



February 17, 2017

Ms. Kana Enomoto
Acting Deputy Assistant Secretary
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically via www.regulations.gov

Re: Confidentiality of Substance Use Disorder Patient Records Supplemental Notice of Proposed Rulemaking (SAMHSA-4162-20; RIN 0930-AA21)

Dear Ms. Enomoto:

On behalf of the nation's Medicaid Directors, thank you for the opportunity to comment on the Supplemental Notice of Proposed Rulemaking, "Confidentiality of Substance Use Disorder Patient Records (SAMHSA-4162-20; RIN 0930-AA21)."

The National Association of Medicaid Directors (NAMD) is a bi-partisan, non-profit association representing Medicaid Directors in all 50 states, the District of Columbia and the territories. Medicaid programs are the largest payer of mental health services in the nation and are an increasingly prominent payer of substance use disorder (SUD) services. By 2020, state Medicaid programs are expected to account for 28 percent of SUD spending.¹

Given the dominant role of Medicaid as a payer of these services, NAMD's members are working to address historical bifurcation in service delivery for affected enrollees. Over 90 percent of Directors responding to NAMD's 2016 Medicaid Operations survey were planning or implementing behavioral innovations in FY2016. Similarly, Medicaid Directors are at the forefront of the nation's response to the opioid epidemic, with two-thirds of Directors who responded to NAMD's Operations Survey noting that they are implementing specific strategies to address opioid addiction.²

¹Tami L. Mark et al., "Spending on Mental and Substance Use Disorders Projected to Grow More Slowly Than All Health Spending Through 2020," *Health Affairs* 33, no. 8 (2014): 1407–1415, <http://content.healthaffairs.org/content/33/8/1407.full>.

²"State Medicaid Operations Survey: 5th Annual Survey of Medicaid Directors." National Association of Medicaid Directors. Dec. 2016. http://medicaidirectors.org/wp-content/uploads/2016/12/5th-AnnualNAMD_OpsSurveyReport_DEC2016-FINAL.pdf.

As we have underscored in previous comments, the separate federal regulations governing the privacy of SUD health information (42 CFR Part 2) have long been an impediment to these state innovations and person-centered care delivery. The outdated regulations have limited the flow of vital health information, prevented coordinated care for those with SUD, and ultimately placed these individuals at risk of overdose and death. As such, we appreciate SAMHSA's effort to modernize the Part 2 requirements in its recent final regulation, such as through the new "to whom" designation. However, these changes do not sufficiently accommodate the movement to collaborative care and rapid communication that is needed between providers. Comprehensive action is needed to ensure Medicaid beneficiaries with SUDs can benefit from the most advanced and innovative care delivery models, and receive high quality, coordinated care.

Therefore, we call on Congress and the Administration to align the requirements for SUD data with the privacy requirements governing all other health information, while retaining the prohibition against use of SUD information for criminal charges or criminal investigation. Medicaid Directors take seriously the need to protect SUD information records from being used to support law enforcement activities and to ensure individuals are not deterred from seeking treatment. Retaining the statutory prohibition against using SUD information to initiate or substantiate criminal charges, while aligning all other aspects of Part 2 with the Health Insurance Portability and Accountability Act (HIPAA), balances important patient privacy protections with the objectives of high quality, coordinated care.

We recognize the need for Congressional action to bring about this comprehensive modernization, and we continue to call on Congress to advance legislative language to repeal the provisions of 42 U.S.C §§ 290dd-2 that are not aligned with HIPAA. We also encourage SAMHSA to work with Congress to articulate statutory barriers that prevent such alignment, and to use its flexibility under the statute to align Part 2 with HIPAA to the greatest extent possible.

In addition, we respectfully make the following specific recommendations on aspects of SAMHSA's supplemental proposed rule that will have a direct impact on the provision of high quality care for those with SUD and on Medicaid operations. In particular, we underscore the need for SAMHSA to recognize that care coordination and case management are vital health care operations, and should be identified as such under the rule.

Our recommendations are as follows:

1. We support the clarification to allow lawful holders to disclose Part 2 data to contractors and subcontractors for health care operations and payment purposes, and ask SAMHSA to further clarify that lawful holders may disclose Part 2 data to the state Medicaid agency with whom it is contracted (§2.33(b)). We appreciate that SAMHSA would explicitly permit certain disclosures for payment and health care operations. Medicaid programs and managed care organizations (MCOs), much like providers, rely on a range of contracted entities and

supports to carry out their duties. These entities, in essence, are an extension of the Medicaid agency or MCO as they support the mandatory functions of the program.

We also ask SAMHSA to further clarify that MCOs with Part 2 information may disclose that data to the state agency that holds the contract with the MCO for health care operation and payment purposes. While this may be SAMHSA's underlying intent, the current language does not explicitly address the flow of information from MCOs to the state agencies that hold the MCO contract. Ultimately, for Medicaid operations to take place, the individual's data must be available to both the MCO and the Medicaid agency, regardless of whether the MCO or the Medicaid agency is listed on the disclosure. State Medicaid agencies, for example, rely on encounter data to carry out its mandatory oversight functions and set appropriate capitation payments to the health plans.

2. "Care coordination" and "case management" should be considered health care operation functions for which disclosure to contractors or subcontractors is permitted (§2.33). We are troubled that the proposed rule explicitly prohibits payers from disclosing Part 2 information to contractors and subcontractors for care coordination or case management purposes. Medicaid programs are increasingly contracting with MCOs for the delivery of services, with nearly 80 percent of Medicaid beneficiaries enrolled in some form of managed care. Care coordination and case management are essential features and operational responsibilities of MCOs serving Medicaid beneficiaries. In addition to helping consumers navigate the system, MCOs use these tools to closely monitor the treatment plan and connect providers to one another.

Further, health information technology and health information exchange are essential building blocks of integrated care. These tools can be implemented in a way that uses existing safeguards, such as consent management, to protect patient privacy. But by excluding care coordination and case management from permitted health care operations uses, SAMHSA will make it extremely difficult for state Medicaid agencies, MCOs and providers to use this technology to provide high quality, integrated care. Ultimately, this puts Medicaid beneficiaries with SUD at a significant disadvantage to those individuals without SUDs. They will be less likely to benefit from coordinated care and may be placed at risk of overdose and death.

3. We also ask SAMHSA to more broadly define those activities that would be included under "payment and health care operations" (§2.33(b)). As noted above, allowing care coordination and case management to fall under the rubric of payment and operations is a helpful first step towards ensuring high quality, person-centered care. But SAMHSA could best support this shared objective through a broader definition of those activities that are considered "payment and health care operations." Ideally, state Medicaid agencies should be able to identify those activities that fall under this definition, rather than SAMHSA specifying these activities in regulation. However, if SAMHSA feels it is necessary to list activities that are considered

payment and health care operations, we recommend the following also be included:

- a. Care coordination and case management (as discussed above);
 - b. Health information exchange activities; and
 - c. Payment and delivery system reform efforts, such as pay-for-performance models, episodes of care, population-based payment models, etc.
4. We urge SAMHSA to permit contracts that require compliance with all applicable federal laws and regulations to meet the proposed requirement in §2.33(c). We appreciate SAMHSA's goals in requiring contractors and subcontractors to have specific contract language that requires compliance with Part 2. However, mandating new contract language specific to Part 2 may create an unnecessary financial and administrative burden on states, and would also be duplicative. Updating contract language requires significant state time and resources, and contracts must undergo CMS review and approval. At the same time, Medicaid agencies already include contract language that requires compliance with all applicable federal laws and regulations. Therefore, we request that contracts requiring compliance with "applicable federal laws and regulations" be deemed as satisfying the requirement of §2.33(c).
5. We support the provision allowing Part 2 data to be disclosed for purposes of carrying out a Medicaid or CHIP audit or evaluation (§2.53(a)(1)(i)). We appreciate that the rule clarifies that holders of Part 2 data may disclose data to audit and oversight entities, consistent with their responsibility to respond to lawful audit or evaluation requests. As programs jointly financed by the federal and state government, state Medicaid programs and their contractors are subject to oversight by numerous federal and state entities. Clear authority to disclose Part 2 information during a lawful audit (including for quality improvement purposes and program integrity), is critical to the programs' operations.

Once again, we appreciate the opportunity to comment on this supplemental proposed rule and look forward to continued engagement with SAMHSA as we explore opportunities to advance our shared objective of improving health outcomes for those with SUDs.

Sincerely,



Christian L. Soura
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South Carolina Department of Health and
Human Services
President, NAMD



Judy Mohr Peterson
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