

Chapter 2

Legal Issues

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Key Points

- Drug addiction and crime
- Pain management rules
- Pain management clinics
- Legislative strategies
- Medical license revocation
- Laws regulating controlled substances

Drug Addiction and Crime

Drug abuse and addiction have placed a drain on society, law enforcement, and the court system, not to mention the toll it has taken on countless human lives. The most recent incident that comes to mind is the death of Michael Jackson and his apparent addiction to Propofol. The role Jackson's physician played resulted in a criminal conviction as determined by a jury. Perhaps the role involved the physician being placed in a compromised position that resulted in the exercise of poor judgment and substandard medical management. Regardless, the problem of drug addiction is mounting and every segment of society need take notice—including physicians.

The statistics involving drugs and crime in the United States are staggering—and somewhat surprising. For example, the prison population in America reveals that 1 in 100 US citizens is now confined in jail or prison and 80 % of the offenders abuse alcohol or other drugs; 50 % of jailed or prison inmates are clinically addicted,

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and 60 % of individuals arrested for most types of crimes test positive for illegal drugs at arrest. Perhaps not surprising is that 60–80 % of drug abusers commit a new crime (typically a drug-driven crime) after release from prison, and approximately 95 % return to drug abuse after release from prison [1]. Drug courts have been established in most jurisdictions in an attempt to stem the tide of prison overpopulation, and in response to the fact that imprisonment has little effect on drug abuse. Drug courts seek to strike a balance between the need to protect community safety and the need to improve public health and well-being. It is in conjunction with this approach that the physician can best attend to the needs of patients addicted to drugs while recognizing the enormous problems that face all of society.

Pain Management Rules

Pain management physicians who deal daily with patients afflicted with chronic pain issues know all-too-well the fine line between medical management of pain and addiction. The enactment of Pain Management Rules establishes specific guidelines for physicians to follow, such as an appropriate physical exam and a subjective reasonable belief on the part of the physician prescribing narcotic medication that the patient is truly in pain as opposed to having an addiction. Other factors such as behavioral indicators, implicit and explicit patient admissions, and evidence of doctor shopping are all factors the physician must weigh and evaluate. While the guidelines are clear and succinct, following them has proven to be a problem for the hundreds and even thousands of physicians who find themselves with suspended or revoked licenses, and worse yet facing federal or state criminal prosecution.

Pain Management Clinics

The quantity of prescription painkillers sold to pharmacies, hospitals, and doctors' offices was four times greater in 2010 than in 1999. Enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for 1 month. Nearly nine out of every ten poisoning deaths are caused by drugs. Every day in the United States 105 people die as a result of drug overdose, and another 6,748 are treated in emergency departments for the misuse or abuse of drugs [2]. As a result of this epidemic, and the emergence of "pill mills," pain clinic regulations have been adopted in every state in the union, primarily designed to prevent facilities from prescribing controlled substances indiscriminately or inappropriately [3].

It is no secret that Pain Management Clinics have heretofore been a haven for doctor-shopping and pill-dispensing factories. Typically, drug addiction in society results in increased crime and increased violent crime. However, surprisingly the association between drugs and criminal behavior is not solely due to people committing crimes to further their drug habit. Drug use is actually a factor in many

crimes that have nothing to do with obtaining money for drugs. Drug use is implicated in 50 % of violent crimes, 50 % of instances of domestic violence, and 80 % of child abuse and neglect cases [4]. The burdens placed on society, law enforcement, and the court system are a matter of daily news. The financial burdens placed on Medicare, Medicaid, and public health hospitals amount to billions of dollars annually. It is the obligation of the physician by not only his/her oath to prevent addiction, but to reverse it—but certainly not to contribute to it.

Legislative Strategies

Physicians need to be aware of the seven types of legislative strategies that have been implemented and have the potential to impact prescription drug misuse, abuse, and overdose. These seven types of “laws” are as follows:

1. Laws requiring examination before prescribing.
2. Laws requiring tamper-resistant prescription forms.
3. Laws regulating pain clinics.
4. Laws setting prescription drug limits.
5. Laws prohibiting “doctor shopping”/fraud.
6. Laws requiring patient identification before dispensing.
7. Laws providing immunity from prosecution/mitigation at sentencing for individuals seeking assistance during an overdose.

Each state has its own set of laws and it behooves the physician to become intimately familiar with the laws of the state wherein the physician practices to assure full compliance.

While the right to practice medicine is deemed a fundamental right, the protection of public health is a duty of the State in its exercise of inherent police powers, and thus it is universally held that it is the duty of the State to regulate and control the practice of medicine. This regulation and control of the practice of medicine is vested in the various state legislatures and involves legislative control over which the federal government lacks jurisdiction. There exists federal legislation that provides grants for training and fellowships which contain guidelines under federal legislation, but the general control of the practice of medicine vests with the individual state legislatures. This does not mean to imply that the federal government cannot enact laws regarding illegal narcotic use and distribution. However, all-in-all, the primary method of regulating the practice of medicine is state legislation requiring physicians and other healthcare professionals (dentists, nurses, chiropractors, physician assistants, nurse practitioners, etc.) to do or refrain from specified activity, or controlling and regulating the manner and circumstances in which certain phases of the practice of medicine shall be performed. Near the top of the list are regulations controlling the administration of anesthetics and narcotics. The most important method of regulating the practice of medicine, and other healthcare pro-

fessionals, is through licensing and the revocation of licenses for specified causes or misconduct.

The issuance of a license to practice medicine does not translate into a contract, and therefore the holder of the license has no right to continue the practice of medicine in the future unrestricted. Any license can be revoked for good cause shown. It is axiomatic that with the power to issue a license comes the power of revocation when the “license” has been improperly issued or when the holder of the license is guilty of improper or unlawful conduct. To be certain, there can be no ambiguity in the law regarding right and wrong conduct. As long as the law enacted by the legislature proscribes reasonable regulations declared with specificity and definiteness, allowing the practitioner to accurately gauge their meaning without confusion, a license can be revoked for causes enumerated in the legislation. Therefore, it is imperative that the physician familiarizes himself/herself with the laws of the state involved, and to seek legal assistance in the interpretation of any areas of the law that may appear ambiguous.

License Revocation

As noted, one of the primary causes of license revocation is the inappropriate, wrongful, or excessive prescription of anesthetic or narcotic medications. Typically these instances involve one or more of the following: (1) the prescription of drugs without a physical examination or an indication of therapeutic necessity; (2) the prescription of drugs to known narcotics addicts or habitual users, and (3) permitting unauthorized persons to obtain or prescribe drugs in the name of the authorized practitioner [5].

Laws Regulating Controlled Substances

In addition to license revocation for practitioners who violate proscribed rules and regulations, the practitioner can also face state and federal criminal liability. The United States Congress has passed a plethora of laws regulating controlled substances. The Food and Drugs Act of 1906 was the beginning of over 200 laws concerning public health and consumer protection. Other laws such as the Federal Food, Drug, and Cosmetic Act (1938) and Kefauver Harris Amendment of 1962 were passed. In 1969 President Richard M. Nixon announced a comprehensive new program to more effectively deal with the narcotic and dangerous drug problems at the federal level, combining all existing federal laws into a single, comprehensive statute. The result was the Federal Controlled Substances Act (CSA), 21 U.S.C. § 801, passed by the 91st Congress as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The CSA is the federal US drug policy

regulating the manufacture, importation, possession, use and distribution of certain substances. This Act created the five Schedules (classifications) of drugs.

Enforcement of the Act is relegated to the Drug Enforcement Administration (DEA) established in 1973. An investigation by the DEA can be begun at any time based upon information received from laboratories, state or local law enforcement and regulatory agencies, or any other source of information. Federal or state prosecution can result from violation of the CSA—such prosecution typically leads to license revocation or suspension, depending on the severity of the violation. There can be no substitute to being familiar with the applicable laws, both federal and state.

In addition to the criminal consequence and license revocation or suspension associated with the illegal administration/distribution of narcotics, there is the civil side of the equation. Typically a civil suit will be stayed pending the outcome of the criminal investigation and trial. A guilty verdict or a guilty plea in a criminal proceeding is normally admissible in a civil proceeding, making the end-result of a civil proceeding, which typically requires evidence by preponderance much easier. Any judgment or settlement against a healthcare provider in a civil proceeding requires notification to the National Data Bank. Any judgment paid would normally be paid by the healthcare provider's professional liability insurer, with the exception in some cases being in euthanasia deaths. However, an argument can and has been made that the illegal dispensing of a scheduled narcotic is outside the stated coverage of the professional liability insurance agreement when the physician has been determined to dispense the medication for monetary reasons as opposed to reasons for treatment purposes only. Awards for the inappropriate administration/prescribing of narcotics and other scheduled substances vary from state-to-state, and range across the board from as little as a few thousand dollars to millions of dollars.

Summary

Physicians and other healthcare providers must walk a fine line when it comes to treating patients with substance abuse problems or potential substance abuse problems. The role of the physician is to treat the whole patient—whether the ailment is a physical issue or a substance abuse issue. It is essential for the physician to become intimately familiar with all of the applicable federal laws and the laws applicable to the state of practice, and to develop a systematic record-keeping process in order to manage effectively the treatment protocol. There is little to no margin for error by the physician in treating those addicted to narcotics—but there is the potential to change the lives of such persons—hopefully, forever.

What really is the physician's role in treating drug abuse and the crisis of prescription abuse? Simply stated, it is the responsibility of the physician to obtain advance training in prescribing controlled substances to avoid causing or contributing to the problem. Medical schools have not met the need adequately, and it is the physician's responsibility in recognizing and managing addictive disease to attend

workshops and seminars to become more knowledgeable in treating the disease. Inadequate education in medical school and residency training about addiction and abuse has resulted in physicians wittingly or unwittingly contributing to the prescription drug epidemic because physicians lack the skill, knowledge and training to diagnose and treat addictive disease. This lack of skill, knowledge and training can lead to licensing issues, including revocation or suspension, and criminal and civil legal issues. Typically, a criminal case revolves around violation of a state or federal statute. A civil case, on the other hand, revolves around the applicable standard of care, or whether the physician possessed the requisite skill, knowledge or training in a given field of medicine.

Thus, there are myriad pitfalls and potential traps for the physician who ventures into this very challenging field. Lest there be need for a reminder of The Hippocratic Oath: “If I fulfill this oath and do not violate it, may it be granted to me to enjoy life and art, being honored with fame among all men for all time to come; if I transgress it and swear falsely, may the opposite of all this be my lot.”

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