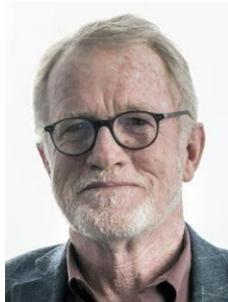


When Medical Judgment Ceases to be Medicine: Federal Prosecution of Physicians Under the Controlled Substance Act



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Anyone who represents physicians who prescribe opioids for chronic pain sufferers understands there are medical/legal risks with such a practice. Patient contracts, urine drug screens and review of prior treatment records are no guarantee that the prescribed narcotics will not be diverted or abused. Most often, diversion is not recognized until a bad event occurs, such as overdose or a patient is arrested for distribution.

Prescribers have long been scrutinized by licensing boards and the Drug Enforcement Administration (DEA) for civil and administrative penalties related to careless prescribing, resulting from insufficient controls or failure to recognize “red flags” of diversion. In those instances, as in other areas of medical negligence, “standard of care” evidence was used to demonstrate that the negligence constituted unprofessional conduct worthy of sanction.

The stakes are significantly higher now. The meteoric rise in opioid addiction and overdose deaths has spawned greater use of the Controlled Substance Act (CSA) against physicians treating chronic pain patients with prescription medication. The legal premise fueling such prosecutions can be found in the determination that, such negligence or recklessness in prescribing, means it’s not medicine at all.

All physicians who practice chronic pain management need to understand that the Department of Justice (DOJ) and the DEA have become the arbiters of what constitutes a “legitimate medical practice” for purposes of prescribing controlled substances. The historical view that the exercise of medical judgment is the sole province of state medical boards is no more.

The loosely defined phrase “legitimate medical practice” can be found in [21 CFR §1306.04\(a\)](#), which states:

A prescription for a controlled substance to be effective must be issued for a *legitimate medical purpose* by an individual practitioner acting in the *usual course of his professional practice* (emphasis added).

Federal agencies and courts have long maintained that it is not possible to expand on this definition in a way that will provide definitive guidelines that address the varied situations that physicians might encounter. As early as 1992, federal courts recognized:

There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice rather, the courts must engage in a case by case analysis of evidence to determine whether a reasonable inference of guilt may be drawn from specific facts. *United States v. August*, 984 F.2d 705, 713 (6th Cir. 1992).

Historically, this undefined phrase was not a significant problem for prescribers since prosecution usually occurred only in instances involving the most glaring examples of illegal activity. In short, the government did not seek prosecution in cases where there was arguably an exercise in medical judgment.

Prescribing physicians and dispensing pharmacists took comfort in the belief that the exercise of professional judgment in prescribing opioids would insulate them from prosecution under the CSA. That belief appeared to be affirmed by the decision in *Oregon v. Ashcroft* 368 F.3d 1118 (9th Cir. 2003), which voided then-Attorney General John Ashcroft's directive that physician-assisted suicide violates the CSA. The ruling, which struck down the directive's grant of authority to DOJ and DEA to determine acceptable health care practices, offered language that appeared to clearly limit the governmental authority to regulate physician decisions within a medical practice. The language of the Ashcroft decision led medical/legal authors to conclude that the exercise of medical decision making meant that the government could not prosecute them for violation of the CSA.

The key phrases "legitimate medical purpose" and "in the usual course of professional practice" are not defined. This omission invites conjecture about the meaning of the phrases. "Legitimate medical purpose" has no meaning unless "illegitimate medical purpose" has meaning. Yet medicine is inherently legitimate; there is no such thing as "illegitimate medicine." A practice that is not legitimate is not medical ... Where this analysis leads is to the conclusion that the words "legitimate" and "medical" are redundant. The phrase "legitimate medical purpose" can be reduced to "medical purpose" without losing any meaning. A practice that is not medical is neither legitimate nor legal under the DEA regulation. A practice that is medical is legitimate and is within the DEA regulation. DEA does not regulate within medical practice but simply discerns whether a practice is medical or nonmedical. David B. Brushwood, *Defining Legitimate Medical Purpose*, *American Journal of Health* 2005; 62(3):306-308.

Buoyed by such analysis, hopeful physicians believed that, if they were engaged in professional health care activities, they were protected as the DOJ/DEA was without authority to pass judgment on the merits of a professional practice. That comfort level was misplaced. Physicians now are prosecuted and often convicted of violating the CSA while prescribing in an otherwise "legitimate medical practice." The new applied standard, though still undefined, requires a physician to consider a "standard of care" type analysis in which they consider the opinions/practices of professional colleagues, or a growing stable of government-retained physician experts, as to the "legitimacy" of their exercise of medical judgment when prescribing opioids.

In practice, an investigation reveals that the prescribing physician failed to recognize diversion or take sufficient steps to monitor a patient's use of the medication. Previously, that could result in an attempted revocation of DEA registration, civil penalties or medical

license sanction. Now, the prosecution position is that those same deficiencies mean that the decision to prescribe was no longer part of a "legitimate medical practice" and the physician can be prosecuted as a drug dealer. The fact that the prescriber of the medication is a licensed physician authorized to prescribe is no defense if a factfinder accepts a government expert's opinion that the decision was flawed enough to render it illegitimate. In essence, the negligent practice of medicine is no longer just deficient; it ceases to be medicine at all.

Educational and research agencies are now trying to catch up to the government's active prosecution of prescribing physicians. In March 2016, the Centers for Disease Control and Prevention issued the [CDC Guideline for Prescribing Opioids for Chronic Pain](#).

The publication provides 12 guidelines, broken into three subcategories:

Determining When to Initiate or Continue Opioids for Chronic Pain

- 1) Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with non-pharmacologic therapy and non-opioid pharmacologic therapy, as appropriate.
- 2) Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.
- 3) Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

- 1) When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.
- 2) When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day.
- 3) Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.
- 4) Clinicians should evaluate benefits and harms with patients within one to four weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should

evaluate benefits and harms of continued therapy with patients every three months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

Assessing Risk and Addressing Harms of Opioid Use

- 1) Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present.
- 2) Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every three months.
- 3) When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- 4) Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.
- 5) Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

The guidelines strongly recommend against prescribing opioids as a first or even an early option in determining the course of treatment for chronic pain. Any prescribing beyond a minimal, short-term dosage runs contrary to CDC recommendations. If these guidelines were adopted and actually applied in practice, most physician charting would fall well short of depicting the detailed analysis called for in the guidelines. If these or other guidelines are adopted as benchmarks of "legitimate medical purpose" The decision to prescribe, dosage and the continuation of treatment are, to some degree, being directed by government as well as physician. Any physician practicing pain management needs to be directed to the CDC Guidelines and other sources, with a strong recommendation that the physician's future charting reflect consideration and application of at least some of the published recommendations.

In the months following a bad patient outcome, the government will undertake a "look back" analysis, not to determine if the physician exercised medical judgment, but to analyze whether the charting of the prescribing physician reflects a "best practice" consideration of available guidelines and recommendations for prescribing opioids. If the current trend continues, physicians falling short of future standards can become non-physicians for purposes of CSA prosecution.

Prescribing physicians need to be advised of available guidelines and the need to incorporate their tenets into their charting practices. Failure to do so risks criminal prosecution even where the prescribing decision was made in good faith, but without sufficient documentation.

Other instructive opioid prescribing practice guides include:

- [The Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain](#) (2013) Federation of State Medical Boards.
- American Academy of Pain Medicine Guidelines for the use of Chronic Opioid Therapy in Chronic Non-Cancer Pain (2009)
- American Society of Interventional Pain Physician Guidelines for Responsible Opioid Prescribing in Chronic, Non-Cancer Pain (2012)
- [Opioids for Chronic, Non-Cancer Pain: American Academy of Neurology Physician Paper](#) (2014)
- [Veteran Affairs/Department of Defense Management of Opioid Therapy for Chronic Pain](#) (2010)

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