



March 30, 2023

Drug Enforcement Administration  
Department of Justice  
ATTN: RIN 1117-AB78

*Submitted via Regulations.gov*

**RE: Expansion of Induction of Buprenorphine via Telemedicine Encounter (RIN 1117-AB78)**

On behalf of the New York State Council for Community Behavioral Health, thank you for the opportunity to comment on the Drug Enforcement Administration's (DEA) Expansion of Induction of Buprenorphine via Telemedicine Encounter proposed rule and other policy changes.

The NYS Council is a statewide membership organization composed of 120 community-based organizations that provide recovery-focused mental health and/or substance abuse/chemical dependence and addiction treatment programs and services for New Yorkers in need. NYS Council members offer a broad array of behavioral health services designed to meet the unique needs of children and adolescents, individuals and families seeking our assistance. Our services are available in a variety of community settings including freestanding agencies, behavioral health divisions of general hospitals, and county mental hygiene programs.

The proposed Expansion of Induction of Buprenorphine via Telemedicine Encounter (hereinafter "Proposed Rule") includes several revisions to the Code of Federal Regulations (CFR) allowing practitioners to prescribe buprenorphine via telemedicine, including audio-only technology, without having had an in-person evaluation under certain circumstances. The Proposed Rule seeks to reflect the evolution of telehealth since passage of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (hereinafter "Ryan Haight Act") and the emergence of the COVID-19 public health emergency (PHE). Additionally, the Proposed Rule updates several definitions pertaining to the use of telemedicine, requirements for documentation of telemedicine encounters, and modified regulations allowing for the prescription of buprenorphine for a maximum 30-day supply before requiring an in-person evaluation.<sup>i</sup>

The NYS Council applauds the swift and timely actions that DEA and the Department of Health and Human Services (HHS) have taken throughout the course of the COVID-19 PHE to ensure continuity of care for patients in need of buprenorphine for opioid use disorder (OUD), particularly through guidance allowing for telemedicine prescriptions without having had an in-person evaluation.<sup>ii</sup> At the onset of the PHE, the NYS Council members quickly pivoted toward serving patients via telehealth in an effort to maintain access to critical, lifesaving mental health and substance use services. Even as the COVID-19 pandemic becomes less invasive to public life, services furnished through telecommunication modalities

remain in high demand. Telehealth, as a service delivery modality, is essential for continued access to mental health and substance use services today and undoubtedly into the future.

Below, we have associated our comments with the topic sections used in the Proposed Rule, and we have placed our comments in the order in which topics appear in the Proposed Rule.

### **Definitions**

The Proposed Rule amends 21 CFR 1300.04 to add definitions for “prescription drug monitoring program” (PDMP) and “telemedicine encounter”.<sup>iii</sup> Under the new definition of a “telemedicine encounter,” practitioners are required to use an “interactive telecommunications system” in alignment with promulgated regulations from the Centers for Medicare and Medicaid Services (CMS). The definition currently in use mirrors the Ryan Haight Act’s statutory definition requiring the use of a “telecommunications system” referred to in the Social Security Act; however, the Social Security Act only references, but does not define, telecommunications systems. Therefore, the Proposed Rule adopts CMS’s definition for “interactive telecommunications system” which states: “Interactive telecommunications system means, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.”<sup>iv</sup>

Notably, the Proposed Rule adopts the CMS carve out for “services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder.”<sup>v</sup> Under the revised definition, interactive communications may include audio-only technology if the patient is located in their home and the provider is technically capable of providing audio-video technology but the patient is not capable of, or does not consent to, the use of video technology. The NYS Council applauds the inclusion of audio-only telemedicine for mental health disorders and recommends that DEA further clarify the intended meaning of “mental health disorders.” The Proposed Rule’s stated intention for aligning the definition of the “practice of telemedicine” with CMS regulations is a result of ambiguity in the original definition provided in the Social Security Act. “Practice of telemedicine” was mentioned in the Social Security Act, but never defined. Notably, the term “mental health disorder” remains undefined in the CMS regulation and the Proposed Rule. The absence of a definition may lead to the same confusion that prompted a clarification for the “practice of telemedicine.” Moreover, it appears that DEA includes opioid use disorder (OUD) under the umbrella of mental health disorders as this is the enabling provision for the use of audio-only technology to provide buprenorphine. To ensure that practitioners have clear parameters for qualifying conditions, the NYS Council proposes a definition for “mental health disorders” to include “someone having a diagnosable mental, behavior, or emotional disorder that causes serious functional impairment that substantially interferes with or limits one or more major life activities.”<sup>vi</sup>

### **Prescriptions**

The Proposed Rule adds several requirements practitioners would have to satisfy to prescribe buprenorphine utilizing telemedicine. In particular, the Proposed Rule requires telemedicine only be used to issue a prescription for a legitimate medical purpose by practitioners acting in the usual course of business; requires all practitioners engaged in telemedicine to be located in a state, territory, or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico at the time of the telemedicine encounter; and requires practitioners be authorized to prescribe controlled

substances under their DEA-registration as well as applicable state registrations in both the state where the practitioner is located and the state where the patient is located.<sup>vii</sup> Under these circumstances, a practitioner may use telemedicine to prescribe buprenorphine in an amount less than or equal to a maximum 30-day supply. After 30 calendar days from the date the telemedicine prescription was issued, practitioners are prohibited from further prescribing until one of the following conditions is met:

1. The prescribing telemedicine practitioner conducts an in-person exam of the patient.
2. The prescribing practitioner conducts a telemedicine encounter with the patient while the patient is located in the physical presence of another DEA-registered practitioner. This telemedicine encounter requires audio-visual technology and does not provide a carve out for individuals being treated for a “mental health disorder.”
3. A DEA-registered practitioner conducts an in-person exam and sends a qualifying telemedicine referral, including the results of the evaluation, to a prescribing practitioner. Under this condition, the prescription may be issued for any controlled substance that the practitioner is otherwise authorized to prescribe.

After completion of one of the above conditions, the Proposed Rule would allow a practitioner to continue prescribing buprenorphine without additional in-person or telemedicine evaluations.<sup>viii</sup>

The NYS Council recognizes the nuanced position required of the DEA in promulgating the above Proposed Rule. The COVID-19 pandemic contributed to increases in behavioral health challenges including symptoms of anxiety and depressive disorder (30.9%), initiation or increased use of substances (13.3%), as well as suicidal ideation (10.7%).<sup>ix</sup> As a result of swift and decisive action from the federal government, including waiving the Ryan Haight Act’s in-person requirement, telemedicine surged for individuals in need of critical services for mental health and substance use disorders.

In May 2020, the National Council for Mental Wellbeing, in partnership with Qualifacts, conducted a survey of behavioral health providers that found prior to the PHE, 93% of survey respondents indicated they provided less than 20% of their care in a virtual setting.<sup>x</sup> The same survey demonstrated that in the span of just weeks the figure soared, with 60% of respondents indicating they were offering up to 80% of care virtually. Additionally, survey respondents cited the expansion of services that may be delivered via telehealth as one of the most impactful policy changes in facilitating the transition to virtual care. During the initial months of the PHE and amidst stay-at-home orders, telehealth enabled mental health and substance use organizations to provide a critical connection to consumers. The efficiency and clinical effectiveness of telehealth for mental health and substance use services on a longer-term basis has become increasingly clear during the COVID-19 pandemic.

While the NYS Council is supportive of the expanded use of telehealth during the COVID-19 pandemic, the opioid crisis continues to present a significant challenge with more than 107,000 Americans dying from a drug overdose in 2021.<sup>xi</sup> The Proposed Rule attempts to strike a balance between the flexibilities provided during the pandemic – which have received significant support from providers and patients – and continued efforts to manage diversion and public health concerns.<sup>xii</sup> Unfortunately, the Proposed Rule’s limitation of a 30-day supply for buprenorphine fails to find an appropriate balance and lacks consideration of compelling data, as well as calls for permanent flexibilities from stakeholders, the scientific community, and other federal agencies. For example, the Proposed Rule seems to indicate that “until recently, there was a nationwide shortage of practitioners authorized to dispense buprenorphine.”<sup>xiii</sup> Although the Proposed Rule is correct that the x-waiver is no longer required, there is limited evidence suggesting that this change alone will lead to an influx of providers prescribing

buprenorphine. For example, a study of 56,000 x-waivered physicians in 2020 found that just under 51% wrote at least one prescription for buprenorphine in the 22-month period studied.<sup>xiv</sup> Moreover, studies of primary care practitioners have indicated that practitioners often have negative attitudes toward buprenorphine, including skepticism about the medication, the behaviors of patients with OUD, and beliefs regarding substance use disorders more generally.<sup>xv</sup> Therefore, without a substantial increase in practitioners willing and able to prescribe buprenorphine, the 30-day limitation on prescriptions will further restrict access to care for individuals with OUD.

The Proposed Rule also acknowledges that rural counties are associated with low buprenorphine dispensing and indicates that the Proposed Rule will increase access in these areas.<sup>xvi</sup> However, as of 2019, 50% of rural U.S. counties were without a single buprenorphine-waivered practitioner.<sup>xvii</sup> Therefore, patients in rural areas may gain initial access to buprenorphine through telemedicine but will still be required to find an in-person provider within 30 days while the country continues to grapple with not only a rural shortage of providers, but a national workforce shortage as well. The Proposed Rule attempts to provide a solution with the implementation of a qualifying telemedicine referral or a practitioner physically present with the patient while conducting a telemedicine evaluation with a prescribing practitioner. However, this requires buy-in from practitioners who may be unfamiliar with substance use disorders and assumes that either the patient or the provider will be knowledgeable about these options. As a result of the 30-day limitation on buprenorphine prescriptions, individuals in rural areas will have reduced access and may face lapses in care.

Finally, the Proposed Rule expresses concern with possible diversion of buprenorphine as a motivation for implementing additional guardrails.<sup>xviii</sup> Notably, the expansion of telemedicine as a result of the PHE was not associated with an increased proportion of overdose deaths involving buprenorphine.<sup>xix</sup> In fact, the telemedicine flexibilities were associated with improved retention in treatment suggesting that buprenorphine-specific guardrails are unnecessary and only serve to complicate a system already struggling to meet the needs of individuals with substance use disorders.<sup>xx</sup>

Ultimately, the Proposed Rule places restrictions on buprenorphine similar to those placed on other controlled substances. The NYS Council urges DEA to consider its own words in the Proposed Rule regarding the “unprecedented trafficking of fentanyl and drug poisoning crisis” and acknowledgement that opioid overdose deaths involving buprenorphine did not increase during the COVID-19 pandemic.<sup>xxi</sup> Therefore, the NYS Council recommends that DEA remove the 30-day prescription limitation for buprenorphine and continue to allow patients to see their providers through telemedicine indefinitely.

If DEA is adamantly opposed to an exemption for buprenorphine, the NYS Council suggests the agency promulgate regulations for the “special registration” originally called for in the Ryan Haight Act that would allow practitioners to prescribe controlled substance via telemedicine in limited circumstances.<sup>xxii</sup> Furthermore, the Substance Use Disorder that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, passed in 2018, also included a provision requiring the Attorney General – in consultation with the Secretary of HHS – to promulgate final regulations related to a special registration.<sup>xxiii</sup> If necessary, the NYS Council urges DEA to promulgate special registration regulations as an additional flexibility for providers that is consistent with effective controls against diversion and public health concerns.

The Certified Community Behavioral Health Clinic (CCBHC) model is a specially designated clinic that receives flexible funding to expand the scope of mental health and substance use services available in the community and includes screening, assessment, and diagnoses services; patient-centered treatment

planning; outpatient mental health and substance use disorder services; and crisis stabilization and services. The 450 active CCBHCs and grantees serving an estimated 2.1 million individuals, including approximately 69,400 individuals receiving medications for opioid use disorder (MOUD), are prime examples of organizations that would benefit from a special registration while also possessing the expertise to address DEA's concerns regarding diversion.<sup>xxiv</sup> Therefore, the NYS Council strongly recommends that DEA consider a special registration for qualified organizations to prescribe non-narcotic controlled substances in Schedule II-V, including buprenorphine, without ever requiring an in-person evaluation.

The Proposed Rule requests comments on whether the Notice of Proposed Rulemaking, entitled "Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation" (RIN 1117-AB40), should be combined with his rulemaking when publishing the Final Rule.<sup>xxv</sup> The NYS Council fully supports this proposal as both Proposed Rules pertain to prescribing controlled substances utilizing telemedicine.

The NYS Council appreciates the opportunity to provide these comments. Please contact Lauri Cole, Executive Director, at 518-461-8200 or at [lauri@nyscouncil.org](mailto:lauri@nyscouncil.org), with any questions or further discussion about the recommendations described here. Thank you for your time and consideration.

Sincerely,



Lauri Cole  
Executive Director

---

<sup>i</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>ii</sup> [https://www.deadiversion.usdoj.gov/faq/coronavirus\\_faq.htm](https://www.deadiversion.usdoj.gov/faq/coronavirus_faq.htm)

<sup>iii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>iv</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>v</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>vi</sup> <https://www.samhsa.gov/find-help/disorders>

<sup>vii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>viii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>

<sup>ix</sup> <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>

- 
- <sup>x</sup> <https://www.thenationalcouncil.org/news/statement-from-national-council-for-mental-wellbeing-president-and-ceo-chuck-ingoglia-on-the-new-role-of-virtual-care-in-behavioral-health-report-in-conjunction-with-qualifacts-systems-inc/>
- <sup>xi</sup> <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>
- <sup>xii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>
- <sup>xiii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>
- <sup>xiv</sup> [https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683?utm\\_source=For\\_The\\_Media&utm\\_medium=referral&utm\\_campaign=ftm\\_links&utm\\_term=082420](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2769683?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=082420)
- <sup>xv</sup> <https://bmcpimcare.biomedcentral.com/articles/10.1186/s12875-019-1047-z>
- <sup>xvi</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>
- <sup>xvii</sup> <https://pubmed.ncbi.nlm.nih.gov/29923637/>
- <sup>xviii</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>
- <sup>xix</sup> <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>
- <sup>xx</sup> doi:10.1001/jamapsychiatry.2022.2284
- <sup>xxi</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>
- <sup>xxii</sup> <https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf>
- <sup>xxiii</sup> <https://www.congress.gov/bill/115th-congress/house-bill/6>
- <sup>xxiv</sup> <https://www.thenationalcouncil.org/resources/2022-ccbhc-impact-report/>
- <sup>xxv</sup> <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter#citation-40-p12894>