

SUBCHAPTER A—GENERAL PROVISIONS

PART 1 [RESERVED]

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Sec.

- 2.1 Statutory authority for confidentiality of drug abuse patient records.
- 2.2 Statutory authority for confidentiality of alcohol abuse patient records.
- 2.3 Purpose and effect.
- 2.4 Criminal penalty for violation.
- 2.5 Reports of violations.

Subpart B—General Provisions

- 2.11 Definitions.
- 2.12 Applicability.
- 2.13 Confidentiality restrictions.
- 2.14 Minor patients.
- 2.15 Incompetent and deceased patients.
- 2.16 Security for written records.
- 2.17 Undercover agents and informants.
- 2.18 Restrictions on the use of identification cards.
- 2.19 Disposition of records by discontinued programs.
- 2.20 Relationship to State laws.
- 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.
- 2.22 Notice to patients of Federal confidentiality requirements.
- 2.23 Patient access and restrictions on use.

Subpart C—Disclosures With Patient's Consent

- 2.31 Form of written consent.
- 2.32 Prohibition on redisclosure.
- 2.33 Disclosures permitted with written consent.
- 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.
- 2.35 Disclosures to elements of the criminal justice system which have referred patients.

Subpart D—Disclosures Without Patient Consent

- 2.51 Medical emergencies.
- 2.52 Research activities.
- 2.53 Audit and evaluation activities.

Subpart E—Court Orders Authorizing Disclosure and Use

- 2.61 Legal effect of order.
- 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.
- 2.63 Confidential communications.
- 2.64 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.
- 2.65 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.
- 2.66 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.
- 2.67 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

AUTHORITY: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852; sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3), as amended by sec. 131 of Pub. L. 102-321, 106 Stat. 368, (42 U.S.C. 290dd-2).

SOURCE: 52 FR 21809, June 9, 1987, unless otherwise noted.

Subpart A—Introduction

§2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were initially authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section as amended was transferred by Pub. L. 98-24 to section 527 of the Public Health Service Act which is codified

§2.2

42 CFR Ch. I (10–1–16 Edition)

at 42 U.S.C. 290ee–3. The amended statutory authority is set forth below:

§ 290ee–3. CONFIDENTIALITY OF PATIENT RECORDS.

(a) *Disclosure authorization*

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) *Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent*

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) *Prohibition against use of record in making criminal charges or investigation of patient*

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a

patient or to conduct any investigation of a patient.

(d) *Continuing prohibition against disclosure irrespective of status as patient*

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) *Armed Forces and Veterans' Administration; interchange of records; report of suspected child abuse and neglect to State or local authorities*

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) *Penalty for first and subsequent offenses*

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than \$500 in the case of a first offense, and not more than \$5,000 in the case of each subsequent offense.

(g) *Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders*

Except as provided in subsection (h) of this section, the Secretary, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§2.2 **Statutory authority for confidentiality of alcohol abuse patient records.**

The restrictions of these regulations upon the disclosure and use of alcohol