

February 14, 2023

Miriam Delphin-Rittmon, Ph.D.  
Assistant Secretary for Mental Health and Substance Use  
Substance Abuse and Mental Health Services Administration  
5600 Fishers Lane  
Rockville, MD 20857

**RE: RIN 0930-AA39; Medications for the Treatment of Opioid Use Disorder**

***Submitted electronically via regulations.gov.***

Dear Dr. Delphin-Rittmon,

The National Rural Health Association (NRHA) is pleased to offer comments on the Department of Health and Human Services' (HHS) and the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed rule on medications for the treatment of opioid use disorder.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

We appreciate the Department's continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

### **Background and Need for Proposed Rule**

NRHA is broadly supportive of SAMHSA's proposed provisions that expand access to medications for the treatment of opioid use disorder (MOUD) at opioid treatment programs (OTPs). Historically, pre-public health emergency (PHE) regulations surrounding MOUD have posed a barrier to rural residents receiving needed services at OTPs. This is especially true for rural patients that would require methadone because OTPs are the only providers authorized to prescribe methadone.

PHE flexibilities that expanded unsupervised, take-home doses of methadone and allowed OTPs to prescribe buprenorphine via telehealth changed the landscape for MOUD. Like many other flexibilities in place during the PHE, SAMHSA's OTP flexibilities increase access for rural residents.

PHE flexibilities, and the new provisions in this proposed rule, also work against the stigma associated with OUD. Other than availability and access, a major barrier to seeking care for behavioral

health concerns for rural residents is acceptability.<sup>1</sup> Stigma and health literacy are challenges in rural communities that impact the acceptability of seeking and receiving behavioral health care.

### **Section-by-Section Description of Proposed Amendments to 42 CFR Part 8**

#### **C. Section 8.1 – Scope**

NRHA supports SAMHSA’s updated language that reflects modern medical terminology and moves away from stigmatizing language. Shifting away from the term “medication-assisted treatment” to “MOUD” emphasizes that medications are successful treatment tools for OUD rather than one part of a larger treatment strategy. Revising language to match current treatment standards and lessen the stigma associated with MOUD is critical for breaking down barriers to seeking treatment for rural residents. Additionally, using clearer language like MOUD (versus medication-assisted treatment), is easier to understand for those with low health literacy.

#### **D. Section 8.2—Definitions**

Similar to Section 8.1, updating definitions to reflect modern terminology and understanding of OUD will lessen the stigma around MOUD. NRHA supports SAMHSA’s proposed revisions to definitions in this section.

Two proposed revisions to staffing-related definitions are positive for rural OTPs. NRHA applauds these changes and expects that they will aid in any workforce challenges that rural OTPs face. First, the clarification that a medical director, who must be a physician, may delegate to non-physician practitioners and other appropriately licensed or credentialed healthcare professionals, is vital for rural OTPs. The current definition only allows delegation under direct supervision to other physicians and health care professionals. The new definition of medical director also changes “direct supervision” of the physician over the other practitioners to “supervision.” NRHA hopes that this affords more flexibility, especially to non-physician practitioners with prescriptive authority, to practice at the top of their license and training while allowing the physician medical director to tend to other OTP business. Current and proposed regulations as well as sub-regulatory guidance do not state how long a medical director must be present, thus the ability to delegate without direct supervision is a significant proposal.<sup>2</sup> Second, the proposed definition of “practitioner” is expanded from only physicians to physicians and all types of non-physician practitioners. These professionals are important to rural communities and fill in gaps where physicians are not able.

NRHA suggests that SAMHSA expand its definition of long-term care facilities. SAMHSA should include other facilities such as adolescent and adult group homes and prisons. Under § 8.12(h)(3), long-term care facilities do not need to be certified as OTPs in order to provide continuous medication treatment or withdrawal management of a patient who is admitted to the facility. Adding group homes, prisons, and similar entities to the definition of long-term care facilities will expand access to MOUD, especially methadone, to individuals in those facilities.

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<sup>1</sup> Brenda Mack, et al., *Mental health in rural areas*, NATIONAL RURAL HEALTH ASSOCIATION, Feb. 2022, at 2, [https://www.ruralhealth.us/NRHA/media/Emerge\\_NRHA/Advocacy/Policy%20documents/NRHA-Mental-health-in-rural-areas-policy-brief-2022.pdf](https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/NRHA-Mental-health-in-rural-areas-policy-brief-2022.pdf).

<sup>2</sup> SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION, *Federal Guidelines for Opioid Treatment Programs*, Jan. 2015 <https://store.samhsa.gov/sites/default/files/d7/priv/pep15-fedguideotp.pdf>

G. Section 8.11—Opioid Treatment Program Certification

NRHA applauds the revisions in this section that support the goal of expanding access to MOUD to geographically underserved areas. In particular, the proposed language that clarifies that medication units, including mobile units, may furnish any services that are provided at the associated OTP has the potential to increase rural communities' access to MOUD. NRHA urges SAMHSA to finalize this policy as proposed.

Current regulations state that medication units may dispense MOUD for “observed ingestion,” meaning that take home doses from medication units are not authorized.<sup>3</sup> This policy disproportionately impacts rural clients that use a medication unit as their primary point of access to an OTP who must travel to the unit each day for a take home dose. Even though medication units are supposed to make OTPs more widely available in geographically underserved or isolated areas, rural clients likely still travel further and longer to reach these units than urban or suburban clients. Allowing medication units to dispense take home doses will help close this disparity for rural clients.

The calendar year 2023 Medicare Physician Fee Schedule finalized that services provided at mobile units will be paid under the Medicare OTP bundled payment codes or add-on codes for medically reasonable services.<sup>4</sup> This policy change, alongside SAMHSA's clarification that mobile units may furnish any services that an OTP furnishes, have the potential to expand lifesaving MOUD to more rural patients.

H. Section 8.12—Federal Opioid Use Disorder Treatment Standards

NRHA thanks SAMHSA for updating § 8.12 to reflect current OUD treatment standards, the evolving opioid crisis, and telehealth flexibilities that allowed clients to continue to access MOUD during the PHE.

NRHA specifically supports the new proposed § 8.12(i) on unsupervised or take-home doses. Allowing practitioners to make patient-centered decisions on whether unsupervised doses are appropriate for a client reflects current treatment standards.

Thus far, some studies have suggested that the PHE flexibilities associated with prescribing unsupervised doses have not led to increased overdose deaths due to opioid agonist medications.<sup>5</sup> The proposed standard for prescribing unsupervised doses requires practitioners to consider six criteria and any additional criteria that may indicate the benefits or risks of unsupervised doses. Additionally, the proposed regulations prescribe limits on how many doses may be prescribed at once but gives room for practitioner discretion. NRHA believes that these guardrails are appropriate to limit misuse and increase flexibility for patients where appropriate.

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<sup>3</sup> 42 C.F.R. § 8.11(i)(1).

<sup>4</sup> 87 FR 69404, 69774.

<sup>5</sup> Lauren J. Tanz, et al., *Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic*, JAMA NETWORK OPEN, Jan. 2023, at10 (2023) <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689?source=email>; Noa Krawczyk, et al., *Synthesizing evidence on the impacts of COVID-19 regulatory changes on methadone treatment for opioid use disorder: Implications for U.S. federal policy*, MedRxiv (Dec. 2022) <https://www.medrxiv.org/content/10.1101/2022.12.15.22283533v1.full-text>.

Importantly for rural communities, the ability to take home up to 28 days of unsupervised doses reduces travel burdens and other transportation challenges that rural patients disproportionately face. Rural residents generally travel further for jobs, health care, and other necessities, which makes daily trips to an OTP extremely onerous to fit within work, school, or caregiver obligations.<sup>6</sup> Take home doses are one step towards giving rural residents seeking MOUD more flexibility and autonomy over their course of treatment.

While NRHA applauds SAMHSA's actions to expand access to OTPs, rural communities need more support and resources in order to fully benefit from the proposed regulations. Access will remain an issue for rural communities. According to NRHA's internal analysis, only about 220 out of the 1,900 SAMHSA-certified OTPs are in rural zip codes. This lack of rural OTPs becomes even more acute depending upon the state. For example, out of 168 OTPs in California, 2 are available in rural areas and only 1 out of 17 OTPs in Minnesota is rural.

Further, studies have shown the differences in accessibility between rural and other areas. For example, one study showed that the average drive time to an OTP in noncore and micropolitan counties was 40 to almost 50 minutes whereas the averages in small metropolitan areas was 35 and large metropolitan areas was less than 8.<sup>7</sup> Using Rural-Urban Commuting Area (RUCA) codes, another study found that small towns accounted for 2% of all OTPs and rural areas accounted for a staggering 0.3%.<sup>8</sup> Additionally, rural RUCA codes had a 56-minute drive time to the nearest OTP with metropolitan RUCA codes ranging from 35- to 10-minute drives.<sup>9</sup>

Overall, authorizing unsupervised doses of MOUD from OTPs will simplify treatment for rural patients. However, SAMHSA should be mindful of remaining barriers to access in rural communities and consider these challenges in future rulemakings.

Unsupervised doses may also help reduce the stigma associated with MOUD. As mentioned, stigma and the perceived acceptability of seeking behavioral health care may stop some rural residents from pursuing treatment. Early studies on the effectiveness of unsupervised doses of methadone during the PHE suggest that this flexibility may break down the negative feelings associated with MOUD. Patients indicated that their ability to receive unsupervised doses improved self-esteem and feelings of autonomy, pride, and accomplishment.<sup>10</sup> These outcomes may help rural patients feel more positive about seeking treatment and thus reduce some stigma.

Proposed § 8.12(e), on patient admission criteria, should be finalized as proposed. NRHA believes that the loosened admission criteria will meaningfully expand MOUD to rural residents, like adolescents. NRHA also supports removing the admission requirement that an individual must be addicted for opioids for one year as it served as an unnecessary barrier and deterrent to treatment.

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<sup>6</sup> See Krawczyk, et al., *supra* note 3 at 5.

<sup>7</sup> Paul J. Joudrey, E. Jennifer Edelman, & Emily A. Wang, *Drive Times to Opioid Treatment Programs in Urban and Rural Counties in 5 US States*, 322 JAMA 1310 (2019) <https://jamanetwork.com/journals/jama/fullarticle/2752051>.

<sup>8</sup> Solmaz Amiri, et al., *Access to medication-assisted treatment in the United States: Comparison of travel time to opioid treatment programs and office-based buprenorphine treatment*, 224 DRUG AND ALCOHOL DEPENDENCE 108727 (2021) <https://www.sciencedirect.com/science/article/abs/pii/S0376871621002222>.

<sup>9</sup> *Id.*

<sup>10</sup> Krawczyk, et al., *supra* note 3 at 5 and Table 3.

NRHA supports proposed § 8.12(f)(2) which allows for a non-OTP practitioner to complete both the initial screening exam and the full exam as well as the use of telehealth for both exams. Permitting a patient to receive the two required exams from another practitioner allows rural patients to avoid traveling further to an OTP and instead see a more local practitioner such as their normal primary care or family physician. Using telehealth for the screening and full exams also provides flexibility for rural patients that live farther from an OTP or other practitioner that would perform the exams in-person.

NRHA also supports the provision to prescribe methadone and buprenorphine via telehealth. Telehealth has the potential to expand access to rural areas with few providers; however, for MOUD and other OUD treatments, there is research to suggest that prescribing via telehealth did not expand access but instead supplemented in-person services.<sup>11</sup> The lowest uptake of telehealth for OUD was in rural and micropolitan areas,<sup>12</sup> suggesting that broadband and internet access are barriers to treatment and thus rural patients may still travel for OUD treatment or forgo treatment altogether. NRHA appreciates the flexibility to use telehealth at OTPs but recognizes the challenges that rural communities face in utilizing this flexibility.

NRHA applauds SAMHSA for its changes to interim treatment programs. The revisions to interim treatment will make it more accessible for rural patients, which is important considering that oftentimes OTPs are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. However, NRHA suggests that SAMHSA modify § 8.12(j) by allowing for-profit entities, in addition to public and non-profit private entities, to provide interim treatment. As discussed, the extreme lack of OTPs in rural areas is problematic and not allowing for-profit OTPs to provide interim treatment compounds this issue if a for-profit provider is the only one in a geographic area. Rural residents deserve equal access to interim treatment.

NRHA thanks SAMHSA for the opportunity to comment on this proposed rule. We appreciate SAMHSA's efforts to reduce barriers to MOUD and bring regulations in line with current treatment standards and clinical knowledge. NRHA looks forward to working with SAMHSA to ensure rural communities are able to access to behavioral health services. Please contact Alexa McKinley ([amckinley@ruralhealth.us](mailto:amckinley@ruralhealth.us)) for more information or with any questions.

Sincerely,



Alan Morgan  
Chief Executive Officer  
National Rural Health Association

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<sup>11</sup> Ruth Hailu, et al., *Telemedicine Use and Quality of Opioid Use Disorder Treatment in the US During the COVID-19 Pandemic*, JAMA NETWORK OPEN, Jan. 2023, at 8 (2023)

[https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718?utm\\_source=For The Media&utm\\_medium=referral&utm\\_campaign=ftm\\_links&utm\\_term=012423&source=email](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800718?utm_source=For%20The%20Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=012423&source=email).

<sup>12</sup> *Id.* at 5.