AAHPM
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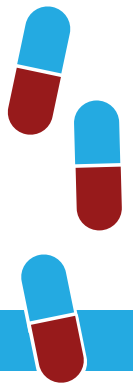
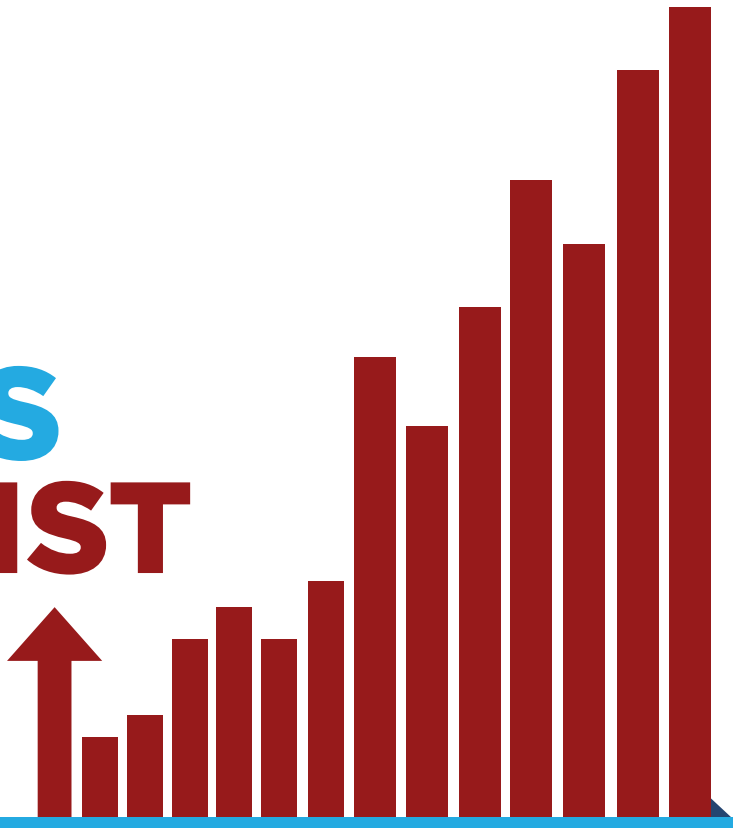
DRUG SHORTAGES PERSIST IN 2012
—what's the cause?





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Opioid Prescribing Faces Increased Scrutiny

Ronald J. Crossno, MD FAAFP FAAHPM, and Gregg K. VandeKieft, MD MA FAAHPMP

Concerns regarding opioid prescribing for pain management have been and will continue to be an area that garners policymakers' attention. With the distractions of the presidential and congressional campaigns over, there is pressure to get back to business as usual at the federal level. Several advocacy groups are generating the perception of rampant opioid overprescribing with resultant deaths due to overdoses. This viewpoint has gained traction with some policymakers. As a result, a number of bills have been submitted that include legislative measures that would restrict opioid prescribing.

Threats to Legitimate Patient Access

The proposal that proceeded the furthest toward passage was an amendment to the Prescription Drug User Fee Act (PDUFA) reauthorization. The amendment—offered by Sen. Joe Manchin (D-WV) and agreed to by unanimous consent in the Senate—would have mandated that hydrocodone-combination products be rescheduled from C-III to C-II. After input by a number of specialty groups, including AAHPM, this provision was ultimately removed from the reauthorization bill, in return for a promise that the Food and Drug Administration (FDA) would hold hearings on the matter. The FDA performed a similar evaluation several years ago, concluding that while further restricting hydrocodone access would limit its availability for misuse and abuse, this goal was outweighed by the public's need to keep this agent more readily available for pain management.

Complicating the issue further, a citizen petition advocating changes in opioid labeling was submitted to the FDA by 37 signatories calling themselves "Physicians for Responsible Opioid Prescribing." They requested the FDA indication for opioids be limited in noncancer pain for only "severe" pain (deleting the indication for "moderate" pain). They also requested an FDA upper limit for the dosage of an opioid that could be prescribed for noncancer pain (limit of 100 mg morphine daily). Finally, they advocated a limit of no more than 90 days for the length of time that noncancer pain could be treated with opioids. It seemed that the advocates were only considering chronic ambulatory pain patients, as there was no provision for exceptions, such as for terminal patients. Several physician groups, including AAHPM, sent comments refuting the scientific evidence upon which the above requests were based. (Readers can submit individual comments on the PROP petition at regulations.gov; search FDA-2012-P-0818-0001). The Academy also plans to offer in-person testimony when the FDA's Drug Safety and Risk Management Advisory Committee convenes its hearing, which was postponed due to Hurricane Sandy. Interestingly, in briefing materials prepared for the committee, the FDA cites a lack of evidence supporting claims that hydrocodone-containing products have the same potential for abuse as Schedule II drugs and recommends they not be reclassified.

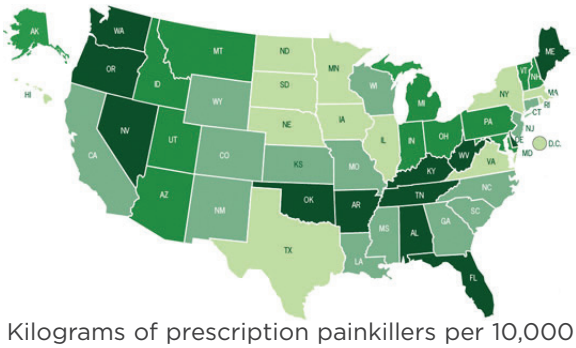
Prescriber Education

Even if the FDA upholds the current C-III scheduling, we should expect more attempts to limit opioid prescribing to arise in the new Congress. There are strong feelings that opioids are frequently overprescribed and misused. These conclusions are often supported by anecdotes based on testimonials by bereaved family members of opioid overdose victims, though there is some supportive clinical evidence. Nevertheless, it is apparent that education about opioid prescribing is necessary so that opioids remain available and accessible when needed to appropriately manage suffering from pain regardless of origin, and this must be balanced with evidence-based safeguards that limit inappropriate prescribing, misuse, and diversion.

In July 2012, after 3 years of work, the FDA, in conjunction with the Drug Enforcement Administration (DEA) and the Office of National Drug Control Policy, released its final Risk Evaluation and Mitigation and Evaluation Strategy (REMS) for extended release and long-acting opioid medications. Under the new REMS, drug manufacturers will be required to make education programs available to prescribers based on an FDA blueprint. Companies plan to provide educational grants to accredited continuing education providers to offer training to prescribers at no or nominal cost.

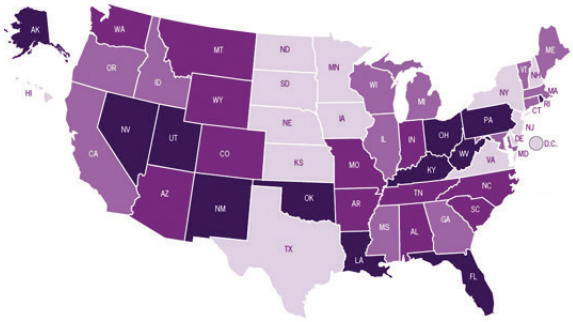
AAHPM is part of the Collaboration for REMS Education (CO*RE), which is one of several efforts to create an educational curriculum directed to DEA registered prescribers. Other members of CO*RE include large primary care physician organizations, representatives from the addiction specialty community and the pain management community, and physician assistant and nursing organizations. The target audience numbers are in the hundreds of thousands of potential prescribers. While the actual content is still being finalized, it will cover the basics of opioid prescribing, patient education about opioids, and recommendations for safe storage and disposal. One concern had been ensuring that recommendations for prescribing to chronic ambulatory pain patients not create undue burdens or access barriers for other groups of patients who may appropriately benefit from opioids, such as those managed by hospice and palliative medicine specialists. Thanks to the efforts of AAHPM, the curriculum developers have been sensitized to these issues and such concerns are being addressed.

Figure 1: Amount of prescription painkillers sold by state per 10,000 people (2010)



Kilograms of prescription painkillers per 10,000 people
3.7–5.9 6.0–7.2 7.3–8.4 8.5–12.6

Figure 2: Drug overdose death rates by state per 100,000 people (2008)



Rate per 100,000 people (adjusted for age)
5.5–9.4 9.5–12.3 12.4–14.8 14.0–27.0

Similarly thoughtful approaches are recommended for any advocacy initiatives that aim to balance enforcement efforts to limit misuse, abuse, and diversion with ensuring adequate prescribing availability and access to opioids when needed for pain management. In any potential confrontation over these counterbalancing viewpoints, it is important to validate the suffering that abuse can cause, while also reinforcing that there can be similar suffering from inadequate pain management. To be perceived as being "against" adequate enforcement controls is counterproductive and polarizing. Our standard HPM clinical strategy of encouraging open dialogue so each viewpoint is heard and understood by all parties is clearly the optimal strategy in this realm as well.

State Regulatory Requirements

In addition to federal regulation, numerous states have enacted formal educational and regulatory requirements for opioid prescribers. Opioid prescribing patterns vary greatly state to state. Data from the Centers for Disease Control and Prevention (CDC) indicate that per capita sales of prescription opioids in Florida, which had the highest rate in 2010, are more than three times that of Illinois, whose rate is the lowest **(Figure 1)**. The CDC's data also demonstrate a correlation between *per capita* sales of prescription opioids and the rate of overdose-related deaths from these drugs **(Figure 2)**. Not surprisingly, those states with the highest overdose death rates are moving forward the most aggressively to restrict opioid prescribing.

Last year, Washington state enacted what are widely viewed as the tightest state restrictions on opioid prescribing to date. Established advisory guidelines for patients covered by state-run health plans, including the state's Medicaid and workers' compensation programs, served as the basis for a new law mandating evaluation by a pain specialist for any patient on the equivalent of 120 mg or more of oral morphine per day. Advocacy efforts led to exceptions for hospice and palliative care patients; training standards, by which prescribers may be exempted from the mandatory referral requirement; and innovative telemedicine options for multidisciplinary pain management consultations. Although the long-term impact of these regulations is not yet clear, two trends are emerging.

As hoped, overdose deaths from prescription opioids are indeed declining. However, many chronic pain patients report being "dropped" by their primary providers—who cite the law as the impetus—and were unable to find willing providers in or near their communities. A number of states are reportedly monitoring Washington's experience and are considering enacting similar regulations.

All states (except Missouri) have passed legislation to establish prescription drug monitoring programs (PDMPs), although many of these programs lack operational funding. Although PDMPs have been shown to lower overall opioid prescribing rates, they have not yet been demonstrated to reduce prescription opioid abuse or overdoses. Other variables, such as the state's population and the structure of the PDMP, have a significant impact on the PDMP's effectiveness.

Many states also mandate continuing medical education (CME) on pain management and prescribing controlled substances as a provision for state licensure or as an eligibility requirement for opioid prescribing. Although educational mandates seem less prohibitive to policymakers, physicians and specialty societies have pushed back strongly against them, citing excessive intrusion into individual physician's medical practice and the cumulative burden of mandating CME in various topic areas.

The challenge remains to strike the optimal balance between ensuring access to these essential medications for those who need them, while recognizing and minimizing the associated risks of abuse and diversion. This will require additional research, extensive dialogue, and engagement in advocacy efforts at the federal and state levels. AAHPM is committed to representing our members and assuring that primary interests are those of the patients they serve.

Ronald J. Crossno, MD FAAFP FAAHPM, is AAHPM's immediate past president and a member of the Academy's Public Policy Committee. Contact him at ronald.crossno@vistacare.com.

Gregg K. VandeKieft, MD MA FAAHPM, chairs the AAHPM Public Policy Committee's State Issues Working Group. Contact him at gregg.vandekieft@providence.org.