

## Department of Veterans Affairs

## § 1.475

Health Service Act (42 U.S.C. 241(d) and the implementing regulations at 42 CFR Part 2a); or Sec. 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These “research privilege” statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* Sections 1.460 through 1.499 of this part restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under §§ 1.490 through 1.499 of this part of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under those regulations. Thus, if a court order entered in accordance with §§ 1.490 through 1.499 of this part authorizes a VA facility to disclose certain information about its patients, the facility may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

(Authority: 38 U.S.C. 7334)

### § 1.469 Patient access and restrictions on use.

(a) *Patient access not prohibited.* Sections 1.460 through 1.499 of this part do not prohibit a facility from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that VA maintains about the patient, subject to the provisions of the Privacy Act (5 U.S.C.

552a(d)(1)) and 38 CFR 1.577. If the patient is accompanied, giving access to the patient and the accompanying person will require a written consent by the patient which is provided in accordance with § 1.475 of this part.

(b) *Restrictions on use of information.* Information obtained by patient access to patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under § 1.461(d)(1) of this part.

(Authority: 38 U.S.C. 7334)

### §§ 1.470–1.474 [Reserved]

#### DISCLOSURES WITH PATIENT’S CONSENT

### § 1.475 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under §§ 1.460 through 1.499 of this part must include:

(1) The name of the facility permitted to make the disclosure (such a designation does not preclude the release of records from other VA health care facilities unless a restriction is stated on the consent).

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 1.464 of this part; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 1.465 of this part in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the facility which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

**§ 1.476**

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

- (1) Has expired;
- (2) On its face substantially fails to conform to any of the requirements set forth in paragraph (a) of this section;
- (3) Is known to have been revoked; or
- (4) Is known, or through a reasonable effort could be known, by responsible personnel of VA to be materially false.

(c) *Notification of deficient consent.* Other than the patient, no person or entity may be advised that a special consent is required in order to disclose information relating to an individual participating in a drug abuse, alcoholism or alcohol abuse, HIV, or sickle cell anemia program or activity. Where a person or entity presents VA with an insufficient written consent for information protected by 38 U.S.C. 7332, VA must, in the process of obtaining a legally sufficient consent, correspond only with the patient whose records are involved, or the legal guardian of an incompetent patient or next of kin of a deceased patient, and not with any other person.

(d) It is not necessary to use any particular form to establish a consent referred to in paragraph (a) of this section, however, VA Form 10-5345, titled Request for and Consent to Release of Medical Records Protected by 38 U.S.C. 7332, may be used for such purpose.

(Authority: 38 U.S.C. 7332(a)(2) and (b)(1))

**§ 1.476 Prohibition on redisclosure.**

Each disclosure under §§ 1.460 through 1.499 of this part made with the patient's written consent must be accompanied by a written statement similar to the following:

This information has been disclosed to you from records protected by Federal confidentiality rules (38 CFR Part 1). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 38 CFR

**38 CFR Ch. I (7-1-05 Edition)**

Part 1. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient or patient with sickle cell anemia or HIV infection.

(Authority: 38 U.S.C. 7334)

**§ 1.477 Disclosures permitted with written consent.**

If a patient consents to a disclosure of his or her records under § 1.475 of this part, a facility may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 1.478 and 1.479 of this part, respectively.

(Authority: 38 U.S.C. 7332(b)(1))

**§ 1.478 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs; not applicable to records relating to sickle cell anemia or infection with the human immunodeficiency virus.**

(a) *Definitions.* For purposes of this section:

(1) *Central registry* means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

(2) *Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

(3) *Maintenance treatment* means the dispensing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(4) *Member program* means a non-VA detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any

border of the State in which the central registry is located.

(b) *Restrictions on disclosure.* VA may disclose patient records to a central registry which is located in the same State or is not more than 125 miles from any border of the State or to any non-VA detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 1.475 of this part, except that:

(i) The consent must list the name and address of each central registry and each known non-VA detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any non-VA detoxification or maintenance treatment program established within 200 miles after the consent is given without naming any such program.

(c) *Use of information limited to prevention of multiple enrollments.* A central registry and any non-VA detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not re-disclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under §§ 1.490 through 1.499 of this part.

(Authority: 38 U.S.C. 7334)

**§ 1.479 Disclosures to elements of the criminal justice system which have referred patients.**

(a) VA may disclose information about a patient from records covered by §§ 1.460 through 1.499 of this part to those persons within the criminal justice system which have made partici-

pation in a VA treatment program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent as a condition of admission to the treatment program meeting the requirements of § 1.475 of this part (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment recognizing that revocation of consent may not generally be effected while treatment is ongoing;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when the final disposition will occur; and

(3) Such other factors as the facility, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state that it is revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event. The time or occurrence upon which consent becomes revocable may be no earlier than the individual's completion of the treatment program and no later than the final disposition of the conditional release or other action in connection with which consent was given.

(d) *Restrictions on redisclosure and use.* A person who receives patient information under this section may redisclose

**§§ 1.480–1.484**

**38 CFR Ch. I (7–1–05 Edition)**

and use it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given, including parole.

(Authority: 38 U.S.C. 7334)

**§§ 1.480–1.484 [Reserved]**

DISCLOSURES WITHOUT PATIENT  
CONSENT

**§ 1.485 Medical emergencies.**

(a) *General rule.* Under the procedures required by paragraph (c) of this section, patient identifying information from records covered by §§ 1.460 through 1.499 of this part may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.

(b) *Special rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any 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))

**§ 1.486 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 re-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 records indicating that a patient is infected with the HIV if the disclosure is made to the spouse of the patient, or to an individual whom the patient has, during the process of professional counseling or of testing to determine whether the patient is infected with such virus, identified as being a sexual partner of such patient.

(b) A disclosure under this section may be made only if the physician or