SUBCHAPTER III—PROTECTION OF PATIENT RIGHTS

§ 7331. Informed consent

The Secretary, upon the recommendation of the Under Secretary for Health and pursuant to the provisions of section 7334 of this title, shall prescribe regulations establishing procedures to ensure that all medical and prosthetic research carried out and, to the maximum extent practicable, all patient care furnished under this title shall be carried out only with the full and informed consent of the patient or subject or, in appropriate cases, a representative thereof.

(Added Pub. L. 94–581, title I, § 111(a)(1), Oct. 21, 1976, 90 Stat. 2849, § 4131; renumbered § 7331 and amended Pub. L. 102–40, title IV, §§ 401(a)(4)(A), 402(d)(1), 403(a)(1), May 7, 1991, 105 Stat. 221, 239; Pub. L. 102–405, title III, § 302(c)(1), Oct. 9, 1992, 106 Stat. 1984.)

Editorial Notes

AMENDMENTS

1992—Pub. L. 102–405 substituted ''Under Secretary for Health'' for ''Chief Medical Director''.

1991—Pub. L. 102–40, § 401(a)(4)(A), renumbered section 4131 of this title as this section.

Pub. L. 102–40, § 403(a)(1), substituted ''Secretary'' for ''Administrator''.

Pub. L. 102–40, § 402(d)(1), substituted ''7334'' for ''4134''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Subchapter effective Oct. 21, 1976, see section 211 of Pub. L. 94–581, set out as an Effective Date of 1976 Amendment note under section 111 of this title.

§ 7332. Confidentiality of certain medical records

(a)(1) Records of the identity, diagnosis, prognosis, or treatment of any patient or subject which are maintained in connection with the performance of any program or activity (including education, training, treatment, rehabilitation, or research) relating to drug abuse, alcoholism or alcohol abuse, infection with the human immunodeficiency virus, or sickle cell anemia which is carried out by or for the Department under this title shall, except as provided in subsections (e) and (f), be confidential, and (section 5701 of this title to the contrary notwithstanding) such records may be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(2) Paragraph (1) prohibits the disclosure to any person or entity other than the patient or subject concerned of the fact that a special written consent is required in order for such records to be disclosed.

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

(2) Whether or not any patient or subject, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed by the Secretary 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 or subject in any report of such research, audit, or evaluation, or otherwise disclose patient or subject identities in any manner.

(C)(i) In the case of any record which is maintained in connection with the performance of any program or activity relating to infection with the human immunodeficiency virus, 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.

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

(D) 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 or subject, 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.

(E) To an entity described in paragraph (1)(B) of section 5701(k) of this title, but only to the extent authorized by such section.

(F)(i) To a representative of a patient who lacks decision-making capacity, when a practitioner deems the content of the given record necessary for that representative to make an informed decision regarding the patient's treatment.

(ii) In this subparagraph, the term ''representative'' means an individual, organization, or other body authorized under section 7331 of this title and its implementing regulations to give informed consent on behalf of a patient who lacks decision-making capacity.

(G) To a State controlled substance monitoring program, including a program approved by the Secretary of Health and Human Services under section 399O of the Public Health Service Act (42 U.S.C. 280g–3), to the extent necessary to prevent misuse and diversion of prescription medicines.

(H)(i) To a non-Department entity (including private entities and other Federal agencies) for purposes of providing health care, including hospital care, medical services, and extended care services, to patients or performing other health care-related activities or functions.