Final Rule Amending Requirements for Accessing Patient Records Containing Substance Use Disorder Information

On January 18, 2017, the Substance Abuse and Mental Health Service Administration (SAMHSA) released a final rule that eases sharing of substance use disorder information for providers and restores access to this information for researchers. The changes also facilitate the electronic exchange of substance use disorder information for treatment and are much needed since the last substantive regulatory update to these requirements occurred in 1987. The final rule makes changes to current requirements to modernize privacy standards in a new era of integrated care to ensure that patients with substance use disorders can participate in and benefit from new and emerging health care models that promote integrated care and patient safety, such as Accountable Care Organizations (ACOs).

Currently, a federally assisted substance use disorder program generally may only release identifiable information related to substance use disorder diagnosis, treatment, or referral for treatment with the individual's express consent. In this final rule, CMS updates these regulations to allow these patients to benefit from highly coordinated healthcare delivery models, such as ACOs, by facilitating information sharing within health systems to support better integrated care, while also maintaining privacy protections for patients seeking treatment for substance use disorders. In order to take advantage of these improvements, ACOs will need to take steps to comply with disclosure requirements, including making updates to health IT systems to accommodate the new requirements, providing staff training, and making updates to patient consent forms and disclosure handouts.

The final rule is effective February 17, 2017; however, due to the Presidential executive order enacted on January 20, 2017, implementation of this rule may be delayed. NAACOS will update this resource in the event that the implementation date changes as a result of this executive order. NAACOs provided comments on the Confidentially of Substance Use Disorder Proposed Rule during the comment period.

Modification to the Definition of Qualified Service Organizations

A qualified service organization (QSO) is an individual or entity that provides a service to a part 2 substance use disorder program, which is defined by SAMHSA as a federally assisted program, consistent with a qualified service organization agreement (QSOA). In the final rule SAMHSA has revised the definition of a QSO to include population health management (PHM) in the list of examples of services a QSO may provide. SAMHSA also clarifies that PHM refers to increasing desired health outcomes and conditions through monitoring and identifying patients within a group. NAACOS is pleased SAMHSA is recognizing the importance of PHM for patients with

substance use disorders, who often have comorbid conditions and therefore require care that is coordinated among multiple clinicians and specialists.

SAMHSA states that a QSOA executed between a part 2 program and an organization providing PHM services would be limited to the office or unit responsible for the PHM in the organization (such as an ACO), not the entire organization and not its participants (e.g., case managers, physicians, addiction counselors, hospitals, and clinics). However, the presence of a QSOA does not preclude disclosures of patient identifying information to other individuals within these organizations based on a valid part 2-compliant consent. NAACOS urged SAMHSA to instead consider a more comprehensive approach to avoid confusion within ACOs, however, SAMHSA believes this is a needed safeguard to limit disclosures to that which is reasonably necessary to carry out services under the QSOA.

Changes to Consent Requirements

Under the part 2 governing statute, patient records pertaining to the patient's substance use disorder may be shared only with the prior written consent of the patient or as permitted under the part 2 statute, regulations, or guidance. The final rule has made certain revisions to the consent requirements, as well as certain changes to the consent form. Specifically, SAMHSA is revising the consent requirements to allow a general designation in certain circumstances. Upon request, patients who have opted to include a general designation in the "To Whom" section of their consent form must be provided, by the entity that serves as an intermediary, a list of entities to which their information has been disclosed pursuant to the general designation (List of Disclosures). The list is limited to disclosures made within the past two years. Further, entities named on the consent form that disclose information pursuant to a patient's general designation (entities that serve as intermediaries) must respond to requests for a List of Disclosures in 30 or fewer days of receipt of the request, and they must provide, for each disclosure, the name(s) of the entity(ies) to which the disclosure was made, the date of the disclosure, and a brief description of the patient identifying information disclosed. SAMHSA strongly encourages, but does not require, entities to provide the List of Disclosures at no charge to the patient. Finally, SAMHSA also notes that the part 2 program is not responsible for complying with the List of Disclosures requirement; rather the entity that serves as an intermediary, as described in § 2.31(a)(4)(iii)(B), is responsible for compliance with the List of Disclosures requirement.

The final rule specifies that an entity that serves as an intermediary (e.g., HIE, ACO) must comply with the List of Disclosures provision in order to disclose information pursuant to a general designation provided on the consent form. SAHMSA notes that some entities that serve as intermediaries may elect never to disclose information pursuant to a general designation and in these cases, would not need to comply with the List of Disclosures requirement. Those that choose to disclose information pursuant to general designations must ensure the capability to

comply with the List of Disclosures requirements before they disclose the information pursuant to a general designation.

SAMHSA notes that the entity that serves as an intermediary should be provided a copy of the part 2-compliant consent form or the pertinent information on the consent form necessary for the intermediary to comply with the signed consent. The final rule also states that the providers with a treating provider relationship with the patient whose information is being disclosed would be aware of the part 2 protections because the disclosure would also be accompanied by the prohibition on re-disclosure notice. SAMHSA plans to issue subregulatory guidance in the future that clarifies how the patient may request the List of Disclosures from intermediaries.

Medical Emergencies

The final rule revises the medical emergency exception to give providers more discretion to determine when a ''bona fide medical emergency'' as defined at 42 U.S.C. 290dd–2(b)(2)(A)) exists. As a result, patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained. NAACOS supports this change that will help mitigate delays in information sharing that can lead to additional complications and/or death among patients with substance use disorders who require emergency medical treatment.

SAMHSA continues to require the part 2 program to immediately document in writing specific information related to the medical emergency. Specifically, when a disclosure is made in connection with a medical emergency, SAMHSA notes the part 2 program must document in the patient's record the name and affiliation of the recipient of the information, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the emergency. Therefore, data systems must be designed to ensure that the part 2 program is notified when a ''break the glass'' disclosure occurs and part 2 records are released pursuant to a medical emergency. The notification must include all the information that the part 2 program is required to document in the patient's records. SAMHSA also notes that the information about emergency disclosures should also be maintained in the Health Information Exchange (HIE) electronic system. In the final rule, SAMHSA also states their plans to further address part 2 applicability to information disclosed pursuant to a medical emergency in subregulatory guidance in the future.

<u>Other Key Changes</u>
Revisions to the Research Exception

The final rule revises the research exception to permit certain substance use disorder data protected by 42 CFR part 2 to be disclosed to qualified personnel for the purpose of conducting scientific research by a part 2 program or any other individual or entity that is in lawful

possession of part 2 data if the researcher provides documentation of meeting certain requirements related to other existing protections for human research. SAMHSA also made revisions to address data linkages to enable researchers holding part 2 data to obtain linkages to other datasets, provided that appropriate safeguards are in place.

Clarifications to the Prohibition of Re-Disclosure

The final rule clarifies that the prohibition of re-disclosure only applies to information that would identify an individual who has been diagnosed, treated, or referred for substance use disorder, allowing other health-related information shared by the part 2 program to be re-disclosed. Further, if the historical data likewise reveals information that would identify, directly or indirectly, any individual as having or having had a substance use disorder then the information is prohibited from being re-disclosed.