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Opioid Crisis Continues to Pressure Physicians, But Patients Bear the Pain



The efforts to crack down on opioids are coming to a head. As a result, patients are hurting—literally.

Payors and legislators are limiting physicians' ability to prescribe, said Joseph Ranieri, DO, an addiction medicine and pain specialist who is medical director of Seabrook House, in Newell, N.J. Moreover, even where rules are absent, the specter of monitoring has many physicians caught between protecting their practices and protecting their patients.

"The pressure on physicians is already intense," Stefan G.

Kertesz, MD, wrote in The Hill (<http://thehill.com/?blogs/?pundits-blog/?healthcare/?326095-as-a-physician-i-urge-other-doctors-to-cut-back-on-prescribing>). Dr. Kertesz described a 60-year-old chronic arthritis patient who had had a kidney transplant, when her opioid dose was reduced without her consent—an all too common result of the crackdown. “Predictably, she fell apart, as did her adherence to other medications, including ones to protect her kidney. ... The threat of losing her kidney compounded the uncontrolled pain of her arthritis,” wrote Dr. Kertesz, associate professor in the Division of Preventive Medicine at the University of Alabama School of Medicine, in Birmingham.

The crackdown had been brewing for most of the decade, but things heated up in the spring of 2016, when the Centers for Disease Control and Prevention (CDC) issued the “Guideline for Prescribing Opioids for Chronic Pain” (*MMWR Recomm Rep* 2016;65:1-49). The recommendations, the pain physicians who commented on this article mostly agree, were not unreasonable, although the evidence for many was scant, by the CDC’s own admission. The problem was that they were oft interpreted to be rules, rather than guidelines.

For example, a proposal from the National Committee for Quality Assurance followed last winter that was seen as creating an incentive for physicians to unilaterally reduce doses among patients receiving more than 120 morphine milligram equivalents (MME) of opioids. Eighty pain physicians, including Dr. Kertesz, responded to that agency, stating that such dose reductions had “never been tested in prospective trials and ... could actually increase risk to individual patients, as illustrated by scholarly and popular reports of acute withdrawal (with death) ... and suicide associated with incautious unilateral opioid discontinuation or unrelenting pain.”

The Centers for Medicare & Medicaid Services proposed similar measures concurrently. However, that proposal

appears to have been softened. An agency press release in the spring stated that a requirement to deny coverage above certain dose limits would not be implemented for 2018, contrary to the initial proposal. This change appears to be in response to a letter signed by 83 professionals, including four who worked on the CDC guideline.

Ironically, the ratcheting down of opioid prescriptions may be aggravating the problems it was meant to reduce. From 2010 to 2015, overdose deaths involving natural and semisynthetic opioids fell from 29% to 24% of all overdoses. But these were swamped by the rise of overdose deaths from heroin and synthetic opioids, excluding methadone, which tripled to 25% and doubled to 18% of the total, respectively.

Unfortunately, suicide and medical harm after an involuntary dose reduction “are not usually recorded in any database, and therefore, it is very hard for health authorities to measure the size of this new problem,” Dr. Kertesz said. “All we have now are anecdotes.”

But pain patients are particularly vulnerable. They die by suicide at twice the rate of the general population. In 2014, 28,000 took their lives.

Patients Hurting

In March, a year after release of the CDC guideline, an online survey of more than 3,000 patients, physicians and health care providers conducted by *Pain News Network* found that the guideline had “harmed pain patients, reduced access to pain care, and failed to reduce drug abuse and overdoses,” commented Lynn R. Webster, MD, vice president of scientific affairs at PRA Health Sciences, in Salt Lake City, past president of the American Academy of Pain Medicine, and a *Pain Medicine News* editorial advisory board member.

That survey, Dr. Webster noted in his comments to *Pain News Network*, found that “over 70% of pain patients say they are no

longer prescribed opioid medication or are getting a lower dose. ... Eight out of 10 patients say their pain and quality of life are worse.”

In a survey of 72 patients with arachnoiditis or Tarlov cyst disease, conducted by the Arachnoiditis Society for Awareness and Prevention, slightly more than half said they'd been completely cut off from their opioids.

In another portent, in articles published with comments sections, such as one in the *Boston Globe* health publication *STAT* by Dr. Kertesz and Adam J. Gordon, MD, some commenters have expressed a desire to die by suicide, or have described considering it, in the wake of the crackdown. “That suggests we are in some really dangerous territory,” Dr. Kertesz said (www.statnews.com/?2017/?02/?24/?opioids-prescribing-limits-pain-patients/?).

Attempts at Control

The medical community had long undertreated pain. In the early 1990s, physicians, finally recognizing the problem, turned to opioids in an effort to mitigate that epidemic. Prescriptions rose steadily, tripling at 219 million in 2011.

As prescriptions rose, so did overdoses and deaths from overdoses. “Excessive prescribing without sufficient close monitoring meant that prescriptions received by patients often wound up in others’ hands, through sales, theft or giving them away,” Dr. Kertesz said. Federal data indicate that 12.5 million people misused opioids at least once in 2015, and that 2 million would qualify as having an addiction diagnosis.

By 2010, the profession had become concerned, and in 2012, the number of prescriptions for opioids fell.

The March 2016 CDC guideline hit the media with a splash. Former CDC Director Tom Frieden, MD, was quoted saying that “opioids are just as addictive as heroin,” a statement widely

interpreted as implying that most opioid addiction originates in pain patients, a controversial view.

The guideline is flawed by low-quality evidence, said Jeffrey Fudin, PharmD, owner and managing editor of PainDr.com, founder and chair of Professionals for Rational Opioid Monitoring & Pharmacotherapy, and co-editor of the Opioids, Substance Abuse and Addictions section of *Pain Medicine*.

Nonetheless, the CDC was “extremely careful” not to directly mandate dose reductions in patients “evaluated as benefiting from opioid prescriptions,” Dr. Kertesz said.

The guideline suggests a 90-MME ceiling, and states that for treatment of acute pain, three days or less often suffices, and that more than seven days is rarely necessary.



However, legislators are enshrining these provisions as law, and many insurers are using them to determine coverage.

Ohio, for example, has proposed legislation restricting primary care physicians and dentists to prescribe no more than 50 MME per day, in no more than three-day increments, unless they complete eight hours of training about opioids and addiction, and can provide treatment for the latter. The bill presently awaits committee hearings.

Maine legislation capped doses at 100 MME, requiring patients already on higher doses to be tapered to that level by July 1, 2017. An estimated 16,000 Mainers are prescribed higher doses, and Patrick Mellor, a lawyer in Rockland representing two chronic pain patients, said they “would lose substantial functionality by having to taper down,” as would

around 1,500 of the 16,000.

But the real problem, Mr. Mellor said, lies in the legal language, not in the law itself. The Maine legislation includes a “palliative care exception” to the tapering requirement, Mr. Mellor said. Under the statute, “palliative care” is not limited to end of life, as a nonlawyer might reasonably assume, but includes treating “a physical injury or condition that substantially affects a patient’s quality of life.”

Nonetheless, the July 1 deadline for tapering is problematic because “the doctors in the state haven’t been adequately informed as to the exceptions to the new law,” Mr. Mellor said. Whereas the physician of one of his clients knew to apply the palliative care exception, the other client’s physician did not. Therefore, that client’s dose—450 MME for the last 16 years—has already been tapered to 300 MME, much to the client’s distress.

Among other states that have enacted legislation, seven—California, Colorado, Indiana, New Hampshire, Ohio, South Carolina and Vermont—have soft limits on doses, which lack force of law, but can be used to assess a physician’s practice. Besides Maine, Massachusetts and Washington have hard limits.

Even under soft limits, “doctors feel it increases liability,” Dr. Fudin said. “And even if the prescriber has documentation, they are being scrutinized. ... They can be called on by state regulatory agencies to explain any patients with morphine equivalent daily dosages (MEDD) that fall [beyond] a predetermined limit. ... The clinician may reduce the dosage to meet the state MEDD limit because they don’t want to deal with it.”

In Massachusetts, former Gov. Deval Patrick banned Zohydro ER (Pernix), the first extended-release, single-entity hydrocodone. “Eventually, the federal government overturned Gov. Patrick’s ruling, but doctors were still afraid to prescribe

it," Dr. Fudin said.

Washington requires patients to be referred to pain specialists if the prescribed MEDD exceeds 120 mg per day. "The trouble is, there aren't enough pain specialists to go around, and ... most prefer interventional procedures and shy away from or refuse to prescribe medication therapies," Dr. Fudin said.

Payors

Meanwhile, "insurance companies are incorporating guidelines into what they're willing to pay for under any circumstance, thus driving a lot of clinical decision making on what are supposed to be guidelines applying only to primary care doctors," said Edward Michna, MD, director of the Pain Trials Center, Brigham and Women's Hospital, in Boston, and a board member of the American Pain Society. All this is done "under the guise of patient safety, but it's really about saving money."

"Health plans are addressing a very serious crisis, the opioid epidemic," said Cathryn Donaldson, director of communications for America's Health Insurance Plans. Payors, she added, "are focusing on fighting the epidemic, while ensuring that people have a proven pathway to manage their pain."

"It has been my experience that ... some commercial plans have already been imposing [dosage ceilings] when it's not currently required," said James DeMicco, PharmD, of J&J State Street Pharmacy, in Hackensack, N.J. "Anything above 90 mg of MEDD becomes problematic." Dr. DeMicco added that despite changes in some plans allowing soft edits and enabling pharmacist overrides at the point of sale, "it is still very challenging."

Similarly, some insurance companies will not pay for extended release, or "have created incredibly lengthy red tape" that must be navigated before payment, in response to the CDC guideline's fourth recommendation to avoid extended-release

opioids when starting therapy, said Sanford Silverman, MD, director-at-large of the American Society of Interventional Pain Physicians. These strictures apply even when these opioids are prescribed by pain specialists, although the CDC guideline only applies to primary care physicians, he noted.

Worse, insurance companies often require prior authorization anew when a patient already on opioids switches physicians, Dr. Silverman said.

“Some insurance companies—WellCare in Florida is one—don’t even cover extended release, long acting in the formulary,” despite the fact that it often works better for patients, and it is less prone to diversion, Dr. Silverman said. (WellCare did not return phone calls for this story.)

Big Pharmacy Chains

Even when an insurance company covers a high dose, a pharmacy may refuse to dispense the dose or the drug. Pharmacies have grown wary following instances when the authorities have legitimately clamped down on them.

For example, in 2013, Walgreens paid \$80 million in civil penalties, and was prohibited from dispensing controlled substances for two years. The giant pharmacy chain had failed to comply with Drug Enforcement Administration regulations requiring reporting of suspicious prescription drug orders that its Jupiter distribution center received from six Florida Walgreens retail pharmacies. During that time (2009-2011), all six stores saw skyrocketing increases in orders for controlled substances, the greatest of which was 21-fold.

Numerous fines have been levied elsewhere in the United States, such as an \$8 million levy on CVS in Maryland earlier this year for similar violations of the Controlled Substances Act.

As a result, pharmacies are often reluctant to fill opioid prescriptions. Patients frequently are forced to drive to numerous pharmacies to find one that will fill such a prescription, Dr. Silverman noted. This is called the “pharmacy crawl.”

In one instance, Dr. Silverman had to spend 20 minutes convincing a pharmacy staff member that it was legal to give an opioid-naive patient a short-acting opioid. “This is only one of millions of stories,” he added.

Walgreens created a lengthy checklist that staff members must use when filling opioid prescriptions, which includes 11 items (e.g., “quantity is 120 units or less; or 60 units or less if paid by cash or cash discount card”) and more than two pages of “procedures,” in small type. (Walgreens’ media relations did not respond to a phone call and email.)

Dr. Silverman called the checklist “ridiculous,” pointing out that the pharmacist can check the state prescription drug monitoring program to see whether the patient in question has obtained drugs elsewhere.

Physicians in the Middle

“For physicians wishing to stay out of the firing line, the implicitly encouraged step is involuntary dose reduction, even if the patient is functionally stable on their current dose,” Dr. Kertesz said. “That course of action has absolutely no trial data to support it,” he added.

But with the growing medical-legal liabilities, “more and more primary care practices are saying they won’t offer opioids for any reason,” Dr. Michna said. The restrictions “have driven up the amount of time you need to spend, and with all these laws and regulations, there hasn’t been a concurrent increase in reimbursement.”

“I have cared for a few patients in the immediate aftermath of

involuntary tapers introduced by others,” Dr. Kertesz said. “We have a rising tide of concerning reports. I am aware of hospital legal teams that are concerned about the liability implications of such practices.”

Crisis/Opportunity

All this notwithstanding, the opioid crackdown represents an opportunity to educate pain physicians to approach mitigating chronic pain more creatively, said Melanie Rosenblatt, MD, director of pain management at Broward Health North, in Pompano Beach, Fla.

For many patients, doses sufficient to numb the pain frequently numb the rest of living, Dr. Rosenblatt noted. But both physicians and patients frequently prefer to do what they know, rather than try something new, she said.

“I say to all my patients, ‘I promise I can help you.’ It just may not be exactly what they want.”

Dr. Rosenblatt has spent years adjusting treatments to make them more effective, with fewer side effects. For the patient who faces tapering from a high dose of opioids, “maybe a spinal cord stimulator would work better,” she said.

“Many patients might be better managed with newer alternatives, and maybe a fresh set of eyes,” she added. One patient came to her miserable with pain from metastatic prostate cancer. “The pain meds he was taking were making him sleepy, and nauseous, and they weren’t working,” she said. “I put an intrathecal pump into him that delivers opioid to the spine.” He came into his follow-up appointment, “walking, saying I had given him his life back.”

Dr. Rosenblatt has developed a protocol for treating pain patients that de-emphasizes opioids, which is being distributed by her new company, Melrose Pain Solutions.

Conclusion

As the opioid crackdown continues, two ironies remain. First, “this is the safest time in recent history to prescribe opioids,” said Steven Passik, PhD, vice president of scientific affairs, education and policy at Collegium Pharmaceuticals, in Canton, Mass. “We have potentially safer drugs, abuse-deterrent drugs, buprenorphine, etc. We also have prescription drug monitoring in almost every state. And urine drug tests now come back in 24 hours, with accurate results. Give-back programs and counseling programs have shown efficacy in clinical trials in helping people to avoid abusing. And screening tools are available to ascertain someone’s risk of abusing.”

The second irony: Although opioid prescriptions have dropped tremendously, abuse and overdoses continue to rise. The primary drugs of abuse are no longer prescription opioids but heroin and illicit fentanyl, and their abuse is driven partly by desperate patients who have lost access to opioids.

—David C. Holzman