copy have implemented encryption to encrypt the data at rest so that there is a low probability of assigning meaning without the use of a confidential process or key and implemented access controls for the confidential process or key.

(ii) Within one year of the discontinuation or acquisition of the program, all electronic media on which the patient records or patient identifying information resided prior to being transferred to the device specified in paragraph (b)(2)(i)(A) of this section or the original and backup electronic media specified in paragraph (b)(2)(i)(B) of this section, including email and other electronic communications, must be sanitized to render the patient identifying information non-retrievable in a manner consistent with the discontinued program's or acquiring program's policies and procedures established under § 2.16.

(iii) The portable electronic device or the original and backup electronic media must be:

(A) Sealed in a container along with any equipment needed to read or access the information, and labeled as follows: ''Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, court order or other legal authority requiring that records be kept] until a date not later than [insert appropriate date];'' and

(B) Held under the restrictions of the regulations in this part by a responsible person who must store the container in a manner that will protect the information (*e.g.*, climate-controlled environment).

(iv) The responsible person must be included on the access control list and be provided a means for decrypting the data. The responsible person must store the decryption tools on a device or at a location separate from the data they are used to encrypt or decrypt.

(v) As soon as practicable after the end of the required retention period specified on the label, the portable electronic device or the original and backup electronic media must be sanitized to render the patient identifying information non-retrievable consistent with the policies established under § 2.16.

[82 FR 6115, Jan. 18, 2017, as amended at 89 FR 12622, Feb. 16, 2024]

§ 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 use or 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 use or disclosure prohibited by the regulations in this part.

[89 FR 12623, Feb. 16, 2024]

§ 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.* The regulations in this part restrict the use and disclosure of information about patients, while administrative action taken under the research privilege statutes and implementing regulations in paragraph (a) of this section 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.

[82 FR 6115, Jan. 18, 2017, as amended at 89 FR 12623, Feb. 16, 2024]

§ 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 their medical status, as soon thereafter as the patient attains such capacity, each part 2 program shall inform the patient that Federal law protects the confidentiality of substance use disorder patient records.

(b) *Content of notice.* In addition to the communication required in paragraph (a) of this section, a part 2 program shall provide notice, written in plain language, of the program's legal duties and privacy practices, as specified in this paragraph (b).

(1) *Required elements.* The notice must include the following content:

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed.

NOTICE OF PRIVACY PRACTICES OF [NAME OF PART 2 PROGRAM]

This notice describes:

• HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED

• YOUR RIGHTS WITH RESPECT TO YOUR HEALTH INFORMATION

• HOW TO FILE A COMPLAINT CONCERNING A VIOLATION OF THE PRIVACY OR SECURITY OF YOUR HEALTH INFORMATION, OR OF YOUR RIGHTS CONCERNING YOUR INFORMATION

YOU HAVE A RIGHT TO A COPY OF THIS NOTICE (IN PAPER OR ELECTRONIC FORM) AND TO DISCUSS IT WITH [ENTER NAME OR TITLE] AT [PHONE AND EMAIL] IF YOU HAVE ANY QUESTIONS.

(ii) *Uses and disclosures.* The notice must contain:

(A) A description of each of the purposes for which the part 2 program is permitted or required by this part to use or disclose records without the patient's written consent.

(B) If a use or disclosure for any purpose described in paragraph (b)(1)(ii)(A) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law.

(C) For each purpose described in accordance with paragraphs (b)(1)(ii)(A) and (B) of this section, the description must include sufficient detail to place the patient on notice of the uses and disclosures that are permitted or required by this part and other applicable law.

(D) A description, including at least one example, of the types of uses and disclosures that require written consent under this part.

(E) A statement that a patient may provide a single consent for all future uses or disclosures for treatment, payment, and health care operations purposes.

(F) A statement that the part 2 program will make uses and disclosures not described in the notice only with the patient's written consent.

(G) A statement that the patient may revoke written consent as provided by §§ 2.31 and 2.35.

(H) A statement that includes the following information:

(*1*) Records, or testimony relaying the content of such records, shall not be used or disclosed in any civil, administrative, criminal, or legislative proceedings against the patient unless based on specific written consent or a court order;

(*2*) Records shall only be used or disclosed based on a court order after notice and an opportunity to be heard is provided to the patient or the holder of the record, where required by 42 U.S.C. 290dd–2 and this part; and

(*3*) A court order authorizing use or disclosure must be accompanied by a subpoena or other similar legal mandate compelling disclosure before the record is used or disclosed.

(iii) *Separate statements for certain uses or disclosures.* If the part 2 program intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(D) of this section must include a separate statement as follows:

(A) Records that are disclosed to a part 2 program, covered entity, or business associate pursuant to the patient's written consent for treatment,