individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA jurisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) Procedures. Immediately following disclosure, any VA employee making an oral disclosure under authority of this section shall make an accounting of the disclosure in accordance with the Privacy Act (5 U.S.C. 552a(c) and 38 CFR 1.576(c)) and document the disclosure in the patient’s records setting forth in writing:

(1) The name and address of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
(2) The name of the individual making the disclosure;
(3) The date and time of the disclosure;
(4) The nature of the emergency (or error, if the report was to FDA);
(5) The information disclosed; and
(6) The authority for making the disclosure (§ 1.485 of this part).

(Authority: 38 U.S.C. 7332(b)(2)(A))

§ 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 or tissue bank has complied with the FDA registration requirements of 21 CFR part 1271 and that the registration status is active before permitting an eye bank or tissue bank to receive protected health information.

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


§ 1.486 Disclosure of information related to infection with the human immunodeficiency virus to public health authorities.

(a) In the case of any record which is maintained in connection with the performance of any program or activity relating to infection with the HIV, information may be disclosed to a Federal, State, or local public health authority, charged under Federal or State law with the protection of the public health, and to which Federal or State law requires disclosure of such record, if a qualified representative of such authority has made a written request that such record be provided as required pursuant to such law for a purpose authorized by such law. In the case of a State law, such law must, in order for VA to be able to release patient name and address information in accordance with 38 U.S.C. 5701(f)(2), provide for a penalty or fine or other sanction to be assessed against those individuals who are subject to the jurisdiction of the public health authority but fail to comply with the reporting requirements.

(b) A person to whom a record is disclosed under this section may not disclose or use such record for a purpose other than that for which the disclosure was made.

(Authority: 38 U.S.C. 7332(b)(2)(C))

§ 1.487 Disclosure of information related to infection with the human immunodeficiency virus to the spouse or sexual partner of the patient.

(a) Subject to paragraph (b) of this section, a physician or a professional counselor may disclose information or