Institute for Health Policy and Practice

SAMHSA
42 CFR Part 2 Rule Update

APCD Council

July 22, 2020

General Information

- This final rule is effective August 14, 2020 (pg. 42986).
- SAMHSA received 684 public comment submissions (pg. 42988).
- SAMHSA recognizes the need for educational outreach both to persons with SUD and to providers in connection with the final rule, and is considering opportunities for further guidance and for carrying out related educational outreach. SAMHSA will continue to monitor the response to part 2 in the SUD treatment community, and will consider future refinements and further clarification to the part 2 rules as needed (pg. 42991).

General Information

- Special Emphasis about the CARES Act
  - Section 3221 of the CARES Act, Confidentiality and Disclosure of Records Relating to Substance Use Disorder, substantially amended several sections of the part 2 authorizing statute; specifically, sections 42 U.S.C. 290dd–2(b), (c) and (f), which specify requirements for patient consent, restrict the use of records in legal proceedings, and set penalties for violations of the statute, respectively…
  - The statutory timeline in § 3221 prevents the part 2-related provisions of the CARES Act from taking effect before March 27, 2021
  - HHS anticipates releasing a new proposed rule within the next 12 months to implement § 3221 of the CARES Act

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Questions

2.52 Research

- Background Information
  - …better aligns the requirements of part 2, the Common Rule, and the Privacy Rule around the conduct of research on human subjects, and seeks to streamline duplicative requirements for research disclosures under part 2 and the Privacy Rule in some instances.

2.52 Research

- Public Comment Response
  - …the disclosure by a lawful holder of SUD records for the purpose of research to a state agency without a part 2 patient consent may be barred, given that most state agencies are neither HIPAA-covered entities nor directly subject to the Common Rule. It is not SAMHSA's intention or policy to make it more burdensome for these sorts of stakeholders to carry out scientific research.
  - SAMHSA proposed to modify the text of § 2.52(a), in order to allow research disclosures of part 2 data from a HIPAA covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule, provided that any such data will be disclosed in accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i).

2.52 Research

- Public Comment Response
  - Under our revisions, a part 2 program or other lawful holder of part 2 data is authorized to disclose part 2 data for research purposes, including to state agencies, provided that the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i). Broadening the research exception further is beyond the scope of the current rulemaking activities. Note, however, that the CARES Act specifically permits disclosures of de- identified data to a public health authority whether or not a patient gives written consent. HHS anticipates future rulemaking to implement § 3221 of the CARES Act (pg. 43020).

2.52 Research

- Rule Language Revisions
  - Notwithstanding other provisions of this part, including paragraph (b)(2) of this section, patient identifying information may be disclosed for the purposes of the recipient conducting scientific research if:

    (ii) Subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46), and provides documentation either that the researcher is in compliance with the requirements of 45 CFR part 46, including the requirements related to informed consent or a waiver of consent (45 CFR 46.111 and 46.116) or that the research qualifies for exemption under the HHS regulations (45 CFR 46.104) or any successor regulations (pg. 43038).

    (2) The part 2 program or other lawful holder of part 2 data is a HIPAA covered entity or business associate, and the disclosure is made in accordance with the HIPAA Privacy Rule requirements at 45 CFR 164.512(i) (pg. 43039).

2.53 Audit and Evaluation

- Background Information
  - Audit and evaluation (2.53) clarifies that federal, state and local governmental agencies and third-party payers may conduct audits and evaluations to identify needed actions at the agency or payer level to improve care; that audits and evaluations may include reviews of appropriateness of medical care, medical necessity,
  - Section 2.53 allows for patient identifying information to be disclosed to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by statute or regulation (pg. 42989).

2.53 Audit and Evaluation

- Public Comment Response
  - government agencies and third-party payer entities would be permitted to obtain part 2 records without written patient consent to periodically conduct audits or evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving care and outcomes for part 2 patients (e.g., provider education, recommending or requiring improved health care approaches); targeting limited resources more effectively to better care for patients; or adjusting specific Medicaid or other insurance components to facilitate adequate coverage and payment

2.53 Audit and Evaluation

- Public Comment Response
  - The part 2 authorizing statute does not include a broad public health exception to the consent requirements, government agencies that have the authority to regulate, or that financially support part 2 programs, may conduct audits and evaluations of those programs in an effort to ensure that current and future patients receive the best care possible (pg. 43027).
  - One commenter suggested that the rules should be revised to apply this exception not just for audits and evaluations required by law, but for any mandated reporting or disclosure required by law (pg. 43028).

2.53 Audit and Evaluation

- Rule Language Revisions

  (c) Activities included. Audits and evaluations under this section may include, but are not limited to: (1) Activities undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to: (i) Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, to improve care and outcomes for patients with SUDs who are treated by part 2 programs; (ii) Ensure that resources are managed effectively to care for patients; or (iii) Determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD. (2) Reviews of appropriateness of medical care, medical necessity, and utilization of services (pg. 43039)