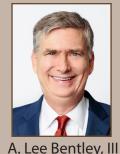
# Averting Government Scrutiny in the Wake of an Opioid Prescribing Crackdown



Two former federal prosecutors offer pain practitioners guidance on how to use their own "data mining" to avoid potential prosecution.



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he scourge of opioid-related addiction and risk is a well-known story among the pain management community. In response to this federally declared public health crisis, government prosecutors are upping their game. Almost daily, a new press release touts the United States Department of Justice's (DOJ) "crackdown" on this issue, with the focus not only on illicit drug dealers but, also increasingly, on prosecuting physicians—particularly pain practitioners. These prosecutions present a foreboding picture of the DOJ's priorities, and there's no reason to expect this focus to die down in the near future.

Current US Attorney General Jeff Sessions has been touring the country, speaking about the department's expanded efforts, including its new Opioid Fraud and Abuse Detection Unit. He describes the unit as being able to "tell us important information – like who is prescribing the most drugs, who is dispensing the most drugs, and whose patients are dying of overdoses."<sup>1</sup>

While the federal use of data mining may be commendable, the government appears to be using relatively rudimentary metrics. By using data to ascertain "who is prescribing the most drugs [and] who is dispensing the most drugs," prosecutors are likely to capture well-meaning, non-fraudulent physicians. Put another way, in the authors' opinions, simply looking at "who is prescribing the most drugs" is an incomplete metric. It would come as little surprise to most, for example, that pain management physicians are prescribing more opioids than, say, podiatrists, dermatologists, or gynecologists.

### **Potential Issues & Recommendations**

Nonetheless, as the government continues to push datadriven prosecutions in the healthcare space, we make several recommendations to help pain management physicians prepare so as to avoid DOJ scrutiny. Just as the government is using data mining to develop potential targets and cases, we suggest that practitioners use their own data to proactively address potential questions. While these suggestions are not exhaustive, the recommendations are designed to help pain practitioners understand potential red flags that might stand out to government regulators.

### Account for Your Aggregate Rx History

**Potential Issue:** The government appears to be focused on a prescriber's total aggregate opioid prescription history. While this number may be misleading, practitioners would be well advised to know that this is a utilized threshold measure for prosecutors. Therefore, for those prescribers who have a high volume of patients receiving opioids, a best practice would be to expect examination of this metric and to spend time mitigating against risk.

**Recommendation:** In particular, we recommend engaging external medical coders or auditors to perform file-reviews to ensure the proper documentation of necessity of prescriptions. While all providers are likely to benefit from these prophylactic compliance reviews, prescribers with particularly high-volume opioid prescriptions should view these compliance reviews as a necessity in today's highly regulated climate of opioids.

#### Perform Regular File Reviews

**Potential Issue:** Regardless of DOJ scrutiny, a best practice is to periodically review patient files and ensure that each patient is receiving a uniquely tailored medication portfolio. Put another way, the government is paying attention to practitioners that indiscriminately prescribe opioids to all patients—regardless of condition and history. Other metrics under examination are whether practitioners are prescribing opioids even when patients are taking other medications. **Recommendation:** Thus, we recommend that pain management physicians periodically self-audit patient files. Reviewing these files on a quarterly basis, for example, to ensure that each patient is receiving an individualized prescription plan is not just a good way to dent possible civil or criminal liability – it is also a good medical practice.

## Standardize Times between a Patient's First Visit and First Prescription

**Potential Issue:** The government is further focused on the length of time between a practitioner's first encounter with a patient and the first prescription of opioids to that patient. As a general rule, the closer in time between the initial encounter and the first opioid prescription, the greater the chance of potential abuse. There are, of course, exceptions to this rule. Consistent prescribing of opioids on the initial encounter – particularly before the initial drug urinalysis is complete – is potentially problematic.

**Recommendation:** Understand this metric and carefully evaluate new patients on initial visits. Be sure to document the diligence undertaken before prescribing an opioid.

#### Document Urine Drug Monitoring

**Potential Issue:** The federal government is increasingly looking at the relationships between pain practitioners and toxicology laboratories. DOJ is honing in on whether healthcare providers are actually using urinalysis results to modify treatment modalities.

**Recommendation:** A best practice is to document in the patient file expressly how the urinalysis was analyzed and how it affected—if at all—the treatment provided to the patient. Also, we recommend that pain management physicians tailor their drug testing panels to reflect patients' individual needs—for example, not all patients need to be tested for all classes of drugs every time they visit.

#### Pay Attention to Your Prescribing Patterns

**Potential Issue:** Prescribing patterns of opioids to relatives or members of the same household are also coming under examination. While there are exceptions, it should be the rare occasion where multiple members of the same address are receiving opioids.

**Recommendation:** Physicians are advised to review basic demographic and contact information of patients to ensure that the physicians are not unwittingly being targeted by drug-abusing individuals. For example, carefully examine whether your practice is receiving a large number of patients

who reside at out-of-state addresses as this may be indicative of drug-seeking patients. Similarly, if a large number of patients use the same address, perform some basic due diligence to ensure that these patients are not illicit drug-seekers.

### Follow-up Any Adverse Events

**Potential Issue:** Law enforcement is increasingly mining states' autopsy records to determine whether patients dying of opioid-related overdoses, whether from illicit drugs or prescribed medications, are linked to certain prescribers. For example, if many patients dying of overdoses obtained opioids from the same prescriber, there is potentially, at best, a non-discerning provider or, at worse, a drug-diverting prescriber.

**Recommendation:** Given this situation, we recommend that pain practitioners track their own patients' (and former patients') long-term health outcomes. When significant adverse events happen, a best practice is to review the patient file to determine whether different treatment options might have prompted different outcomes and make note of that conclusion.

While each patient is no doubt unique, retrospective self-analysis will not only help improve clinical outcomes for future patients but it may also meaningfully undercut any possible allegations of opioid abuse or fraud.

#### Stay the Course

These types of prophylactic measures do not ensure that the government will not ask questions. In an era of highly regulated medicine, scrutiny is the norm, not the exception. Nonetheless, following these recommendations may provide a level of comfort to above-board pain practitioners, as well as help to negate any allegations of wrongdoing.

Ultimately, by viewing this enhanced enforcement as an opportunity, rather than a risk, practitioners may avoid legal attention—but also promote better healthcare outcomes.

**Author Bios:** A. Lee Bentley, III, is the former US Attorney for the Middle District of Florida. During his tenure (2014-2017), his office recovered more than \$1.2 billion in fines and penalties from healthcare providers and other regulated providers. Jason Mehta served as Assistant US Attorney in the same office, responsible for more than a quarter of a billion dollars in financial recoveries. Both attorneys are now partners in the Government Enforcement and Investigations Practice Group at Bradley Arant Boult Cummings, LLP, in Tampa, FL.

#### Reference

<sup>1.</sup> US Department of Justice. Attorney General Sessions Delivers Remarks on Efforts to Reduce Violent Crime and Fight the Opioid Crisis. Office of Public Affairs. January 30, 2018, Louisville, KY.