NATIONAL ASSOCIATION OF Community Health Centers

Main Office
7501 Wisconsin Ave.
Suite 1100W
Bethesda, MD 20814
301.347.0400 Tel
301.347.0459 Fax

Division of Federal, State and Public Affairs
1400 Eye Street, NW
Suite 910
Washington, DC 20005
202.296.3800 Tel
202.296.3526 FAX

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

Submitted electronically via www.regulations.gov.

RE: SAMSHA-4162-20, Proposed Rule on the Confidentiality of Substance Use Disorder Patient Records

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) appreciates 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 or "Part 2"). NACHC is the national membership organization for federally qualified health centers (FQHCs or "health centers"). FQHCs play a critical role in the health care system, serving as the health home to over 24 million people, the majority of whom live below the Federal Poverty Level. In 2014, FQHCs served over 1 in 6 Medicaid beneficiaries nationwide. With over 9,300 sites, FQHCs provide affordable, high quality, comprehensive primary care to medically underserved individuals, regardless of their insurance status or ability to pay for services. For additional information on FQHCs, please see Attachment A.

Substance abuse has become a top public health concern in the United States, and health centers are seeing the consequences first hand. In 2014, health centers provided substance abuse treatment services to well over half a million individuals, through more than 2.2 million visits. In addition, 271 health centers were recently awarded $94 million to help to improve and expand the delivery of substance abuse services, with a specific focus on treatment of opioid use disorders in underserved populations. This investment is expected to help awardees treat nearly 124,000 new patients.

Health centers are ready and able to serve their patients who are struggling with substance abuse and addiction, but there is a clear need for additional support and policy change to enable them to do so more effectively. Towards that goal, we summarize our comments on the proposed rule below, and then discuss each.

Summary of Comments from National Association of Community Health Centers (NACHC)

1. **NACHC generally supports SAMHSA's efforts to modernize the regulations on patient confidentially for substance abuse patient records, with the caution that patient confidentiality should not be compromised by any of these changes or alignments.**

2. **NACHC 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.**

3. **NACHC 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 from the rest of the electronic patient record.**

Discussion of Comments

1. NACHC supports SAMHSA's efforts to modernize the regulations on patient confidentially for substance abuse patient records, with the caution that patient confidentiality should not be compromised by any of these changes or alignments.

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 abuse disorders. 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 abuse. Too often, the stigmas associated with substance abuse 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 abuse disorders. As stated in the proposed rule, "(t)he purpose of the regulations at 42 CFR part 2 is to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment." Therefore, NACHC cautions SAMSHA to remain diligent in the oversight of these regulations to ensure that the information is only being conveyed to the appropriate health care parties with the sole intent to improve patient care.

2. **NACHC 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.**

Section B.2.a.viii of the preamble discusses the definition of the term "program", meaning those federally-assisted substance abuse 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 (emphasis added):

> "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, NACHC recommends this clarification be incorporated into the Final Rule, preferably in the regulatory text.

3. **NACHC 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 from the rest of the electronic patient record.**

As discussed above, 42 CFR Part 2 often does not apply to individual health centers; nonetheless, it 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 Health Information Exchanges (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 (and, in reality, it is not feasible) to track and manage secondary disclosure to the standard outlined in the current regulation. In practical terms, most HIEs and EHRs 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. Unfortunately, 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.

NACHC appreciates the opportunity to comment on this important proposed rule. NACHC staff and our member health centers would be happy to provide SAMSHA with any further information that would be beneficial to help finalize this rule. Please contact me at 202.296.0158 or cmeiman@nachc.org.

Sincerely,

Colleen P. Meiman, MPPA
Director, Regulatory Affairs
National Association of Community Health Centers

Attachment A:

OVERVIEW OF FEDERALLY QUALIFIED HEALTH CENTERS

For 50 years, Health Centers have provided access to quality and affordable primary and preventive healthcare services to millions of uninsured and medically underserved people nationwide, regardless of their ability to pay. At present there are almost 1,300 health centers with more than 9,300 sites. Together, they serve ***over 24 million patients***, including nearly seven million children and more than 1 in 6 Medicaid beneficiaries.

Health centers provide care to all individuals, regardless of their ability to pay. All health centers provide a full range of primary and preventive services, as well as services that enable patients to access health care appropriately (e.g., translation, health education, transportation). A growing number of Health Centers also provide dental, behavioral health, pharmacy, and other important supplemental services.

To be approved by the Federal government as a Health Center, an organization must meet requirements outlined in § 330 of the Public Health Service Act. These requirements include, but are not limited to:

- ***Serve a federally-designated medically underserved area or a medically underserved population.*** Some Health Centers serve an entire community, while other target specific populations, such as persons experiencing homelessness or migrant farmworkers.
- Offer services to all persons, regardless of the person's ability to pay.
- Charge no more than a nominal fee to patients whose incomes are at or below the Federal Poverty Level (FPL).
- Charge persons whose incomes are between 101% and 200% FPL based on a sliding fee scale
- Be ***governed by a board of directors, of whom a majority of members must be patients of the health center.***

Most §330 Health Centers receive Federal grants from the Bureau of Primary Health Care (BPHC) within HRSA. BPHC's grants are intended to provide funds to assist health centers in covering the otherwise uncompensated costs of providing care to uninsured and underinsured indigent patients, as well as to maintain the health center's infrastructure. Patients who are not indigent or who have insurance, whether public or private, are expected to pay for the services rendered. In 2014, on average, the insurance status of Health Center patients is as follows:

- 47% are Medicaid recipients
- 28% are uninsured
- 16% are privately insured
- 9% are Medicare recipients

No two health centers are identical, but they all share one common purpose: to provide primary health care services that are coordinated, culturally and linguistically competent, and community-directed care to uninsured and medically underserved people.