

March 21, 2023

The Honorable Merrick B. Garland
Attorney General

Department of Justice

Comments in response to RIN 1117-AB78: Expansion of Induction of Buprenorphine Via a
Telemedicine Encounter

Dear Attorney General Garland,

Medications for opioid use disorder (MOUD) such as buprenorphine are first-line treatments for opioid use disorder (OUD) with established safety and effectiveness over a broad range of people.¹⁻³ Yet most who could benefit from these medications do not get them.⁴ At the same time, opioid partial agonists such as buprenorphine involve some risks to patients as well as to other individuals to whom they may be diverted.⁵ There are concerns that telemedicine initiation of buprenorphine could lead to inappropriate use. The challenge for regulators is to find the right balance between an overly restrictive system that limits patient access to MOUD and an overly lax system that could result in harm to patients and to the community.

The U.S. has regulated MOUD tightly relative to other countries.⁶ In light of the worsening opioid crisis, with fatal overdoses involving opioids nearly quadrupling between 2010 and 2021,⁷ a key goal of policymakers in the U.S. is to improve access to effective treatments, especially MOUD.⁸ In recent years, Congress and the Department of Health and Human Services have removed many barriers to MOUD and implemented policies expanding coverage of telemedicine for treatment of OUD. Examples include the recent elimination of the X-waiver,⁹ which removed caps on how many patients an individual MOUD provider can treat with buprenorphine; the Comprehensive Addiction and Recovery Act (CARA) expansion of buprenorphine prescribing privileges to include nurse practitioners and physician assistants;¹⁰ the SUPPORT Act, which expanded telemedicine coverage to all Medicare beneficiaries with substance use disorders¹¹; and recent SAMHSA regulatory proposals for Opioid Treatment Programs (OTPs) that expand the ability to use telemedicine for the initiation of methadone and buprenorphine.¹²

Evidence from our research and that of others leads us to conclude that the DEA's proposed rule on telemedicine for buprenorphine fails to strike the right balance. The proposed rule is overly restrictive and would likely create more harm than benefit. Specifically, the evidence to date does not support concerns about substantial medication diversion or misuse associated with prescribing of buprenorphine via telemedicine.¹³ We are concerned that the new rule would cut off access to buprenorphine for many patients and decrease the number of patients initiating MOUD. In doing so, the new policy could lead to increased overdose deaths.

In this letter, we summarize evidence on the use of telemedicine for the prescribing of buprenorphine and comment on specific components of the proposed rule.

WHAT IS KNOWN ABOUT USING TELEMEDICINE TO INITIATE TREATMENT FOR OUD DURING THE PANDEMIC

During the COVID-19 pandemic, the Ryan Haight Act restrictions on use of telemedicine for the prescribing of controlled substances were temporarily relaxed. This has created a natural experiment to understand how telemedicine can be used to treat OUD and prescribe buprenorphine.

Evidence from the pandemic indicates that clinicians who treat OUD have taken a measured approach to using telemedicine for buprenorphine initiation; they appear to recognize that telemedicine is not appropriate for some patients. For example, in a national survey of clinicians who prescribe MOUD, a much larger proportion (89%) reported that they were comfortable using telemedicine to care for established patients who were clinically stable in their recovery versus for established patients not clinically stable in their recovery (49%) or for new patients with OUD (38%).^{14,15} In studies of Medicare and private insurance data, approximately 15% of buprenorphine initiations were conducted via telemedicine during the first year of the pandemic.^{16,17} Even at its peak in April 2020, the proportion of buprenorphine initiations delivered via telemedicine (approximately one-third or fewer) were lower than the rates of telemedicine use for other behavioral health conditions such as schizophrenia and bipolar-1 (65%) or anxiety (54%).^{18,19} In new unpublished analyses using data from the Medicare fee-for-service program, we find that the percentage of buprenorphine inductions via telemedicine is stable through the end of 2022 (Figure). This demonstrates that while telemedicine has established itself as an important modality for delivering MOUD, there is little evidence that telemedicine has “opened the floodgates.”

Figure. Percentage of buprenorphine inductions in month that are via telemedicine, March 2019 to December 2022



The data show that telemedicine is a safe way of providing OUD care. Early in the pandemic, telemedicine was critical for maintaining MOUD treatment and offsetting the decline in in-person initiations.^{16,17,20} In a national study comparing care received by patients with OUD who were treated by clinicians who were more likely versus less likely to use telemedicine, we found similar rates of OUD-related clinical events including drug overdose, inpatient detoxification and rehabilitation center stay, and injection drug use-related infections.²¹ Other work has found that patients who receive telemedicine for OUD care were more likely to stay on MOUD and less likely to have an overdose.²⁰

There are reasonable concerns that opioid partial agonists such as buprenorphine may create some risks to patients and to individuals to whom they may be diverted. Certainly, there is likely

some inappropriate prescribing via telemedicine and related diversion. However, during the COVID-19 pandemic, there does not appear to be an increase in the proportion of overdose deaths involving buprenorphine.¹³ Even prior to the pandemic, overdoses that were primarily attributable to buprenorphine, as opposed to another substance also present at death, were quite rare.²² The diversion of buprenorphine that does occur has primarily been for the purpose for which it was intended – helping people with OUD to reduce use of other opioids and to treat symptoms of withdrawal.²³ Additionally, buprenorphine diversion, when it occurs, can lead to initiation of professional OUD care, and is associated with longer retention in care.²⁴ Therefore, on balance, it does not appear there has been a meaningful increase in harms from telemedicine prescribing of buprenorphine.

In summary, it appears that OUD clinicians have generally taken a prudent approach to use of telemedicine for buprenorphine initiation and there is evidence that telemedicine prescribing of buprenorphine has been safe. In the absence of the new DEA rule, telemedicine would likely play an important role in ensuring access to life-saving MOUD for many Americans.

COMMENTS ABOUT SPECIFIC COMPONENTS OF PROPOSED POLICY

1. Requirement that individuals who initiate buprenorphine via a telemedicine encounter must receive an in-person medical evaluation within the next 30 days will create barriers to MOUD access.

The proposed rule acknowledges that a clinician may often have only a short window of opportunity to get someone started on MOUD before the individual experiences severe withdrawal and seeks to resume misuse of opioids. Allowing clinicians to prescribe via telemedicine is vital for promoting expanded access to treatment and getting patients on the road to recovery. However, requiring an in-person visit in the next 30 days will reduce MOUD use.

MOUD discontinuation within 30 days is already common, with rates anywhere from about a third to two-thirds, depending on the specific medication and population.^{25,26} We are concerned that the new policy will introduce more barriers to continuing MOUD and increase the rate of discontinuation. First, many patients do not have an accessible OUD clinician to go to for an in-person visit given fully 40% of counties lack buprenorphine prescribers.²⁷ While Congress's recent removal of the X-waiver requirement is a welcome change, this new policy may not substantially increase MOUD prescribing capacity.²⁹ Evidence from before the removal of the X-waiver suggests that despite completing training, a large proportion of X-waivered prescribers did not prescribe buprenorphine at all.³⁰ In a 6-year national study of pharmacy claims, among X-waivered clinicians with at least one buprenorphine prescription, almost three-quarters treated only 1-2 patients monthly for a period and then discontinued prescribing.³¹

Second, it will be difficult for many patients to obtain a timely (i.e., within 30 days of buprenorphine prescription fill) in-person appointment in their community.³² Third, it will require a substantial change in current practice. In new unpublished analyses, we identified all buprenorphine initiations via telemedicine among patients in the Medicare fee-for-service program between October 2021 and September 2022 (n=2,186). In the 30 days after starting buprenorphine, we observe an in-person visit between the prescribing clinician and the patient in only 12% of cases and between the prescribing clinician's practice and the patient in only 22% of cases. Lastly, patients initiating MOUD are often in a vulnerable and unstable period, and, on average, have fewer resources than the average American. Therefore, various barriers associated with in-person care, from coordinating childcare, to requesting leave from work, to transportation, may impede patients' efforts to continue care.

2. Exception for buprenorphine prescriptions of the proposed requirement to flag controlled substance prescriptions written by a telemedicine visit is prudent.

Our understanding of the proposed DEA rule RIN 1117-AB40 (released along with the RIN on which these comments are focused) is that a prescription for a controlled substance initiated via telemedicine must be flagged on the prescription. However, the DEA has made an exception for buprenorphine prescriptions, which do not need to be flagged. We strongly support this exception.

Another significant barrier to MOUD treatment is that many pharmacies will not fill buprenorphine prescriptions.³³⁻³⁷ For example, in one secret shopper study of pharmacies in 11 states, more than half of the pharmacies did not fill MOUD prescriptions.³⁸ Recent news reports suggest that this problem has worsened during the pandemic as some large pharmacy chains such as Walmart have begun to refuse to fill any buprenorphine prescriptions.³⁶ Other studies find some pharmacies refuse to fill prescriptions from prescribers who live outside the local community which would include telemedicine providers.³⁹ Pharmacists state the threat of DEA scrutiny is a major driver of their decision to not fill buprenorphine, a potentially life-saving medication.^{33,40}

Flagging telemedicine prescriptions for buprenorphine would exacerbate this issue as pharmacists may decide not to fill these prescriptions because they are concerned about DEA investigation. Therefore, we commend the decision not to flag buprenorphine prescriptions.

3. Telemedicine-only care models for MOUD treatment will be threatened.

Telemedicine-only companies provide MOUD treatment for a large and growing number of patients with OUD.⁴¹ Many insurers including Medicaid plans now contract with these companies. For example, UnitedHealthcare, the nation's largest health insurer, has contracted with several companies, including Bicycle Health, Bright Heart Health, and Workit Health, for its commercial, Medicare Advantage, and Medicaid members. In preliminary unpublished data, we find the number of UnitedHealthcare enrollees (with commercial and/or Medicare Advantage) that received OUD care from these companies increased three-fold from January 2020 to June 2022.

Some patients turn to these companies because they have shorter wait times for an appointment, more flexible hours, the convenience of treatment at home, and less stigma from providers.⁴² Over three-quarters of patients with prior experience receiving in-person MOUD treatment described care through the fully-virtual model as more patient-centered.⁴² Though there has been research on this model of care,^{43,44} to our knowledge, currently, there are no data directly comparing fully-virtual telemedicine OUD companies to in-person providers on the quality of care provided, including prescribing buprenorphine appropriately. Scrutiny of these companies through rigorous independent evaluation is needed. However, given the opioid crisis and limited treatment opportunities for OUD, absent evidence of lower quality care, limiting the availability of telemedicine-only care to patients does not seem prudent.

The clinical model for these companies depends on telemedicine to start and continue patients on MOUD. If the proposed rule requiring an in-person evaluation within 30 days of buprenorphine initiation goes into effect, this source of MOUD treatment will be difficult to access.

RECOMMENDATIONS

The challenge for the DEA is to find an appropriate balance between an overly restrictive system that makes it hard for patients to access MOUD and an overly lax system that results in

patient harm. Based on our interpretation of the evidence, the proposed rule falls on the overly restrictive side of the balance given the high death toll of the opioid epidemic, the growing evidence that the use of telemedicine for prescribing of MOUD is generally safe, the emerging evidence that expansion of buprenorphine prescribing via telemedicine has not resulted in worsened OUD outcomes, and the concerns that the proposed rule will decrease the number of patients receiving MOUD support.

The proposed rule is out of step with the recent approaches taken by Congress and the Department of Health and Human Services to expand MOUD treatment and telemedicine use. They have removed barriers to MOUD treatment, expanded telemedicine coverage for the treatment of OUD, and proposed new rules allowing OTPs to use telemedicine for MOUD initiation. Lastly, in absence of data that telemedicine expansion has been harmful, Congress has extended the existing flexibilities for telemedicine payment through December of 2024.

Our primary recommendation is to temporarily extend the current flexibilities regarding telemedicine initiation of buprenorphine through December 2024. This interim period will allow continued monitoring for safety and quality of care issues (including for telemedicine-only companies that provide MOUD treatment) and will lead to a more-informed permanent policy starting in January 2025.

If this is not possible, the DEA should:

- Extend the requirement of an in-person medical evaluation within 30 days of buprenorphine initiation to at least 90 days, allowing buprenorphine initiators more time to stabilize on the medication and secure an in-person appointment.
- Consistent with the Congressional mandate in the SUPPORT Act, create a special registration pathway that allows clinicians who meet certain standards to pursue a fully telemedicine approach to MOUD treatment. This pathway could require continued monitoring of safety and quality for clinicians delivering such care but still allow clinicians operating in fully-telemedicine models to prescribe buprenorphine via telemedicine without an in-person visit. These fully-telemedicine clinicians may reach patient populations that have limited access to in-person care or for whom barriers to in-person care may be extremely high. The proposed rule noted that DEA considered such a pathway, but rejected it because it was potentially burdensome to providers and patients. We believe this was the wrong decision. It is unclear to us why this would be particularly burdensome and the DEA should offer some pathway for fully-telemedicine medicine models of OUD care.

Sincerely,

Haiden A. Huskamp, PhD
Harvard Medical School

Alisa B. Busch, MD
Harvard Medical School

Pushpa Raja, MD
David Geffen School of Medicine at UCLA

Michael L. Barnett, MD
Harvard T.H. Chan School of Public Health

Richard G Frank, PhD
Brookings Institution

Ateev Mehrotra, MD
Harvard Medical School

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