AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
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The Substance Abuse and Mental Health Services Administration
Attn: SAMHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, Maryland 20857

**RE: Arizona Comments to Proposed Rules: Confidentiality of Substance Use Disorder Patient Records**

The Arizona Health Care Cost Containment System (AHCCCS), Arizona's Single State Medicaid Agency, appreciates the opportunity to provide comments to the proposed rules concerning Confidentiality of Substance Use Disorder Patient Records issued in the Federal Register on February 9th, 2016, at Vol. 81. No. 26. These proposed regulations are delineated in 42 CFR Part 2.

AHCCCS recognizes the dire need for updating the outdated regulations governing privacy and security of substance use disorder records. Comprehensive revisions to the Part 2 regulations are imperative in light of dramatic transformations in health care delivery since these provisions were last updated nearly three decades ago as well as the compelling importance of health care coordination and integration for effective treatment of persons with substance use disorders. Arizona has experienced first-hand the adverse impact of Part 2's barriers to providing high-quality care to persons with substance use disorders, especially with the continuing innovations in health care in recent years, including federal advocacy for, and the expanding presence of, health information exchanges (HIE's).

AHCCCS appreciates the difficult task the Substance Abuse and Mental Health Services Administration (SAMHSA) faced in attempting to balance vital patient privacy protections with the need to modernize the regulations so that persons with substance use disorders may benefit from advancements in care delivery systems. While AHCCCS strongly supports SAMHSA's goals in updating this rule, we believe that the proposed changes will not remedy the longstanding issues and concerns with the rule, but may only serve to further hinder efforts to integrate the areas of physical, mental health, and substance use disorder care. In order to provide the highest quality health care, while ensuring patient safety and efficiencies within the system, it is vitally important that all providers be engaged in and work collaboratively across the delivery system. Thus, it is crucial that greater alignment exist between existing regulations and that the current administrative burdens to healthcare payers, providers, and health information exchanges be diminished so that more effective delivery of health care can be achieved.

The proposed regulations fail to accomplish these objectives. AHCCCS respectfully disagrees with SAMHSA's perspective that the proposed regulations represent an improvement which facilitate the exchange of critical information in the health care delivery system and support new models of health care. Accordingly, we urge SAMHSA to extensively rewrite the proposed regulations to achieve alignment with existing privacy regulations established under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The lack of alignment between the regulations proposed in Part 2 and the existing federal requirements under HIPAA will make care coordination and program administration significantly more challenging. The proposed regulations will impose unnecessary impediments in sharing vital health care information necessary for providing effective treatment to AHCCCS members.

In the following sections, AHCCCS identifies some of its many concerns with the proposed rules.

Costs of Implementation: AHCCCS believes that the proposed rules greatly understate the costs and time needed to comply with the requirements. The outreach and education that will be necessary for members/patients, as well as their participating providers, will be far more substantial than noted in the proposed regulations, due, in large part, to the changes necessary for consent forms to be compliant with the regulations:

- Developing language in the forms that can be understood by members and providers, as well as dissemination of this information, will be enormously challenging. To someone experienced and well-educated in the field, the language pertaining to the requirements of the consent form are already difficult to comprehend. Drafting language in the forms themselves so that they can be easily understood by the general public will be very difficult, requiring extensive and ongoing education for both providers and their employees as well as for members/patients. This responsibility will necessitate significant investments in both time and money.
- The proposed rule would require the consent form to contain an explicit description of the types of substance use disorder treatment records to be disclosed. In other words, the authorization is not valid if it simply says "all my records"; the authorization must describe the substance use disorder records with particularity, although it appears that a statement authorizing "all substance use disorder records" may suffice. This revision represents a substantial differentiation from what is currently required in the majority of healthcare consent forms, causing widespread confusion. Because many patients will not understand what records to provide consent to release, they will likely say "all records" as reflected by most consent forms currently in circulation.

Impact to Member/Patient Care: AHCCCS believes that the proposed rules will not serve to positively impact the care that is provided to members/patients especially when integration and coordination of care is concerned. The following are some of our concerns in this area:

- The proposed rule potentially makes it more difficult to disclose necessary information to an organization without a treating relationship that currently would be permissible. Currently, consent can include "the name or title of an individual or the name of an organization to which disclosure is to be made". Under the proposed rule, if the recipient organization does not have a treating provider relationship with the patient, then the recipient must either be a third party payer or the consent must include the name of the receiving entity AND the name of the individual recipient. Such a requirement may severely limit the ability of patients to authorize Part 2 programs to send their information to entities that do not have a treatment relationship.

- The requirements and proposed changes in Part 2 make it difficult for providers to understand precisely what information can be shared which likely will result in providers not communicating any information, thus compromising care delivery with significant adverse impacts on the quality of care members/patients receive.
- Cost effectiveness of complying with the proposed regulations will also impact members/patients due to the additional costs associated with implementation of measures which undermine care coordination and effective delivery of services.
- As previously mentioned, the proposed regulations will create widespread confusion for members/patients and for providers. Many will not understand the distinction between a treating provider and a non-treating provider, particularly because the definition of treating provider does not require actual treatment by the provider.
- Drug seeking behaviors are widespread. Enhanced communication between Emergency Departments, Pharmacies, Health Plans, Physicians, Law Enforcement, Case Managers (Care Coordinators) and others is essential for effective treatment of persons with substance use conditions. Existing Part 2 regulations hinder such vital communications. Astoundingly, the proposed rules fail to remedy these shortcomings, perpetuating the obstacles present in current regulations which interfere with effective treatment of persons with drug seeking behaviors.

Impact to Medicaid Administration, Managed Care Organizations, Providers, and HIE's:

- We are concerned with SAMHSA's definition of "treating provider" in the proposed regulations. It is troublesome that an actual in-person encounter is irrelevant. It is our opinion that merely making an appointment which is later cancelled does not makes that provider a "treating provider". In some cases, this characterization may lead to unnecessary disclosures of information, thereby undermining the very purpose of the privacy rules and the outcomes they are intended to prevent.
- The proposed definition of "Program" in 42 CFR 2.11 defines entities and individuals subject to the Part 2 provisions. Although this definition appears to carve out from Part 2 requirements entities and individuals in general medical facilities and general medical practices, the proposed language serves to expand the scope and applicability of the Part 2 regulations. According to the definition, the carve out does not apply when "an identified unit within either holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment" or when there are "medical personnel or other staff in a general medical facility or general medical practice whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers." Thus, the carve-out from Part 2 regulation is exceedingly limited, and the stringent Part 2 requirements will apply to many treatment settings. The revision provides little flexibility despite its stated intentions.
- The proposed regulation expands the definition of "patient" to include a former patient.

- The proposed regulation imposes enormous burdens on providers. First, the provider that receives a general designation "must have a mechanism in place to determine whether a treating provider relationship exists with the patient whose information is being disclosed". This requirement is only discussed in the Preamble and is not a part of the proposed regulations. Nevertheless, SAMHSA clearly expects organizations to address the issue: "We encourage innovative solutions to implement this provision. For example, the HIE in the aforementioned example could have a policy in place requiring their participating providers to attest to having a treating provider relationship with the patient. Likewise, the HIE could provide a patient portal that permits patients to designate treating providers as members of "my health care team" or "my treating providers."" More significantly, SAMHSA proposes that providers conduct due diligence into whether entities such as HIEs can comply with the requirements of Part 2. In a discussion of changes to the medical emergency exception, SAMHSA addresses the responsibility of a provider to investigate this issue: "Before a part 2 program enters into an affiliation with an HIE, it should consider whether the HIE has the capability to comply with all part 2 requirements, including the capacity to immediately notify the part 2 program when its records have been disclosed pursuant to a medical emergency….Similarly, SAMHSA recommends that the part 2 program consider whether the HIE has the technology, rules, and procedures to appropriately protect patient identifying information." These two requirements alone place great and unrealistic burdens on providers to not only comply themselves but to further ensure others downstream are in compliance as well.
- With regard to the revision of the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a "bona fide medical emergency" exists, the proposed rule, although helpful, does not permit disclosures to avert other risks of harm, such as when a patient makes a credible threat against a third person or the public. These and other instances should be included.
- Another aspect of the proposed rules that will undoubtedly create compliance concerns are the heightened security obligations that would be placed upon "other lawful holders" of Part 2 information which often are entities that are not health care providers or facilities, let alone the types of providers that are subject to Part 2. In the rules, any person who receives information disclosed pursuant to Part 2 automatically becomes bound by the provisions of that law, and may not further disclose the information unless such disclosure complies with Part 2. However, the proposed rule would now require these other lawful holders "of patient identifying information to have in place formal policies and procedures to reasonably protect against reasonably anticipated threats or hazards to the security of patient identifying information." While well intentioned, this requirement will likely be challenging, if not impossible, to implement. The category of "other lawful holders" encompasses a broad, if not limitless, spectrum of individuals and entities – courts, law firms, family members, other private citizens, etc. This requirement may be seen as overreaching, especially if it is interpreted to apply to private citizens who could not be expected to implement policies to comply with Part 2 records requirements.

- In order to comply with these proposed rules, HIEs will be required to create the architecture for data management that provides for the segmentation for substance abuse and general behavioral health data from physical health care data. In addition, the HIE will have to create a way to have consent operate differently in each of the environments. This is both a costly and challenging administrative burden that does nothing to promote the sharing of information between all necessary providers for the integration and coordination of care.
- With respect to the accounting of disclosures, the proposed rule provides patients with the right to an accounting of disclosures that HIPAA has shown to be of dubious value when compared to its burden. Although the idea of providing patients the ability to see where their information has gone is quite fair and reasonable, our experience implementing related HIPAA requirements indicates that the burden of maintaining an accounting of disclosures often far outweighs the benefit. The proposed rule states that SAMHSA "anticipates there will be few requests…", yet SAMHSA is expanding this right nonetheless, thereby creating an administrative nightmare. There may be systems that make it relatively easy to track disclosures in the manner proposed, but there may be other scenarios, as in the research setting, where disclosures may occur manually and the burden of tracking them may far outweigh the benefit.
- The consent form in the proposed rule would be required to include a statement that the patient understands the terms of the consent, and, when using a general designation in the "To Whom" section, that the patient has a right to obtain, upon request, a list of entities to which the patient's information has been disclosed, as discussed above. Notably, this language is not currently required for an authorization to be compliant under HIPAA. To the extent this requirement in the proposed rule is finalized, those Part 2 programs that use HIPAA-compliant authorizations will have to add additional language to comply with the Part 2 Regulations as well. This added requirement is unnecessary.
- The definition of "patient identifying information" or "PII" will only confuse both patients and providers without providing corresponding benefits. If Part 2 were aligned with HIPAA regulations, the information would be covered under the term "protected health information (PHI)" and would actually be more encompassing of the relative information than the term currently proposed under Part 2. Patient identifying information does not account for the assigned AHCCCS ID number which provides access to a plethora of health care related information. Moreover, the abbreviation "PII" is already understood within the industry as "personally identifiable information." Therefore, adding this definition will simply add to the existing confusion in the community regarding these patient protection definitions.
- Requiring formal policies to be adopted that preserve the security and "sanitation" of records is administratively burdensome, and having a separate set of rules and requirements than those already spelled out in the HIPAA standards seems redundant and unnecessary.

As the Single State Medicaid Agency for more than 1.8 million persons, AHCCCS is deeply committed to ensuring strong privacy protections for all members, including persons with substance use disorders. AHCCCS is also deeply committed to ensuring all members receive the highest quality health care necessary for effective treatment, including treatment of substance use disorders. Due to the enormous burdens imposed by these provisions, the proposed rules will significantly hinder vital work across the country dedicated to delivering effective and critical patient care.

AHCCCS fully supports SAMSHA's goal of modernizing the rules to address the significant changes in technology and the innovations in the delivery of health care, particularly since the Part 2 regulations have not been substantively updated since 1987. However, despite the stated objectives of the proposed rules, the revised provisions will not decrease the burdens associated with the existing Part 2 provisions. Nor will they promote integrated care and safety. We disagree that they will facilitate information exchange within new and emerging health care models, and our comments point to some of the many challenges and impediments posed by the proposed rules.

AHCCCS greatly appreciates this opportunity to comment and provide Arizona's perspective regarding the proposed regulations. Although we acknowledge SAMHSA's laudable efforts in developing the proposed regulations governing confidentiality and disclosures of records for patients of substance abuse treatment programs, we respectfully request that the proposed regulations be withdrawn and substantially rewritten to ensure far greater alignment with HIPAA regulations. Alignment with HIPAA regulations will permit all programs and providers to increase access to substance use disorder services, integrate services, ensure patient safety, and ultimately improve the well-being of all patients, regardless of the condition, illness, or disease. Regulations that carve out substance use disorders only serve to erect barriers to care and foster the stigma surrounding these disorders. As long as persons with substance use disorders are treated differently than persons with other disorders, they will never receive the same quality of care or care coordination as other individuals.

Sincerely,

Monica Coury
Assistant Director

cc: Jessica Woodward, CMS
Brian Zolynas, CMS