Managing Increasing Liability Risks Related to Opioid Prescribing

The increase in prescription opioid-related overdose deaths has increasingly led to liability and sanctions for physicians. For instance, in January 2010, Maurice Conte, MD was found negligent for prescribing a combination of Vicodin, Xanax, and Soma, which caused an overdose death, and was fined over $9 million. Conte, as the Medical Director of pain clinics, rarely saw patients and instead sold signed prescription pads to clinic owners, resulting in over 15,000 controlled-substance combination prescriptions. In February 2016, Hsiu-Ying Tseng, DO was sentenced to 30 years to life in prison after being found guilty of second-degree murder for 3 patient opioid overdose deaths. Tseng wrote 27,000 opioid prescriptions over 3 years, including for patients whom she knew exhibited problematic drug use.

While liability can serve to deter physicians with reckless prescribing behaviors like Conte and Tseng, it may also discourage well-intentioned prescribers and compromise patient pain management. Yet our review of the growing body of case law and consideration of prescribing guidelines suggests that opioid-prescribing liability threats can be reasonably managed. Providing an understanding of the legal frameworks and risk-limiting measures may counteract the potential chilling effect of recent cases and give physicians confidence that liability exposure need not be a barrier to appropriate opioid prescribing.

CIVIL LIABILITY

The most conventional form of liability opioid prescribers face is a medical malpractice lawsuit for an injury resulting from opioids prescribed, brought by the patient or patient’s family. If a case isn’t settled, determining whether the physician breached her duty of care is often a central point of contention. Courts, increasingly guided by now widely available opioid-prescribing guidelines, look to what a “reasonable prudent physician” would have done in the same situation.

Courts have established certain negligent opioid-prescribing indicia, and those found guilty typically exemplify many such practices. For example, Conte prescribed over a prolonged period in quantities and frequencies that were far in excess of what is medically supportable failed to obtain patient medical histories or perform physical examinations and overlooked the cause of patient pain. Other practices that contribute to negligence findings include failure to maintain accurate records of opioids prescribed and to take any action to limit opioid prescriptions for known-addicted patients.

CRIMINAL LIABILITY

While prescribers can be fined in civil cases, those convicted in criminal cases brought by government prosecutors can further face prison time or the death penalty. Opioid prescribers can be criminally charged under the federal Controlled Substances Act and state equivalents. Under the Controlled Substances Act, the Drug Enforcement Administration is increasingly prosecuting physicians who knowingly and intentionally prescribe drugs outside of the usual course of medical practice or for non-legitimate medical purposes. According to the National Practitioner Data Bank, from 2011 to 2014, adverse actions by the Drug Enforcement Administration against physicians have quadrupled from 88 to 371 cases. In practice, courts often look to the “reasonable prudent physician” standard applied in negligence cases to determine “legitimate medical purpose” or “usual course of medical practice.”

Physicians can also face homicide charges under state laws when opioids they prescribe result in overdose death. To be found guilty of lesser involuntary manslaughter, a physician typically must show a reckless indifference to the patient’s life. Murder charges require more blameworthy behavior on the part of the prescriber. For example, to be found guilty of second-degree murder like Tseng, a physician must act in conscious disregard of the life and safety of her patient. Despite being alerted by authorities over a dozen times that her patients had died, Tseng caused further fatalities by continuing to prescribe opioids in the same manner.
PROFESSIONAL SANCTIONS
State medical boards have wide latitude to oversee and discipline physicians, either in connection with legal charges or not. Inappropriate prescribing accounts for a substantial proportion of the 41% increase in adverse actions by medical boards against practitioners from 2004-2014.10 State medical boards investigate complaints initiated by patients, colleagues, or any concerned party.7 They also increasingly identify outlier prescribing practices from sources such as prescription drug monitoring programs, now available in 49 states.7 Unsurprisingly, Conte’s medical license was suspended soon after the overdose death for which he was later found negligent, and Tseng’s license was ultimately permanently revoked.

OPIOID PRESCRIBING RECOMMENDATIONS
While most physicians would agree that Conte and Tseng engaged in inappropriate, risky prescribing, many have concerns about liability exposure in less clear-cut examples where there is a tradeoff between known risks and potential benefits of prescription opioids. We believe liability risks and sanctions can be managed by following good clinical practice. Myriad opioid-prescribing guidelines are available, and there is substantial agreement in their content.6 Some differences exist between guidelines—for instance, the thresholds to define “high dosage” range from 90 to 200 mg morphine equivalents, and recommendations about the frequency and universality of conducting urine drug tests vary. However, we found no evidence that physicians have been found guilty solely for adhering to a lesser standard along these varying parameters.

The Centers for Disease Control and Prevention (CDC) in March 2016 finalized a list of recommended practices5 to help physicians navigate assessment and management of the risks and benefits of opioid prescribing for chronic pain. CDC recommendations provide several specific suggestions that can mitigate clinical and legal risks, including: discussing known risks of opioids directly with patients; reevaluation of patients every 3 months to assess for risks in relation to benefits; considering use of urine drug testing; avoiding co-prescribing of benzodiazepines and opioids; and referring or offering treatment for patients identified as having an opioid use disorder.5 Use of prescription drug monitoring programs is supported by the CDC guidelines, and increasingly, states require checking prescription drug monitoring programs prior to opioid prescribing. In the Conte and Tseng cases, a panoply of the CDC recommendations was not followed, collectively resulting in failure to meet a “reasonable prudent physician” standard.5

To further inform their practice, physicians should avail themselves of one of the numerous training courses targeting safety in opioid prescribing, which may soon become a requirement for opioid prescribers.11 Finally, if physicians have concerns about initiating or continuing opioids for specific patients, they should consider alternative treatment modalities and seek a second opinion from a pain management expert or addiction specialist.

Prescription opioid therapy is associated with substantial known risks. Although new tools are needed to guide physicians’ assessment of risk—benefit tradeoffs, by knowing and availing themselves of best practices and available tools, liability potential can be mitigated—a strategy that will also serve to reduce prescription opioid-related morbidity and mortality.

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