

Assistant Secretary Elinore F. McCance-Katz, M.D., Ph.D.
Substance Abuse and Mental Health Services Administration

October 25, 2019

To Whom it May Concern,

Recently the U.S. Department of Health and Human Services (HHS) published a proposed regulation (SAMHSA-4162-20 RIN 0930-AA32) from the Substance Abuse and Mental Health Services Administration (SAMHSA) which affects the confidentiality of Substance Use Disorder (SUD) patient records. HHS seeks public comment on this Notice of Proposed Rulemaking (NPRM).

We are respectfully submitting comments on behalf of Colorado's Office of eHealth Innovation (OeHI), an Office of the Governor, and the Colorado eHealth Commission - a governor appointed advisory committee to OeHI and steering committee for Colorado's Health IT Roadmap efforts. To cohesively explain the impact to Colorado, OeHI and the eHealth Commission are submitting comments together.

The eHealth Commission, as expressed during their October eHealth Commission meeting, supports the steps taken by HHS and SAMHSA to clarify existing rules relating to the confidentiality of SUD patient records. However, we do not believe that the regulations go far enough to ensure information is broadly shared to support care coordination while adhering to the appropriate privacy safe guards and controls.

HHS SAMHSA should consider further changes to harmonize the confidentiality of SUD patient records with HIPAA. In particular, HHS should evaluate how 42 CFR Part 2 coverage is defined and what privacy safeguards and controls are in place for both HIPAA and 42 CFR Part 2. Individuals who receive treatment for substance use disorders should be able to receive the care they need from their provider of choice without prosecution from law enforcement or other rediscloses of their information that are not directly related to the coordination of their care.

Once HHS has completed this harmonization to support care coordination with appropriate privacy controls, states will need to address the technical challenges of integrating systems, automating consent, and segmenting data. All of these technical aspects will require a significant investment in time and resources to ensure the alignment of technical infrastructure and policy approaches for both electronic health records and health information exchanges. For example, the technical and workflow challenges of separating addiction treatment medications from other medications within electronic health records and health information exchanges requires extensive work to implement from both technical and policy perspectives. This is complicated when new medications for addiction treatment are introduced by pharmaceutical companies or health IT systems evolve. These changes will require policy responses as well as the upgrade and maintenance of data dictionaries and technology components.

Regarding addiction treatment medications specifically, the eHealth Commission and OeHI believe this information should be excluded from any 42 CFR Part 2 restrictions on the electronic exchange of health information. Until SUD patient records are treated the same as other healthcare records, logistical, technological, and financial barriers will continue to impede the safe and secure electronic exchange of information and undermine patient safety, care coordination, and treatment efficacy.

The highest risk to patient safety due to 42 CFR Part 2 electronic exchange restrictions is the segregation and prohibition against redisclosure of addiction treatment medications such as suboxone, naloxone, and methadone. Any restriction on communication about these medications between 42 CFR Part 2 and 42 CFR non-Part 2 healthcare providers creates immediate risk of duplicate prescribing and fatal adverse drug interactions. HHS should consider how this information can be accessed broadly with the proper access and use.

Another opportunity to harmonize 42 CFR Part 2 with HIPAA is regarding patient consent and corresponding privacy controls. It is important that patients have an opportunity to understand how their SUD treatment information is accessed and used by care providers. Doing so should be simple and easy for the patient to understand and should not create an undue burden from either policy or technical perspectives.

The eHealth Commission and OeHI believe that harmonizing both HIPAA and 42 CFR Part 2 is the right thing to do, as long as the appropriate privacy controls are in place. Because technical enhancements will require a sizable investment in time and resources to execute, the eHealth Commission and OeHI advocate for funding opportunities for both states and providers to accomplish this task and to ultimately ensure care is coordinated for individuals seeking treatment for substance use disorders without prosecution from the law.

Thank you for your careful consideration in reviewing and applying the comments herein from Colorado's OeHI and eHealth Commission. If you have any questions, please contact our office.

Thank you,



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