

525 Clinton Street
Bow, NH 03304
Voice: 603-228-2830
Fax: 603-228-2464



61 Elm Street
Montpelier, VT 05602
Voice: 802-229-0002
Fax: 802-223-2336

April 8, 2016

Comments submitted via www.regulations.gov

The Substance Abuse and Mental Health Services Administration (SAMHSA)
Department of Health and Human Services
Attn: SAMHSA-4162-20
5600 Fishers Lane
Room 13N02B
Rockville, Maryland 20857

Re: Comments on Proposed Rule to Modify 42 C.F.R. Part 2

To Whom It May Concern:

On behalf of Bi-State Primary Care Association and our members, I submit the following comments in response to the proposed rule to modify 42 C.F.R. Part 2, otherwise known as Part 2, included in the Substance Abuse and Mental Health Services Administration (SAMHSA) February 9, 2016 Proposed Rule (81 Fed. Reg. 6998).

Established in 1986, Bi-State 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 works with federal, state and regional health policy organizations, foundations and payers to develop strategies, policies and programs that provide and support community-based primary health care services in medically-underserved areas. Our members include Community Health Centers, which include Federally Qualified Health Centers (hereafter interchangeably referred to as Health Centers or FQHCs); Rural Health Clinics; private and hospital-supported primary care practices; Community Action Programs; Health Care for the Homeless programs; Area Health Education Centers; Clinics for the Uninsured; and social service agencies.

Bi-State and our members appreciate and support the intent of these proposed rule changes, which is to facilitate information exchange within increasingly integrated health care models while continuing to protect the legitimate privacy concerns of patients seeking treatment for a substance use disorder. The comments submitted in this document reflect the views of our New Hampshire office representing 15 Health Centers with 39 locations. We kindly ask that you refer to the State of Vermont's comments for the Vermont Health Center comments on the proposed rule.

These proposed changes are particularly timely given the increasing volume of patients being seen at Health Centers for substance use disorder treatment. In New Hampshire, all of our member Health Centers offer substance use disorder services, typically in the form of Screening, Brief Intervention, and Referral to Treatment (SBIRT), Medication Assisted Treatment (MAT), and outpatient counseling. Many of them have existing referral relationships with their local substance use disorder treatment providers and other behavioral health service providers.

Much like the trend nationally, New Hampshire has seen an increase in the need for access to substance use disorder treatment. In 2015, New Hampshire had 431 overdose deaths¹ which exceed the number of highway fatalities in the state that same year². In 2014, FQHCs provided substance use disorder treatment services to over

¹See Office of the Chief Medical Examiner Report, <http://1nqay01ego5543dp1rgf30j1.wpengine.netdna-cdn.com/files/2016/03/Drug-Data-Update-from-NH-Medical-Examiners-Office-3-28-16-3.pdf> (March 2016).

²See New Hampshire Driving Toward Zero, <http://www.nhdtz.com/numbers> (April 2016).

100,000 patients nationally³. In addition, 271 Health Centers were recently awarded \$94 million to help to improve and expand the delivery of substance use disorder services, with a specific focus on treatment of opioid use disorders in underserved populations. Four New Hampshire Health Centers were recipients of this funding. This investment is expected to help awardees treat nearly 124,000 new patients⁴.

Health Centers are ready and able to serve their patients who are struggling with substance use disorder, but there is a clear need for additional support and policy changes to enable them to do so more effectively. The Health Center model is designed to treat the whole person, which strengthens outcomes for those with substance use disorders who often have co-occurring mental health and chronic physical health conditions. Our comments below address our concerns as to how the proposed rule changes may affect New Hampshire's Health Centers' ability to provide quality care for patients with substance use disorder.

Stigma

Bi-State generally supports SAMHSA's efforts to modernize the regulations on patient confidentiality for substance use disorder patient records, with the recommendation that SAMHSA consider the risk of proliferating stigma associated with this population by requiring unique accommodations for such records.

The current regulations need significant updating due to numerous innovations in patient care over the last 29 years. These include, but are not limited to: the implementation of electronic medical records; increased reliance on care teams; and greater integration of physical and behavioral health care. Health Centers have been national leaders in all of these areas, thereby expanding their capacity to provide more comprehensive and cost effective care. Health Centers pride themselves on the ability to offer comprehensive and integrated care to the most vulnerable populations and communities, and unfortunately the current Part 2 regulations have been cited by many Health Centers across the country as a barrier to providing integrated, patient-centered care to individuals seeking treatment for substance use disorders. Anecdotally, Health Centers in New Hampshire report care challenges for integration as the primary care physician is currently unable to view information related to a patient's substance use disorder treatment and progress. This creates a significant barrier to treating the whole person, which is the goal for Health Centers. As health care providers aiming to create nurturing and more deeply integrated practices, it is crucial that they be able to appropriately share information that will lead to better care for their patients. Therefore, we appreciate the steps that SAMSHA has taken to modernize and align these regulations to take these improvements into account. Allowing providers to more efficiently and effectively share critical patient data can only lead to better health outcomes for patients.

At the same time, as care providers to low-income and vulnerable populations, Health Centers also understand the critical importance of maintaining patient privacy, especially in the area of substance use disorder. Too often, the stigmas associated with substance misuse and the fear that this information may be used against an individual will lead them to not seek treatment. It is because of this concern that there is still a need for appropriate confidentiality protections for substance use disorder treatment. At the same time, treating these records with accommodations beyond regular confidentiality standards also run the risk of inadvertently proliferating the stigma associated with these conditions among medical professionals. Substance use disorder is a chronic medical condition, much like diabetes and heart disease, and the ideal standard would be that these patient records are treated in the same manner as those for all other medical conditions. We urge SAMHSA to continue to invest in messaging and programs that are designed to break down the stigma associated with these conditions so that these records no longer need the protections that presently exist through this rule.

Application to Primary Care

Bi-State appreciates SAMHSA's explicit clarification that paragraph (1) of the definition of "program" does not apply to "general medical facilities" such as FQHCs, and requests that this language be added to the regulatory text.

³HRSA <http://bphc.hrsa.gov/uds/datacenter.aspx?year=2014&state=NH&compare=Nat> (last accessed April 2016)

⁴HRSA <http://www.hhs.gov/about/news/2016/03/11/hhs-awards-94-million-to-health-centers.html> (last revised March 2016)

Section B.2.a.viii of the preamble discusses the definition of the term “program,” meaning those federally-assisted substance use disorder programs to which the regulations discussed in this proposed rule apply. In this discussion, SAMHSA proposes “to make clear that paragraph (1) of the definition of ‘program’ would not apply to ‘general medical facilities’ and ‘general medical practices.’” Later in this subsection, SAMHSA states that:

“While the term “general medical facility” is not defined at 42 CFR 2.11 (Definitions), hospitals, trauma centers, or federally qualified health centers would generally be considered “general medical facilities.” Therefore, primary care providers who work in such facilities would only be covered by the Part 2 definition of a “Program” if: (1) they work in an identified unit within such general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment, or (2) the primary function of the providers is substance use disorder diagnosis, treatment or referral for treatment and they are identified as providers of such services by the general medical facility.”

As stated elsewhere in the preamble, these statements are consistent with the regulations that are currently in effect. Nonetheless, we appreciate SAMHSA’s efforts to make clear that primary care providers who work in FQHCs are not included under Paragraph 1 of the “program” definition. To minimize any future confusion, Bi-State recommends this clarification be incorporated into the Final Rule, preferably in the regulatory text.

Health Information Exchange

Bi-State is concerned that the proposal for sharing information via a Health Information Exchange (HIE) will continue to create barriers because most current technology cannot keep certain data, i.e., “Part 2” information, separate or segmented from the rest of the electronic patient record.

New Hampshire’s Health Centers serve over 100,000 residents annually, of which 30,000 are uninsured. The Health Centers see firsthand how integrated care and using the whole-person approach for health care delivery benefits every resident, especially low-income families. 42 CFR Part 2 creates significant barriers when Health Centers seek to work with one another and with other provider types to integrate and coordinate care for their patients. These types of collaborative, patient-centered arrangements generally rely on the use of HIEs, which enable providers to query data collected by other providers on their patients. Unfortunately, both the current and proposed regulations create substantial barriers to this type of “secondary disclosure” by HIEs because of the inability to “segment” or separate the Part 2 information. At best, it would be impractical to track and manage secondary disclosure to the standard outlined in the current regulation. In practical terms, most HIEs and electronic medical records today do not support data segmentation. As a result, the easiest way for HIEs to react to 42 CFR Part 2 providers is to exclude them. We have concerns that the revised consent definitions will not change that situation. For additional information on this issue, we ask that you review the comments submitted by OCHIN, the largest Health Center Controlled Network (HCCN) in the United States, consisting of more than 90 health care organizations in over 400 clinics in 18 states.

This issue is of particular concern to Bi-State given the recent Centers for Medicare and Medicaid Services (CMS) Transformation Waiver that was awarded to our state. On January 5, 2016 CMS approved New Hampshire’s Section 1115 Research and Demonstration Transformation Waiver to access new federal funding to help transform its behavioral health delivery system. The Transformation Waiver has four main targets:

1. Deliver integrated physical and behavioral health care that better addresses the full range of individuals’ needs.
2. Expand capacity to address emerging and ongoing behavioral health needs in an appropriate setting.
3. Reduce gaps in care during transitions across care settings by improving coordination across providers and linking patients with community supports.

4. Move fifty percent of Medicaid reimbursement to alternative payment models by the end of the demonstration period.

The state is implementing this waiver through the creating of integrated delivery networks (IDNs), which will be groups of provider systems within designated regions of the state with the goal of better integrating primary care and behavioral health. There is specific attention being paid to the use of this funding for opioid treatment and recovery programs and as a means to address New Hampshire's substance use disorder epidemic. The current proposal for these projects also includes the expected use of HIEs to facilitate care coordination between providers in these IDNs. Bi-State asks SAMHSA to consider the challenges that the existing and proposed 42 CFR Part 2 regulations will have on the ability for these projects to be successful given the restrictions on substance use disorder patient records.

Parity Enforcement

Bi-State asks SAMHSA to review the existing provisions through the lens of state access to insurance claims data and protected health information for those accessing substance use disorder treatment, with the intent of enforcing The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

With the increased coverage of behavioral health services under insurance, states have been exploring their role in parity enforcement for these vulnerable populations. The MHPAEA is a federal law that generally prevents group health plans and health insurance issuers that provide mental health or substance use disorder benefits from imposing less favorable benefit limitations on those benefits than on medical/surgical benefits. New Hampshire has recently begun an extensive analysis on the implementation of the parity law. The New Hampshire Insurance Department (NHID) is currently conducting a market conduct analysis, and a workgroup of stakeholders is looking at ongoing emerging concerns related to parity enforcement. Key to the success of this work is that the NHID has access to patient information as it relates to coverage and benefits administration for substance use disorder services. For example, if a provider alerts the NHID to concerning carrier practices related to a patient's substance use disorder treatment, it is crucial that the NHID has the ability to use that information to conduct an investigation. Bi-State asks SAMHSA to work with other federal entities that are exploring parity enforcement to ensure that the proposed rule changes would not create barriers for states working on enforcement of the parity law.

Bi-State appreciates the opportunity to comment on this critically important proposed rule. Our staff and member Health Centers would be happy to provide SAMSHA with any further information that would be beneficial to help finalize this rule. Please do not hesitate to contact me at (603) 228-2830 extension 112 or via e-mail at tkuening@bistatepca.org if you require clarification on the comments presented above.

Sincerely,



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