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October 24, 2019

Elinore McCance-Katz
Assistant Secretary
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Submitted electronically via www.regulations.gov

RE: RIN: 0930-AA32 Confidentiality of Substance Use Disorder Patient Records (SAMHSA 4162-20)

Dear Assistant Secretary McCance-Katz:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, writes in response to the Substance Abuse and Mental Health Services Administration's proposed revisions to the Confidentiality of Substance Use Disorder Patient Records, 42 Code of Federal Regulations, Part 2.

While we understand the statutory limitations on SAMHSA and appreciate the additional steps to ease the burdens on providers who treat patients for substance use disorders, we continue to advocate with Congress to pursue legislation fully aligning 42 CFR Part 2 with the Health Insurance Portability and Accountability Act for the purposes of treatment, payment and healthcare operations. HANYYS strongly urges SAMHSA to educate Congress on the significant burdens the existing statutory framework imposes for the integration of substance use disorder and physical healthcare. SAMHSA must work with legislators to help align Part 2 with the HIPAA requirements that govern all other patient health information.

HANYYS' members are continually embracing new models of patient-centric care and are fully committed to implementing innovative healthcare reform, such as New York's Delivery System Reform Incentive Payment program and other value-based payment initiatives. The need for secure, timely and robust exchange of clinical data is central to these efforts.

HANYYS believes it is important to maintain patient privacy while facilitating efficient care coordination and transformation to value-based care. Unfortunately, the complicated patchwork caused by the differences between HIPAA and Part 2 frequently restrains our members' ability to accomplish these goals. The persistence of two different privacy laws invites disruptive results as it confuses clinicians and impedes the robust sharing of critical patient

information that is necessary to deliver the most effective and efficient care. Patients must submit written consent prior to the disclosure of their SUD record for purposes of treatment, payment and healthcare operations. Without that consent, providers cannot have access to the full scope of a patient's medical information. Obtaining multiple consents from the patient is challenging and creates barriers to person-centered, integrated care.

Applying the same requirements to all patient information, whether behavioral- or physical-health related, would support the appropriate information sharing essential for clinical care coordination and population health improvement in the current patient care environment. Many individuals who experience a SUD also have a comorbid physical health condition. Partitioning a patient's record to keep SUD diagnoses and treatments hidden, as required by Part 2, is dangerous for the patient, problematic for providers and contributes to the stigmatization of SUD. Failure to integrate services and supports can lead to risks to individual patients, such as contraindicated prescription medicines and medication adherence problems.

Additionally, the patchwork of differing requirements creates significant challenges for providers' use of a common electronic health record, which is necessary for effective care coordination. Many EHR systems do not have the capacity to fully sequester Part 2 data in the context of a multispecialty facility. Therefore, to ensure compliance with Part 2, providers often have to maintain two separate medical records, which create a burden and expense but no benefit.

Our comments on specific proposals are below.

Applicability and re-disclosure

HANYS supports SAMHSA's proposed change to §2.12 clarifying that the Part 2 disclosure restrictions apply only to SUD records originating with the Part 2 program and not to records created by non-Part 2 providers, even if those records mention SUD status and treatment. Though not substantive, the change should provide some clarification around Part 2's parameters for records created by a non-Part 2 provider.

HANYS requests that SAMHSA provide additional clarity on the definition of a Part 2 provider versus a non-Part 2 provider. The statute currently defines Part 2 providers as alcohol and drug treatment programs that receive federal funds in any form, including Medicare or Medicaid funding or via their tax-exempt status, and "hold themselves out as providing" alcohol or drug abuse diagnosis, treatment or referral for treatment. However, in the current healthcare environment and its emphasis on integrated care, providers are likely to apply the Part 2 requirements to more treatment settings and providers than is required. We ask that SAMHSA clarify what "holding oneself out as providing" means.

Disclosures to entities without naming a recipient

HANYS supports the proposal to allow a SUD patient to consent to disclose his or her Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure. Currently, when disclosing protected information to entities that do not have a treating provider relationship with the patient, patients must identify individuals to whom the disclosure may be made. However, patients may wish to disclose this information to entities for which they do not have a specific name, which can result in frustration and delays in receiving services.

Natural disasters as “bona fide medical emergencies”

HANYS supports SAMHSA’s proposal to add declared major and natural disasters to the list of permitted exceptions for the disclosure of SUD records without patient consent. We appreciate that SAMHSA recognizes the need for providers to quickly and safely share information during a crisis. Currently, Part 2 permits the disclosure of SUD records without patient consent in a “bona fide medical emergency” – when an individual requires immediate clinical care to treat a life-threatening condition and it is not possible to seek written consent to release records. In situations where natural disasters disrupt the usual access to services, requiring providers to follow the disclosure requirements is overly burdensome.

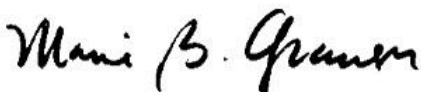
The proposed would apply only when a state or federal authority declares a state of emergency because of the disaster and the Part 2 program is closed and unable to provide services or obtain informed consent; the exception would be immediately rescinded once the Part 2 program resumes operations.

Opioid treatment program enrollment in prescription drug monitoring programs

HANYS supports SAMHSA’s proposal to permit OTPs to report patient identifying information with the patient’s written consent into a PDMP. Per a 2011 guidance letter, SAMHSA currently prohibits OTPs from disclosing patient identifying information to a PDMP (with a few exceptions). The lack of OTP data in a PDMP may put patients at risk for duplicate or contraindicated prescriptions, particularly if they are receiving medication-assisted treatment.

Thank you for the opportunity to provide feedback on potential modifications to the Part 2 regulations. If you have questions regarding our comments, please contact Victoria Aufiero, director, behavioral health, at (518) 431-7889 or vaufiero@hanys.org.

Sincerely,



Marie B. Grause, RN, JD
President