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October 24, 2019

Substance Abuse and Mental Health Services Administration (SAMHSA)
Department of Health and Human Services
Attention: Deepa Avula
5600 Fishers Lane
Room 17E41
Rockville, Maryland 20857

Submitted electronically via www.regulations.gov.

RE: SAMHSA-4162-20, RIN 0930-AA32: Proposed Rule on the Confidentiality of Substance Abuse Disorder Patient Records

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed rule to modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (also known as 42 CFR Part 2). We believe that this latest set of clarifications to this rule will have a positive impact on the health of the patients served by our members. We would appreciate going a step further in clarification of information sharing regulations to facilitate care coordination in the particular instance of smaller health centers and safety net organizations that do not currently have the option of rebuilding EHR systems. We also welcome technical assistance in transitioning Health Information Exchanges to appropriate Part 2 data sharing.

Bi-State Primary Care Association is a nonpartisan, nonprofit 501(c)(3) charitable organization that promotes access to effective and affordable primary care and preventive services for all, with special emphasis on underserved populations in Vermont and New Hampshire. Bi-State's combined Vermont and New Hampshire membership includes 29 Community Health Centers¹ (CHCs) delivering primary care at 126 sites and serving over 315,000 patients. Part of our providers' mission is to serve everyone, regardless of ability to pay, and to deliver comprehensive medical services. We provide preventive and primary care that helps achieve the best possible health outcomes and contains overall costs within the system. Access to substance misuse treatment for substances, including opioids, is critical for this work.

Our providers have worked to reduce the stigma of addiction and provide holistic care for patients in need of substance misuse treatment. The number of patients served in New Hampshire continues to grow as more MAT providers are recruited and trained, while in Vermont, patient access continues to grow with over 1600 MAT patients seen in 2018. Additionally, our providers find significant

¹ Community Health Centers includes: 22 Federally Qualified Health Centers, 1 Federally-Quality Health Center Look-Alike, Planned Parenthood of Northern New England, Area Health Education Centers in New Hampshire and Vermont, Weeks Medical Center, and Vermont Coalition of Clinics for the Uninsured.

comorbidities between behavioural and other chronic conditions, with upwards of 70% of total patient population experiencing this.

Comments:

Community Health Centers, and especially Federally Qualified Health Centers (FQHCs) in New Hampshire and Vermont continue to expand services that are subject to 42 CFR Part 2 requirements. We support SAMHSA's effort to reduce barriers in patient care and safety.

The FQHCs in New Hampshire and Vermont have rapidly expanded their mental health and substance misuse treatment offerings to address the needs of their patients. They continually evaluate whether and how 42 CFR Part 2 applies to their activities. Clarity regarding this regulation is especially helpful as it impacts the data segregation options and disclosure/redisclosure requirements imposed on them. Bi-State appreciates the efforts by SAMHSA to promulgate regulations that continue meet the 40-year old statutory framework, but address current patient needs more effectively.

The 42 CFR Part 2 regulations have historically limited the ability of our providers to optimize coordinated patient care and results in unnecessary costs in the health care system:

- Limited coordination of care: Our health care providers employ numerous processes to ensure compliance with 42 CFR Part 2. This includes creating duplicate records so that the 42 CFR Part 2 data are segregated, not sharing any patient information that could have these data in it, and establishing lengthy workflows. All of these activities increase the administrative burden to clinicians whose focus should be on patients, not paperwork. Additionally, these tasks result in a high probability of information being unavailable for patient care. Any additional guidance provided by SAMHSA to reduce this burden and enhance care coordination will be greatly appreciated.
- Unnecessary costs: The cost of maintaining additional systems, and obtaining consent, along with ensuring appropriate sharing of data covered under 42 CFR Part 2, is born by health care providers. These providers have additional technology and staffing costs as a result of 42 CFR Part 2, diverting resources that could be better used for treatment. We appreciate the work to-date to reduce these unnecessary costs and encourage SAMHSA to continue.

As indicated above, our FQHCs regularly evaluate how this regulation applies to them. We appreciate SAMHSA's clarification in the proposed rule regarding disclosure, and redisclosure, of information between Part 2 and non-Part 2 entities. However, we would appreciate additional clarification for entities, such as those we represent, that provide general medical services and substance misuse treatment. Specifically, we request information clarifying the scenario where one entity has Part 2 and non-Part 2 providers utilizing the same electronic health record and diagnosis and prescription information is automatically populated for better patient care. This existing system means that the non-Part 2 treating clinician will see the Part 2 information. The current solutions to this involve: additional consent within the same clinical practice, which is a barrier for patients who intentionally seek our practices for their comprehensive delivery model; and/or using a separate electronic health record (or paper) for the Part 2 data. Neither option optimizes patient care. We recommend that SAMHSA provide that in this scenario, ie. when a single entity has Part 2 and non-Part 2 providers, basic information within the electronic health record is not subject to 42 CFR Part 2.

We appreciate SAMHSA's work to advance the development of standards for Data Segmentation for Privacy and encouragement for electronic health records to meet those standards. However, at this time, relatively few electronic health record systems meet these standards and upgrading to the few systems that do is generally not viable for our providers and other safety net entities. Unfortunately, this means that for the foreseeable future, our providers, like many, will need to maintain duplicate systems and employ workarounds to meet the requirements of 42 CFR Part 2. To the extent that SAMHSA can clarify allowable information sharing as indicated above for entities like those we represent, more resources can be focused on patient care and safety.


We appreciate SAMHSA's continued support of training and technical assistance tools.

We thank SAMHSA for the guidance regarding PDMPs. We have seen increased use of this tool and the value of having a resource available to the benefit of our patients.

We also appreciate SAMHSA's work regarding data sharing for non-treating entities like Health Information Exchanges (HIEs). In both New Hampshire and Vermont, we have identified numerous opportunities for better patient care and more efficient information sharing utilizing these types of entities. Unfortunately, the workflows and technical solutions are a barrier to implementing these opportunities. We support SAMHSA in their efforts to ensure appropriate data sharing with Health Information Exchanges, and suggest that SAMHSA also offer additional technical assistance to these entities. Specifically, we have several of our providers who will not send data to the Health Information Exchange in Vermont because that HIE does not yet have the ability to accept Part 2 data in a manner that is compliant with 42 CFR Part 2.13(d). This means that our patients are unable to benefit from the enhanced care coordination through the HIE even when the patient has consented. While our HIE is working on solving this technological problem, we believe that additional support for them, and other HIEs could facilitate faster transitions that support our patients.

Our medical providers continually find ways to have a significant, positive impact on their patients' health. Providing comprehensive care is key to that success and we appreciate SAMHSA's efforts to reduce barriers and improve data sharing. We appreciate the opportunity to discuss how 42 CFR Part 2 will impact our members' ability to respond to their patient needs, especially those patients with opioid addiction. If you have any questions, please contact Georgia Maheras at gmaheras@bistatepca.org or 802-229-0002, ext. 218. Thank you for your consideration.

Sincerely,



Tess Stack Kuenning, CNS, MS, RN
President and Chief Executive Officer
Bi-State Primary Care Association