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White Collar Courier: Delivering News and Providing Guidance in White Collar Matters

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The new DOJ initiative – aggressively investigating and prosecuting pain management practitioners

Part Four: "Pill Mill" Red Flags and Strategies to Avoid Them

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In part one of this series, I detailed how the U.S. Department of Justice has focused its attention on the aggressive investigation and prosecution of "pill mill" cases. See "Part One: DOJ Devotes Resources, Vows to Come After 'Pill Mills.'" In part two, I discussed what consequences doctors and other medical professionals could face as the result of a "pill mill" investigation. See "Part Two: What's At Stake for Prescribing Professionals in 'Pill Mill' Cases." In part three, I gave a detailed explanation of how the government investigates these cases. See "Part Three: Anatomy of a 'Pill Mill' Investigation." In this last installment, I explain the red flags investigators look for and suggest practices that pain management professionals can implement in order to avoid government scrutiny.

I. RED FLAGS

As explained in part three of this series, the government has several investigative tools at its disposal in "pill mill" cases. Investigators use these tools to identify what they claim are "red flags" suggesting that the targeted medical practice is functioning as an illegal "pill mil." The government will heavily rely on evidence of these supposed red flags at trial to establish that the doctor was prescribing drugs for an illegitimate purpose and outside the usual course of professional medical practice. For that reason, it is important for medical professionals to identify those red flags. Several of the red flags the government most often relies upon in these cases are as follows:

- The doctor prescribes a large volume of opioids, as reflected in data maintained by the state's prescription drug monitoring program ("PDMP").
- The doctor has an extremely high patient volume, which regularly results in long lines of patients waiting outside the practice to see the doctor and an overcrowded parking lot.
- The doctor either fails to conduct patient medical examinations or conducts only cursory ones during initial and follow-up visits.
- Patient visits with the doctor are brief, typically lasting five minutes or less; or patients do not see the doctor at all, and receive prescriptions that non-medical staff members write (by using prescription pads that are "pre-signed" by the doctor).

- Patients are not required to provide medical histories or treatment records (including diagnostics records) at any time during their treatment.
- Most of the doctor's patients are prescribed controlled drugs, and the doctor never suggests alternate treatment methods such as non-narcotics drugs, physical therapy, or surgery.
- Patients travel from long distances -- sometimes in groups -- to see the doctor, bypassing other pain management practices on the way.
- The pain management practice owns an "in-house" pharmacy or rents space to a nearby pharmacy, resulting in the pharmacy filling the majority of the prescriptions the practice issues (which may be evidence of an alleged kickback scheme or that the doctor believes his prescriptions will not be scrutinized by the pharmacy).
- Prescriptions are unsupported by patient records (or are supported by falsified records) and objective diagnostic testing confirming the patient's complaints of pain, including MRI's, x-rays, or CT scans.
- The doctor does not monitor patients for "drug diversion" by checking PDMP data or ordering urine drug screens, or ignores signs of diversion (such as drug screens returning negative for the presence of an opioid in the patient's system, patient's routinely "losing" prescriptions, or patients requesting refills before the prescription runs out).
- The doctor ignores clear signs of drug-seeking and addiction, and fails to refer patients to specialists for drug rehabilitation or psychiatric evaluation.
- The practice is a "cash-only" business that does not accept medical insurance.
- The doctor engages in suspect prescribing practices, such as: giving a patient a month-long prescription every two weeks; prescribing different opioids for the same patient during the same visit (e.g., prescribing a patient a 30-day supply of both Oxycodone and Hydrocodone); prescribing certain combinations of drugs, such as the "Holy Trinity" (the combination of an opioid, muscle relaxer, and anti-anxiety drug); prescribing controlled drugs that are not appropriate to treat the patient's complaints; and continually increasing a patient's dosage or prescribing a more powerful opioid without medical justification.

II. SUGGESTED PRACTICES

As these red flags indicate, to avoid government scrutiny and potential prosecution under the Controlled Substances Act, doctors should, in general, prescribe reasonably and when medically necessary in the context of each patient's presentation and carefully document their treatment. To that end, the following are suggested practices pain management doctors should implement, among others:

- The practice should maintain a thorough intake procedure which requires the patient to give a detailed medical history. Along those lines, the patient should be required to provide customary intake documents, such as a medical history questionnaire and a medical records release form. The practice should make efforts to obtain all pertinent records reflecting the patient's treatment and prescription history, and the patient should be required to bring any previous diagnostic studies to the initial visit. If applicable, the patient should sign an "opioid treatment agreement," which sets out the side effects and risks of such treatment and requires the patient to abide by certain opioid use guidelines (which should be renewed at least once a year).
- Before prescribing opioids, doctors should perform a thorough physical examination during the patient's initial visit, not just an examination focused on the patient's primary complaint. Doctors should, at certain points in the patient's treatment, repeat these physical examinations during follow-up visits. Doctors should thoroughly describe the examinations in the patient's records.
- Before prescribing opioids, doctors should consider alternative treatment options, such as non-narcotic drugs, physical therapy, and surgery. If it is determined that these alternative treatment methods would be ineffective, this decision should be clearly documented in the patient's records. Also, doctors should order, where warranted, appropriate diagnostic testing to confirm the patient's complaints of pain.
- Doctors should prescribe the lowest dosage and quantity of opioids possible to treat a patient's complaints. For example, doctors should consider limiting a patient's prescription interval to a 30-day supply. As another example, doctors should avoid, when medically appropriate, providing a 30-day supply during the patient's initial visit if the doctor does not have the patient's previous medical records and diagnostic tests. In that scenario, doctors should consider issuing a 14-day supply until the records are in hand.
- Doctors must monitor for signs of diversion and addiction. To accomplish that, doctors must regularly review the patient's PDMP data and order drug screens. All results should be documented in the patient's file. Doctors should have a frank conversation with the patient about suspected diversion, and, once again, document that conversation in the patient's records. If necessary, doctors should be prepared to terminate the patient's treatment due to continued diversion. Similarly, patients demonstrating signs of addiction should be referred to an appropriate specialist.
- Doctors should consider having regular independent audits by a billing consultant or other pain management specialist (preferably once a year) done to ensure compliance with all applicable regulations and laws.

White Collar Courier Quote of the Day:

> ***In striking a between the dangers of [opioids] and their medical value, the law entrusts medical practitioners to serve as gatekeepers. Licensed doctors, pharmacists, and other practitioners are authorized to provide these drugs to patients during the course of treatment. However, this gatekeeping authority is not absolute. Where a medical practitioner distributes a controlled substance in bad faith, the act is treated no differently than a sale by a street dealer.***[1]

To discuss the information further, please contact:

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[1] Benjamin R. Barron, *Strategies for Investigators and Prosecutors in Prescription Drug Diversion Cases*, UNITED STATES ATTORNEY'S BULLETIN (September 2016).