Public Health Service, HHS

§ 2.22 Notice to patients of federal confidentiality requirements.

(a) Notice required. At the time of admission to a part 2 program or, in the case that a patient does not have capacity upon admission to understand his or her medical status, as soon thereafter as the patient attains such capacity, each part 2 program shall:

(1) Communicate to the patient that federal law and regulations protect the confidentiality of substance use disorder patient records;

(2) Give to the patient a summary in writing of the federal law and regulations.

(b) Required elements of written summary. The written summary of the federal law and regulations must include:

(1) A general description of the limited circumstances under which a part 2 program may acknowledge that an individual is present or disclose outside the part 2 program information identifying a patient as having or having had a substance use disorder;

(2) A statement that violation of the federal law and regulations by a part 2 program is a crime and that suspected violations may be reported to appropriate authorities consistent with §2.4, along with contact information;

(3) A statement that information related to a patient’s commission of a crime on the premises of the part 2 program or against personnel of the part 2 program is not protected;

(4) A statement that reports of suspected child abuse and neglect made under state law to appropriate state or local authorities are not protected; and

(5) A citation to the federal law and regulations.

(c) Program options. The part 2 program must devise a notice to comply with the requirement to provide the patient with a summary in writing of the federal law and regulations. In this written summary, the part 2 program also may include information concerning state law and any of the part 2 program’s policies that are not inconsistent with state and federal law on the subject of confidentiality of substance use disorder patient records.

§ 2.20 Relationship to state laws.

The statute authorizing the regulations in this part (42 U.S.C. 290dd–2) does not preempt the field of law which they cover to the exclusion of all state laws in that field. If a disclosure permitted under the regulations in this part is prohibited under state law, neither the regulations in this part nor the authorizing statute may be construed to authorize any violation of that state law. However, no state law may either authorize or compel any disclosure prohibited by the regulations in this part.

§ 2.21 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 regulations in this part and by administrative action taken under section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR part 1316); or section 301(d) of the Public Health Service Act (42 U.S.C. 241(d) and the implementing regulations at 42 CFR part 2a). 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. These regulations 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 subpart E 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.

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