February 17, 2017

The Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 13E89A
Rockville, MD 20857
Attn: Danielle Tarino

Dear Ms. Tarino:

On behalf of the Partnership to Amend 42 CFR Part 2 (Partnership), I appreciate the opportunity to submit comments on the supplemental notice of proposed rulemaking regarding 42 CFR Part 2 (SAMHSA-4162-20; RIN 0930-AA21).

The Partnership is a coalition of 28 health care stakeholders committed to aligning 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of health care treatment, payment, and operations (TPO) to allow appropriate access to patient information that is essential for providing whole-person care.

We welcome the Administration's efforts to modernize Part 2, as we share the same goal of protecting the confidentiality of patients while improving access to advances in the delivery of health services. Below, please find the Partnership's comments on the areas you proposed in the supplemental notice of proposed rulemaking (SNPRM).

Issue for Comment: Retain in regulation the notice found in § 2.32 regarding re-disclosure of Part 2 data but consider whether it would be appropriate to add an abbreviated notice and in which circumstances the shorter notice may be warranted.

The prohibition on re-disclosure in § 2.32 effectively prevents providers participating in a health information exchange (HIE), health home, accountable care organization (ACO), or care coordination entity (CCE) from disclosing substance use disorder treatment information among each other for treatment and care coordination purposes. We recommend allowing for the re-disclosure of substance use disorder treatment information by and among provider-members of the above mentioned integrated care settings with a direct treatment relationship for the purposes of TPO. SAMHSA's clarification in the Final Rule that the prohibition on re-disclosure only applies to information that would identify an individual as a person with substance use disorder, and allows other health-related information to be re-disclosed is appreciated. However, it still does not accomplish the goal of

coordinated care. The end result of these revisions would still present a clinically incomplete record of a patient's treatment, since the substance use disorder information cannot be re-disclosed. Health care providers and plans will still be working with incomplete data which still pose the same clinical risks, failure to coordinate care, and lack of an integrated approach. This results in less effective care, less reliable health records, and less coordination.

Issue for Comment: Further revise § 2.33 regarding disclosures permitted with written consent in order to define and limit the circumstances in which certain disclosures for the purposes of payment and health care operations can be made.

The Partnership recommends further revising this section to include "care coordination" as one of those such circumstances and to define the term. Care coordination is not treatment, but rather the facilitation of care. Care coordination goes beyond just navigating the system, to closely monitoring the treatment plan and connecting providers to one another. The National Quality Forum defines care coordination as "a function that helps ensure that the patient's needs and preferences for health services and information sharing across people, functions, and sites are met over time. Coordination maximizes the value of services delivered to patients by facilitating beneficial, efficient, safe, and high-quality patient experiences and improved healthcare outcomes." As allies in the coordination of care, Partnership members connect patients to, and treat them with, appropriate services in a safe and effective manner. Our inability to view the whole record presents a huge barrier to patients receiving the best possible care.

Issue for Comment: Further revise § 2.53 regarding disclosures related to audits and evaluations to expressly address further disclosures by contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or Children's Health Insurance Program (CHIP) audit or evaluation.

Partnership members believe it could be helpful to specify that it is permissible to disclose this information to contractors and subcontractors, but we do not believe further revision is necessary.

Issue for Comment: Additional purposes for which lawful holders should be able to disclose Part 2 patient identifying information.

Recognition of population health management as an important service that a qualified service organization (QSO) may provide is a positive step in expanding the definition of a QSO. We request that care coordination also be added to the list of services a QSO can provide. Once a Qualified Service Organization Agreement (QSOA) is in place, this addition would allow a Part 2 program to communicate information from a patient's records to the organization providing care management services as long as it is limited only to patient information that is needed by the QSO to provide such services. SAMHSA stated in the proposed rule, in regard to population health management, that "this revision would benefit patients' health, safety, and quality of life while maintaining the confidentiality protections that attach to the Part 2 program's patient records." We believe that including care coordination as a service offered by QSOs would result in similar benefits.

Issue for Comment: Further subregulatory guidance that SAMHSA and other agencies could provide to help facilitate implementation of 42 CFR Part 2 in the current healthcare environment.

The Partnership strongly believes that aligning Part 2 with HIPAA for TPO will promote safe, effective, coordinated care for persons with opioid addiction and other substance use disorders. All of the recent steps taken to address the opioid crisis will be moot without removing communication barriers and promoting care coordination.

Part 2 requirements should be harmonized with HIPAA authorization requirements. SAMHSA should allow appropriate disclosures of substance use disorder records for treatment, payment, and healthcare operations. This would improve patient care by ensuring that providers and organizations that have a direct treatment relationship with the patient have access to the complete health care record (unless otherwise indicated in the initial disclosure). Without access to a complete record, providers cannot properly treat the whole person and may, unknowingly, endanger a person's recovery and their life. For example, a medical doctor in primary care may not know that he or she is prescribing pain medication to someone with a history of addiction. Harmonization would also increase care coordination and integration among treating providers and other entities. Whole health care, care coordination and integrated care are extremely important for patients with a substance use disorder because many of these individuals also have co-occurring mental health or physical health illnesses that also need to be addressed together in a coordinated fashion. The proposed rule's lack of conformity with HIPAA does not reflect the current realities of our health care delivery system and does not achieve long sought after parity because it does not provide a uniform standard of care (i.e., as reflected in the patient record) between physical and mental health. While we seek HIPAA alignment for TPO, we also support preserving certain patient protections afforded under Part 2. We encourage you to align Part 2 with HIPAA whenever possible in any future guidance on this issue.

We appreciate the opportunity to comment on SAMHSA's proposals to further update Part 2 and thank you for your consideration of our recommendations. Attached, you will find a document about the Partnership, which includes the list of the coalition's member organizations. If you have any questions or would like to discuss any of these issues further, please contact me at (202) 449-7660 or klein@abhw.org.

Sincerely,

Rebecca Murow Klein, Chair
Partnership to Amend 42 CFR Part 2

Attachment: Partnership to Amend 42 CFR Part 2

PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF OVER 20 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

The undersigned organizations agree on the following:

- Part 2 provisions are not compatible with the way health care is delivered currently.
- Access to a patient's entire medical record, including addiction records, ensures that providers and organizations have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient's health needs.
- Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence.
- Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care that have proven to produce the best outcomes for our patients.
- Part 2 requirements should be aligned fully with the HIPAA requirements that allow the use and disclosure of patient information for **treatment, payment, and health care operations**.
- Health care professionals, insurers, and others who receive basic health information through a health information exchange or a shared electronic health record should not use this information to discriminate against patients regarding quality of care, payment of covered services, or access to care.
- Part 2 information should not be disclosed for non-treatment purposes to law enforcement, employers, divorce attorneys, or others seeking to use the information against the patient, which the HIPAA privacy framework already easily accommodates. Existing penalties for unauthorized release and use of confidential medical information should apply.
- The Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a final rule and supplemental notice of proposed rulemaking which take some steps to modernize Part 2 but do not go far enough. Legislative action is also necessary in order to modify Part 2 and bring the sharing of substance use records into the 21st century.

Academy of Managed Care Pharmacy · Alliance of Community Health Plans · American Association on Health and Disability · American Dance Therapy Association · American Hospital Association · American Orthopsychiatric Association · American Psychiatric Association · American Society of Addiction Medicine · America's Health Insurance Plans · AMGA · Association for Ambulatory Behavioral Healthcare · Association for Behavioral Health and Wellness · Association for Community Affiliated Plans · Blue Cross Blue Shield Association · Corporation for Supportive Housing · Employee Assistance Professionals Association · Hazelden Betty Ford Foundation · Healthcare Leadership Council/Confidentiality Coalition · InfoMC · The Kennedy Forum · Mental Health America · National Alliance on Mental Illness · National Association of Psychiatric Health Systems · National Association of State Mental Health Program Directors · National Rural Health Association · Netsmart · Otsuka America Pharmaceutical, Inc. · Premier Healthcare Alliance

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February 14, 2017