New rule improves the exchange of medical information in ways that protect the privacy of people receiving substance use treatment

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The U.S. Department of Health and Human Services (HHS) finalized changes to Confidentiality of Alcohol and Drug Abuse Patient Records regulations, (42 CFR Part 2) to facilitate health integration and information exchange within new health care models while continuing to protect the privacy and confidentiality of patients seeking treatment for substance use disorders. The new rule is published in today's *Federal Register*: https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records.

"Today's changes will further enhance health services research, integrated treatment, quality assurance and health information exchange activities while at the same time safeguarding the essential privacy rights of people seeking treatment for substance use disorders," said HHS Deputy Assistant Secretary, Kana Enomoto. "These efforts clear the way for integrated health care models that can provide a better, more cost-effective health care system that also empowers people to make key decisions about their health care."

The current rules governing the confidentiality of substance use disorder records, often referred to as "Part 2," were promulgated in 1975 because of the concern that if the identities of people in treatment for substance use were revealed those patients might be subject to criminal prosecution and a wide range of other serious social consequences. These harmful consequences could deter people from seeking needed treatment.

In February 2016, HHS issued a notice of proposed rulemaking (NPRM) proposing changes to Part 2 to reflect the current health care delivery system, promote health integration and permit appropriate research and data exchange activities. This final rule carefully balances the public health benefits of information exchange and continued protection of patient privacy.

The process of finalizing the rule involved intensive evaluation of public comments on the NPRM from associations, health care providers, health insurers, state and local governments, patients, and people in recovery. Public comments were responded to in the Final Rule.

Major provisions that have been finalized in today's Final Rule include:

- SAMHSA will allow any lawful holder of patient identifying information to disclose Part 2 patient identifying information to qualified personnel for purposes of conducting scientific research if the researcher meets certain regulatory requirements. SAMHSA also permits data linkages to enable researchers to link to data sets from data repositories holding Part 2 data if certain regulatory requirements are met. These will enable more needed research on substance use disorders.
- SAMHSA will continue to apply Part 2 rules when a program is federally assisted and holds itself out as providing substance use disorder diagnosis, treatment, or referral for treatment.
- SAMHSA will allow a patient to consent to disclosing their information using a general designation to individual(s) and/or entity(-ies)(e.g., "my treating providers") in certain circumstances. This change is intended to allow patients to benefit from integrated health care systems. This provision also ensures patient choice, confidentiality, and privacy as patients do not have to agree to such disclosures.
- SAMHSA has added a requirement allowing patients who have agreed to the general disclosure designation, the option to receive a list of entities to whom their information has been disclosed to, if requested.

- SAMHSA has made changes that outline the audit or evaluation procedures necessary to meet the requirements of a CMS-regulated accountable care organization or similar CMS-regulated organizations (including CMS-regulated Qualified Entities). This change will ensure CMS-regulated entities can perform necessary audit and evaluations activities, including financial and quality assurance functions critical to Accountable Care Organizations and other health care organizations.
- SAMHSA has updated and modernized the rule to address both paper and electronic documentation.
- SAMHSA will monitor implementation of the final rule and is working to develop additional sub-regulatory guidance and materials on many of the finalized provisions.

In addition to the Final Rule, HHS is also issuing a Supplemental Notice of Proposed Rulemaking (SNPRM) today. The SNPRM is being issued to seek public input on some additional clarifications and suggestions, especially regarding the important role of contractors, subcontractors and legal representatives in the health care system with respect to payment and health care operations.

Provisions being proposed in the SNPRM include:

- A new provision clarifying and limiting circumstances in which disclosures to contractors, subcontractors and legal representatives of lawful holders may receive and utilize Part 2 data for purposes of carrying out the lawful holder's payment and health care operations activities.
- SAMHSA also seeks public comment on an abbreviated alternative statement for the notice to accompany disclosure.
- A new provision outlining CMS-regulated entities' (e.g., ACO's and QE's) use of contractors, subcontractors and legal representatives to carry out audit and evaluation activities that are necessary to meet the requirements of a CMS-regulated program.

All persons are invited to comment on the proposed clarifications by using one of the methods outlined in the Supplemental Notice of Proposed Rulemaking. Please note that to be assured consideration, comments must be received, no later than 5 p.m. on February 17, 2017. All comments received by that deadline will be considered by SAMHSA.