# Increased Scrutiny of Medical Providers: A Cause for Reflection and Diligence

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## Increased Scrutiny

Nationwide we are witnessing increased scrutiny of healthcare providers who prescribe controlled substances, especially those involved in pain management practices. Physicians are being scrutinized to make sure they are prescribing responsibly, documenting appropriately, and not personally abusing or diverting controlled substances.

Medical journals note this scrutiny and offer a variety of explanations. On one end of the spectrum are those who believe that going after physicians and healthcare facilities with increased fervor is simply the government's way of funding our increasingly unaffordable healthcare system. At the other end are practitioners who believe that the Drug Enforcement Administration (DEA) and state regulators are simply opposed to dispensing addictive and powerful opioids as a means of treating pain.

Rather than subscribe to either of these viewpoints, I believe that this trend is a result of several factors, including the increasing availability and abuse of controlled substances. Those with the highest rates of abuse include oxycodone, hydrocodone, morphine, fentanyl, and other newly-formulated opioids used to treat short- and long-term pain conditions.

Other reasons for increased scrutiny are the high Medicaid and Medicare costs attributable to pain patients, the cost of opioids, and the lack of clarity as to what may constitute a proper dose.

Statistics also contribute to this scrutiny: the National Drug Intelligence Center noted in the National Prescription Drug Threat Assessment 2009 (1) that overdoses and deaths from opioids have increased more than 100% in the last 5 years; some of this is due to diversion. The estimated cost of this abuse to public and private medical insurers exceeds $72 billion per year, much of which is passed on to consumers through higher insurance premiums. In addition, over the last 10 years, while the population of the US has increased at a rate of about 14%, the number of prescriptions for controlled substances has increased more than 500% in the general population. Sales of oxycodone products have also increased more than 500% during this same period. Studies reflect that approximately 30% of those abusing prescription medications began by obtaining those medications pursuant to a written prescription (1).

There have been numerous instances where physicians have been detected unlawfully diverting controlled substances and committing records violations, which has contributed to this increased scrutiny. Further, medical and governmental circles genuinely debate the best way to treat opioid dependency. Is it through products such as buprenorphine and methadone or some other form of enforced or volitional drug abstinence? This interest will continue to rise as the federal government creates more healthcare fraud task forces and utilizes antidiversion resources designed to detect fraud, waste, abuse, and criminal conduct by healthcare professionals.

All of this makes it an appropriate time for physicians engaged in pain practices and general practitioners who dispense opioids to ensure that they are in compliance with law or they may face unexpected and costly consequences. For example, in January 2010, an otorhinolaryngologist (Mark Capener, MD), who had been charged with 52 counts of healthcare fraud in federal court in Nevada was acquitted of those charges, but he was denied his claim for attorney fees and damages sustained in his occupation as a result of the costly federal trial.

## Unlawful Diversion

Controlled substances are subject to federal regulation, and the possession and distribution of these substances are governed by federal law. Title 21, US Code, Section 843(a)(3), commonly known as the "unlawful diversion statute," makes it a federal felony to knowingly and intentionally acquire, or aid and abet someone else in acquiring a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge. This offense is punishable by up to 4 years imprisonment and a $250,000 fine.

Within the last few years, this statute resulted in the felony conviction within the State of Washington of a psychiatrist who was splitting oxycodone prescriptions with his patients; a surgery resident who was delivering blank scripts to friends to acquire oxycodone; and a dentist and an anesthesiologist who were ordering quantities of hydrocodone for their mutual use and writing scripts for each other to satisfy their addictions.

The federal "unlawful diversion statute" is violated virtually every time a healthcare professional diverts a controlled substance for any purpose. Diversion can include:

- Taking controlled substances from your practice, place of employment, or any other lawful supply for which you do not have a lawful prescription.
- Writing prescriptions that are based on inadequate medical examination and filling prescriptions you know to be unlawful.
- Taking actions to help others improperly obtain prescription medications, such as providing illegitimate scripts to others or prescribing medications with no reasonable medical purpose.

Indeed, diversion includes a myriad of fact patterns where controlled substances are purposefully removed from a lawful supply by a healthcare professional for anything other than legitimate reasons. Unfortunately, what is "legitimate" may remain a question for a jury to someday consider, and may indeed become a battle of competing medical experts, as was the case with Dr. Capener.

Rather than being prosecuted for felony diversion, sometimes these cases are charged as simple unlawful possession cases, a federal misdemeanor. Within the last several months, a family practice physician in the Seattle area who was unlawfully diverting meperidine from his place of work for personal use and a Bellevue dermatologist who was using an alias to write himself prescriptions for oxycodone were convicted of unlawful possession of a controlled substance, in violation of Title 21, US Code, Section 844, the federal misdemeanor statute. Although it was treated as a misdemeanor, the convictions had a very serious impact on the physicians, including suspension and/or revocation of their DEA licenses, a significant monetary fine, and a probation period.

## Recordkeeping

Federal recordkeeping requirements are imposed on everyone authorized to dispense controlled substances (Title 21, US Code, Section 827(a)(3)). These requirements impose a legal duty upon dispensers to maintain accurate and up-to-date records of distribution

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of controlled substances. These records are subject to audit and administrative inspection by the DEA (Title 21, US Code, Section 880). These recordkeeping requirements provide the DEA with an independent means to monitor prescription drug distribution and to detect controlled substances being unlawfully diverted. In addition, Title 21, Code of Federal Regulations contains detailed requirements as to the records that need to be maintained by physicians, including those that relate to the appropriate dispensing and prescribing practices. These regulations, however detailed, need to be understood and followed in order to avoid engaging in conduct that may be construed as a violation of law.

Following a DEA investigation in the summer of 2009, a Seattle osteopath was convicted of failing to maintain records of receipt and distribution of a controlled substance in violation of Title 21, US Code, Sections 842(a)(5) and 842(c)(2)(A), a federal misdemeanor. To implement Title 21, US Code, federal regulations require that all licensed healthcare professionals maintain records of all controlled substances received and dispensed in their practices. Examining these records for accuracy is one of the first tasks DEA agents and investigators will perform if they visit and audit your practice.

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Failure to maintain proper records may be charged as a misdemeanor, as above, or as a felony (Title 21, US Code, Section 843(a)(4)(A)), if one knowingly and intentionally furnishes false material information or omits material information from a report or record that is required to be kept under law. This offense is punishable by up to 4 years imprisonment, a $250,000 fine, and a 1-year period of supervised release.

For example, upon examining the records of the Seattle osteopath, the DEA found significant discrepancies between controlled substances that were received and were lawfully dispensed. The practitioner was sentenced to 1-year probation, 100 hours of community service, and fined $10,000.

## Lawful Prescription and Drug Distribution

Pain practitioners should also understand the general legal standard as to what differentiates lawful prescription versus drug distribution. In order to be lawful, a controlled substance must be authorized "for a legitimate medical purpose" by a practitioner "acting in the usual course" of his or her "professional practice" (21 Code of Federal Regulations, Section 1306.04). This applies to the dispensing of drugs by a healthcare professional in an office, in a hospital setting, or writing and calling-in prescriptions or having someone else do so at your direction. If you are the authorizing healthcare professional, you are responsible for that distribution. Title 21, US Code, Section 841(a)(1) provides that anyone who knowingly, intentionally, and unlawfully distributes, aids and abets, or causes the distribution of a controlled substance is guilty of a felony. The penalty for this offense includes a period of imprisonment of up to 20 years, a $1 million fine, and a period of supervised release following imprisonment of up to 3 years.

Recent cases report multiple instances where federal agents, or private individuals hired by agents, have posed as patients and entered a physician's office equipped with a hidden device to record his or her actions. They also include instances where existing patients have elected to cooperate with law enforcement to record their interactions with a treating physician. These investigative practices are wholly lawful and, however invasive, are often relied upon by law enforcement in its quest to gain admissible evidence of a crime.

## Recommendations

Various initiatives have been launched within governmental and professional circles to assist the medical profession in ways other than criminal prosecution and civil penalties. In Washington State, for example, the State Attorney General initiated a 2010 Prescription Drug Advisory Task Force, consisting of medical professionals and pharmaceutical industry experts, to develop dosing standards for opioid products. Further, the recently enacted federal healthcare reform bill ("Patient Protection and Affordable Care Act of 2010"), calls for a national pain care conference, with the purpose to "increase the recognition of pain as a significant health problem in the United States," "identify barriers to appropriate pain care," "establish an agenda for action in both the public and private sectors that will reduce such barriers," and encourage education and research in the pain treatment area (HR 3590-469). Such well-reasoned legislation and public policy initiatives cannot be expected, however, to alleviate the very real pressures being faced by medical practitioners on a daily basis who worry that their prescribing practices as physicians will become fodder for criminal prosecution by government authorities.

My purpose here is not to frighten, but to educate. It is extremely important that physicians remain abreast of the law and legal developments relating to their practice. Reported events occur every day relating to healthcare professionals being prosecuted for healthcare fraud for procedures not being performed or for improper coding and billing practices. In addition, there has been rigorous enforcement of antikickback statutes in the healthcare professional arena, and close examination of the financial relationships between physicians, hospitals, pharmaceutical companies, and medical supply companies. Physicians and healthcare facilities are also experiencing increased regulation and legal exposure in regard to disclosure of patient health information, where reckless or improper disclosure of such information, or security breaches regarding this information, can lead to hefty civil and criminal penalties under the federal HIPAA and HITECH Acts. Recently implemented federal regulations must be carefully followed.

We live in an era where medication samples are frowned upon; accepting any benefit from a pharmaceutical company in return for recommending or prescribing its medications is deemed a violation of law; where too many prescriptions of one medication or

another can lead to a federal criminal investigation; and where statements made by an addicted patient to authorities as to the relative ease of acquiring pain medications from a physician can lead to a broad and time-consuming criminal investigation of one's practice.

Given the prevailing winds, physicians are advised to act diligently and with care. In this regard, here are 10 recommendations:

1. As a practitioner, it is always wise to assume (however odd this may seem) that all of your interactions with your patients are being recorded, and that someday these recordings will be made available to legal authorities. Never say anything to a patient, perform any action, write a prescription or advocate a course of treatment for a patient that you would not feel comfortable being reviewed by your peers.

2. Be familiar with the standard of care and prescriptive practices of trained physicians in your area and field of practice. Get any additional continuing medical education you deem necessary to render more informed judgments.

3. Read and make sure that you are fully familiar with the federal regulations set forth in Title 21, US Code, and that all appropriate and required records are kept. Failure to do so may constitute a violation of law and have dire consequences to your ability to practice. Consult with trained legal counsel, the DEA, or other healthcare professionals if you have questions concerning the applicability or meaning of such regulations. Consider having an independent professional review your records and procedures annually to ensure and maintain proper record compliance.

4. Make especially sure that you adequately document all of your patient interactions and the reasons for your actions, especially where you are prescribing controlled substances to patients over a period of time. All of your actions must be medically and legally defensible and within the standard of care. Detailed records will go a long way to justifying your decisions, especially when they are being questioned many months after the fact. As previously explained, all prescription medications dispensed must be "for a legitimate medical purpose" by a practitioner "acting in the usual course" of his or her "professional practice."

5. Only prescribe medications to those with whom you have a truly constituted physician-patient relationship and as part of a legitimate course of treatment. Always perform an adequate physical examination and use appropriate diagnostic tests and procedures prior to prescribing a controlled substance. Sometimes it will be necessary to turn down a patient's request for opioids, or appropriate to refer the patient to an addiction specialist who can wean the patient from certain addictive medications.

6. If you have your patients sign an agreement not to divert their medications, and you become aware of conduct indicating that such distribution or diversion is taking place, you should end your relationship with the patient. Indeed, any violation of a physician-patient contract suggesting unlawful conduct by the patient must be taken seriously. Not enforcing such written patient agreements is fraught with peril.

7. If you maintain a supply of opioids at your practice, keep them under appropriate lock and key, and in conformity with DEA regulations requiring licensed practitioners to follow antidiversion measures as well as having an antidiversion compliance program. Your failure to do so can result in civil fines and loss of your DEA license. Consider having an independent professional review your practice and assist you in having a written antidiversion protocol sufficient to withstand regulatory scrutiny.

8. You are also well-advised to consider whether you have compliance procedures in place at your practice, for meeting HIPAA and HITECH standards, that implement federal regulations regarding the proper disclosure of patient health information. Make sure you have implemented these safeguards to avoid improper or reckless disclosure. Further, there are specific legal requirements that must be followed in the event of even innocent and unintentional security breaches and disclosures.

9. If, within your practice, you develop your own substance abuse issues, it is highly recommended that you seek immediate treatment for chemical dependency as well as legal counsel to protect your interests. Chemical dependency by physicians can

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result for a variety of reasons, including stress and access to obtain controlled substances. Such chemical dependency is a hazard of the job that can happen to anyone, and is not as a basis for self-imposed embarrassment, career destruction, or denial. Many states, including Washington, have excellent treatment programs (Washington Physicians Health Program) designed specifically for impaired healthcare professionals. Such treatment programs protect physician confidences and are an invaluable resource to impaired healthcare professionals, enabling them to recover and maintain their licenses and medical practices. Feeding that addiction through criminal means by diverting drugs to which you have preferred access as a physician is a huge mistake.

10. If you become aware that you are the target of a criminal or regulatory investigation or wish to consult with counsel prior to entering any discussions with regulatory authorities, please remember that it is your right to do so and that any statements you do make to authorities, unless formally protected, may be used against you. Although the DEA may have the right to audit your practice or obtain an administrative inspection warrant, you always maintain the right to be silent, the right to have counsel present to interact with regulatory authorities on your behalf, and the right to have counsel present for any audit or inspection. While the aim is not to antagonize those seeking legitimate regulation, the aim is to ensure fairness and that your rights and your patients' rights are respected.

## Conclusion

Healthcare professionals, especially those involved in pain management, face a great many challenges in their practice. The law should not be allowed to have a "chilling effect" on the physician-patient relationship, such as to deprive patients of needed medications or make physicians hesitant to act due to fear of being second-guessed, prosecuted, or civilly fined. The diligent physician needs to be armed with an adequate understanding of the law and regulations in this area. The challenge, of course, is to continue to practice good medicine and to help those in need, notwithstanding what may be an increased governmental presence in this area. That is each physician's noble privilege and responsibility.

Regardless of the myriad of reasons for the increased scrutiny of physicians dispensing pain medications, all prescribers should consider how others in this arena have run into trouble, and ensure that they understand the laws involved. Through such understanding, adequate legal counsel, and adequate medical education and training specific to pain management, one can acquire the necessary knowledge to decrease the chance that the DEA will ever come knocking at your office door. And if they do, you will be confident the DEA will be pleased with your recordkeeping procedures and find you to be a physician in full compliance with the law. ■

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## REFERENCE

1. National Drug Intelligence Center. National Prescription Drug Threat Assessment 2009. April 2009. Product No. 2009-L0487-001. http://www.justice.gov/ndic/pubs33/33775/33775p.pdf. Accessed May 6, 2010.