Prescribing Opioids
During the Diversion Crackdown

Patrick J. Knight, JD

D iversion of narcotic pain medication has reached epidemic levels. The Centers for Disease Control and Prevention reports a tripling in opioid overdose deaths over the last decade. Wisconsin has been hard hit by the diversion and misuse of Oxycontin over that same period. Prescription medication was involved in over 70% of overdose deaths in Southeastern Wisconsin in recent years. Increased government scrutiny, investigation, and prosecution of those suspected of contributing to diversion require physicians to look beyond physical examinations and patients’ reported symptoms to justify prescribing controlled substances.

Diversion Enforcement
Most government investigations of physicians begin with a bad event—an overdose, a sale of prescribed controlled substances—triggering inquiry into prescribing practices. Thus, investigations begin with the assumption the physicians were either remiss or indifferent to risks of diversion or misuse of the prescribed medications.

Law enforcement authorities often combine resources when investigating physicians, with regulatory licensing agencies frequently participating. Investigative tactics include offering arrested patients the opportunity to serve as confidential informants, covertly interviewing physicians’ current or former employees, and scheduling appointments with physicians to seek prescriptions for opioids, often secretly recording office visits.

Successfully responding to investigations requires physicians to demonstrate proactive attempts to discover diversion or misuse. Physicians must understand the legal standards, available resources, and potential red flags of diversion.

The Legal Standards
Physicians can be prosecuted under the Controlled Substance Act for activities falling “outside the usual course of professional practice.” Prescriptions for controlled substance must “be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” But what do those standards really mean?

“Legitimate medical purpose” in the “usual course of professional practice” has been construed to mean the prescription must conform to “standard medical practice generally accepted in the United States.” Courts have declined to issue definitive guidelines as to what constitutes “the usual course.” Some medical-legal authors believe neither courts nor prosecutors can make this determination, maintaining it is uniquely vested in state medical boards.

Proponents of state medical board jurisdiction were buoyed by Gonzalez v. Oregon, where the Department of Justice (DOJ) sought to prohibit the prescribing of medications for use in physician-assisted suicide, even though Oregon law permits that procedure. The Supreme Court rejected the DOJ’s position, holding the federal Controlled Substances Act did not authorize prohibition of dispensing medications for physician-assisted suicide because Oregon law permitted that conduct.

Since Gonzalez, courts have ruled that federal prosecutions of prescribing physicians need not await a medical board determination of unprofessional conduct. United States v. Lovern held Gonzalez applies only to attempts to unilaterally define the scope of professional practice, stating the “course of practice” question should be left “where it has been for over 30 years – with the jury.” Thus, a jury may decide the uniquely medical issue of whether prescribing conduct is for a legitimate medical purpose. Even more troubling, another court has ruled expert testimony is not required to prove whether a physician’s actions were for a legitimate medical purpose or in the usual course of professional practice.

These ill-defined standards create great difficulty for physicians prescribing opioids for known chronic

From the Office of the General Counsel
pain conditions if a bad event later occurs. Although expert testimony is not required, the government has not shied away from using expert physicians to opine that prescriptions were not for legitimate medical purposes due to some indicators of diversion. Such opinions can lead to civil and/or criminal prosecutions, licensing actions and loss of Department of Administration (DEA) prescribing privileges.14

The enormity of the opioid diversion problem mandates that physicians be vigilant in prescribing them. The commitment of government resources to preventing diversion will only increase in the foreseeable future. Even the most conscientious physicians can be deceived by drug-seeking patients. The only real defense to investigations is an established policy of using all available data and resources intended to detect and prevent diversion.

**Prescription Drug Monitoring Program**

The Wisconsin Legislature has directed the Pharmacy Examining Board to create a Prescription Drug Monitoring Program (PDMP).15 Such programs allow pharmacists to log filled prescriptions into a database, thereby helping prevent patients from obtaining prescriptions from multiple physicians. These programs require health care professionals to generate an electronic record documenting each dispensing of a prescription drug and to deliver that record to the Board. While governing rules await implementation, the statute requires records generated by Wisconsin’s PDMP to be shared with other states.16 Once implemented, the rules will be crucial to determining the PDMP’s impact on prescribing physicians.

Studies evaluating other states’ PDMPs reveal 2 general categories: (1) Reactive PDMPs that respond to specific inquiries made by prescribers, dispensers, or other authorized parties17 and (2) proactive PDMPs that identify and investigate cases, are law enforcement-oriented in their approach, and generate reports whenever suspicious behavior is detected.18

PDMPs address the primary goal of preventing “doctor shopping” by allowing prescribers/dispensers of controlled substances to learn whether patients have obtained other prescriptions. Every prescribing physician should assume government investigators will use data accessible from the PDMP to evaluate a physician’s actions following a bad event. The PDMP will assist investigators in determining what physicians might have learned if they had taken time to review a patient’s history of receiving scheduled substances.

Before PDMPs, “legitimate medical purpose” and “the usual course of professional practice” were evaluated based on patients’ known behaviors and treatment history charts (which often provide some indication of diversion red flags), but it was difficult to refute patients’ reporting of symptoms and physicians’ subjective conclusion that medications were being properly used. PDMPs have emerged as powerful tools for investigators to establish that patients’ unlawful activities could have been determined with a simple inquiry. All physicians should assume that PDMPs will be used in assessing professional conduct in future investigations.

**Red Flags**

Numerous sources identify conduct that should alert physicians to potential diversion or abuse.19-22 Unfortunately, many of these red flags may be present in legitimate patients suffering from undertreated chronic pain.21 Philosophy and policy considerations aside, self-protection requires physicians to attempt a “rear-view” analysis of their prescribing decisions; physicians must learn to practice “defensive medicine” to protect themselves from the inquiry that will follow the occurrence of any bad event. Failure to take proactive measures—urinalysis, PDMP monitoring, and investigating the accuracy of patient history—significantly compromises physicians’ ability to defend investigations into their prescribing decisions.

**Conclusion**

The government’s increasing scrutiny of opioid prescriptions is a reality. Any chilling effect on the treatment of chronic pain will not deter the aggressiveness of investigators and prosecutors. Conscientious physicians must expect such scrutiny and be prepared to defend both their prescribing decisions and practice policies.

**Acknowledgment**

Thank you to my colleague Kathryn A. Keppel, JD, Gimbel, Reilly, Guerin & Brown, LLP, for assistance editing this article.

**References**

5.  21 C.F.R. §1306.04(a).
6.  Moore, 423 U.S. at 139.

continued on page 294
Prescribing Opioids
continued from page 292

10. *Id* at 274-75.
12. *Id*.
15. Wisconsin Statute §450.19.
16. *Id*.
18. *Id*.
The mission of the Wisconsin Medical Journal is to provide a vehicle for professional communication and continuing education of Wisconsin physicians.

The Wisconsin Medical Journal (ISSN 1098-1861) is the official publication of the Wisconsin Medical Society and is devoted to the interests of the medical profession and health care in Wisconsin. The managing editor is responsible for overseeing the production, business operation and contents of Wisconsin Medical Journal. The editorial board, chaired by the medical editor, solicits and peer reviews all scientific articles; it does not screen public health, socioeconomic or organizational articles. Although letters to the editor are reviewed by the medical editor, all signed expressions of opinion belong to the author(s) for which neither the Wisconsin Medical Journal nor the Society take responsibility. The Wisconsin Medical Journal is indexed in Index Medicus, Hospital Literature Index and Cambridge Scientific Abstracts.

For reprints of this article, contact the Wisconsin Medical Journal at 866.442.3800 or e-mail wmj@wismed.org.

© 2010 Wisconsin Medical Society