April 11, 2016

Kana Enomoto, MA
Acting Administrator
Substance Abuse and Mental Health
Services Administration
Department of Health and Human Services
Attention: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, MD 20857

Submitted via www.regulations.gov

Re: Confidentiality of Substance Use Disorder Patient Records; Proposed Rule, file code SAMHSA 4162–20.

Dear Acting Administrator Enomoto:

The National Association of ACOs (NAACOS) appreciates the opportunity to submit comments on the proposed rule, "Confidentiality of Substance Use Disorder Patient Records; Proposed Rule (file code SAMHSA 4162–20), as published in the February 9, 2016 Federal Register. We support the Substance Abuse and Mental Health Services Administration's (SAMHSA's) efforts to modernize regulations to better align them with developments in the nation's health care delivery system since the last substantive regulatory update in 1987, while at the same time preserving important patient privacy protections. By finalizing the proposed changes, patients with substance use disorders will be able to benefit from new integrated health care models, such as ACOs, without exposing them to adverse consequences that could act as a deterrent to their seeking needed care.

NAACOS is the largest association of Medicare ACOs, representing over 3 million beneficiary lives through 180 Medicare Shared Savings Program (MSSP) ACOs, Next Generation, and Pioneer ACOs. NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency. Our members, more than many other healthcare organizations, want to see an effective, coordinated patient-centric care process. Our recommendations reflect our expectation and desire to see the MSSP achieve the long-term sustainability necessary to enhance care coordination for Medicare beneficiaries, reduce healthcare costs, and improve quality in the Medicare program.

We understand that the laws and regulations governing the confidentiality of substance abuse records were written out of great concern about the potential use of substance abuse information against individuals, deterring individuals with substance use disorders from seeking needed treatment. Under the current regulations, 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. Current regulations impede care coordination and quality improvement efforts

for patients with a history of substance abuse. Updating these regulations is critical to allow these patients to benefit from highly coordinated healthcare models such as ACOs, which work to improve care with better data sharing and coordination. Facilitating the electronic exchange of patient information across providers is a fundamental ACO activity that improves the quality of care that individual patients receive.

Proposals and NAACOS Feedback

Among the proposed changes are several definitional changes as well as provisions intended to simplify the electronic exchange of information for treatment and other legitimate healthcare purposes while maintaining appropriate confidentiality protections for records that might identify an individual as being diagnosed with substance use disorder. We support the proposed rule's goal to facilitate the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having or having had a substance use disorder. Because this information is essential for proper care coordination to effectively treat Medicare patients with substance use disorders, we strongly urge SAMHSA to work with CMS to ensure that when proper criteria are met, such as through a qualified service organization agreement and/or a signed consent form, patient substance use claim information is available to ACOs through their Claim and Claim Line Feed files.

Section III.B (ix), Modifying Definition of Qualified Service Organization to Include Population Health Management

A qualified service organization (QSO) is an individual or entity that provides a service to a part 2 program consistent with a qualified service organization agreement (QSOA). Recognizing the importance of population health management, SAMHSA proposes to revise the definition of QSO to include population health management in the list of examples of services a QSO may provide. To achieve the best outcomes, providers must supply proactive, preventive, and chronic care to all of their patients, both during and between encounters with the health care system. For patients with substance use disorders, who often have comorbid conditions, proactive, preventive, and chronic care is important to achieving desired outcomes.

As stated in the proposed rule, any QSOA executed between a part 2 program and an organization, such as an ACO, that provides population health management services would be limited to the specific office or unit responsible for population health management in the organization, not the entire organization (*e.g.,* the entire ACO). While we appreciate SAMHSA's efforts to recognize and include population health management in the definition of a QSO, the proposal is confusing and could create potential for misinterpretation, especially related to which "office" or "unit" within an ACO would be considered responsible for population health management. All clinicians and support staff in an ACO are focused on population health and are subject to existing privacy protections and requirements. An approach that designates particular units within an ACO as those responsible for population health management undermines the goal of comprehensive population health management which occurs across an entire ACO. We request SAMHSA consider this comprehensive approach to care and not implement a policy that encourages unnecessary and confusing fragmentation within an ACO, which could operate under a QSOA. Further, as detailed later in the rule, SAMHSA's own proposal for written consent would allow an ACO to be covered under the general designation. Thus, SAMHSA recognizes that ACOs as an entity are providing population health and treating patients, thus SAMHSA should also recognize this reality in its definition of QSOA.

Sections III.D and III.H, Confidentiality Restrictions and Safeguards; Consent Requirements

Patient records subject to part 2 regulations may be disclosed or used only as permitted by the regulations. An organization such as an ACO, which provides population health management services may disclose part 2 information that it has received from a part 2 program to its participants only if the patient signs a part 2-compliant consent form agreeing to those disclosures. Current regulations require the patient consent form

to include the specific name or title of the individual or the name of the organization to whom disclosure of the patient's records is to be made. This requirement ensures that the patient may identify, at the point of consent, who they are authorizing to receive their records. SAMHSA believes that these requirements may deter patients from participating in new delivery models such as ACOs, because under current rules patient consent could be required every time an ACO participant is added to an ACO. As the Centers for Medicare & Medicaid Services (CMS) recently explained in their February 3 ACO benchmarking proposed rule, ACO participant TIN changes happen frequently. For example, for the 2015 performance year 245 of 313 MSSP ACOs (78 percent) had changes in ACO participants. To address this issue, SAMHSA proposes, in certain circumstances, to allow a "general" designation in the consent form, which the administration believes this would increase the number of individuals with substance use disorders who participate in ACOs.

A general designation of an individual, entity, or class of participants must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. SAMHSA proposes to require the consent form to explicitly describe the substance use disorder-related information to be disclosed. This may include diagnostic information, medications and dosages, lab tests, allergies, substance use history, trauma history, employment information, living situation and social supports, and claims/encounter data. This designation of "Amount and Kind" of information to be disclosed must have sufficient specificity to allow the disclosing program/entity to comply with the request. For example, SAMHSA would permit the following description: "All of my substance use disorder-related claims/encounter data." SAMHSA also proposes to require the "From Whom" section of the consent form to specifically name the Part 2 Program(s) or other lawful holders of the patient identifying information permitted to make the disclosure. SAMHSA believes that these proposed changes would permit all ACOs to include substance use disorder treatment in their care coordination programs.

We support the new opportunities provided by a general designation in the consent form and recommend SAMHSA finalize this proposal but incorporate even more flexibility. If the intended goal of simplifying the electronic exchange of information for treatment and other legitimate healthcare purposes is to be achieved, we urge SAMHSA to use a flexible approach to the specific designations in the "From Whom" or "To Whom" sections of the consent form. Specifically, if a patient notes this information may be shared with current and future healthcare providers, the specific name of the ACO or other provider should not be required. In certain instances, a patient may know the name of their doctor or physician's medical group practice but may not realize that practice is part of an ACO and would therefore not list the ACO on the general consent form. Excluding the ACO would undermine one of the key goals of this proposal, which is to allow patients to benefit from enhanced care coordination provided by new healthcare delivery models such as ACOs. It is also important to note that SAMHSA would still require the general designation consent to be limited to those individuals or entities with a treating provider relationship. Another, more workable option might be the approach that HIPAA has taken, allowing a patient to request restrictions on the disclosure of their protected health information (PHI). This would enable electronic exchange of information for treatment purposes while still allowing those patients who wish to limit the disclosures of their information to do so in an easy and effective manner consistent with how other PHI is treated.

SAMHSA also proposes that entities named on the consent form (such as ACOs) that disclose patient identifying information to their participants under the general designation must provide to patients, upon their request, a list of entities to which their information has been disclosed. Those included on the List of Disclosures would be based on their entity affiliation, such as the name of their practice or place of employment, and specific individuals would not need to be listed. Patients who wish to know the name of the individual to whom their information was disclosed may ask the entity on the List of Disclosures to provide that information, however, 42 CFR part 2 would not require the entity to comply with a patient's request. We support SAMHSA's use of the entity rather than the individual, as documenting the latter would

entail significant administrative burdens as organizations, such as ACOs, would have to put in place complicated systems to track and document each individual who received the information in order to be prepared on the off chance a patient requested this information. As SAMHSA notes in the proposed rule, they anticipate there will be few requests of this nature. We urge SAMHSA to finalize its proposal that would focus on disclosures to entities and not to individuals.

Section III. K, Medical Emergencies

SAMHSA proposes to modify the language of the medical emergency exception to provide medical personnel with more discretion to determine when a "bona fide medical emergency exists." We strongly support this proposed change and urge SAMHSA to finalize the proposal, which would 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.

Conclusion

If finalized, this rule would help modernize privacy standards in a new era of high quality, integrated care and help patients with substance use disorders benefit from emerging care models that require enhanced health information exchange for better care coordination that these patients urgently need. We request the agency consider the feedback from the ACO community outlined in this letter. Thank you for your consideration of our comments.

Sincerely,

Clif Gaus
President and CEO