.C. 264). The implementing regulations are in 21 CFR part 1271. These regulations establish the requirements for eye banks and tissue banks.

Under these respective sets of regulations, OPOs on the one hand and eye banks and tissue banks on the other hand are provided access by medical facilities to the protected health information of patients who are deceased or whose death is imminent without the prior written authorization of the patients so that representatives of the OPOs and eye banks and tissue banks may determine whether the patients may be suitable potential donors.

The rule promulgated by HHS under section 264 of the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191, 110 Stat. 1936, 2033-34 (1996)) (commonly referred to as the HIPAA Privacy Rule) provides express authority at 45 CFR 164.512(h) for disclosures of protected health information by covered health care providers to "OPOs, or other entities engaged in the procurement, banking or transplantation of organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation" conducted under the provisions of the PHS Act and its implementing regulations. Disclosures to eye banks and tissue banks are authorized under this language.

The Veterans Health Administration (VHA) is a covered entity under the HIPAA Privacy Rule for purposes of

care provided under chapter 17 of title 38, U.S.C. However, VHA protected health information covered by the HIPAA Privacy Rule is also covered by sections 5701 and 7332 of title 38, U.S.C. Prior to enactment of section 204 of Public Law 109-461, section 5701(a) limited VA's authority to release the names and home addresses of veterans and their dependents, and section 7332 precluded VHA from releasing protected health information concerning treatment for sickle cell anemia, drug abuse and alcoholism and alcohol abuse, and testing and treatment for the human immunodeficiency virus infection for all but a very limited number of purposes. Neither section provided statutory authority for VHA to provide protected health information on deceased patients or patients whose death was imminent to OPOs, eye banks, and tissue banks for consideration as non-living donors in the national donation programs.

Although not subject to the mandatory provisions of section 1138 of the Act and section 361 of the PHS Act, VHA tried to collaborate with OPOs, eye banks, and tissue banks in accordance with the statutes and regulations governing these entities to the extent possible within the restrictions on disclosure of individually-identified patient medical information imposed by sections 5701 and 7332. However, VHA discovered that the limitations of these statutes rendered VHA collaboration with these entities ineffective. Consequently, VA requested legislation to amend sections 5701 and 7332 to provide specific statutory authority for VHA to disclose protected health information covered by these statutes to OPOs, eye banks, and tissue banks without the prior written authorization of deceased patients or patients whose death is imminent for evaluation whether the patients may be suitable potential donors.

Congress responded by enacting section 204 of Public Law 109-461, which amended sections 5701 and 7332 of title 38, U.S.C., to authorize VHA to release information about deceased or near-death veterans or their dependents to donor organizations, so that they may determine whether these individuals are, or after death, will be suitable organ, tissue or eye donors. The legislation directs the Secretary of Veterans Affairs to prescribe regulations implementing VA's new disclosure authority by June 20, 2007.

New section 5701(k)(2) of title 38, U.S.C., specifically states that an OPO for purposes of disclosure authority under section 5701 (and under section 7332 as that statute was amended) has the meaning given the term "qualified

organ procurement organization" in section 371(b) of the PHS Act. Section 5701(k)(1)(B)(i) provides that OPOs include eye and tissue banks. However, section 5701, as amended, does not define eye and tissue banks, and the definition of OPOs in section 371(b) of the PHS Act does not include eye and tissue banks. In fact, OPOs are not tissue banks or eye banks, although some OPOs have eye banks or tissue banks that are administratively separate from the OPOs.

The amendment to section 5701 also provides that OPOs include entities that the Secretary of Veterans Affairs has determined are "(I) substantially similar in function, professionalism, and reliability to an organ procurement organization [as defined in section 371(b) of the PHS Act]; and (II) should be treated for purposes of this subsection in the same manner as an organ procurement organization." 38 U.S.C. 5701(k)(1)(B)(ii). The VA construes this language to provide authority for VA to promulgate regulations to authorize disclosure of protected health information to eye and tissue banks regulated by HHS under the authority of section 361 of the PHS Act, and the implementing regulations in 21 CFR part 1271.

As discussed above, there are long-established, dynamic, national organ, eye and tissue donation programs in the United States involving non-VHA medical facilities. HHS periodically certifies and recertifies OPOs and requires eye banks and tissue banks to register with the Food and Drug Administration in order to participate in these programs.

VHA medical facilities also perform organ, eye and tissue transplants with organs, eyes and tissues received from hospitals subject to section 1138(a) of the Act and the regulation at 42 CFR 482.45. The regulation requires every Medicare and Medicaid hospital to perform the following concerning organ, eye, and tissue procurement activities: Have an agreement with its designated OPO to report all deaths and imminent deaths to the OPO in a timely manner, collaborate with the OPO to inform families of potential donors of their donation options, and cooperate with the OPO to maintain potential donors while testing takes place. The regulation also requires hospitals to cooperate with tissue banks and eye banks to ensure that all usable tissues and eyes are obtained.

The Secretary of Veterans Affairs, in the exercise of the Secretary's discretion in administering title 38, U.S.C., has determined that in light of all factors, it is unnecessary, counterproductive and

confusing to the general public for VHA to establish a separate approval process for OPOs, eye banks, and tissue banks so that VHA's medical facilities can provide information about potential donors to these entities. Consequently, VHA will disclose protected health information to certified OPOs, and to eye banks and tissue banks that have registered with the FDA, and are procuring organs, corneas, and tissues from deceased donors for the purpose of transplantation in compliance with the applicable HHS regulations. VHA will not require these organizations to submit any information or meet any requirements beyond those required by HHS. These regulations provide that VHA medical facilities are to periodically confirm with HHS its approval or certification of each OPO, eye bank or tissue bank that seeks to obtain access to VHA protected health information in order to perform its duties under HHS statutes and regulations.

Sections 5701 and 7332, as amended by section 204 of Public Law 109-461, and as implemented by these regulations, are limited to disclosure of information about veterans and their dependents. Consequently, the regulations do not address disclosure of protected health information about other individuals who may be treated in VHA medical facilities to OPOs, eye banks, or tissue banks. For example, these regulations do not apply to disclosure of protected health information about members of the armed forces because disclosure of their protected health information for donation purposes is governed by 10 U.S.C. 1109 and the implementing Department of Defense regulations.

The regulations implementing the amendments to 38 U.S.C. 5701 and 7332 are inserted in the VA regulations implementing those provisions. The regulations addressing section 7332 are at 38 CFR 1.460-499, and the regulations concerning section 5701 are at 38 CFR 1.500-527. As part of the interim final rule, VA is amending the definitions contained in 38 CFR 1.460 to include definitions for terms used in the new 1.485a implementing the organ donation amendments to section 7332.

The amendments to sections 5701 and 7332 concerning living patients are intended to be limited to disclosures of information about individual patients whose death is imminent. VA has provided a definition of what the term "near death" means for donation purposes. This definition was drafted by the VA National Transplant Program in association with the Veterans Health Administration (VHA) National Center

for Ethics, which provides guidance to VHA health care practitioners on medical ethics issues in VHA. VHA understands the proposed definition of "near death" to be consistent with the standard historically applied in non-VHA health care facilities when determining whether to make a living patient's medical records available for representatives of OPOs, eye banks and tissue banks, specifically under 42 CFR 482.45(a) Medicare and Medicaid hospitals will make available records on "an individual whose death is imminent." However, VHA recognizes that this issue may be a sensitive subject. VA therefore specifically solicits comments on the definition of "near death" used in the regulations.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(3)(B), we find that there is good cause to dispense with advance public notice and opportunity to comment on this rule because any delay in promulgating the rule would be contrary to the public interest. In enacting section 204 of Public Law 109-461, Congress recognized the public's immediate need for VA's disclosure of organ donor information and specified that VA shall prescribe rules implementing the new law within 180 days. Also, as documented by information and data on www.organdonor.gov, the number of patients awaiting organ transplants far exceeds the number of available organs. Every day, 17 patients die waiting for an organ. VA's immediate collaboration with OPOs, eye banks, and tissue banks to facilitate organ, eye and tissue donation will result in individuals receiving life-saving or life-enhancing transplants that otherwise would be unavailable. Accordingly, it would be contrary to the intent of Congress to delay an initiative that seeks to address a compelling public need, while VA engages in advance notice and opportunity to comment. Pursuant to 5 U.S.C. 553(d), and for the reasons stated above, we also find that there is good cause to dispense with the requirement that a substantive rule be published no less than 30 days before its effective date.

Paperwork Reduction Act of 1995

This rule contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as

they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This rule governs VA's disclosure of individuals' medical records to certain Organ Procurement Organizations, eye banks, and tissue banks, some of which may be small entities. However, it will not affect a substantial number of small entities and will not have a significant economic impact on any such entity. Therefore, under 5 U.S.C. 605(b), this interim final rule is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this interim final rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in the Executive Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, and tribal

governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.011, Veterans Dental Care.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Archives and records, Cemeteries, Claims, Courts, Crime, Flags, Freedom of information, Government contracts, Government employees, Government property, Infants and children, Inventions and patents, Parking, Penalties, Privacy, Reporting and recordkeeping requirements, Seals and insignia, Security measures, Wages.

Approved: June 18, 2007.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

■ For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 1 to read as follows:

PART 1—GENERAL PROVISIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

■ 2. In § 1.460, add definitions for "Agreement", "Deceased", "Eye bank and tissue bank", "Individual", "Near death", "Organ Procurement Organization", "Procurement organization", and "VHA health care facility" in alphabetical order to read as follows:

§ 1.460 Definitions.

* * * * *

Agreement. The term "agreement" means a document that a VA health care facility develops in collaboration with an Organ Procurement Organization, eye bank or tissue bank with written, detailed responsibilities and obligations of the parties with regard to identifying potential donors and facilitating the donation process.

* * * * *

Deceased. The term "deceased" means death established by either neurological criteria (brain death) or cardiopulmonary criteria (cardiac death). Brain death is the irreversible

cessation of all brain function. Cardiac death is the irreversible cessation of circulatory and respiratory function. In both cases, "irreversible" means that function will not resume spontaneously and will not be restarted artificially.

* * * * *

Eye bank and tissue bank. The term "eye bank and tissue bank" means an "establishment" as defined in 21 CFR 1271.3, pursuant to section 361 of the Public Health Service Act (42 U.S.C. 264) that has a valid, current registration with the Federal Food and Drug Administration (FDA) as required under 21 CFR part 1271.

Individual. The term "individual" means a veteran, as defined in 38 U.S.C. 101(2), or a dependent of a veteran, as defined in 38 U.S.C. 101(3) and (4)(A).

* * * * *

Near death. The term "near death" means that in the clinical judgment of the patient's health care provider, the patient's death is imminent.

Organ Procurement Organization. The term "Organ Procurement Organization" (OPO) means an organization that performs or coordinates the procurement, preservation, and transportation of organs and maintains a system of locating prospective recipients for available organs.

Procurement organization. The term "procurement organization" means an organ procurement organization, eye bank, and/or tissue banks as defined in this section.

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VHA health care facility. The term "VHA health care facility" means a VA medical center, VA emergency room,

VA nursing home or other facility as defined in 38 U.S.C. 1701(3).

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■ 3. Add new § 1.485a, to read as follows:

§ 1.485a Eye, organ and tissue donation.

A VHA health care facility may disclose the individually-identified medical record information of an individual covered by §§ 1.460 through 1.499 of this part to an authorized representative of a procurement organization for the purpose of facilitating determination of whether the individual is a suitable potential organ, eye, or tissue donor if:

(a) The individual is currently an inpatient in a VHA health care facility;

(b) The individual is, in the clinical judgment of the individual's primary health care provider, near death or deceased;

(c) The VHA health care facility has a signed agreement with the procurement organization in accordance with the applicable requirements of the United States Department of Health and Human Services (HHS); and

(d) The VHA health care facility has confirmed with HHS that it has certified or recertified the organ procurement organization as provided in the applicable HHS regulations. VA medical centers must verify annually in January of each calendar year with the Food and Drug Administration (FDA) that an eye bank and tissue bank has complied with the FDA registration requirements of 21 CFR part 1271 before permitting an eye bank or tissue bank to receive protected health information.

(Authority: 38 U.S.C. 5701(k), 7332(b)(2)(E))

■ 4. Add new § 1.514b, to read as follows:

§ 1.514b Disclosures to procurement organizations.

A VHA health care facility may disclose the name and home address of an "individual" as defined in § 1.460 to an authorized representative of a "procurement organization" as also defined in § 1.460 for the purpose of facilitating a determination by the procurement organization of whether the individual is a suitable potential organ, eye, or tissue donor if:

(a) The individual is currently an inpatient in a VHA health care facility;

(b) The individual is, in the clinical judgment of the individual's primary health care provider, near death or is deceased as defined in § 1.460;

(c) The VHA health care facility has a signed agreement with the procurement organization in accordance with the applicable requirements of the United States Department of Health and Human Services (HHS); and

(d) The VHA health care facility has confirmed with HHS that it has certified or recertified the organ procurement organization as provided in the applicable HHS regulations. VA medical centers must verify annually in January of each calendar year with FDA that an eye bank or tissue bank has complied with the FDA registration requirements of 21 CFR Part 1271 before permitting an eye bank or tissue bank to receive protected health information.

(Authority: 38 U.S.C. 5701(k), 7332(b)(2)(E))

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