Clinical Practice Environment for Opioid Prescribing and Pain Management
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Implications for Physicians

In response to the opioid morbidity and mortality crisis, the prescription of opioid analgesics has become highly scrutinized and more regulated. State laws and regulations, state medical board oversight, Food and Drug Administration regulatory activities, and the U.S. Drug Enforcement Administration, along with changes in pharmacy dispensing practices, payer policies and the CDC Guidelines on Opioid Prescribing for Chronic Pain, in particular, are directly impacting how and when physicians can prescribe opioid medications.

Federal Agencies

Drug Enforcement Administrations

The Controlled Substances Act (CSA) is the basis for US efforts to prevent the abuse and illegal use of drugs. Under this law, all substances regulated by the federal government are placed into 1 of 5 schedules based on medicinal value, harmfulness, and potential for addiction. The CSA assigns the Drug Enforcement Administration (DEA) authority to regulate controlled substances. The official position of the DEA is that it does not intend to restrict practitioners in the usual course of medical practice. Federal laws and regulations do not set standards as to what constitutes a “legitimate medical purpose” or “the usual course of professional practice,” the requisite elements of lawful prescriptions under the CSA and DEA regulations. Pharmacists have a similar corresponding responsibility under this Act.

U.S. Food and Drug Administration

In 2007 Congress expanded the ability of the Food and Drug Administration (FDA) to regulate the safe use and mitigate potential harms from prescription drug products, including controlled substances. This added authority enables the FDA to require the development of a specific “Risk Evaluation and Mitigation Strategy (REMS).” Manufacturers submit a proposed REMS as part of the application prior to approval if the Agency determines that it is “necessary to ensure that the benefits of the drug outweigh the risks of the drug.” The Agency may also require REMS after a product’s approval if FDA “becomes aware of new safety information that makes a determination that such is necessary to ensure that the benefits of the drug outweigh the risks of the drug.”

In 2012, the FDA required companies to develop a classwide REMS for long-acting Schedule II opioid products (transdermal fentanyl, methadone, and extended/controlled release formulations). This REMS was initially based on an initiative to provide voluntary prescriber education in a CME-compliant fashion. In May 2016, a combined FDA Advisory Committee reviewed the activities of this REMS and voted in an unanimously fashion to require some sort of mandatory training for prescribers. In addition, the FDA revised product labeling for both immediate and extended release opioid products.
The latter are indicated “for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.” Warnings have been strengthened for all prescription opioid medications on their potential for addiction, abuse, and misuse, life-threatening respiratory depression, an abstinence syndrome for neonates exposed in utero, and interaction with alcohol.

The White House Office of National Drug Control Policy has issued its own blueprint for addressing prescription drug abuse.

**Pharmacy Practice**

The requirements of the CSA have significant implications for the pharmacy practice. Dispensing pharmacists have a “corresponding responsibility” under the CSA to ensure that a drug is dispensed for a “legitimate medical purpose in the usual course of professional practice.” In the aftermath of DEA sanctions against some national pharmacy chains and distributors, pharmacies have implemented proprietary policies (e.g., good faith dispensing algorithms) which have led to increased scrutiny of opioid prescriptions, and denial of dispensing services in some cases, either for patients, or specific physician prescribers. Physicians need to be aware that they may sometimes have to provide more information in response to pharmacy queries, in the interests of their patients.

**Payers**

Some insurance companies have instituted programs designed to address what they perceive as overprescribing of opioids.\(^1\),\(^2\) One program is based on exceeding predetermined 90-day thresholds for the number of controlled substance prescriptions, number of prescribers, or number of dispensing pharmacies. Prescribers are notified in writing of the decision to include the member in the program. Another approach attempts to rely on existing prevention, wellness, and chronic disease management programs, and to increase prevention and treatment of substance use disorders. Fundamentals include adoption of the CDC guidelines on opioid use, requiring PDMPs checks when the prescription exceeds a 21-day supply, and other options to limit supply for “high-risk” customers.

**Practice Guidelines**

In response to the mounting evidence of harm from opioid analgesics, but also affected by the view that opioids are helpful in some patients with chronic pain, many professional and health care institutional organizations developed guidelines over the last decade on the use of opioid analgesics. These guidelines emphasized ways in which harm could potentially be reduced, while preserving a role for opioids in patients with chronic pain. This issue continues to be an evolving area and one of some disagreement.
It is important to note that most of these treatment guidelines were developed before more recent evidence of prescription opioid-related harms was available, and before the intersection between prescription opioids and increased heroin use began to take shape. For a list of selected guidelines, refer to the job aid on this topic in the Resources tab.

**State Guidelines**

In addition to guidelines developed by physician groups and health care institutions, several state-based guidelines or training materials have been developed. For an up-to-date list, please consult the website of the AMA Task Force to Reduce Opioid Abuse.

**State Legislation and Regulations**

Many states have passed laws or regulations that directly impact physicians’ ability to provide pain management services and/or prescriber opioid analgesics as part of their treatments plan. These include the following types of mandates or restrictions.

- Mandatory registration with the state prescription drug monitoring program and, sometimes and a requirement to query the PDMP prior to authorizing a prescription for an opioid analgesic.
- Opioid dose and duration limits for prescriptions to treat acute pain episodes.
- A need for obtaining informed consent and the use of a written treatment plan when opioids are used for chronic pain.
- Increased regulations on physicians who own or practice in a “pain clinic.”
- Mandatory referrals to a pain specialist when dosage thresholds in morphine milligram equivalents (MME) are exceeded.
- Legislative requirement for increased level of monitoring or tapering when certain dosage thresholds in MME are exceeded.

At the state level, a health care provider’s prescribing habits may be reviewed by a variety of agencies, including state justice departments, electronic prescription monitoring programs, medical boards, and local law-enforcement agencies. Ultimately, these laws and regulations are intended to identify and protect the public from physicians who prescribe outside the boundaries of accepted medical practice. Inevitably, however, debates arise around what is and is not legitimate medical practice.
Federation of State Medical Board Guidelines

The FSMB developed and approved Model Guidelines for the Use of Controlled Substances for the Treatment of Pain to encourage adequate pain management and to dispel physician concerns about disciplinary action by medical boards. Last updated in 2013, these guidelines propose professional standards for the appropriate prescribing of opioid analgesics for pain management and have been endorsed by both the American Pain Society and the American Academy of Pain Medicine. Most state medical boards have adopted the model guidelines. Several provisions in the FSMB Guidelines address concerns about opioid use and identify multiple elements of what constitutes good practice. The FSMB formally recognizes that controlled substances may be needed to treat acute and persistent (cancer and non-cancer) pain. They also acknowledge that the threat of investigation or sanction may result in inappropriate or inadequate treatment of persistent pain, but they stress that physicians should not fear disciplinary action from the board or state regulatory and enforcement agencies for prescribing, dispensing, and administering controlled substances for legitimate medical purposes, as long as the validity of prescribing is based on proper documentation of patient treatment.

State Medical Boards

Mandatory CME for relicensing: Seventeen states currently require mandatory training in pain management and/or prescribing of controlled substances for re-licensure; in some cases, this is limited to operators or employees of pain clinics. The number of states with this requirement is expected to continue to increase and local law-enforcement agencies. Ultimately, these laws and regulations are intended to identify and protect the public from physicians who prescribe outside the boundaries of accepted medical practice. Inevitably, however, debates arise around what is and is not legitimate medical practice.

Centers for Disease Control and Prevention

In March 2016, the CDC released voluntary guidance to provide recommendations about opioid prescribing for primary care clinicians treating adult patients with chronic pain outside of active cancer treatment, palliative care, and end-of-life care. The guidelines comprised 12 recommendations (see the CDC Guidelines on Opioid Prescribing for Chronic Pain Job Aid). The guideline are “intended to improve communication about benefits and risks of opioids for chronic pain, improve safety and effectiveness of pain treatment, and reduce risks associated with long-term opioid therapy.” Recommendations fall into three broad categories: (1) determining when to initiate or chronic pain; (2) opioid selection, dosage, duration, follow-up, and discontinuation; and (3) assessing risk and addressing harms of opioid use. These guidelines are already significantly influencing the policies and procedures of state governments, payers, and health care institutions.
Reference

