VA drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia treatment program. A facility may require patients to use or carry cards or other identification objects on the premises of a facility. Patients may not be required to wear clothing or colored identification bracelets or display objects openly to all facility staff or others which would identify them as being treated for drug or alcohol abuse, HIV infection, or sickle cell anemia.

(b) Treatment locations should not be identified by signs that would identify individuals entering or exiting these locations as patients enrolled in a drug or alcohol abuse, HIV infection, or sickle cell anemia program or activity.

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

§ 1.468 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege description.* There may be concurrent coverage of patient identifying information by the provisions of §§ 1.460 through 1.499 of this part and by administrative action taken under Sec. 303(a) of the Public 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.

(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 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))