Law Enforcement Leaders’ Comments Re: Proposed Rule For Expansion of Induction of Buprenorphine via Telemedicine Encounter (RIN 1117-AB78)

The undersigned are current and former law enforcement leaders, including elected local prosecutors from around the nation.1 We write to provide comment on RIN 1117-AB78, Proposed Rule For Expansion of Induction of Buprenorphine via Telemedicine Encounter (the “Proposed Rule”). In particular, we urge DEA to reconsider its proposal that buprenorphine only be made available in a single, nonrenewable 30-day supply without an in-person medical evaluation.

All of us are intimately familiar with the tremendous human costs that have been wrought by the opioid epidemic. The opioid epidemic—spurred, in large part, by the illegal diversion of prescription short-acting opioids like oxycodone and hydromorphone into the black market—has caused untold death and devastation in communities across the nation. We appreciate DEA’s commitment to stemming the tide of diverted drugs, as reflected both in the Proposed Rule and in RIN 1117-AB40, Telemedicine Prescribing of Controlled Substances When the Practitioner and Patient Have Not Had a Prior In-Person Medical Evaluation.

We further appreciate the nuanced considerations that go into crafting a regulatory regime for a medicine like buprenorphine. In recent years, buprenorphine has been widely—and effectively—prescribed for those recovering from opioid addiction. It is a medication that has saved countless lives.

In contrast to the short-acting opioids that have flooded the black market, buprenorphine stabilizes the neurochemistry of those with an opioid addiction by providing relief from intense opioid cravings and withdrawal symptoms. Buprenorphine is a long-acting partial opioid agonist, which means that it “activate[s] the opioid receptors in the brain, but to a much lesser degree than” drugs such as heroin and oxycodone.2 Though buprenorphine is technically an opioid, it does not cause the same physiological effects as drugs like heroin that fully activate the brain’s opioid receptors. Patients who use buprenorphine do not generally become intoxicated.3 They demonstrate significantly improved cognitive function.4 And users are generally safe to drive.5

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1 We thank Ethan Smith, Anuttara Lath, and members of the Washtenaw County Prosecutor’s Office’s Substance Use Working Group for their help in preparing this comment.
4 Id.
5 Id.
Most patients who use buprenorphine, then, are using it to control cravings—as an \textit{alternative} to deadly drugs such as heroin and fentanyl. Towards that end, the risks associated with buprenorphine diversion are different than the risks associated with diversion of drugs like oxycodone or other prescription opioids. Again, buprenorphine does not generally lead to a euphoric high.\(^6\) It does not generally cause addiction.\(^7\) And crucially, buprenorphine is not typically used recreationally. Instead, “[a]lmost everybody takes it to manage their addiction, to stave off withdrawal, to self-treat.”\(^8\)

Buprenorphine, then, is not a “gateway drug for first-time users.”\(^9\) Instead, it is “a lifeline \ldots for long-term [opioid] users looking for some way out of addiction.”\(^10\) Nearly every person who takes buprenorphine uses it as an alternative to drugs like fentanyl or heroin. Without access to buprenorphine, many of those people are likely to backslide into more dangerous substances. Some will die. And many more will again become mired in a struggle with chemical dependency.

Given all of this, we applaud many of the proposed changes outlined in the Proposed Rule. In particular, allowing buprenorphine to be prescribed via audio-only telemedicine will expand access to a potentially life-saving medication for many of our most vulnerable communities. We also support the proposed requirement that practitioners review and consider Prescription Drug Monitoring Program (PDMP) data prior to prescribing buprenorphine.

We urge \textit{reconsideration}, however, of two specific aspects of the Proposed Rule. Those are: (1) the requirement that only a 30-day supply of buprenorphine may be prescribed via an initial telemedicine encounter; and (2) the requirement for an in-person medical examination if a patient wishes to receive buprenorphine beyond that 30-day period. Taken together, these requirements would limit a patient to only one 30-day supply of buprenorphine until and unless that patient obtained an in-person medical evaluation.

We understand DEA’s concern with the diversion of controlled substances. As current and former law enforcement leaders, all of us work or have worked in partnership with DEA and other law-enforcement agencies to combat the diversion of drugs into the black market. We respectfully submit, however, that the risks associated with diversion in this context are comparatively slight—and are outweighed by the risks associated with denying patients access to a medication proven to save lives.\(^11\)

For that reason, we urge DEA \textbf{not to adopt the 30-day limit on buprenorphine prescribed via telemedicine}. \textit{See, e.g.}, Executive Order 12866 (requiring agency consideration of all costs and benefits of regulatory action, including public health, safety, and equity).

\(^{6}\) Id.
\(^{7}\) Id.
\(^{9}\) Id.
\(^{10}\) Id.
\(^{11}\) Lindsay A. Pearce et al., \textit{Opioid agonist treatment and risk of mortality during opioid overdose public health emergency: population based retrospective cohort study}, \textit{BMJ}. 2020 Mar 31;368:m772. doi: 10.1136/bmj.m772. PMID: 32234712; PMCID: PMC7190018.
I. The Risk Associated With Buprenorphine Diversion Is Comparatively Small Compared With Other Controlled Substances

The risks associated with diverted buprenorphine are different in kind than the risks associated with other controlled substances. As an initial matter, it bears emphasis that buprenorphine diversion is relatively rare when compared to other controlled prescription drugs. “Among all opioid agonist medications, methadone and buprenorphine together make up 15 percent of diversion reports, while oxycodone and hydrocodone are responsible for 67 percent.”12

This is not to say that buprenorphine diversion does not happen. It does. In one study, 50.5% of those who had been prescribed buprenorphine reported sharing it, and another 28% reported selling it.13 But as the National Institutes of Health has concluded, “most data suggest that the majority of buprenorphine . . . misuse (use without a prescription) is for the purpose of controlling withdrawal and cravings for other opioids and not to get high.”14 Indeed, some 97% of those who used buprenorphine without a prescription “reported using it to prevent cravings,” with 90% using it to “prevent withdrawal.”15 And among those who reported sharing or selling prescription buprenorphine, the most common reason given was to help a “dope sick” friend.16

Indeed, for most buprenorphine prescribed in the United States, it is nearly impossible to divert the drug for recreational use. The vast majority of outpatient buprenorphine prescriptions in the United States are for Suboxone, which is formulated to prevent diversion for recreational use. Suboxone is co-formulated with naloxone, an opioid reversal agent. Buprenorphine is absorbed through the cheeks or under the tongue, but naloxone is not. Thus, when Suboxone is taken orally, the patient benefits from the therapeutic effects of buprenorphine alone; the naloxone has no effect. But if one were to try to melt down Suboxone and inject the drug intravenously, the naloxone will (1) reverse any effects the user was trying to get out of the buprenorphine, and (2) prevent a fatal overdose.17

For these reasons, overdose deaths from buprenorphine are vanishingly rare. Buprenorphine-involved overdose deaths account for just 2.2% of overdose deaths nationwide.18 Of those deaths, nearly 93% also involved a substance other than buprenorphine.19 Fewer than one

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14 Id.  
15 Id., supra n. 13.  
18 Id.
in 600 opioid-related overdose deaths, then, are attributable to buprenorphine alone.\textsuperscript{20}

What is more, the COVID-19 pandemic saw a dramatic increase in deaths from opioid overdoses. However, when the rules around telemedicine-prescribed buprenorphine were relaxed during the pandemic, overdose rates from buprenorphine remained stagnant.\textsuperscript{21} In fact, “[b]etween July 2019 and June 2021, the share of opioid-related deaths involving buprenorphine dropped from 3.6% to 2.1%.”\textsuperscript{22}

Of course, even one overdose death is too many. But the available data thus indicates that increased access to buprenorphine via telemedicine has not led to an increase in buprenorphine-related overdoses.

II. The Costs Associated With Limiting Buprenorphine Access Are Significant

By contrast, the costs associated with the proposed 30-day restriction on telemedicine-prescribed buprenorphine are significant.

As the Proposed Rule highlights, many people who are suffering from opioid addiction face barriers that make it difficult to obtain an in-person medical appointment. Many are unhoused, and lack access to “reliable transportation.” 88 Fed. Reg. 12900. Others may have “work or caretaking commitments.” Id. Still others may live in areas where there are a lack of practicing physicians. See id. That is why—as the Proposed Rule concludes—it makes good sense to allow people to access potentially life-saving medication like buprenorphine via telehealth.

But barriers that make it difficult for a person to access in-person medical treatment are unlikely to disappear after 30 days. And those who are unable to make an in-person appointment within 30 days of obtaining a prescription—and who are also unable to continue in recovery without medication-assisted treatment—will thus be faced with two realistic choices. First, they could revert to dangerous street drugs such as fentanyl or heroin. Second, they could seek to obtain buprenorphine (or another opioid agonist) illegally on the black market.

Either of these outcomes will impose significant costs and will ultimately undermine both public health and diversion-prevention. Most obviously, a person who uses a drug like fentanyl in lieu of buprenorphine will be at significantly higher risk of overdose. As noted, buprenorphine overdose deaths are vanishingly rare. The same, however, is not true of fentanyl. Indeed, in 2021, synthetic opioids like fentanyl accounted for some 71,238 of the 107,622 overdose deaths in the United States.\textsuperscript{23}

Alternatively, if a person denied a second buprenorphine prescription obtains that medicine on the black market, it will mean that person is taking buprenorphine without any ongoing

\textsuperscript{20} Id.\
\textsuperscript{21} Id.\
guidance from a medical professional. To be clear, buprenorphine is a medicine that should ideally be taken with a prescription, and as part of a medically supervised recovery program. But eliminating the availability of a telehealth-only prescribing regimen will mean that many will be using buprenorphine without any medical consultation at all. Even more disturbingly, it could mean that those seeking buprenorphine through the black market will receive (and take) contaminated drugs that increase the risk of overdose death. Safe and effective telemedicine-based buprenorphine treatment has been amply described in the medical literature during the pandemic.\textsuperscript{24}

Undoubtedly there are a number of conditions, as the Proposed Rule points out, that cannot adequately be screened for via telehealth. See \textit{id.} at 12895. And doctors should retain the flexibility to require an in-person examination as a precondition for a prescription. But mandating an inflexible all-or-nothing choice—an in-person examination or no access to medication at all—will ultimately cause more harm than good.

Finally, the Proposed Rule’s 30-day restriction could counterproductively \textit{increase} the demand for diverted buprenorphine. Research has demonstrated that one of the main reasons a person unlawfully uses buprenorphine is because they are unable to access treatment.\textsuperscript{25} There is, correspondingly, a pronounced “decrease in illicit use when opioid-dependent treatment seekers gain access to legal prescriptions.”\textsuperscript{26}

The market for illicit buprenorphine, in other words, is largely driven by those who lack a prescription. And the larger the market, the more opportunities for diversion. As noted above, the most common reason buprenorphine is diverted is because a person prescribed the medication wishes to share it with someone in need. But tellingly, too, some 57\% of those who had sold buprenorphine did so because they “needed money.”\textsuperscript{27} Cutting off a person in recovery’s supply of buprenorphine after 30 days will only increase the demand for diverted buprenorphine. That, in turn, will increase the chance that a prescribed patient will sell their supply for money. And it will ultimately \textit{increase} the market for diverted buprenorphine.

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In short, we believe that the potential public-health and public-safety costs associated with the proposed 30-day restriction on telehealth-prescribed buprenorphine far outweigh their benefits. Thus, while we applaud many aspects of the Proposed Rule, we urge DEA to eliminate the proposed 30-day restriction on telehealth-prescribed buprenorphine.


\textsuperscript{25} Zev Schuman-Olivier, Mark Albanese, Sarah Nelson, Lolita Roland, Francyne Puopolo, Lauren Klinker, Howard J. Shaffer, \textit{Self Treatment: Illicit Buprenorphine Use By Opioid-Dependent Treatment Seekers}, 39 J. Substance Abuse Treatment 41-50 (July 2010).

\textsuperscript{26} \textit{Id.}

\textsuperscript{27} Kenney \textit{et al.}, \textit{supra} n. 13.
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