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Health Care Litigation Flash

Pilluted: Prescribe painkillers responsibly or face serious consequences

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Wisconsin and the United States face a public health crisis from prescription opioid abuse and overdoses. Opioid-related deaths in Wisconsin tripled from 2003 to 2014, with 622 deaths in 2014 alone. Nationally, more than half of all opioid overdoses involved prescription opioids, and the social and health costs of opioid prescription abuse topped $55 billion in 2014. Wisconsin Governor Scott Walker recently convened a special session of the legislature to urge action on legislation to reduce opioid abuse and provide more resources for detection, treatment and recovery.

Many prescription drug abusers go directly to physicians and pain clinics for these powerful drugs. With such high stakes, it is no surprise that federal and state agencies are working together to focus on physicians and pain clinics that over-prescribe.

Federal and state agencies have a robust toolkit to punish or prosecute prescribers for misconduct. The Drug Enforcement Agency can revoke physician registrations that allow physicians to prescribe controlled substances and state medical boards can revoke medical licenses for prescription infractions.

In addition, prescribers can face significant civil and criminal liability for over-prescription under federal and state law. Charges can cripple physicians' careers and even lead to forfeiture of significant personal assets law enforcement can trace to ill-gotten gains from over-prescribing.

Federal and state controlled substances laws impose penalties of up to $25,000 for each medically unnecessary prescription issued. These statutes punish physicians just like "street-drug" dealers.

The federal Health Care Fraud Statute imposes steep penalties for defrauding either public or private health care benefit programs by issuing unnecessary prescriptions. Violators can be imprisoned for up to 10 years for a violation, 20 years if serious bodily injury results, or even life in prison if a violation results in death.

Federal prosecutors also use the federal False Claims Act to pursue physicians for defrauding federal health care programs like Medicare and Medicaid by issuing medically unnecessary prescriptions. Violators are subject to penalties of $5,000 to $11,000 per false claim and are liable for three times the government's actual damages from any fraud.

Federal and state law enforcement agencies also have broad authority to seize assets

traced to profits from over-prescribing. "Pill mill" operators across the country have individually forfeited hundreds of thousands – even millions – of dollars traced to peddling prescription drugs. Doctors caught over-prescribing may lose everything, just like Dr. David Procter – a Northern Kentucky pill mill operator – who spent a decade in prison and saw his mansion seized and converted into an in-patient rehabilitation center for prescription drug abusers.

In addition to these civil and criminal penalties, physicians convicted of crimes related to federal health care programs, neglect or abuse of patients, or felony violations related to controlled substances must be barred from participating in federal health care programs by the "Exclusion Statute" at 42 U.S.C. § 1320a-7.

Physicians have been convicted of manslaughter and even second-degree murder for irresponsible prescription practices that resulted in death. In 2016, a California court sentenced Dr. Lisa Tseng to 30 years to life in prison for second-degree murder stemming from three patient deaths. Prosecutors hailed Tseng's conviction as showing doctors "can't hide behind a white lab coat and … writ[e] a prescription to someone knowing that they're going to abuse it and potentially die."

Federal and state law enforcement agencies are increasingly coordinating with each other to crack down on over-prescribing. In 2015, in a joint operation coined "Operation Pilluted," the DEA, federal prosecutors and state and local law enforcement in Alabama, Arkansas, Louisiana and Mississippi completed a 15-month operation that led to 280 arrests, including 22 physicians and pharmacists.

The federal and state governments' renewed focus on individual prescribers puts the onus squarely on health systems and providers to monitor physicians, nurses and staff to ensure responsible prescription and dispensing. Prescribers have resources to decrease their exposure to liability and protect their patients, but they must develop best practices to ensure compliance to avoid harm to patients and significant liability.

Prescribers should consult opioid prescribing guidelines and best practices promulgated by the Centers for Disease Control and the Wisconsin Medical Examining Board. Opioid prescribing guidelines from Wisconsin's Dentistry Examining Board are also on the way. Best practices require thorough physical examination of patients and require that physicians and providers be aware of the patient's medical history before prescribing powerful drugs. In addition, the guidelines suggest a "low and slow" approach starting with a low dosage coupled with close follow-up with patients before adjusting dosages higher.

Wisconsin's legislature has also recently enhanced Wisconsin's Prescription Drug Monitoring Program (PDMP), a powerful tool that allows prescribers to monitor the number of prescriptions their patients may have obtained from other sources. Pharmacies are now required to enter prescription information for all monitored drugs on the first business day after the drugs were dispensed, rather than within seven days. In addition, doctors and law enforcement officers are now able to enter patient information. Faster reporting by pharmacies and the addition of physician and law enforcement data will reduce critical information gaps, getting closer to "real time" patient prescription history to help physicians and providers assess their patients' risk of abuse and combat "doctor shopping" or over-prescription, even across state lines. As of April 1, 2017, all prescribers will be required to view their patients' PDMP records before first issuing a prescription for a monitored drug.

In addition to checking PDMP records as required, prescribers should continue to monitor patients' PDMP records and periodically reevaluate opioid drug therapies to avoid over-prescription and monitor for abuse. Health systems, providers and pain clinics must commit to continuing professional education as well as development of internal best practices to safely prescribe and avoid liability in the event patients do abuse opioids. Health systems, providers and pain management clinics should remember to include not only medical experts but also in-house or outside attorneys while developing procedures to ensure responsible prescription practices.

If a health system, provider or pain clinic suspects over-prescription or unlawful distribution of opioids by a physician, nurse or staff member, they must be sure to involve in-house or outside attorneys immediately. Information created during a provider's "peer-review" investigation process for potential disciplinary action may be confidential and protected in the context of malpractice suits, but will not be protected if the federal government starts an investigation into potential violations of any of the federal laws mentioned above. Using attorneys to manage any internal investigation may afford providers more control over whether and when to disclose to the government information learned in such an investigation. You can read more about "peer-review" privilege in federal investigations here.

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