

State Initiatives *in* End-of-Life Care

Issue 14, May 2002

Focus: Pain Management—An Update

The Need for Balance in Controlled Substances Policy

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Kristin Petersen

Comprehensive pain management is dependent upon the powerful painkillers known as opioids, but it is not limited strictly to their use. Hospice workers like Ailene Josephs (above, massaging the back of an end-stage breast cancer patient enrolled at Forbes Hospice/West Penn Allegheny Health System, Pittsburgh) know that opioid therapy is one of many modalities used to treat the different types and degrees of pain experienced at the end of life. They also know that opioid therapy, when tailored to the individual patient, can indeed be as caring and as life-enhancing as the massage shown above.

Unfortunately, one result of the public effort to prevent drug diversion is that legitimate pain patients are being prevented from access to opioids. A recent Brown University study found that 40 percent of nursing home residents experience moderate to excruciating daily pain that goes inadequately treated for two to six months after they first report it to staff (see p. 2). In addition, fears and misperceptions about opioids and addiction still abound among doctors, patients, and policymakers alike.

Effective Pain Control: Still Elusive for Many Dying Americans

By the year 2020 nearly half of all Americans facing the end of life will be nursing home residents. Currently, nearly half of Americans living into their eighties spend some time in a nursing home. For 40 percent of nursing home residents, here's what that means: living with "moderate" to "excruciating" daily pain that goes inadequately treated two to six months after they first report it to staff.

This disturbing finding is one result of a Brown University study that appeared in the April 25, 2001, issue of the *Journal of the American Medical Association*. The study was the first to take a comprehensive, data-based look at pain among elderly nursing home residents nationally, and it finds that, overall, pain among the more than 2.2 million Americans living in nursing homes is epidemic and poorly treated. What's more, the researchers believe the findings *underestimate* these residents' pain burden, since the findings are based on nursing home staff reports, and staff generally under-report residents' pain.

Nursing home residents aren't the only ones suffering pain at the end of life. Even cancer patients still find palliative care elusive. A recent Institute of Medicine study found that of the half-million Americans who die from cancer each year only about half receive any pain and symptom management at all.

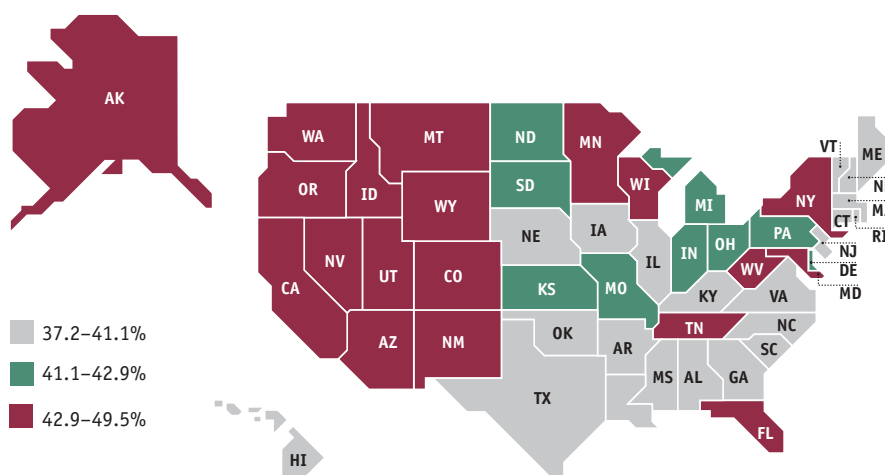
What's behind the lack of pain management at the end of life?—persistent, mistaken beliefs about the class of controlled substances known as *opioids*.

This brief follows up our 1999 brief about the state of pain management policy as it pertains to end-of-life care. Some gains have been made in the past five years or so. For example, the DEA Office of Diversion Control reports that prescriptions dispensed for all common opioids from 1996 to 2000 increased by 23 percent. This is a sign that medical use of opioids is increasing and perhaps that more pain is being treated.

But chronic pain patients continue to have unduly limited access to opioids. Chronic pain—whether malignant or nonmalignant—remains a major public health concern, with more than 50 million American sufferers. Recently, sensational media reports of cases of diversion and abuse of a relatively new long-acting pain medication, OxyContin (OC), have renewed policymakers' concern about increasing medical use of opioids: a congressional hearing was held on the matter in December 2001 and an FDA hearing in January 2002.

But those familiar with drug enforcement and controlled substances policy—including DEA Administrator Asa Hutchinson—are calling for a balanced attitude toward this latest crisis and toward drug enforcement policy in general. This brief will explore the diversion and abuse of OC and those calls for balance. It will take a look at a historic joint statement advocating a balanced policy, issued in October 2001 by the DEA, pain organizations, and pain policy groups. Finally, this brief will summarize other recent advances in pain policy that have been implemented, or that need to be implemented, in order to improve the care of Americans facing the end of life.

Percentage of U.S. Nursing Home Patients in Persistent Pain



Opioid Diversion: A Renewed Call for a Balanced Drug Policy

Tracking the Damage of Today's "Drug du Jour"

The opioid making headlines recently is the long-acting painkiller OxyContin (OC), recently the subject of hearings before a House Appropriations subcommittee and the FDA. When it comes to "Oxy," it's hard to get a clear picture of the toll the abuse and diversion problem has taken. Lots of numbers appear in the media:

- The *Philadelphia Inquirer* reported that oxycodone, the opioid in OC, was linked to 41 deaths in 2000 and 39 deaths in the first half of 2001.
- *USAToday* reported 268 deaths in 1999 due to oxycodone overdose.
- *National Public Radio* reported 42 oxycodone overdose deaths in western Virginia from 1997 to 2001.

The OC diversion problem began to make headlines in 2000. Since then its manufacturer, PurduePharma, has maintained that it is difficult to quantify the number of casualties of the drug's abuse. "Any death with oxycodone present in the blood is called an 'OxyContin death.' But there are 59 products on the market with oxycodone in them," says PurduePharma spokesman Robin Hogen, adding that many of the overdose cases involved alcohol and other drugs. Media reports sometimes confuse oxycodone with OC, leading to further confusion.

The best available data on U.S. drug abuse deaths comes from the Drug Abuse Warning Network (DAWN). DAWN data are compiled from medical examiners reporting from 14 U.S. cities. DAWN's most recent overdose data available put the number of U.S. heroin- and cocaine-related deaths at more than 9,700 per year, more than 30 times greater than the oxycodone-related deaths. Although estimates of oxycodone deaths vary widely, for this comparison, one of the high estimates—262—was used. OC deaths

"It's not cancer pain patients who are dying of OxyContin overdose; sadly, it's people abusing drugs who are dying."

Kathleen Foley, MD,
Attending Neurologist,
Pain and Palliative Care Service,
Memorial Sloan-Kettering Cancer Center

would be, of course, a subset of total oxycodone deaths. One issue clearly revealed in the DAWN data is the prevalence of polydrug use and combined drug and alcohol abuse, which make attributing any death to one particular drug quite problematic. A further complication in assessing DAWN data with respect to OC is that OC diversion has been concentrated in rural areas and DAWN reports from urban centers. Still, the DAWN death reports for heroin and cocaine far exceed the OC-related death estimates, contrary to media reports. "One journalist wrote, 'The OxyContin abuse problem is greater than that of heroin and cocaine,'" says June Dahl, PhD, director of the Wisconsin Cancer Pain Initiative. "This was his interpretation of the DAWN data. The media have at times been very irresponsible."

Dying Patients Are Not Involved

Despite all the confusion surrounding the abuse of OC, two things are clear. First, OC is indeed being diverted and abused to the point that it is now the "street drug of choice" in some areas, especially on the rural Appalachian ridge from Maine to Kentucky, and more recently in Philadelphia. Second, OC is not yet widely prescribed to fight cancer pain—though pain physicians agree that it is an



important and appropriate drug for that use. Couple these two facts and it's clear that patients having pain at the end of life have nothing to do with this latest crisis.

Pain specialists and pain policy experts are concerned that mistaken and sensationalistic media reports will create a backlash among policymakers against treating pain, which they say has become at least as much a public health epidemic as drug abuse, with 50 million adult American sufferers "and an untold number of children," according to Russell K. Portenoy, MD, chair of the Pain Medicine and Palliative Care department at Beth Israel Medical Center in New York.

Moreover, they stress that prescription drug diversion is a criminal act that should be addressed without adverse effect on medical practice and treatment of pain. "It's not cancer pain patients who are dying of OxyContin overdose; sadly, it's people abusing drugs who are dying," says Kathleen Foley, MD, a preeminent neurooncologist at Memorial Sloan-Kettering Cancer Center.

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Examples of Balanced and Unbalanced Policy

Examples of Balanced Policy

- Police pursuing organized crime rings involved in prescription-drug thefts and pharmacy burglaries
- Law enforcement identifying physicians and pharmacies who are prescribing or dispensing drugs for addicts or for resale
- States moving toward electronic prescription monitoring to prevent doctor-shopping, forgery, and diversion
- The agency that oversees a state's Medicaid program investigating for doctor-shopping any patients receiving controlled substance prescriptions from more than one physician
- State legislatures making the theft of a prescription pad a felony offense
- State medical boards adopting the Federation of State Medical Boards' model guidelines for the treatment of pain (www.fsmb.org/pain.htm)

Examples of Unbalanced Policy

- States restricting dispensation of opioid drugs to a limited number of pharmacies
- States limiting opioid prescribing privileges to pain specialists, of whom there are only 1,200 in the country
- States, such as California, adhering to multiple-copy prescription form programs, which are time-consuming and which discourage physicians from treating pain because of fear of oversight (for more about electronic monitoring versus special prescription forms, see p. 6)
- States adopting Intractable Pain Treatment laws, which place undue restrictions on medical decision making and patient access by defining opioids as treatment of last resort and requiring second opinions for pain patients
- Law enforcement officials or narcotics agents "going fishing"—that is, investigating pharmacy or physician records without specific evidence that diversion is occurring

Opioid Diversion: A Renewed Call for a Balanced Drug Policy

Continued

OC Is Not Most Commonly Abused Opioid

"Proportionately, diversion [of prescription opioids] is in line with medical use. What's out of proportion is the drug-enforcement response. They have not stopped to look at the data," says Betty Ferrell, PhD, FAAN, a nurse and pain policy researcher at the City of Hope Medical Center who chairs the Southern California Cancer Pain Initiative (SCCPI).

According to the most recently available annual data (1997) published by the U.S. government's Drug Abuse Warning Network (DAWN), oxycodone in all forms was mentioned in 2 percent of all prescription medication-related emergency department visits in which abuse was suspected. This ranked oxycodone—not OC—fourteenth on the list of drugs of abuse—well behind such well known medications as Vicodin (an opioid), Valium, acetaminophen, ibuprofen, and even aspirin. With 39 preparations of oxycodone besides OC on the market, that puts OC even lower on the list.

"Drug abuse is serious—it affects human lives and families. But we have to realize that prescription drug abuse is a cyclical phenomenon—that it comes and goes," says David Joranson, MSSW, senior scientist and director of the Pain and Policy Studies Group (PPSG) at the University of Wisconsin–Madison, which conducts annual studies of pain policies. "Looking back, you can see outbreaks of abuse that are successfully addressed. Also, there is a certain constant level of drug abuse that's going to affect the prescription drugs like the opioids. Addressing abuse of prescription pain medications requires a balanced approach to drug policy."

Pharmacists agree. "Clearly, the time has come for . . . the development of a more effective but balanced approach to opioid regulation," wrote David Brushwood, JD, RPh, a professor at the University of Florida College of Pharmacy, in the October 2001 newsletter of the National Association of Boards of Pharmacy (www.nabp.net). "We hold the key to the medicine chest and, while we need to lock the chest when inappropriate requests are made of us, we need to open the chest when legitimate patients in need of pain relief seek our products and services."

What Is Balanced Pain Policy?

Joranson says balanced policy identifies and addresses the sources of diversion without interfering with medical practice and patient care. He compares opioid prescribing to a pipeline, and says diversion can occur when

- the proper outlets in the pipeline malfunction, such as improper prescribing or dispensing. This has been shown to be a fringe activity of a very few unscrupulous physicians or pharmacists—and is a primary target of law enforcement.
- the pipeline is punctured from the outside, resulting in leaks: doctor-shopping, prescription forgery, and theft. These sources make up a major part of diversion—but are more difficult for law enforcement to address.

"The litmus test for balanced policy and enforcement is to ask these two questions: 'Does the policy get directly to the source of diversion?' And, 'Does it interfere with medical practice or patient care?' If the answer to the first is Yes and to the second is No, then the policy is balanced," Joranson says.

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DEA Teams with Pain Groups on Historic Statement

On October 23, 2001, DEA Administrator Asa Hutchinson announced that his agency and 21 leading health care organizations had endorsed a statement supporting medical use of opioids (see excerpt, below). The document articulated no new DEA position except for the administrator's willingness to align himself with pain groups. "It certainly is without precedent that the DEA would join with key health care and pain organizations to reiterate existing policy," says the PPSG's Joranson. "But policy is worth nothing unless it's communicated, understood, and observed." Adds Purdue's Hogen: "The problem is not in Washington, the problem is in small towns hundreds of miles away, where there are DEA agents terrorizing pharmacists and physicians for dispensing opioids. The enlightened attitude of the DEA administrator needs to trickle down to DEA agents on the front lines."

DEA staff say the agency has worked hard to change physician and pharmacist fears. The DEA has organized seminars for practitioners about appropriate prescribing and has endorsed the Federation of State Medical Board Guidelines (see p. 7). Pat Good, chief of the DEA's Liaison

and Policy Section, calls physicians' fear of DEA scrutiny "a false perception. But with a million doctors and only 400 of us, it's kind of hard to overturn that perception." Numerous studies show the perception's pervasiveness. Appearing with Hutchinson at the press conference was preeminent pain researcher Russell K. Portenoy, MD, citing results of a recent survey of 1,400 New York physicians conducted by the state's Department of Health: nearly 40 percent of doctors admitted to changing their prescribing behavior for fear of DEA and other regulatory scrutiny.

The Southern California Cancer Pain Initiative's Ferrell cites DEA and other law enforcement's opposition to a state bill in 2000 that would have revoked the state's multiple-copy prescription law. (The state has an electronic monitoring system; see p. 6). Ferrell joins many others in applauding the DEA's involvement in the statement, but she expresses the medical community's wait-and-see attitude: "There's just no detail about how these promises are going to be kept. The DEA needs to articulate how it will really help break down the ridiculous, insane barriers to patient access to pain management." ■



"We don't want to cause patients who have legitimate needs for these medications to be discouraged or afraid to use them. And we don't want to restrict doctors and pharmacists from providing these medications when appropriate."

Asa Hutchinson, Administrator,
Drug Enforcement Administration

For the full text of the Joint Statement and a list of signatories, go to:
www.medsch.wisc.edu/painpolicy/dea01.htm

Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act

As of May 8, 2002, 42 health care organizations joined the DEA in endorsing this statement.

As representatives of the health care community and law enforcement, we are working together to prevent abuse of prescription pain medications while ensuring that they remain available for patients in need. Both health care professionals, and

law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law

enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical. Preventing drug abuse is an important societal goal, but there is consensus, by law enforcement agencies, health care practitioners, and patient advocates alike, that it should not hinder patients' ability to receive the care they need and deserve.

A Roundup of Recent Pain Policy Advances and Trends

Three types of policies affect pain management: state and federal law, state and federal regulations and guidelines or standards adopted or instituted by state and federal organizations that license practitioners or accredit institutions. What follows are explorations of the major state-level policy trends or actions affecting pain management at the end of life that have emerged in the past two years.

Unprecedented Boom in State Pain Policy

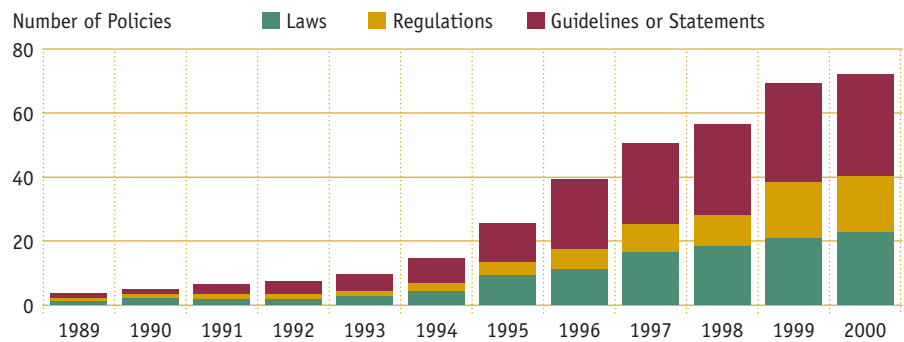
State medical boards—not legislatures—are charged with upholding the standard of care among a state’s physicians. So pain policy experts say medical board pain treatment guidelines are one of the most effective ways to address doctors’ fear of treating pain.

The Federation of State Medical Boards’ model guidelines on the use of opioids in pain management, released in May 1998, are often cited as an example of progressive pain policy because they:

- accept opioids’ medical importance
- reject quantity and chronicity of prescribing as regulatory measurements of good medical practice—embracing instead patients’ needs and quality of follow-up and documentation
- state that the medical board will not discipline a physician for failing to adhere strictly to the guidelines if good cause is shown for deviation

The DEA was quick to endorse the model guidelines. In the past two years, an unprecedented number of state medical boards have adopted these guidelines (see chart above). But the PPSG, which closely monitors state pain policy, is concerned that this trend may have reached a plateau, and that those states that haven’t already adopted the guidelines should consider doing so, says Joranson.

State Pain-Specific Policies, 1989–2000



Source: University of Wisconsin Pain and Policy Studies Group/WHO Collaborating Center, 2000

Moves Toward Electronic Prescription Monitoring

One of the best ways to prevent diversion caused by doctor-shopping, some pain policy experts say, is for a state to institute an electronic system for pharmacies to transfer prescription information to regulatory agencies. An authorized agency can then monitor whether individuals are receiving opioid prescriptions from multiple physicians. Such a monitoring system is less invasive and expensive than special forms, which are onerous to physicians and patients.

California Assemblywoman Helen Thomson (D) sponsored a bill in 2000 that would have shifted the oversight of prescriptions entirely from a triplicate-form system to a computerized system already up and running (see *State Initiatives in End-of-Life Care*, Issue 9, p. 4). But due to strong opposition from the state attorney general and other law enforcement agencies, the bill was watered down and the triplicate system retained. “The regulatory agencies, including the DEA, made sure that this bill failed,” says the SCCPI’s Betty Ferrell. “They used political means to sabotage it. It was supported by both legislative chambers, and 30 major consumer groups advocated for it, but after it passed, the governor vetoed it because of pressure from law enforcement.”

Kay Felt, JD, a Michigan attorney and member of the Michigan Commission on End-of-Life Care and the governor’s Advisory Committee on Pain and Symptom Management, says a 2001 commission study showed any type of “special” monitoring reduced physicians’ likelihood of treating pain. The commission last year recommended the total disbanding of the state’s Official Prescription Program, which requires “a huge, monstrous prescription pad you can’t carry in your pocket,” says Felt. The special prescription-form law “interferes with medical treatment of pain.

... Physicians have the feeling that somehow they’re scrutinized—even though they’re actually not. Pharmacies are very reluctant to carry or dispense these medications. Plus, the program costs \$800,000 per year to administer—and *nothing is done with the information*,” says Felt.

Currently 16 states have electronic programs, but seven of those, including Michigan, still require some special form. She says the commission hopes the state will eventually use only electronic monitoring. “There’s now legislation in the house to do that,” Felt says of Michigan.

Persistent Regulatory Scrutiny Continues to Discourage Docs

To understand why physicians worry so much about regulatory scrutiny, the case of Joan Lewis, MD, is illustrative. Lewis is a prominent Albuquerque pain specialist who helped write New Mexico's Pain Relief Act. But her credentials and experience with pain treatment did not prevent her from being investigated in 2001 by the state board of medical examiners on six counts of "injudicious prescribing" of opioids to patients with chronic non-cancer pain.

The investigation went forward even though Lewis scrupulously adhered to state policy by monitoring her patients closely, even asking them also to document their use of the medications she prescribed. Many of her patients—including four of the six whose cases were cited in the investigation—came forward in her support, as did other prominent physicians, by contributing friend of the court briefs on Lewis's behalf.

Even though Lewis had co-authored the pain management guidelines used by the medical board to evaluate physicians' prescribing actions—including Lewis's own—the board apparently found sufficient evidence of "injudicious prescribing" to consider revoking or suspending her license. The state attorney general personally reviewed Lewis's case and declined to prosecute. The medical board never held a hearing, so no findings were ever issued against Lewis. But Lewis was not off the hook. In exchange for stopping its investigation, the board of medical examiners has required her to practice under supervision for two years and obtain more training in pain management out of state.

Not surprisingly, pain treatment advocates, including those working in end-of-life care, are concerned that this board's attitude not be permitted to touch off a wildfire of scrutiny of the 1,200 pain specialists throughout the country, who are often the only doctors in their communities willing to treat pain aggressively. Three organizations filed amicus briefs in Lewis's support: the Compassion in Dying Federation and the Americans for Better Care of the Dying, both national nonprofit groups supporting better end-of-life care, including improved pain care; and the American Academy of Pain Management, North America's largest multidisciplinary pain management organization. "There has been a series of other cases across the country, of physicians charged with overprescribing," says the SCCPI's Betty Ferrell. "There has been a series of lawsuits and medical board investigations. They involve enormous expense and time for doctors. Of course, every one of these cases has an enormous chilling effect."

In California, a Physician Is Sued for Pain Undertreatment

On the other side of the coin, there is the case of Dr. Wing Chin, a California physician found guilty in 2001 of elder abuse for failing to give a dying lung cancer patient adequate pain medication. When the patient's family's complaints about Chin's practice were ignored by the state medical board, the family filed a civil suit—and won \$1.5 million.

Pain treatment advocates see both benefits and problems with using lawsuits to influence practice. "I'm not enthusiastic about lawsuits, but such a case surely does make physicians sit up and take notice," says June Dahl. Ferrell notes that a lawsuit allows the public to take control: "A lawsuit

State Initiatives *Kicks Off New Audio Series*

HEART TO HEART: Improving Care for the Dying through Public Policy is a new four-part series of half-hour audio documentaries for policymakers and professionals. The series offers policy solutions to improve the quality of end-of-life care given by hospitals, nursing homes, physicians, and other providers.

Part I: Pain Management, the series' first program, has been released simultaneously with this brief and can be ordered using the order information below. Featured in this first program are many of the leading experts in pain management and public policy quoted in this brief, such as DEA Administrator Asa Hutchinson and PPSG Director David Joranson, and others, including Richard Payne, MD, chair of Sloan-Kettering's Pain and Palliative Care Service, and Joanne Lynn, MD, president of Americans for Better Care of the Dying.

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speaks to us in a different way than a published paper, a set of guidelines, or a medical board action. It says that this is no longer a professional issue—it's a social issue, a public issue."

Susan Tolle, MD, director of the Center for Ethics in Health Care in Oregon, says lawsuits feel more like a bolt of lightning, while board discipline "feels more like a consistent

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Opioid Diversion: A Renewed Call for a Balanced Drug Policy

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Yet states are proposing policies to combat OC diversion that include

- limiting OC prescribing privileges to pain specialists
- limiting dispensing of OC to designated pharmacies
- making Schedule II opioids the treatment of “last resort” for chronic pain
- taking OC off the market
- making prescription-form theft a distinct offense punishable as a third-degree felony

According to the litmus test, the first four do not meet the criteria for balanced policy, while the last—proposed by Pennsylvania Attorney General Mike Fisher—does.

A Perennial Problem

It has been suggested that abuse of prescription medication is generally on the rise. Joranson’s team is studying the DAWN data from 2000 to see whether the rate at which prescription pain medication is abused has any correlation to an apparent increase in the past four or five years in medical use of opioids to treat pain.

The best that can be hoped for, some pain policy experts suggest, is simply to reduce diversion. “We will never be able to completely eliminate the diversion and abuse of scheduled prescription medications unless we ignore our responsibilities to patients in pain and take the drugs off the market,” says June Dahl. While a solution to this latest crisis is being sought, she says, dying patients are the last who should suffer undue consequences. “There is no evidence that diversion by pain patients is a significant problem,” Dahl says. “For cancer patients and people at the end of life, diversion is simply not an issue.” ■

A Roundup of Recent Pain-Policy Advances and Trends

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pattern.” The first—and so far, only—physician to be disciplined by a medical board for undertreatment of pain was in Oregon in 1999, and Tolle says, “The minute the board’s action came out, the medical students fixated on it. It was an ‘ah-ha’ moment for these young doctors—that undertreatment of pain could be a standard of practice, too. That there is a certain floor in pain management, below which you’re unacceptable.” But Tolle says civil suits move oversight of opioid use away from the infrastructure of policy and into the capricious arena of the civil courts. “In Oregon, you can get investigated if you go too far in either direction, and the goal is balance,” she believes. “In California, there’s only one way you appear to get in trouble—their board disciplines docs only for overprescribing. So, California doctors see that the safe path is to prescribe less.” In other words, to undertreat pain.

The Joint Commission’s Recent Call to Action

In 2000, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) released new pain treatment standards for hospitals, nursing homes, home-health agencies, and other institutions that provide direct patient care. One of the standards requires accredited facilities to assess pain in all patients. The first data on these standards’ clinical results are starting to roll in, but have not been analyzed yet.

“The pain standard is really critical because it means that accredited facilities can no longer ignore pain,” Dahl says. “It puts pain on every institution’s radar screen. These standards affect all patients in pain and thus should have a major impact on the quality of care for those who are dying.” ■

Information about the Series

“Pain Management—An Update: The Need for Balance in Controlled Substances Policy” is the fourteenth in a series of briefs profiling promising new policies and practices in end-of-life care.

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