Public Policy Statement on Reducing Risk of Federal Investigation or Prosecution for Prescribing Controlled Addiction Medications for Legitimate Medical Purposes

Background

Addiction medications,* such as medications for opioid use disorder (MOUD), are lifesaving treatments for addiction. Methadone and buprenorphine (i.e., agonist MOUD) are the current gold standard for treating opioid use disorder (OUD),[1] decreasing mortality risks by 50% among people with OUD.[2] Unfortunately, in 2023 fewer than 20% of people with OUD in the US received MOUD.[3] Several reasons exist for the underutilization of MOUD, including the limited number of practitioners who offer buprenorphine and the limited supply of opioid treatment programs. For example, an estimated 30% of counties lack buprenorphine prescribers, with particularly low rates in rural counties.[4] Despite the elimination of the federal waiver requirement, buprenorphine prescribing remains low.[5] Fear of intrusion into clinical practice by the Department of Justice (DOJ), including the Drug Enforcement Administration (DEA), is a key buprenorphine prescribing barrier.[6-12] Practitioners fear they will be investigated or prosecuted for well-intentioned actions that violate ambiguous federal law. Nevertheless, as compared to other known barriers to buprenorphine prescribing (e.g., prior authorization requirements and lack of OUD treatment knowledge), advocates and policymakers have paid little attention to fear of DOJ or DEA intrusion as an important deterrent to practitioners' willingness to offer this MOUD.

Regardless of whether buprenorphine prescribing *actually* increases the risk of DOJ investigation/prosecution, the *perception* that buprenorphine prescribing could increase risks of investigation/prosecution is a prescribing barrier. Even if a DOJ investigation or prosecution does

* Addiction medications are medications that are specifically indicated for and prescribed to treat substance use disorders as an initial lifesaving measure, as a motivational engagement strategy (i.e., withdrawal management), and as part of a long-term treatment plan similar to medications used to treat other chronic conditions, such as bipolar disorder, hypertension, or diabetes.

not result in a conviction, the costs (personal, professional, and financial) of responding to an investigation/prosecution could prevent practitioners from initiating and/or continuing to offer MOUD. The perceived risk of investigation/prosecution can be particularly powerful when combined with other barriers to prescribing, such as prior authorization burdens,[8] inadequate reimbursement,[13] state law requirements for buprenorphine prescribing,[14,15] low self-confidence in treating OUD,[16] and stigma against patients with OUD,[8] potentially contributing to the belief that buprenorphine treatment is more complicated and "risky" than treatment for other comparable chronic conditions.[8,16,17] Given the high mortality rate of untreated OUD,[18] the effectiveness of buprenorphine for treating OUD and reducing the risk of death,[2] and the limited supply of buprenorphine prescribers,[4] it is imperative that policymakers and regulators take actions to encourage practitioners to enter and stay in the OUD treatment field.

Federal regulations implementing the CSA grant authority for prescribing controlled substances, like buprenorphine, for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."[19] However, neither the CSA nor implementing federal regulations define "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." Furthermore, federal circuit courts have been inconsistent in determining whether a CSA violation requires proof of *both* (a) violation of legitimate medical purposes and (b) deviation from the usual course of professional practice,[20,21] or whether proof of only one of these conditions is sufficient.[22-28] Jurisdictions that require proof of both conditions are said to use a conjunctive standard, whereas those requiring proof of only one condition are said to have a disjunctive standard. Courts have been increasingly using the disjunctive standard.[29]

The conjunctive standard does not separate "legitimate medical purpose" from "by an individual practitioner acting in the usual course of his professional practice." Importantly, a conjunctive standard is better aligned with the original purposes of the CSA to prevent drug trafficking,[30] addresses concerns about the amorphous meaning of "the usual course of professional practice," and could decrease practitioners' fears about DOJ intrusion that serve as a prescribing barrier.

A disjunctive standard allows for prosecution with only proof of violation of the "usual course of professional practice." This standard has led to fear, because the "usual course of professional practice" is amorphous and ambiguous. The "usual course of professional practice" may vary among well-intentioned practitioners due to the heterogeneity of state regulations governing the practice of addiction medicine,[14,15] as well as the heterogeneity of patients with substance use disorder (SUD), practitioners who treat SUD, and practice settings. Patients have a wide range of potential complexity. A practitioner may need to spend more time treating a patient with complex clinical problems than a patient with fewer health-related conditions or whose conditions have stabilized; therefore, the usual course of practice may differ significantly between practitioners who tend to treat more complex cases versus practitioners who tend to treat less complex cases. Similarly, a practitioner who is the only buprenorphine prescriber in a high-need community may have a significantly higher patient volume than a practitioner in a lower-need community with more prescribers per capita. Practitioners treating a higher proportion of patients with OUD involving fentanyl may need to use higher doses, on average, than practitioners treating OUD involving heroin or prescription opioids like oxycodone or hydrocodone, because OUD involving fentanyl is more effectively managed at higher doses.[31] Furthermore, practitioners serving vulnerable populations, including patients experiencing homelessness, patients living in remote and indigenous communities, pregnant and parenting individuals, or justice-involved

individuals may need to utilize patient centered treatment plans that vary widely from typical practice, including low-threshold, flexible approaches, or off-label use of medications.

The DEA has explicitly described "red flags" of prescribing practices.[32] DOJ personnel, however, do not typically have the requisite medical expertise to accurately evaluate the *totality of the circumstances*[33] that may explain reasonable differences in prescribing practices across practitioners. In addition, rigidly comparing practitioner practices to guidelines or recommendations found in documents from medical professional organizations is inappropriate. Every patient is unique; practitioners must have the flexibility to exercise their professional judgment, and the pace of change in scientific knowledge and clinical practice often exceeds the speed of updates to these documents,[34] which involve a time-consuming and rigorous development process. For example, an April 2023 study found almost 90% of addiction medicine practitioners surveyed had substantially changed their MOUD prescribing practices over the last five years in response to the recent fentanyl crisis,[35] yet the ASAM clinical document directly addressing buprenorphine treatment for high-potency synthetic opioids like fentanyl, describing the need for high doses of buprenorphine, was not released until July 2023.[36] Additionally, while some practitioners have been prescribing psychostimulant medications off-label to treat stimulant use disorder for years, ASAM did not release a clinical practice guideline on the management of stimulant use disorder until 2024, noting that off-label prescribing of psychostimulant medications for stimulant use disorder may be appropriate for some patients.[37]

It is important for regulatory agencies and the DOJ to consider Congress' intent in passing the CSA, which was to prevent the trafficking or dealing of drugs,[30] not to ensure good quality medical treatment. Patients already have an alternative recourse – civil malpractice lawsuits – if they are harmed following deviation from the standard of care. Problematically, a disjunctive standard of the CSA allows for more severe punishment (including imprisonment) of a practitioner than civil malpractice lawsuits, without the need to prove patient harm.[29]

The DOJ's expertise would best be utilized by focusing on practitioners prescribing for improper reasons – in other words, without a legitimate medical purpose. Although the CSA and its regulations do not define "legitimate medical purpose," case law suggests it means having the intention to improve a patient's health-related condition.[21,23,38-41] Practitioners may be unsure whether they are following the "usual course of professional practice," but they know whether they have the intention to improve a patient's health-related condition. Therefore, practitioners are far less likely to fear DOJ intrusion if the DOJ focuses on violations of "legitimate medical purpose" rather than on violations of the "usual course of professional practice." An amicus brief in the recent US Supreme Court Case, *Ruan v. United States* (2022), argued that a conjunctive standard would address the problem: "Because the standard of care is increasingly used as a proxy for the 'usual course' standard, a mistaken or even somewhat careless prescriber could only be saved from criminal sanction because of her legitimate medical purpose."[29]

A practitioner prescribing without a legitimate medical purpose inherently differs from a well-intentioned practitioner providing atypical or even low-quality care. Criminal sanctions should be reserved for practitioners without a legitimate medical purpose. Citing Supreme Court precedent, the 9th Circuit in *Feingold* said juries in CSA cases should "determine whether a practitioner has acted not as a doctor, or even as a bad doctor, but as a "pusher" whose conduct is without a legitimate medical justification."[20]

Potential indicators of legitimate medical purpose – i.e., intention to prevent, treat, or manage a health-related condition – include but are not limited to assessing a patient, and weighing the risks and benefits of clinical options before treatment. For example, using a person-centered approach, practitioners may weigh the relative risks and benefits of continued buprenorphine prescribing to patients who sometimes misuse their medication and decide that treatment cessation would pose a greater risk of harm (e.g., overdose) to the patient than continued treatment.[42]

Recommendations

1. The US Attorney General should address relevant federal regulations to clarify that "legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice" is a conjunctive standard.
2. To avoid confusion about the definition of "legitimate medical purpose," the US Attorney General should address relevant federal regulations to clarify that "legitimate medical purpose" means "for the purpose of preventing, treating, or managing a patient's health-related condition."
3. When enforcing controlled substance prescribing requirements under the CSA, the DOJ and DEA should focus their efforts on practitioners who are not prescribing controlled substances for legitimate medical purposes.
4. Federal circuit courts should adopt a conjunctive standard rather than a disjunctive standard.
5. The US Supreme Court should decide that the CSA and its regulations require a conjunctive standard. The US Supreme Court could base their rationale on the following: a) the original purpose of the CSA was to stop drug trafficking rather than to regulate the practice of medicine; b) the DOJ violates bedrock principles of federalism when it prosecutes practitioners merely for veering from the usual course of professional practice; and c) the plain text of the existing relevant federal regulation does not separate "legitimate medical purpose" from "by an individual practitioner acting in the usual course of his professional practice."

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